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SMALL BUSINESS ADMINISTRATION

13 CFR Part 109

RIN 3245–AH15

Regulatory Reform Initiative: Intermediary Lending Pilot Program

AGENCY: U.S. Small Business Administration.

ACTION: Final rule.

SUMMARY: The U.S. Small Business Administration (SBA) is removing three regulations governing the application and selection process for Intermediary Lending Pilot (ILP) program Intermediaries. These regulations are no longer necessary because SBA is no longer authorized to select new ILP Intermediaries. The removal of these regulations will assist the public by simplifying SBA's regulations. SBA is also making two conforming amendments to avoid confusion.

DATES: This rule is effective December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Daniel Upham, Chief, Microenterprise Development Division, Office of Financial Assistance (202) 205–7001 or *daniel.upham@sba.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information

Part 109, Intermediary Lending Pilot Program

The Intermediary Lending Pilot (ILP) program was authorized by Congress as a 3-year pilot program in the Small Business Jobs Act of 2010, Public Law 111–240, enacted September 27, 2010. Under the ILP program, SBA provided loans to selected nonprofit intermediaries (ILP Intermediaries) for the purpose of providing loans to small businesses. Currently, there are 33 lenders participating in the ILP program. SBA was authorized to make loans to ILP Intermediaries in fiscal years 2011, 2012, and 2013. SBA published a proposed rule on March 5, 2020, proposing to remove three regulations from the Code of Federal Regulations (CFR) that are no longer necessary because SBA is no longer authorized to select new ILP Intermediaries. 85 FR 12875 (March 5, 2020). The proposed rule also contained two conforming amendments. SBA received no comments to these proposed ILP changes. Therefore, SBA is proceeding with the changes as proposed.

II. Section by Section Analysis

A. Section 109.200, Application To Become an ILP Intermediary

This section describes the application process to become an ILP Intermediary, including publication of a Notice of Funds Availability (NOFA) in the **Federal Register** to announce the availability of funds for the program and specify any special rules, procedures, and restrictions for a particular funding round. This section also includes the requirements for an ILP Intermediary application.

B. Section 109.210, Evaluation and Selection of ILP Intermediaries

This section describes the process by which SBA evaluates ILP Intermediary applications. The rule specifies that SBA will make loans to not more than 20 selected ILP Intermediaries, and that applications will be evaluated and scored based on the criteria specified in the NOFA.

C. Section 109.220, Loan Limits—Loans to ILP Intermediaries

Section 109.220 states that no ILP Intermediary may receive more than $1 million in ILP Loans.

SBA's authority to make loans to ILP Intermediaries has expired; therefore, SBA is not accepting any new ILP Intermediary applications. Since the program no longer allows for new ILP Intermediaries, the removal of these three regulations will reduce confusion and regulatory burden. Requirements for current ILP Intermediaries are found in the remaining provisions of part 109.

D. Conforming Amendments

In addition to removing the three regulations described above, the final rule also makes two conforming amendments. First, SBA is revising the definition of ILP Intermediary in section 109.20 to remove reference to the competitive application process. Because the regulations describing the application process (sections 109.200 and 109.210) have been removed, this revision is necessary to avoid confusion. Second, SBA is removing the cross-reference to section 120.173, Lead-based paint, in section 109.440. Section 109.440 states that loans made by an ILP Intermediary must comply with all applicable laws, including SBA's Lead-based paint regulation in section 120.173. In a separate rulemaking, SBA is proposing to remove section 120.173 because it is no longer necessary—16 CFR part 1303 already bans paint containing a concentration of lead in excess of 0.009% (90 parts per million) for use in residences, schools, hospitals, parks, playgrounds, and public buildings or other areas where consumers will have direct access to the painted surface. Therefore, SBA is removing the cross-reference in part 109 as well.

III. Compliance With Executive Orders 12866, 13771, 12988, and 13132, the Paperwork Reduction Act (44 U.S.C., Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

A. Executive Order 12866

The Office of Management and Budget (OMB) has determined that this rule does not constitute a significant regulatory action for purposes of Executive Order 12866 and is not a major rule under the Congressional Review Act, 5 U.S.C. 801, *et seq.*

B. Executive Order 13771

This final rule is expected to be an Executive Order 13771 deregulatory action with an annualized net savings of $8,980 and a net present value of $128,285 in savings, both in 2016 dollars. This rule will remove information about applying to the ILP program which will save potential applicants time in reading and researching/inquiring about this obsolete program and reduce confusion around whether applications are being accepted.

SBA is aware of approximately 500 nonprofit lenders that could potentially search for and read about applying for the ILP program. Assuming that, each year, 20 percent of these nonprofit lenders would review SBA's ILP regulations and that each would save one hour of review time due to removal

of the regulations discussed in this rule, these nonprofits would be relieved of 100 burden hours. Valuing this time at $124.90 per hour—the wage of a financial manager based on 2019 BLS data and adding 100% more for benefits and overhead, this produces total savings per year of $12,450 in current dollars.

C. Executive Order 13777

On February 24, 2017, the President issued Executive Order 13777, Enforcing the Regulatory Reform Agenda, which further emphasized the goal of the Administration to alleviate the regulatory burdens placed on the public. Under Executive Order 13777, agencies must evaluate their existing regulations to determine which ones should be repealed, replaced, or modified. In doing so, agencies should focus on identifying regulations that, among other things: Eliminate jobs or inhibit job creation; are outdated, unnecessary or ineffective; impose costs that exceed benefits; create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies; or are associated with Executive orders or other Presidential directives that have been rescinded or substantially modified. SBA has engaged in this process and has identified the regulations in this rulemaking as appropriate for removal in accordance with Executive Order 13777.

D. Executive Order 12988

This action meets applicable standards set forth in sec. 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

E. Executive Order 13132

This rule does not have federalism implications as defined in Executive Order 13132. It will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Executive order. As such it does not warrant the preparation of a Federalism Assessment.

F. Paperwork Reduction Act

The SBA has determined that this final rule does not affect any existing collection of information.

G. Regulatory Flexibility Act

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA) requires the agency to ''prepare and make available for public comment an initial regulatory flexibility analysis'' which will ''describe the impact of the proposed rule on small entities.'' (5 U.S.C. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

SBA is aware of approximately 500 nonprofit lenders that could potentially search for and read about applying to the ILP program. The removal of obsolete regulations related to the ILP program would reduce confusion for these lenders and the time required to read and/or inquire about obsolete regulations. The total annual savings to these nonprofit lenders is $12,450 in current dollars, or about $25 per nonprofit lender. More information on this estimate can be found in the Executive Order 13771 discussion above.

Accordingly, the Administrator of the SBA hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 13 CFR Part 109

Community development, Loan program—business, Reporting and recordkeeping requirements, Small businesses.

Accordingly, for the reasons stated in the preamble, SBA amends 13 CFR part 109 as follows:

PART 109—INTERMEDIARY LENDING PILOT PROGRAM

■ 1. The authority citation for part 109 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6), (b)(7), and 636(l).

■ 2. Amend § 109.20 by revising the definition of ''ILP Intermediary'' to read as follows:

§ 109.20 Definitions.

* * * * *

ILP Intermediary means a private, nonprofit entity that has received an ILP Loan.

* * * * *

§§ 109.200, 109.210, and 109.220 [Removed and reserved]

■ 3. Remove and reserve §§ 109.200, 109.210, and 109.220.

§ 109.440 [Amended]

■ 4. Amend § 109.440 by removing the words ''120.173 (Lead-based paint),''.

Jovita Carranza,

Administrator.

[FR Doc. 2020–25555 Filed 11–25–20; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0893; Product Identifier 2018–SW–032–AD; Amendment 39–21319; AD 2020–23–03]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2017–09–05 for Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1, AS332L2, and EC225LP helicopters. AD 2017–09–05 required repetitively checking screws in the emergency flotation gear. This new AD retains the requirements of AD 2017–09–05 but also requires installing a modification (MOD), which is a terminating action for the repetitive checks. This AD was prompted by the development of the MOD by Airbus Helicopters that addresses the unsafe condition. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD is effective January 4, 2021.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of January 4, 2021.

ADDRESSES: For service information identified in this final rule, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone 800–232–0323 or Fax: 972–641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* 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. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0893.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov in* Docket No. FAA–2018–0893; 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 AD, the European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, any service information that is incorporated by reference, any comments received, and other information. The street address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, AD Program Manager, Operational Safety Branch, Airworthiness Products Section, General Aviation & Rotorcraft Unit, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *matthew.fuller@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to remove AD 2017–09–05, Amendment 39–18867 (82 FR 21913, May 11, 2017) (''AD 2017–09–05''), and add a new AD. AD 2017–09–05 applied to Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1, AS332L2, and EC225LP helicopters with emergency flotation gear installed. The NPRM published in the **Federal Register** on August 7, 2020 (85 FR 47921). The NPRM proposed to require, within 15 hours time-in-service (TIS) and thereafter, before each flight over water, visually checking each emergency flotation gear left-hand (LH) and right-hand (RH) rear upper fitting for the presence of screw heads and looseness. An owner/operator (pilot) may perform the required visual check but must enter compliance with the applicable paragraph of this AD in the helicopter maintenance records in accordance with 14 CFR 43.9(a)(1) through (4) and 91.417(a)(2)(v). A pilot may perform this check because it involves visually checking the rear upper fittings of the LH and RH emergency flotation gears for the presence of screw heads and twisting the screws by hand. This action can be performed equally well by a pilot or a mechanic. This check is an exception to the FAA's standard maintenance regulations. If any screws are loose or any screw heads are missing, the NPRM proposed to require removing from service the screws on each LH and RH side on the flotation gear rear fitting and installing MOD 0728456, base washers and spherical washers. The NPRM also proposed to require, within 300 hours TIS, installing MOD 0728456 as a terminating action for the repetitive checks.

AD 2017–09–05 was prompted by EASA AD 2015–0239–E, dated December 18, 2015 (EASA AD 2015–0239–E), issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1, AS332L2, and EC225LP helicopters. EASA advised that a screw ruptured on the rear upper fitting on the LH emergency flotation gear of an AS332 helicopter. EASA stated that this condition, if not detected and corrected, could result in the failure of an emergency flotation system when ditching and unstable floating of the helicopter, possibly resulting in injuries to the occupants. The EASA AD consequently required repetitive inspections of the lower attachment screws of rear upper fitting on the rear LH and RH emergency flotation gears. EASA stated that the root cause of the failure had not yet been identified.

After the FAA issued AD 2017–09–05, Airbus Helicopters identified the root cause of the screw rupture as a tapering gap under the fitting attachment screw heads creating excessive stress loads. Consequently, EASA issued AD No. 2018–0090, dated April 20, 2018 (EASA AD 2018–0090), to supersede EASA AD 2015–0239–E. EASA AD 2018–0090 retains the repetitive inspection requirements in EASA AD 2015–0239–E and also requires the installation of Airbus Helicopters MOD 0728456 as a terminating action for the repetitive inspections. MOD 0728456 involves the installation of spherical washers and longer screws on the rear upper fittings of the flotation gear to remove the stress applied to the screw heads.

Actions Since the NPRM Was Issued

Since the FAA issued the NPRM, it was identified that the NPRM specified installing MOD 0728456 by using Airbus Helicopters Alert Service Bulletin (ASB) No. AS332–25.03.43 or ASB No. EC225–25A207, each Revision 0 and dated April 4, 2018, in paragraphs (f)(3)(i) through (iii) of this AD. However, the FAA intended to update this service information to Airbus Helicopters ASB No. AS332–25.03.43 or ASB No. EC225–25A207, each Revision 2 and dated March 21, 2019. Since the updated service information does not affect compliance, this final rule allows the use of either Revision 0 or Revision 2 of this service information to install MOD 0728456.

Comments

The FAA gave the public the opportunity to participate in developing this final rule, but the FAA did not receive any comments on the NPRM or on the determination of the cost to the public.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA of the unsafe condition described in its AD. The FAA is issuing this AD after evaluating all of the information provided by EASA and determining the unsafe condition exists and is likely to exist or develop on other helicopters of these same type design and that air safety and the public interest require adopting the AD requirements as proposed except for minor editorial changes. The two instances of 17mm (+ 0.1/+ 0.1) as published in the Required Actions of the NPRM have been corrected to 17mm (+ 0.1/− 0.1). These minor editorial changes are consistent with the intent of the proposals in the NPRM and will not increase the economic burden on any operator nor increase the scope of this AD.

Differences Between This AD and the EASA AD

The EASA AD allows using tools for the inspection, while this AD requires checking by hand. The EASA AD requires contacting Airbus Helicopters if a screw is missing or loose, while this AD does not. The EASA AD requires that repetitive inspections occur at intervals not to exceed 15 hours TIS, while this AD requires the repetitive checks before each flight over water.

Related Service Information Under 1 CFR Part 51

Airbus Helicopters has issued ASB No. AS332–25.03.43, Revision 0, dated April 4, 2018, for Model AS332C, AS332C1, AS332L, AS332L1, and AS332L2 helicopters and for military Model AS332B, AS332B1, AS332F1, AS332M, and AS332M1 helicopters. The FAA also reviewed ASB No. EC225–25A207, Revision 0, dated April 4, 2018, for Model EC 225 LP helicopters. This service information specifies, within 12 months, installing MOD 0728456 by installing spherical leveling washers and longer screws to attach the rear upper fittings of the LH and RH emergency flotation gear. Airbus

Helicopters specifies that helicopters that have undergone MOD 0728456 are exempt from these service information requirements. Airbus Helicopters revised each of these ASBs, now at Revision 2 and dated March 21, 2019, to specify an alternative to the protection of the spotfacing(s) and add an instruction to apply primer after the protection and before painting the parts.

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

Airbus Helicopters has issued Emergency Alert Service Bulletin (EASB) No. 05.01.06, Revision 0, dated December 18, 2015, for Model AS332C, AS332C1, AS332L, AS332L1, and AS332L2 helicopters and for military Model AS332B, AS332B1, AS332F1, AS332M, and AS332M1 helicopters, and EASB No. 05A047, Revision 0, dated December 18, 2015, for Model EC225LP helicopters. This service information specifies repetitively inspecting the lower screws of the rear upper fitting on the rear LH and RH emergency floating gears for the presence of the heads and stressing the screw heads using a tool to make sure that the screw head does not move. If all screw heads are present, the service information requires no further action. If at least one screw head is missing or is loose, the service information specifies replacing the two lower screws and the upper screw and informing Airbus Helicopters. Airbus Helicopters revised each of these EASBs to Revision 1, dated April 4, 2018, to exclude helicopters with MOD 0728456 installed from the effectivity.

Costs of Compliance

The FAA estimates that this AD affects 29 helicopters of U.S. Registry. The FAA estimates that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at $85 per work-hour.

Checking the screws for looseness and a missing head takes about 5 minutes, for an estimated cost of about $7 per helicopter and $203 for the U.S. fleet.

Performing the MOD takes about 16 work-hours, and parts cost about $3,030 for total estimated cost of $4,390 per helicopter and $127,310 for the U.S. fleet.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA has 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) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

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:

■ a. Removing Airworthiness Directive (AD) 2017–09–05, Amendment 39–18867 (82 FR 21913, May 11, 2017); and

■ b. Adding the following new AD:

2020–23–03 Airbus Helicopters: Amendment 39–21319; Docket No. FAA–2018–0893; Product Identifier 2018–SW–032–AD.

(a) Applicability

This airworthiness directive (AD) applies to Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1, AS332L2, and EC225LP helicopters with emergency flotation gear installed, certificated in any category, except those helicopters that have Airbus Helicopters Modification (MOD) 0728456 already installed.

(b) Unsafe Condition

This AD defines the unsafe condition as failure of a rear upper screw fitting on the emergency flotation gear. This condition, if not detected and corrected, could result in failure of the emergency flotation system and subsequent capsizing of the helicopter.

(c) Affected ADs

This AD replaces AD 2017–09–05, Amendment 39–18867 (82 FR 21913, May 11, 2017).

(d) Effective Date

This AD becomes effective January 4, 2021.

(e) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(f) Required Actions

(1) Within 15 hours time-in-service (TIS), and before each flight over water thereafter, visually check each emergency flotation gear left hand (LH) and right hand (RH) rear upper fitting to determine whether the heads of the lower screws are present. Figure 1 to paragraph (f)(1) of this AD depicts where the lower three screws (noted as B and E) are located. Check each screw for looseness by determining whether it can be rotated by hand. These actions may be performed by the owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9(a)(1) through (4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

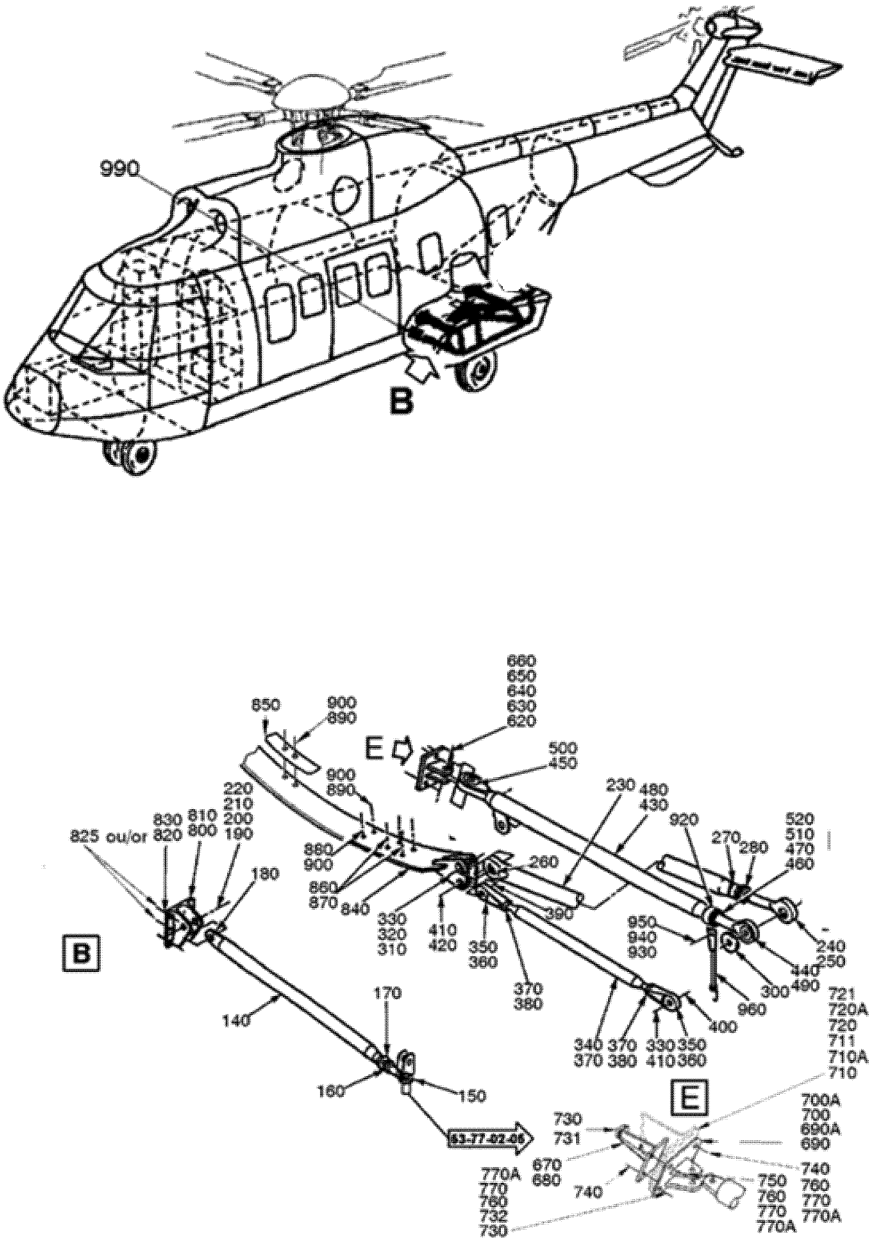

Figure 1 to Paragraph (f)(1)

(2) If a screw head is missing, or if a screw is loose, before further flight over water, install MOD 0728456 by completing paragraph (f)(3) of this AD.

(3) Within 300 hours TIS, unless required before further flight over water by paragraph (f)(2) of this AD, install MOD 0728456 by doing the following:

Note 1 to paragraph (f)(3): The installation of MOD 0728456 on the LH and RH sides is identical.

(i) Remove external fitting (a) and remove from service screws (c), (d) and (e), washers (f), and nuts (g) as shown in Figure 1, Detail A of Airbus Helicopters Alert Service Bulletin (ASB) No. AS332–25.03.43, Revision 0, dated April 4, 2018 (ASB AS332–25.03–43 Rev 0), or ASB No. EC225–25A207, Revision 0, dated April 4, 2018 (ASB EC225–25A207 Rev 0), as applicable to your model helicopter. As an option, you may use Airbus Helicopters ASB No. AS332–25.03.43 or ASB No. EC225–25A207, each Revision 2 and dated March 21, 2019 (ASB AS332–25.03–43 Rev 2 or ASB EC225–25A207 Rev 2), as applicable to your model helicopter, instead of ASB AS332–25.03–43 Rev 0 or ASB EC225–25A207 Rev 0.

(ii) Install base washers (1) (structural side), spherical washers (2) (screw side), and screws (3) and coat with sealing compound (or similar) on the smooth surface of the nuts (5) as shown in Figure 2 of ASB AS332–25.03–43 Rev 0 or ASB EC225–25A207 Rev 0, as applicable to your model helicopter. As an option, you may use ASB AS332–25.03–43 Rev 2 or ASB EC225–25A207 Rev 2, as applicable to your model helicopter, instead of ASB AS332–25.03–43 Rev 0 or ASB EC225–25A207 Rev 0.

(iii) Inspect each washer on the external fitting (a) for contact with a weld as shown in Figure 2, Detail A of ASB AS332–25.03–43 Rev 0 or ASB EC225–25A207 Rev 0, and inspect each washer on the internal fitting for contact with the fitting radius. As an option, you may use or ASB AS332–25.03–43 Rev 2 or ASB EC225–25A207 Rev 2, as applicable to your model helicopter, instead of ASB AS332–25.03–43 Rev 0 or ASB EC225–25A207 Rev 0.

(A) If a washer on the external fitting makes contact with a weld, perform a spotfacing to the diameter of 17mm (+ 0.1/ − 0.1) with a cutter root radius of 0.5mm.

(B) If a washer on the internal fitting falls in the radius of the bracket, perform a spotfacing to the diameter of 17mm (+ 0.1/ − 0.1) with a cutter root radius of 0.5mm.

(iv) Torque each nut to 169–203 lbf.in (1.9–2.3 daN.m), and apply sealing compound to outer edge of the LH rear upper fitting.

(4) Completion of the requirements in paragraph in (f)(3) of this AD constitutes terminating action for the repetitive checks required in paragraph (f)(1) of this AD.

(g) Special Flight Permits

Special flight permits are prohibited for flights over water.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Matthew Fuller, AD Program Manager, Operational Safety Branch, Airworthiness Products Section, General Aviation & Rotorcraft Unit, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, the FAA suggests that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(i) Additional Information

(1) Airbus Helicopters Emergency Alert Service Bulletin (EASB) No. 05.01.06, and EASB No. 05A047, each Revision 0 and dated December 18, 2015, and each Revision 1 and dated April 4, 2018, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone 972–641–0000 or 800–232–0323; fax 972–641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may view a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD No. 2018–0090, dated April 20, 2018. You may view the EASA AD on the internet at *https://www.regulations.gov* in Docket No. FAA–2018–0893.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 3212, Emergency Flotation Section.

(k) Material Incorporated by Reference

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

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

(i) Airbus Helicopters Alert Service Bulletin (ASB) No. AS332–25.03.43, Revision 0, dated April 4, 2018.

(ii) Airbus Helicopters ASB No. AS332–25.03.43, Revision 2, dated March 21, 2019.

(iii) Airbus Helicopters ASB No. EC225–25A207, Revision 0, dated April 4, 2018.

(iv) Airbus Helicopters ASB No. EC225–25A207, Revision 2, dated March 21, 2019.

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

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

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

Issued on October 27, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–25493 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0788; Product Identifier 2020–NM–091–AD; Amendment 39–21327; AD 2020–23–11]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus SAS Model A300 series airplanes; and Airbus SAS Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Airbus SAS Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). This AD was prompted by reports of cracking at a certain hole location on the left-hand (LH) side of a certain frame (FR). This AD requires repetitive inspections for discrepancies of certain areas in and around the fuselage, as specified in two European Union Aviation Safety Agency (EASA) ADs, which are incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 4, 2021.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of January 4, 2021.

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0788.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0788; 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, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *Dan.Rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0110R1, dated May 27, 2020; and EASA AD 2020–0111R2, dated June 16, 2020 (''EASA AD 2020–0110R1'' and ''EASA AD 2020–0111R2'') (also

referred to as ''the Mandatory Continuing Airworthiness Information,'' or ''the MCAI''); to correct an unsafe condition for all Airbus SAS Model A300 series airplanes and Airbus SAS Model A300–600 series airplanes.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A300 series airplanes and Airbus SAS Model A300–600 series airplanes. The NPRM published in the **Federal Register** on September 1, 2020 (85 FR 54286). The NPRM was prompted by reports of cracking at hole location #10 on the LH side of FR4. The NPRM proposed to require repetitive inspections for discrepancies of certain areas in and around the fuselage, as specified in two EASA ADs.

The FAA is issuing this AD to address fatigue cracking, which could result in reduced structural integrity of the fuselage. See the MCAI for additional background information.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA has considered the comment received. FedEx indicated its support for the NPRM.

Conclusion

The FAA reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has 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.

Related Service Information Under 1 CFR Part 51

EASA AD 2020–0110R1 describes procedures for repetitive special detailed inspections for discrepancies (*i.e.,* cracking) of the fuselage internal structure at certain frames, windshield frame lower section and closing panel, fuselage skin lap joint, and center wing bottom skin internal angle; and applicable corrective actions (repairing discrepancies).

EASA AD 2020–0111R2 describes procedures for repetitive special detailed inspections for discrepancies of the outer wing bottom skin internal joint plate, outer wing bottom skin, fuselage internal structure at certain frames, and windshield frame lower section and closing panel; and applicable corrective actions (repairing discrepancies).

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.

Costs of Compliance

The FAA estimates that this AD affects 118 airplanes of U.S. registry. The FAA estimates 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
90 work-hours × $85 per hour = $7,650	$0	$7,650	$902,700

The FAA has received no definitive data that would enable the agency to provide cost estimates for the on-condition actions specified in this AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

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 adding the following new airworthiness directive:

2020–23–11 Airbus SAS: Amendment 39–21327; Docket No. FAA–2020–0788; Product Identifier 2020–NM–091–AD.

(a) Effective Date

This airworthiness directive (AD) is effective January 4, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS airplanes identified in paragraphs (c)(1) and (2) of this AD, certificated in any category.

(1) Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.

(2) Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes; Model A300 B4–605R and B4–622R airplanes; Model A300 F4–605R and F4–622R airplanes; and Model A300 C4–605R Variant F airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage; 57, Wings.

(e) Reason

This AD was prompted by reports of cracking at hole location #10 on the left-hand side of frame 4. The FAA is issuing this AD to address fatigue cracking, which could result in reduced structural integrity of the fuselage.

(f) Compliance

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

(g) Requirements

(1) For airplanes identified in paragraph (c)(1) of this AD: Except as specified in paragraphs (h)(1) and (3) of this AD, comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2020–0110R1, dated May 27, 2020 (''EASA AD 2020–0110R1'').

(2) For airplanes identified in paragraph (c)(2) of this AD: Except as specified in paragraphs (h)(2) and (3) of this AD, comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2020–0111R2, dated June 16, 2020 (''EASA AD 2020–0111R2'').

(h) Exceptions to EASA AD 2020–0110R1 and EASA AD 2020–0111R2

(1) Where EASA AD 2020–0110R1 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (4) of EASA AD 2020–0111R2 refers to June 3, 2020 (''the effective date of this [EASA] AD at original issue''), this AD requires using the effective date of this AD.

(3) The ''Remarks'' section of EASA AD 2020–0110R1 and EASA AD 2020–0111R2 does not apply to this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3225; email *Dan.Rodina@faa.gov.*

(k) 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 this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2020–0110R1, dated May 27, 2020.

(ii) European Union Aviation Safety Agency (EASA) AD 2020–0111R2, dated June 16, 2020.

(3) For EASA AD 2020–0110R1 and EASA AD 2020–0111R2, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* Internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0788.

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

Issued on November 4, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–26046 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No.: FAA–2017–0768; Amdt. No. 91–348C]

RIN 2120–AL55

Extension of the Prohibition Against Certain Flights in the Damascus Flight Information Region (FIR) (OSTT)

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This action extends the prohibition against certain flight operations in the Damascus Flight Information Region (FIR) (OSTT) by all: U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when the operator of such aircraft is a foreign air carrier. The FAA finds this action necessary to address significant, continuing hazards to U.S. civil aviation associated with the ongoing and complex conflict in Syria. The FAA also republishes the approval process and exemption information for this Special Federal Aviation Regulation (SFAR), consistent with other recently published flight prohibition SFARs, and makes minor administrative revisions.

DATES: This final rule is effective on November 27, 2020.

FOR FURTHER INFORMATION CONTACT: Stephen Moates, Air Transportation Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone 202–267–8166; email *Stephen.moates@faa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

This action extends the expiration date of the prohibition against certain U.S. civil flight operations in the Damascus FIR (OSTT) by all: U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when the operator of such aircraft is a foreign air carrier. Specifically, this amendment extends the expiration date of SFAR No. 114, § 91.1609 of title 14, Code of Federal

Regulations (CFR), from December 30, 2020, to December 30, 2023, due to the significant, continuing hazards to U.S. civil aviation operation in the Damascus FIR (OSTT) associated with the ongoing and complex conflict in Syria, as described in the preamble to this final rule. This action also republishes the approval process and exemption information for this SFAR, consistent with other recently published flight prohibition SFARs, and makes minor administrative revisions.

II. Legal Authority and Good Cause

A. Legal Authority

The FAA is responsible for the safety of flight in the U.S. and for the safety of U.S. civil operators, U.S.-registered civil aircraft, and U.S.-certificated airmen throughout the world. Sections 106(f) and (g) of title 49, U.S. Code (U.S.C.), subtitle I, establish the FAA Administrator's authority to issue rules on aviation safety. Subtitle VII of title 49, Aviation Programs, describes in more detail the scope of the Agency's authority. Section 40101(d)(1) provides that the Administrator shall consider in the public interest, among other matters, assigning, maintaining, and enhancing safety and security as the highest priorities in air commerce. Section 40105(b)(1)(A) requires the Administrator to exercise this authority consistently with the obligations of the U.S. Government under international agreements.

The FAA is promulgating this rulemaking under the authority described in 49 U.S.C. 44701, General requirements. Under that section, the FAA is charged broadly with promoting safe flight of civil aircraft in air commerce by prescribing, among other things, regulations and minimum standards for practices, methods, and procedures that the Administrator finds necessary for safety in air commerce and national security.

This regulation is within the scope of the FAA's authority because it continues to prohibit the persons described in paragraph (a) of SFAR No. 114, § 91.1609, from conducting flight operations in the Damascus FIR (OSTT) due to the significant, continuing hazards to the safety of U.S. civil flight operations, as described in the preamble to this final rule.

B. Good Cause for Immediate Adoption

Section 553(b)(3)(B) of title 5, U.S. Code, authorizes agencies to dispense with notice and comment procedures for rules when the agency for ''good cause'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Section 553(d) also authorizes agencies to forgo the delay in the effective date of the final rule for good cause found and published with the rule. In this instance, the FAA finds good cause exists to forgo notice and comment because notice and comment would be impracticable and contrary to the public interest. In addition, it is contrary to the public interest to delay the effective date of this SFAR.

The risk environment for U.S. civil aviation in airspace managed by other countries with respect to safety of flight is fluid due to the risks posed by weapons capable of targeting, or otherwise negatively affecting, U.S. civil aviation, as well as other hazards to U.S. civil aviation associated with fighting, extremist or militant activity, or heightened tensions. This fluidity and the need for the FAA to rely upon classified information in assessing these risks make issuing notice and seeking comments impracticable and contrary to the public interest. With respect to the impracticability of notice and comment procedures, the potential for rapid changes in the risks to U.S. civil aviation significantly limits how far in advance of a new or amended flight prohibition the FAA can usefully assess the risk environment. Furthermore, to the extent that these rules and any amendments to them are based upon classified information, the FAA is not legally permitted to share such information with the general public, who cannot meaningfully comment on information to which they are not legally allowed access.

Under these conditions, public interest considerations favor not providing notice and seeking comment for this rule. While there is a public interest in having an opportunity for the public to comment on agency action, there is a greater public interest in having the FAA's flight prohibitions, and any amendments thereto, reflect the Agency's current understanding of the risk environment for U.S. civil aviation. This allows the FAA to protect the safety of U.S. operators' aircraft and the lives of their passengers and crews without overrestricting U.S. operators' routing options.

The FAA has determined extending the expiration date of SFAR No. 114, § 91.1609, is necessary due to safety-of-flight hazards associated with the ongoing and complex conflict in Syria. These hazards continue to present significant risks to U.S. civil aviation operations in the Damascus FIR (OSTT), as described in the preamble to this rule. Therefore, the FAA's flight prohibition for U.S. civil aviation operations in the Damascus FIR (OSTT) must continue, without interruption.

Accordingly, the FAA finds good cause exists to forgo notice and comment and any delay in the effective date for this rule.

III. Background

On December 10, 2018, the FAA amended SFAR No. 114, § 91.1609, to extend the expiration date of the rule from December 30, 2018, to December 30, 2020.[1] In issuing the 2018 final rule, the FAA stated the situation in the Damascus FIR (OSTT) remained hazardous for U.S. civil aviation due to a variety of aviation safety risks associated with the ongoing conflict in Syria.[2]

IV. Discussion of the Final Rule

The situation in the Damascus FIR (OSTT) continues to present an unacceptable level of risk for U.S. civil aviation safety. The conflict in Syria between pro-Assad regime forces, third country military forces, as well as opposition groups, and extremist elements, is extremely complex.

The presence of third parties conducting independent military operations in Syria against pro-Assad regime forces, opposition groups, and extremist elements, exacerbates the situation. Third-party airstrikes in Syria often result in Syrian military air defense responses. Syrian authorities do not adequately de-conflict these air defense activities, which include indiscriminate surface-to-air missile (SAM) fire, with civil aviation operations in the Damascus FIR (OSTT), including, but not limited to, civil flight operations in close proximity to international airports in Syria. For example, in late February 2020, Syrian air defense activities forced a commercial Cham Wings Airbus 320 passenger flight on final approach to Damascus International Airport to divert to an alternate airfield in Syria.

The lack of de-confliction of Syrian air defense activity with civil air traffic is just one of the risks to U.S. civil aviation operations in the Damascus FIR (OSTT) emanating from third-party involvement in Syria. Russia, Iran, and the Lebanese terrorist organization, Hizballah, all of which are Syrian regime allies, continue to conduct military operations in Syria and have deployed significant air defense and electronic warfare capabilities, including Global Positioning System

[1] Extension of the Prohibition Against Certain Flights in the Damascus Flight Information Region (FIR)(OSTT) final rule, 83 FR 63410, December 10, 2018.

[2] Id. at 63411.

(GPS) jammers, which present a risk to U.S. civil aviation operations in the Damascus FIR (OSTT). In March 2020, Russian, Turkish and Syrian forces clashed in Idlib Province. During these clashes, fighter aircraft and possible SAMs shot down several manned and unmanned aircraft.

In addition to the hazards associated with third-party involvement in the Syrian conflict, extremist threats to civil aviation safety continue to exist in Syria. Terrorist groups, including the Islamic State of Iraq and ash-Sham (ISIS) and al Qaida-aligned entities possess, or have access to, a wide array of anti-aircraft weapons that pose a risk to civil aviation operations in the Damascus FIR (OSTT). Anti-regime forces, extremists, and militants have successfully shot down multiple military aircraft using man-portable air defense systems (MANPADS) during the Syrian conflict. Additionally, various elements have successfully targeted military aircraft using advanced anti-tank guided missiles (ATGMs). ATGMs primarily pose a risk to civil aircraft operating near, or parked at, an airport. Finally, various groups employ unmanned aircraft systems to surveil and attack Syrian and Syrian-allied fielded forces and airfields.

As a result of the ongoing military activities by multiple actors and the lack of progress towards ending the conflict, the FAA expects significant hazards to the safety of U.S. civil aviation in the Damascus FIR (OSTT) will endure. Therefore, as a result of the significant, continuing risk to the safety of U.S. civil aviation in the Damascus FIR (OSTT), the FAA extends the expiration date of SFAR No. 114, § 91.1609, from December 30, 2020, to December 30, 2023.

Amendments to SFAR No. 114, § 91.1609, could be appropriate if the risk to aviation safety and security changes. In this regard, the FAA will continue to monitor the situation and evaluate the extent to which persons described in paragraph (a) of this rule might be able to operate safely in the Damascus FIR (OSTT). The FAA may amend or rescind SFAR No. 114, § 91.1609, as necessary, prior to its expiration date.

The FAA also republishes the details concerning the approval and exemption processes in Sections V and VI of this preamble, with clarifications for consistency with other recently published flight prohibition SFARs. Lastly, the FAA makes minor administrative revisions, including updating the applicability paragraph of the regulatory text to make it consistent with other recently published flight prohibition SFARs.

V. Approval Process Based on a Request From a Department, Agency, or Instrumentality of the United States Government

A. Approval Process Based on an Authorization Request from a Department, Agency, or Instrumentality of the United States Government

In some instances, U.S. Government departments, agencies, or instrumentalities may need to engage U.S. civil aviation to support their activities in the Damascus FIR (OSTT). If a department, agency, or instrumentality of the U.S. Government determines that it has a critical need to engage any person described in SFAR No. 114, § 91.1609, including a U.S. air carrier or commercial operator, to transport civilian or military passengers or cargo or conduct other operations in the Damascus FIR (OSTT), that department, agency, or instrumentality may request the FAA to approve persons described in paragraph (a) of SFAR No. 114, § 91.1609, to conduct such operations.

The requesting department, agency, or instrumentality of the U.S. Government must submit the request for approval to the FAA's Associate Administrator for Aviation Safety in a letter signed by an appropriate senior official of the requesting department, agency, or instrumentality.[3] The FAA will not accept or consider requests for approval from anyone other than the requesting department, agency, or instrumentality. In addition, the senior official signing the letter requesting FAA approval on behalf of the requesting department, agency, or instrumentality must be sufficiently positioned within the organization to demonstrate that the senior leadership of the requesting department, agency, or instrumentality supports the request for approval and is committed to taking all necessary steps to minimize operational risks to the proposed flights. The senior official must also be in a position to: (1) Attest to the accuracy of all representations made to the FAA in the request for approval, and (2) ensure that any support from the requesting U.S. Government department, agency, or instrumentality described in the request for approval is in fact brought to bear and is maintained over time. Unless justified by exigent circumstances, requests for approval must be submitted to the FAA no less than 30 calendar days before the date on which the requesting department, agency, or instrumentality wishes the proposed operation(s) to commence.

The requestor must send the request to the Associate Administrator for Aviation Safety, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591. Electronic submissions are acceptable and the requesting entity may request that the FAA notify it electronically as to whether the FAA grants the approval request. If a requestor wishes to make an electronic submission to the FAA, the requestor should contact the Air Transportation Division, Flight Standards Service, at (202) 267–8166, to obtain the appropriate email address. A single letter may request approval from the FAA for multiple persons described in SFAR No. 114, § 91.1609, or for multiple flight operations. To the extent known, the letter must identify the person(s) the requester expects the SFAR to cover on whose behalf the U.S. Government department, agency, or instrumentality seeks FAA approval, and it must describe—

- The proposed operation(s), including the nature of the mission being supported;
- The service that the person(s) covered by the SFAR will provide;
- To the extent known, the specific locations in the Damascus FIR (OSTT) where the proposed operation(s) will occur, including, but not limited to, the flight path and altitude of the aircraft while it is operating in the Damascus FIR (OSTT) and the airports, airfields, or landing zones at which the aircraft will take off and land; and
- The method by which the department, agency, or instrumentality will provide, or how the operator will otherwise obtain, current threat information and an explanation of how the operator will integrate this information into all phases of the proposed operations (*i.e.,* the pre-mission planning and briefing, in-flight, and post-flight phases).

The request for approval must also include a list of operators with whom the U.S. Government department, agency, or instrumentality requesting FAA approval has a current contract(s), grant(s), or cooperative agreement(s) (or its prime contractor has a subcontract(s)) for specific flight operations in the Damascus FIR (OSTT). The requestor may identify additional

[3] This approval procedure applies to U.S. Government departments, agencies, or instrumentalities; it does not apply to the public. The FAA describes this procedure in the interest of providing transparency with respect to the FAA's process for interacting with U.S. Government departments, agencies, or instrumentalities that seek to engage U.S. civil aviation to operate within the area in which this SFAR prohibits their operations.

operators to the FAA at any time after the FAA issues its approval. Neither the operators listed in the original request, nor any operators the requestor subsequently seeks to add to the approval, may commence operations under the approval until the FAA issues them an Operations Specification (OpSpec) or Letter of Authorization (LOA), as appropriate, for operations in the Damascus FIR (OSTT). The approval conditions discussed below apply to all operators, whether included in the original list or subsequently added to the approval. Requestors should send updated lists to the email address they obtain from the Air Transportation Division by calling (202) 267–8166.

If an approval request includes classified information, requestors may contact Aviation Safety Inspector Stephen Moates for instructions on submitting it to the FAA. His contact information appears in the **FOR FURTHER INFORMATION CONTACT** section of this final rule.

FAA approval of an operation under SFAR No. 114, § 91.1609, does not relieve persons subject to this SFAR of the responsibility to comply with all other applicable FAA rules and regulations. Operators of civil aircraft must comply with the conditions of their certificates, OpSpecs, and LOAs, as applicable. Operators must also comply with all rules and regulations of other U.S. Government departments or agencies that may apply to the proposed operation(s), including, but not limited to, regulations issued by the Transportation Security Administration.

B. Approval Conditions

If the FAA approves the request, the FAA's Aviation Safety organization will send an approval letter to the requesting department, agency, or instrumentality informing it that the FAA's approval is subject to all of the following conditions:

(1) The approval will stipulate those procedures and conditions that limit, to the greatest degree possible, the risk to the operator, while still allowing the operator to achieve its operational objectives.

(2) Before any approval takes effect, the operator must submit to the FAA:

(a) A written release of the U.S. Government from all damages, claims, and liabilities, including without limitation legal fees and expenses, relating to any event arising out of or related to the approved operations in the Damascus FIR (OSTT); and

(b) The operator's written agreement to indemnify the U.S. Government with respect to any and all third-party damages, claims, and liabilities, including without limitation legal fees and expenses, relating to any event arising from or related to the approved operations in the Damascus FIR (OSTT).

(3) Other conditions the FAA may specify, including those the FAA might impose in OpSpecs or LOAs, as applicable.

The release and agreement to indemnify do not preclude an operator from raising a claim under an applicable non-premium war risk insurance policy the FAA issues under chapter 443 of title 49, U.S. Code.

If the FAA approves the proposed operation(s), the FAA will issue an OpSpec or LOA, as applicable, to the operator(s) identified in the original request authorizing them to conduct the approved operation(s). In addition, the FAA will notify the U.S. Government department, agency, or instrumentality that requested the FAA's approval of any additional conditions beyond those contained in the approval letter.

VI. Information Regarding Petitions for Exemption

Any operations not conducted under an approval the FAA issues through the approval process set forth previously may only occur in accordance with an exemption from SFAR No. 114, § 91.1609. A petition for exemption must comply with 14 CFR part 11. The FAA will consider whether exceptional circumstances exist beyond those the approval process described in the previous section contemplates. To determine whether a petition for exemption from the prohibition this SFAR establishes fulfills the standard of 14 CFR 11.81, the FAA consistently finds necessary the following information:

- The proposed operation(s), including the nature of the operation;
- The service the person(s) covered by the SFAR will provide;
- The specific locations in the Damascus FIR (OSTT) where the proposed operation(s) will occur, including, but not limited to, the flight path and altitude of the aircraft while it is operating in the Damascus FIR (OSTT) and the airports, airfields, or landing zones at which the aircraft will take off and land;
- The method by which the operator will obtain current threat information and an explanation of how the operator will integrate this information into all phases of its proposed operations (*i.e.,* the pre-mission planning and briefing, in-flight, and post-flight phases); and
- The plans and procedures the operator will use to minimize the risks, identified in this preamble, to the proposed operations, to establish that granting the exemption would not adversely affect safety or would provide a level of safety at least equal to that provided by this SFAR. The FAA has found comprehensive, organized plans and procedures of this nature to be helpful in facilitating the agency's safety evaluation of petitions for exemption from flight prohibition SFARs.

The FAA includes, as a condition of each such exemption it issues, a release and agreement to indemnify, as described previously.

The FAA recognizes that, with the support of the U.S. Government, the governments of other countries could plan operations SFAR No. 114, § 91.1609, affects. While the FAA will not permit these operations through the approval process, the FAA will consider exemption requests for such operations on an expedited basis and in accordance with the order of preference set forth in paragraph (c) of SFAR No. 114, § 91.1609.

If a petition for exemption includes security-sensitive or proprietary information, requestors may contact Aviation Safety Inspector Stephen Moates for instructions on submitting it to the FAA. His contact information appears in the **FOR FURTHER INFORMATION CONTACT** section of this final rule.

VII. Regulatory Notices and Analyses

Changes to Federal regulations must undergo several economic analyses. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 603 *et seq.,* requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act of 1979 (Pub. L. 96–39), as codified in 19 U.S.C. Chapter 13, prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as codified in 2 U.S.C. Chapter 25, requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted

for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

In conducting these analyses, the FAA has determined this final rule has benefits that justify its costs. This rule is a significant regulatory action, as defined in section 3(f) of Executive Order 12866, as it raises novel policy issues contemplated under that Executive Order. This rule also complies with the requirements of the Department of Transportation's administrative rule on rulemaking at 49 CFR part 5. As 5 U.S.C. 553 does not require notice and comment for this final rule, 5 U.S.C. 603 and 604 do not require regulatory flexibility analyses regarding impacts on small entities. This rule will not create unnecessary obstacles to the foreign commerce of the United States. This rule will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector, by exceeding the threshold identified previously.

A. Regulatory Evaluation

This action extends the expiration date of the SFAR prohibiting certain flight operations in the Damascus FIR (OSTT) for an additional three years due to the significant, continuing hazards to U.S. civil aviation detailed in the preamble of this final rule. U.S. Government departments, agencies, and instrumentalities may take advantage of the approval process on behalf of U.S. operators and airmen with whom they have a contract, grant, or cooperative agreement, or with whom their prime contractor has a subcontract. U.S. operators and airmen who seek to conduct operations in the Damascus FIR (OSTT) without any of the foregoing types of arrangements with the U.S. Government may petition for exemption from this rule.

The FAA acknowledges this flight prohibition might result in additional costs to some U.S. operators, such as increased fuel costs and other operational-related costs. However, the FAA expects the benefits of this action exceed the costs because it will result in the avoidance of risks of fatalities, injuries, and property damage that could occur if a U.S. operator's aircraft were shot down (or otherwise damaged) while operating in the Damascus FIR (OSTT).

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), in 5 U.S.C. 603, requires an agency to prepare an initial regulatory flexibility analysis describing impacts on small entities whenever 5 U.S.C. 553 or any other law requires an agency to publish a general notice of proposed rulemaking for any proposed rule. Similarly, 5 U.S.C. 604 requires an agency to prepare a final regulatory flexibility analysis when an agency issues a final rule under 5 U.S.C. 553, after that section or any other law requires publication of a general notice of proposed rulemaking. The FAA concludes good cause exists to forgo notice and comment and to not delay the effective date for this rule. As 5 U.S.C. 553 does not require notice and comment in this situation, 5 U.S.C. 603 and 604 similarly do not require regulatory flexibility analyses.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39) prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to this Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

The FAA has assessed the potential effect of this final rule and determined that its purpose is to protect the safety of U.S. civil aviation from risks to their operations in the Damascus FIR (OSTT), a location outside the U.S. Therefore, the rule complies with the Trade Agreements Act of 1979.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $155 million in lieu of $100 million.

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires the FAA to consider the impact of paperwork and other information collection burdens it imposes on the public. The FAA has determined no new requirement for information collection is associated with this final rule.

F. International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, the FAA's policy is to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined no ICAO Standards and Recommended Practices correspond to this regulation. The FAA finds this action is fully consistent with the obligations under 49 U.S.C. 40105(b)(1)(A) to ensure the FAA exercises its duties consistently with the obligations of the United States under international agreements.

While the FAA's flight prohibition does not apply to foreign air carriers, DOT codeshare authorizations prohibit foreign air carriers from carrying a U.S. codeshare partner's code on a flight segment that operates in airspace for which the FAA has issued a flight prohibition for U.S. civil aviation. In addition, foreign air carriers and other foreign operators may choose to avoid, or be advised or directed by their civil aviation authorities to avoid, airspace for which the FAA has issued a flight prohibition for U.S. civil aviation.

G. Environmental Analysis

The FAA has analyzed this action under Executive Order 12114, Environmental Effects Abroad of Major Federal Actions, and DOT Order 5610.1C, Paragraph 16. Executive Order 12114 requires the FAA to be informed of environmental considerations and take those considerations into account when making decisions on major Federal actions that could have environmental impacts anywhere beyond the borders of the United States. The FAA has determined this action is exempt pursuant to Section 2–5(a)(i) of Executive Order 12114 because it does not have the potential for a significant effect on the environment outside the United States.

In accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 8–6(c), FAA has prepared a memorandum for the record stating the reason(s) for this determination and has placed it in the docket for this rulemaking.

VIII. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this rule under the principles and criteria of Executive Order 13132, Federalism. The Agency has determined this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, this rule will not have federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. The Agency has determined it is not a ''significant energy action'' under the executive order and will not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609 and has determined that this action will have no effect on international regulatory cooperation.

D. Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This rule is not subject to the requirements of Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, because the FAA is issuing it with respect to a national security function of the United States.

IX. Additional Information

A. Availability of Rulemaking Documents

An electronic copy of a rulemaking document may be obtained from the internet by—

- Searching the docket for this rulemaking at *https://www.regulations.gov;*
- Visiting the FAA's Regulations and Policies web page at *https://www.faa.gov/regulations_policies;* or
- Accessing the Government Publishing Office's website at *https://www.govinfo.gov.*

Copies may also be obtained by sending a request (identified by amendment or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677.

Except for classified material, all documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed from the internet through the docket for this rulemaking.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121) (set forth as a note to 5 U.S.C. 601) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the persons listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 91

Air traffic control, Aircraft, Airmen, Airports, Aviation safety, Freight, Syria.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations, as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, 47534, Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.1609 by revising paragraphs (a)(2), (3), and (e) to read as follows:

§ 91.1609 Special Federal Aviation Regulation No. 114—Prohibition Against Certain Flights in the Damascus Flight Information Region (FIR) (OSTT).

(a) * * *

(2) All persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and

(3) All operators of U.S.-registered civil aircraft, except when the operator of such aircraft is a foreign air carrier.

* * * * *

(e) *Expiration.* This SFAR will remain in effect until December 30, 2023. The FAA may amend, rescind, or extend this SFAR, as necessary.

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f) and (g), 40101(d)(1), 40105(b)(1)(A), and 44701(a)(5), on November 16, 2020.

Steve Dickson,

Administrator.

[FR Doc. 2020–25970 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

28 CFR Part 0

[AG Order No. 4917–2020]

Delegation of Defense Production Act Authority

AGENCY: Office of the Attorney General, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule authorizes the Assistant Attorney General in charge of the Antitrust Division to perform, as the delegate of the Attorney General, all functions that the Attorney General is required or authorized to perform by section 708 of the Defense Production Act (''DPA'').

DATES: Effective Date: November 27, 2020.

FOR FURTHER INFORMATION CONTACT: David G. B. Lawrence, Chief, Competition Policy & Advocacy Section, Antitrust Division, U.S. Department of Justice, Washington, DC 20530; telephone (202) 532–4698.

SUPPLEMENTARY INFORMATION: Under the DPA, upon finding that conditions exist which may pose a direct threat to the national defense or its preparedness programs, the President or his designee may consult with representatives of industry, business, financing, agriculture, labor, and other interests in order to provide for the making by such persons, with the approval of the President or his designee, of voluntary agreements and plans of action to help

provide for the national defense. 50 U.S.C. 4558(c)(1)–(2). The DPA requires that each proposed voluntary agreement or proposed plan of action be reviewed by the Attorney General prior to becoming effective. If, after consulting with the Chairman of the Federal Trade Commission, the Attorney General finds that the purposes of 50 U.S.C. 4558(c) ''may not reasonably be achieved through a voluntary agreement or plan of action having less anticompetitive effects or without any voluntary agreement or plan of action,'' the agreement or plan may become effective. 50 U.S.C. 4558(f)(1)(B).

The DPA therefore requires action from the Attorney General from the standpoint of the antitrust laws. As a result, the Assistant Attorney General in charge of the Antitrust Division is already assigned the preparation of the Attorney General's approval or disapproval whenever such action is required by the DPA from the standpoint of the antitrust laws. 28 CFR 0.40(e). Conditions that may pose a direct threat to the national defense or its preparedness programs are inherently dynamic, and it is of utmost importance to be able to respond rapidly to such conditions. Therefore, the Attorney General has made the determination to promulgate a regulation unambiguously delegating to the Assistant Attorney General in charge of the Antitrust Division his authority to perform all functions that the Attorney General is required or authorized to perform by section 708 of the DPA (50 U.S.C. 4558).

Administrative Procedure Act—5 U.S.C. 553

This rule is a rule of agency organization and relates to a matter relating to agency management and is therefore exempt from the requirements of prior notice and comment and a 30-day delay in the effective date. *See* 5 U.S.C. 553(a)(2), 553(b)(A), 553(d).

Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities because it pertains to personnel and administrative matters affecting the Department. Further, a Regulatory Flexibility Analysis is not required to be prepared for this final rule because the Department was not required to publish a general notice of proposed rulemaking for this matter. 5 U.S.C. 604(a).

Executive Orders 12866, 13563, and 13771—Regulatory Review

This action has been drafted and reviewed in accordance with section 1(b) of Executive Order 12866, ''Regulatory Planning and Review,'' and section 1(b) of Executive Order 13563, ''Improving Regulation and Regulatory Review.'' This rule is limited to agency organization, management, and personnel as described in section 3(d)(3) of Executive Order 12866 and, therefore, is not a ''regulation'' or ''rule'' as defined by the order. Accordingly, this action has not been reviewed by the Office of Management and Budget.

This rule is not subject to the requirements of Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' because it is not a significant regulatory action under Executive Order 12866, and because it is ''related to agency organization, management, or personnel'' and thus not a ''regulation'' or ''rule'' under section 4(b) of Executive Order 13771.

Executive Order 13132—Federalism

This rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988—Civil Justice Reform

This rule was drafted in accordance with the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year (adjusted annually for inflation), and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This action pertains to agency management, personnel, and organization and does not substantially affect the rights or obligations of non-agency parties and, accordingly, is not a ''rule'' as that term is used by the Congressional Review Act, 5 U.S.C. 804(3)(B), (C). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 28 CFR Part 0

Authority delegations (Government agencies), Government employees, National defense, Organization and functions (Government agencies), Privacy, Reporting and recordkeeping requirements, Whistleblowing.

Accordingly, by virtue of the authority vested in me as Attorney General, including 5 U.S.C. 301 and 28 U.S.C. 509 and 510, part 0 of title 28 of the Code of Federal Regulations is amended as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

■ 1. The authority citation for part 0 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510, 515–519.

■ 2. Section 0.40(l) is added to read as follows:

§ 0.40 General functions.

* * * * *

(l) As the delegate of the Attorney General, performance of all functions that the Attorney General is required or authorized to perform by section 708 of the Defense Production Act (50 U.S.C. 4558).

Dated: November 20, 2020.

William P. Barr,

Attorney General.

[FR Doc. 2020–26222 Filed 11–25–20; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 26

[Docket Number OAG 171; AG Order No. 4911–2020]

RIN 1105–AB63

Manner of Federal Executions

AGENCY: Office of the Attorney General, Department of Justice.

ACTION: Final rule.

SUMMARY: The Department of Justice (''Department'' or ''DOJ'') is finalizing amendments to regulations to authorize implementation of a sentence in a Federal capital case in any manner consistent with Federal law and to make other amendments.

DATES: This final rule becomes effective December 24, 2020.

FOR FURTHER INFORMATION CONTACT: Laurence E. Rothenberg, Deputy Assistant Attorney General, Office of Legal Policy, U.S. Department of Justice, (202) 514–3116.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

The Federal Death Penalty Act provides that a capital sentence in a Federal case is to be implemented ''in the manner prescribed by the law of the State in which the sentence is imposed.'' 18 U.S.C. 3596(a). However, if the ''law of the State in which the sentence is imposed'' ''does not provide for implementation of a sentence of death,'' then the statute directs the court to designate another State whose law does ''provide for the implementation of a sentence of death, and the sentence shall be implemented in the latter State in the manner prescribed by such law.'' *Id.*

The current execution regulations, promulgated in a final rule published on January 19, 1993, Implementation of Death Sentences in Federal Cases, 58 FR 4898 (Jan. 19, 1993), and codified at 28 CFR part 26, authorize execution only through lethal injection, except to the extent a court orders otherwise. Specifically, they direct the attorney for the government to ''file with the sentencing court a proposed Judgment and Order'' stating that ''[t]he sentence shall be executed by intravenous injection of a lethal substance or substances in a quantity sufficient to cause death.'' 28 CFR 26.2(a). The regulations further state that, except to the extent a court orders otherwise, a sentence of death shall be executed on a date and at a time and at a ''federal penal or correctional institution designated by the Director of the Federal Bureau of Prisons . . . [b]y intravenous injection of a lethal substance or substances in a quantity sufficient to cause death.'' *Id.* § 26.3(a).

Execution by lethal injection is authorized in all States that have capital punishment. *See In re Fed. Bureau of Prisons' Execution Protocol Cases,* 955 F.3d 106, 114 (D.C. Cir. 2020) (Katsas, J., concurring) (''Every state that authorizes capital punishment uses lethal injection 'as the exclusive or primary means of implementing the death penalty.' '' (quoting *Baze* v. *Rees,* 553 U.S. 35, 42 (2008) (plurality opinion))). However, some States also authorize execution by other means in certain circumstances. *See, e.g.,* Ala. Code 15–18–82.1(a) (by lethal injection but electrocution or nitrogen hypoxia may be elected); Miss. Code Ann. 99–19–51(1)–(4) (by lethal injection but by nitrogen hypoxia, electrocution, or firing squad if other methods are held unconstitutional or otherwise unavailable); Okla. Stat. tit. 22, sec. 1014 (same); Ark. Code Ann. 5–4–617(*l*) (by electrocution if execution by lethal injection is invalidated); Fla. Stat. 922.105 (by lethal injection but electrocution may be elected); *see also Bucklew* v. *Precythe,* 139 S. Ct. 1112, 1142 (2019) (Breyer, J., dissenting) (noting States permitting use of nitrogen hypoxia); *Glossip* v. *Gross,* 135 S. Ct. 2726, 2796 (2015) (Sotomayor, J., dissenting) (noting State using firing squad). One State has recently used electrocution. *See Media Advisory,* Tenn. Dep't of Corr. (Dec. 5, 2019, 7:27 p.m.), *https://www.tn.gov/correction/news/2019/12/5/media-advisory.html.* Some States also provide by law that a prisoner may choose the manner of execution from among several options, in at least some circumstances. *See* Ala. Code 15–18–82.1(b); Ariz. Rev. Stat. Ann. 13–757(B); Cal. Penal Code 3604; Fla. Stat. 922.105; Ky. Rev. Stat. Ann. 431.220(1)(b); S.C. Code Ann. 24–3–530(A); Tenn. Code Ann. 40–23–114(b); Va. Code Ann. 53.1–234. States may authorize execution by other means in the future, and it is possible that a State in the future will provide that a manner other than lethal injection is the *only* authorized means of execution. Section 3596(a) would then require execution in that manner for a Federal offender sentenced in the State.

The current regulations also provide that a Federal execution shall occur ''[a]t a federal penal or correctional institution designated by the Director of the Federal Bureau of Prisons.'' 28 CFR 26.3(a)(2). Section 3597(a), however, provides that State and local facilities and personnel may be used in carrying out Federal executions. As discussed above, future situations may arise in which it is necessary to carry out an execution by some means other than lethal injection. However, the Federal Bureau of Prisons (''BOP'') facility for carrying out executions, located at the Terre Haute correctional complex in Indiana, is equipped for carrying out executions only by lethal injection. If cases arise in which the Department is required to execute a Federal inmate according to the law of a State that uses a method other than lethal injection, the most expedient means of carrying out the execution may be to arrange for State assistance.

II. Proposed Rule

The Department published a notice of proposed rulemaking (''NPRM'') on August 5, 2020, Manner of Federal Executions, 86 FR 47324 (Aug. 5, 2020), proposing amendments to 28 CFR part 26 intended to provide the Federal Government with greater flexibility to conduct executions in any manner authorized by section 3596(a) and to implement the statutory authorization in section 3597(a) that provides that State and local facilities and personnel may be used in carrying out Federal executions. The proposed rule also proposed various amendments to other provisions of the regulations, as described in detail below, that would eliminate redundancies, such as eliminating § 26.2 regarding filing of a judgment and order with the sentencing court, and that would update the regulations for current practice by the Department and its components, such as granting authority for decision-making about certain matters to the Director of BOP or his designee, rather than to the Warden of the institution where the execution is to be conducted.

By the end of the 30-day comment period on September 4, 2020, the Department received 23 comments that were responsive to the proposed rule. Following are the Department's responses to those comments.

III. Summary of Changes in the Final Rule

After evaluating the 23 public comments, the Department has determined that no major changes to the proposed rule are necessary. As described in the next section, the majority of public comments reflected general opposition to the death penalty. Although the Department is mindful of those views, no changes are necessary in response to those comments, as the death penalty is expressly authorized by Federal statute and has been repeatedly upheld by the Supreme Court as constitutional. *See Bucklew* v. *Precythe,* 139 S. Ct. 1112, 1122 (2019) (''The Constitution allows capital punishment.''). Other comments opposed various provisions in the rule as unnecessary, unauthorized by the statute, or contrary to the statute. The Department disagrees with those assertions for the reasons stated below and declines to change the proposed rule in response to them. Other comments suggested amendments to the existing regulations that were not proposed by the Department and that the Department has declined to adopt. Other comments raised issues that are more properly addressed in the BOP execution protocol (including its manual and addendum).

In response to three comments, Department has amended the proposed rule as follows: First, the final rule corrects a scrivener's error in the NPRM that deleted ''Except to the extent a

court orders otherwise,'' from the first line of § 26.4; second, it adds, in § 26.4(a), a notice to the prisoner of the method of execution to be employed or, where applicable, of the prisoner's option to choose from among multiple methods; and third, it clarifies in § 26.4(b) that the designee of the BOP Director can allow other persons to visit the inmate in the seven days prior to the date of execution.

Although no commenter objected to a proposed amendment in § 26.3(a)(3) changing the officials responsible for selection of personnel assisting the execution from the United States Marshal and the Warden of the institution to solely the Director of BOP or his designee, the Department has determined upon further reflection that that revision would not be efficient for administrative and management purposes. Instead, the final rule amends the provision to provide that personnel will be selected by the Director of the United States Marshals Service and the Director of BOP or their designees.

IV. Responses to Public Comments on the Proposed Rule

As noted above, a large majority of comments did not address specific proposed changes to the regulations. Rather, they expressed opposition to the use of capital punishment in general. Furthermore, many of those comments misunderstood the nature of the proposed amendments as designed to expedite executions or expand the use of capital punishment. As described above, the proposed amendments are not designed to achieve those objectives.

One comment by counsel for Federal death row inmates, as well as several other comments, had specific comments on the edits proposed in the NPRM. Following are responses to those comments.

A. Manner of Execution

The proposed rule proposed to amend part 26 to provide, in 28 CFR 26.3(a)(4), that Federal executions are to be carried out by lethal injection ''or by any other manner prescribed by the law of the State in which the sentence was imposed or which has been designated by a court in accordance with 18 U.S.C. 3596(a).'' The amendment would ensure that the Department would be authorized to use the widest range of manners of execution permitted by law. Two commenters opposed this amendment.

One commenter argued that the rule should specify the guidelines that the Department would follow to ensure the humane implementation of a sentence and gave several examples of procedures for lethal injection that the commenter argued should be delineated in the regulations, as well as how a prisoner's medical conditions would be accommodated. A second commenter argued that the language of the preamble of the proposed rule inappropriately referred to authorizing any method under Federal law while the statute refers to requiring use of any method authorized by State law.

The Department declines to make changes to the proposed rule in response to these comments.

The issues raised by the first commenter included detailed matters about lethal injection, such as the nature of drugs used, placement and other procedures for use of the IV for provision of the drugs, and use of lethal injection in inmates with certain medical conditions. These are matters that the current regulations do not address and that the proposed rule did not propose to address. To the extent that the comment is arguing that issues it raises should nevertheless be addressed in the regulations, the Department considers these matters properly addressed in the BOP execution protocol, which includes more granular details regarding execution procedures.

The Department notes that this comment included a recommendation for consideration of alternative methods of execution, such as the firing squad, for prisoners with medical conditions for whom the commenter contended lethal injection would be inappropriate. The Department takes this comment as consistent with the overall purpose of the proposed rule to provide for methods of execution besides lethal injection, where they are prescribed by the relevant State law, although the specific application of any method to a particular prisoner is beyond the scope of this rulemaking.

This commenter also recommended that the notice of the date of execution provided to a prisoner also should state the method of execution to be used. The Department agrees with this recommendation. As the final rule provides for the possibility that methods other than lethal injection may be employed by the Department, it is reasonable that a prisoner be provided with notice of the method to implement that prisoner's sentence. In addition, as noted above, some State laws provide the prisoner the option to choose the method of execution.

For these reasons, in § 26.4(a), the final rule inserts ''the manner of execution and'' before ''date designated for execution,'' deletes ''date of'' after ''previously scheduled and noticed,'' and adds a new sentence at the end of the paragraph to read as follows: ''If applicable law provides that the prisoner may choose among multiple manners of execution, the Director or his designee shall notify the prisoner of that option.''

The second commenter misunderstands the proposed rule. The commenter is correct that the Federal Death Penalty Act refers to the use of the method of execution ''prescribed by the law of the State in which the sentence was imposed.'' However, the preamble of the proposed rule properly referred to ''federal'' law, because it is the Federal Death Penalty Act that provides the authority for the rule. In any event, the text of the proposed rule uses exactly the language of the statute, namely, ''by any other manner prescribed by the law of the State in which the sentence was imposed,'' as the commenter apparently was concerned that it should do.

B. Use of State Facilities

The NPRM proposed to permit use of State facilities, in accordance with the authorization in section 3597(a), by striking ''federal'' before ''penal or correctional institution'' in § 26.3(a)(2), and replacing ''[b]y'' with ''[u]nder the supervision of'' a United States Marshal in § 26.3(a)(3). This change also is addressed in the regulatory certification with regard to Executive Order 13132 on federalism, which stated that there were no federalism implications under that order.

Several commenters objected to these changes. One commenter argued that it was ''implausible'' that the change would not have an impact on States and that the federalism implications were ''self-evident.'' In addition, this commenter alleged that the provision could violate the constitutional ''anti-commandeering'' principle. A second commenter opposed the provision on unclear grounds but possibly because the commenter believed that State officials would not be able to implement a Federal sentence without facing criminal liability for doing so. A third commenter stated that rather than using State facilities, the Department should expand the capabilities of the Terre Haute facility or other facilities to be able to implement executions through means other than lethal injection.

The Department declines to make changes to the proposed rule in response to the comments. Each of the commenters misunderstands the need for this change and the nature of the change. First, as noted, the change does nothing more than implement an existing statutory provision, which

expressly provides the Federal Government with the option to contract with willing States to use their facilities and personnel in Federal executions. The policy implications or trade-offs, such as whether to expand Federal capabilities or potential liability for State workers, are not at issue in this rulemaking, which simply ensures that the Department is able to use an option expressly provided by statute.

Second, as to the federalism implications, the Department reiterates that the rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government as laid out in Executive Order 13132. The commenter misunderstands the purpose of Executive Order 13132. It is intended to limit Federal power to make national standards in policy and legislation that would preempt States from developing their own, and to prevent imposition of ''unfunded mandates'' on States by the Federal Government. The amendments at issue here do not implicate these concerns, nor do they implicate the anti-commandeering principle. The Federal Government would be implementing its own policy by an agreement with a willing State government and would cover any costs to the State, as expressly provided by section 3597(a). It is notable that Federal executions routinely occurred in State facilities in the 20th century, and that practice does not appear to have raised any federalism concerns. *See Execution Protocol Cases,* 955 F.3d at 137 (Rao, J., concurring). It also is significant that no State government—that is, none of the affected entities—commented in opposition to the proposed regulation.

For these reasons, the final rule makes no changes to the proposed rule's amendments to implement the statutory authority to use and pay for State facilities.

C. Other Amendments

1. § 26.1

The NPRM proposed to add a new provision, § 26.1(b), that would authorize the Attorney General to vary from the regulation to the extent necessary to comply with applicable law. One commenter commented that the NPRM did not provide sufficient explanation of why the addition of this paragraph was necessary or identify the legal basis for that paragraph. In addition, the commenter claimed that the new paragraph would provide a catch-all provision allowing the Attorney General to ignore or change regulations at will with no further process, and ad hoc, even in specific cases for impermissible reasons, at the last moment, and without notice. The commenter claimed that this would be a conflict of interest as well, because the Attorney General could change the regulations that apply to the individual his agency is responsible for prosecuting and executing. The comment identified these alleged concerns but did not suggest specific changes to the proposed rule.

The Department declines to make changes to the proposed rule in response to the comment. This provision was added to account for the statutory requirement that the Attorney General implement an execution ''in the manner prescribed by the law of the State in which the sentence is imposed.'' 18 U.S.C. 3596(a). The new paragraph is therefore intended only to ensure that the Attorney General can comply with State statutes that contradict the regulations. It is possible that at some point in the future a State statute that applies to the execution of a Federal inmate may differ, even in a minor respect, from the regulations. The specifics of such a difference are not currently foreseeable, however. Hence, in order to allow the execution to proceed without undue delay, this provision authorizes the Attorney General to account for that difference. The language of new § 26.1(b) itself clearly indicates that this is the intended purpose. It states, emphasis added, ''*Where applicable law conflicts* with any provision of this part, the Attorney General may vary from that provision *to the extent necessary to comply with the applicable law*.'' In fact, rather than providing the Attorney General with discretion to act arbitrarily or ad hoc, this provision limits the Attorney General's ability to vary from the regulation only in circumstances where controlling law requires him to do so and only to the extent necessary.

For these reasons, the final rule adopts new § 26.1(b) as proposed.

The NPRM also proposed to add a new provision, § 26.1(c), that would reiterate the Attorney General's authority to manage the Department's execution process, by stating that any task or duty assigned to any officer or employee of the Department of Justice under part 26 may be delegated by the Attorney General to any other officer or employee of the Department of Justice. Two commenters opposed this provision, stating that this change would allow the Attorney General to change regulations without notice to the public, rewrite the statute in violation of Congress's specific designation of certain officials—particularly a United States Marshal—to carry out certain duties, and violate the ''statutory scheme'' for executions in which the U.S. Marshals Service is given responsibility and accountability for implementation.

The Department declines to make changes to the proposed rule in response to the comments. As the NPRM explained, the proposed new paragraph is in line with the Attorney General's well-established authority to manage the Department. The commenters' arguments to the contrary are unavailing. First, one commenter's claim that the Attorney General could change regulations without notice is not relevant, as this provision itself is notice to the public that the Attorney General may re-designate responsibilities to other officials. Second, two commenters argued that the Attorney General lacks authority to reassign responsibilities that Congress has vested in other components by default. These comments ignore the plain language of the relevant sections of title 28 of the U.S. Code: ''All functions of other officers of the Department of Justice and all functions of agencies and employees of the Department of Justice are vested in the Attorney General,'' 28 U.S.C. 509; ''The Attorney General may from time to time make such provisions as he considers appropriate authorizing the performance by any other officer, employee, or agency of the Department of Justice of any function of the Attorney General,'' 28 U.S.C. 510. One commenter also argued that the provision would violate the ''statutory scheme'' for executions because the Director of the U.S. Marshals Service is accountable to Congress, as a Senate-confirmed officer. However, the U.S. Marshals Service is ''a bureau within the Department of Justice under the authority and direction of the Attorney General,'' 28 U.S.C. 561(a), and, as the provisions of title 28 noted above establish, the ultimate accountability for all actions of the Department and its officials lies with the Attorney General, who is also a Senate-confirmed officer. Likewise, the same principle applies to the commenter's arguments that the U.S. Marshals Service is ''uniquely suited'' to carrying out the law in localities across the country. As a matter of law, the Attorney General, through all the components of the Department of Justice, enforces Federal law in all districts of the Nation. This is true notwithstanding the 26-year-old internal DOJ memo cited by the commenter, Memorandum to U.S. Marshals Service

Director Gonzalez et al. from Deborah Westbrook, General Counsel, The ''Violent Crime Control and Law Enforcement Act of 1994'' (House Report 103–771) (Sept. 9, 1994), which makes the factual determination that the U.S. Marshals Service would be responsible for implementation of death sentences. Finally, the commenter is incorrect that implementing executions ''falls squarely within the 'primary role and mission' '' of the U.S. Marshals Service of enforcing court orders—and no other component's role and mission. As explained in more detail later in this preamble, although all death sentences are embodied in court orders, the details of implementing a death sentence by the Department of Justice do not depend on a court order alone.

2. § 26.2

The NPRM proposed removing the content of § 26.2, concerning a proposed Judgment and Order, and reserving it for future use. One commenter commented that the NPRM did not provide sufficient explanation for why the deletion of this section was necessary. In addition, the commenter claimed that deleting this section—and in particular, the requirement that the court's Judgment and Order include a statement that the sentence be executed on a date and at a place designated by the Director of the BOP—runs afoul of a claimed legal principle that BOP's authority to set an execution date is derived solely from the authority of the courts. The commenter further asserted that vesting authority for setting an execution date in BOP would deprive courts of necessary oversight over when and whether death-sentenced inmates had exhausted their judicial remedies.

The Department declines to make changes to the proposed rule in response to the comment. Section 26.2 was promulgated in 1993, requiring prosecutors to submit a proposed Judgment and Order to the court in cases in which the defendant was sentenced to death. The content of the Judgment and Order would include four basic points: (1) The sentence was to be executed by a United States Marshal, (2) by injection of a lethal substance, (3) on a date and at a place designated by BOP, and (4) the prisoner under sentence of death was to be committed to the custody of the Attorney General or his designee for detention pending execution of the sentence. Subsequently, Congress enacted the Federal Death Penalty Act, 18 U.S.C. 3591 *et seq.* Within that Act, section 3596(a) essentially codified two of these points, leaving out that the execution occur by lethal injection and on a date and at a place designated by BOP. The rule's requirement that the Judgment and Order specify the manner of execution as lethal injection is inconsistent with section 3596(a), which authorizes executions ''in the manner prescribed by the law of the State in which the sentence is imposed,'' which may not necessarily involve lethal injection. As to the requirement for the Judgment and Order to specify that executions occur on a date and at a place designated by BOP, that provision is also reflected in § 26.3(a)(1) and (2) (''Except to the extent a court orders otherwise, a sentence of death shall be executed: (1) On a date and at a time designated by the Director of the Federal Bureau of Prisons . . . ; (2) At a federal penal or correctional institution designated by the Director of the Federal Bureau of Prisons . . . .''). The provisions of 18 U.S.C. 3596 and 28 CFR 26.3 thus render § 26.2 unnecessary, meriting its removal.

In any event, the commenter's premise that BOP's authority to set an execution date derives solely from the courts is incorrect as a matter of law. *See, e.g., LeCroy* v. *United States,* 975 F.3d 1192, 1195–96 (11th Cir. 2020) (recognizing that, while the courts may historically have had some ''concurrent'' responsibility in setting execution dates, ''[t]he Code of Federal Regulations vests the Bureau Director with broad authority and discretion to set execution dates as an initial matter''); *United States* v. *Lee,* No. 4:97–cr–00243–LPR–2, 2020 WL 3921174, at *3 (E.D. Ark. July 10, 2020) (expressing skepticism ''that the founding generation . . . understood the *implementation* of a sentence to be of an entirely judicial nature'' and noting that ''until 1830 courts were all over the place as to whether they would set execution dates themselves or leave it to the Executive Branch''). The Executive Branch's authority to set an execution date, and the Attorney General's codification of that authority in the 1993 regulations, also are consistent with the Executive Branch's constitutional and statutory duties in general. *Cf. United States* v. *Tipton,* 90 F.3d 861, 902–03 (4th Cir. 1996) (concluding that ''absent directly preempting congressional action, the Attorney General had constitutional and statutory authority to provide by regulation the means for executing death sentences imposed under [the Anti-Drug Abuse Act of 1988],'' which preceded the Federal Death Penalty Act). Moreover, even if BOP's authority to set an execution date were derived from the authority of the courts, nothing would compel the court to use the precise ''magic words'' contained in § 26.2 to effectuate the delegation of its authority to BOP. *Lee,* 2020 WL 3921174, at *4 (rejecting claim that the only way a court may properly delegate its authority to implement a death sentence is by adopting the content of § 26.2 in an order).

The commenter's concern that removal of § 26.2 would deprive courts of oversight relating to execution dates also is misplaced. Section 26.3(a)'s prefatory language belies this concern, authorizing BOP's Director to set an execution date and time ''[e]xcept to the extent a court orders otherwise.'' And nothing in the proposed amendment of the regulations, including the deletion of § 26.2, alters the courts' power to set aside or postpone execution dates pursuant to their authority to issue stays and injunctions. *See LeCroy,* 975 F.3d at 1196 (''the regulations . . . sensibly recognize—as they must—a court's authority to stay or enjoin a scheduled execution'').

For these reasons, the final rule removes § 26.2 as proposed.

3. § 26.3

Section 26.3(a)(1) addresses the date and time of an execution and specifies that if the date designated for execution passes by reason of a stay of execution, then a new date shall be designated promptly by the Director of the Federal Bureau of Prisons when the stay is lifted. The NPRM did not propose any changes to this paragraph. Nonetheless, several commenters *sua sponte* suggested alterations to this provision, contending that: The BOP Director lacks authority to designate the date and time of an execution; the Department should further define the phrase ''when the stay is lifted'' and the term ''promptly''; and the regulations should set out procedures to follow in the event of a stay.

The Department declines to make changes to the proposed rule in response to the comments. First, the suggested changes are beyond the scope of the current rulemaking, in which the Department did not propose any changes to this portion of the regulations. In any event, as explained above in this preamble, the Attorney General may delegate authority in execution-related matters to the BOP Director. Moreover, as reflected in the current regulations, detailed procedures are better addressed in the Federal execution protocol. The Department also notes that the existing rule (along with § 26.4(a)) appropriately takes into account the possibility that an inmate's or court's last-minute actions may delay an execution past midnight, causing the

execution to be performed the day after it had been formally scheduled. The Department may consider the suggestions and proposals made in the comments if it undertakes further changes to the regulations or execution protocol.

For these reasons, the final rule makes no changes to § 26.3(a)(1).

In § 26.3(a)(3), the NPRM proposed clarifying that ''qualified'' personnel must carry out an execution, regardless of manner. Commenters suggested that ''qualified'' must be defined with objective criteria.

The Department declines to make changes to the proposed rule in response to the comment. The regulatory requirement that the Department employ ''qualified personnel'' in an execution is not new; the current language of § 26.3(a)(4) requires that lethal injections ''be administered by qualified personnel.'' With the expansion of permissible Federal execution methods, moving this phrase from paragraph (a)(4) to paragraph (a)(3) merely ensures that whatever method of execution is employed in light of the relevant State's laws, the personnel implementing that method will be suitably qualified. To the extent that the Department considers it appropriate to set out further details regarding qualifications, it may do so in the Federal execution protocol, as it has done in the addendum to the protocol regarding lethal injection. The Department notes that the relevant qualifications may change depending on the execution method called for by State law, and that to the extent that States change their methods, *see supra* (discussing expansion of Federal execution methods), entrenching static qualification criteria in regulations would be antithetical to the rulemaking's goal of ensuring that Federal executions may be responsibly carried out in accordance with any State's prescribed method of execution.

The amendments to § 26.3(a)(3) in the NPRM also had the effect of revising the official responsible for selection of personnel assisting the execution from the Marshal and the Warden of the institution to solely the Director of BOP or his designee. No commenter commented on this provision. The Department has determined that that revision would not be efficient for administrative and management purposes, however. Instead, the final rule amends the provision to provide that personnel will be selected by the Director of the U.S. Marshals Service and the Director of BOP or their designees.

For these reasons, the final rule revises § 26.3(a)(3) to provide that the sentence of death be executed under the supervision of a United States Marshal designated by the Director of the United States Marshals Service, assisted by additional qualified personnel who are selected by the Director of the United States Marshals Service and the Director of the Federal Bureau of Prisons, or their designees, and acting at the direction of the Marshal.

4. § 26.4

In the first line of § 26.4, the proposed rule eliminated the phrase ''Except to the extent a court orders otherwise''. One commenter claimed that this change was unexplained, contrary to the original justification for the existing regulation, and would ''eliminate judicial oversight over critical aspects of the execution process.''

The Department notes that this change was a scrivener's error that inadvertently appeared in the final text of the NPRM during the process of formatting the operative text of the proposed rule.

For this reason, the final rule re-inserts the phrase ''Except to the extent a court orders otherwise,'' in the first line of § 26.4.

Section 26.4(a) provides that a prisoner will receive notice of the date designated for execution ''at least 20 days in advance, except when the date follows a postponement of fewer than 20 days of a previously scheduled and noticed date of execution, in which case'' the prisoner shall be notified ''as soon as possible.'' The only change proposed to this section in the NPRM was to place responsibility for such notification with the ''Director of the Federal Bureau of Prisons or his designee'' instead of with the ''Warden.''

Commenters provided a number of suggestions unrelated to the proposed change, including arguments that this regulation should: Require notice to counsel; define what constitutes sufficient notice; limit who can be a ''designee'' for purposes of notice; and limit the Government's ability to continue a noticed execution date. Commenters also criticized the existing regime as limiting prisoners' ability to apply for clemency.

The Department declines to make changes to the proposed rule in response to the comments. These suggestions are beyond the scope of the current rulemaking, which sought only to change the official charged with providing notice of an execution date, not to alter the contours of that notice. In all respects relevant to these comments, the proposed rule is the same as the existing rule. Moreover, as discussed in connection with § 26.3(a)(1), the prompt rescheduling of an execution date may be necessary and appropriate where last-minute litigation requires a delay of execution past midnight of an originally scheduled date. Further, the Department observes that prisoners are free to prepare clemency petitions at any time and, per 28 CFR 1.10(b), to file such petitions as soon as proceedings on their direct appeal and first petition under 28 U.S.C. 2255 have terminated.

Furthermore, commenters' suggestion that 28 CFR 1.10(b) provides prisoners with a right to 30 days to file a clemency petition is incorrect; that provision creates a limitation, not an entitlement, providing that such petitions should be filed ''*no later than* 30 days after the petitioner has received notification from the Bureau of Prisons of the scheduled date of execution.'' (Emphasis added.) Nor does the existing regulation conflict with 28 CFR 1.10(c), which permits prisoners' counsel to request to make an oral presentation to the Office of the Pardon Attorney within the Department. Clemency counsel may still request and make such presentations well before a scheduled execution, even if the prisoner receives the minimum 20-day notice. Indeed, a clemency proceeding may be conducted within 20 days where an impending execution date requires such dispatch.

For these reasons, the final rule adopts new § 26.4(a) as proposed. The Department may consider the suggestions and proposals made in the comments if it undertakes further changes to the regulations or to the execution protocol.

Section 26.4(b) governs prisoner access to other persons in the week before the designated execution date, limiting such access to spiritual advisers, defense attorneys, family members, institution officials, and—upon the approval of the BOP Director—''such other proper persons as the prisoner may request.'' The NPRM proposed to clarify that the BOP Director may approve prisoner requests for types of visitors not listed in the regulation, eliminating a reference to the ''Warden.'' It did not propose any other changes to this provision. Commenters nevertheless suggested a wide range of changes nonresponsive to the proposal, suggesting that the language limiting prisoner visits should be deleted, and that the regulation should be revised to permit attendance by anyone the inmate wants, subject to disapproval by officials only for good cause. Commenters also suggested replacing

''defense attorneys'' with ''members of defense team,'' adding ''all'' before ''members of his family,'' and eliminating ''only'' before the list of permitted visitors in the week before the execution. Some commenters even suggested removing all ''restrict[ions on] the type of visitors'' other than that they ''pass the security clearances'' at the facility.

The Department declines to make changes to the proposed rule in response to the comments. The NPRM did not propose substantive changes to the categories of persons to whom a prisoner may have access in the week before his execution date, and the comments are thus beyond the scope of the present rulemaking. The Department may consider the suggestions and proposals made in the comments if it undertakes further changes to the regulations or to the execution protocol.

Even were these comments responsive to proposed changes to the rules, the Department notes that to the extent that commenters desire a regulation creating a prisoner entitlement to unlimited types or numbers of visitors, their proposals are inconsistent with the need to limit visiting when necessary to ensure the security and good order of the institution and consideration of institution resources. The existing rule strikes an appropriate balance between providing a prisoner with access to spiritual, legal, and familial support, while maintaining security and conserving resources. The existing rule also already provides a mechanism to permit additional visitors identified by commenters (such as friends or paralegals working with a legal defense team), where BOP agrees that a prisoner's particular circumstances so warrant and the additions can be made without disrupting that balance or disturbing prison officials' discretion to determine which visitors may enter these high-security facilities, as provided at 28 CFR part 540, subpart D. The Department further notes that additional details, such as those relating to the frequency or method of visitation, are better addressed in the more finely reticulated provisions of BOP policy.

Another comment noted that proposed § 26.4(b), by deleting ''Warden,'' would authorize only the BOP Director to allow other persons to visit the inmate, which may be impractical. The commenter's observation is correct as to the proposed paragraph and the practical impact of deleting ''Warden''; the Department did not add ''or his designee'' after the reference to the BOP Director in § 26.4(b), when it deleted ''Warden,'' whereas the reference to the ''Warden'' throughout the regulation was elsewhere replaced with the BOP Director ''or his designee.'' For the sake of consistency with the rest of the amendments in the proposed rule, the Department agrees with the commenter that § 26.4(b) should also refer to the Director's designee.

For these reasons, the final rule revises § 26.4(b) as proposed, but also adds ''or his designee'' after ''Director of the Federal Bureau of Prisons.''

Section 26.4(c) governs execution attendance, requiring certain official personnel to attend and imposing limits on the numbers and types of other persons whom the prisoner and officials may designate to attend. The NPRM proposed eliminating references to the ''Warden,'' thus eliminating the requirement that the Warden attend executions, while maintaining the requirement that the Marshal attend. The only other proposed change was to vest authority for selecting necessary personnel in the Marshal and the BOP Director or his designee, instead of in the Marshal and the Warden. With respect to § 26.4(c)(1), commenters expressed concern that such authority could not be vested in the BOP Director or his designee and sought clarification whether the regulation was intended to require the agreement of both the Marshal and the BOP Director or his designee regarding personnel attendance. With respect to § 26.4(c)(3), although the commenters recognized that its text in the proposed rule remained materially unchanged from the existing regulation, they nonetheless proposed changes to it. Specifically, commenters requested that the regulation be revised to provide prisoners with an entitlement to have persons they specify attend their executions, suggesting that the inability of a prisoner-designated witness to attend should halt or delay an execution, potentially through litigation.

The Department declines to make changes to the proposed rule in response to the comments.

With respect to § 26.4(c)(1), as explained above, the BOP Director, or his designee, may properly be vested with authority in execution-related matters. With respect to the commenter's concerns about potential disagreements between Department officials regarding the personnel necessary to attend the execution, those concerns are unfounded as a practical matter, as each official selects personnel from his own agency to attend and no disagreements about personnel have ever arisen between the Marshal and the Warden under the existing regulation. In any event, the Attorney General has ultimate authority over all relevant officials and functions of the Department.

With respect to § 26.4(c)(3), no changes were proposed to this provision, and the commenters' proposed alterations are outside the scope of this rulemaking. In any event, the commenters erroneously suggest that the existing rule can be read to provide certain potential witnesses an entitlement to attend an execution. The clear language of the regulation specifies that ''*[n]ot more than* the following numbers of'' certain persons designated by the prisoner ''shall be present'' at an execution. (Emphasis added.) As the Seventh Circuit concluded in interpreting analogous language in § 26.4(c)(4), these terms establish ''a limitation on, not an entitlement to, witness attendance.'' *Peterson* v. *Barr,* 965 F.3d 549, 553 (7th Cir. 2020) (also rejecting the argument that § 26.4(c)(4) required the attendance of witnesses designated by Department officials ''before the execution may proceed''). To the extent commenters suggest that the regulation should instead provide an entitlement for specific persons to attend an execution, or even to permit potential witnesses to delay or halt an execution if unable or unwilling to attend, the Department disagrees. Such a regime could permit a prisoner's lawyers or family members to unilaterally halt an execution they oppose by the simple expedient of refusing to attend. The existing rule provides a reasonable avenue for Department officials to permit a prisoner's spiritual advisor, defense attorneys, and friends or relatives to attend without effecting this unprecedented and potentially disruptive change in execution procedures.

For these reasons, the final rule adopts the amendments to § 26.4(c) as proposed, and declines to make any changes to § 26.4(c)(3) as suggested by the commenters.

Current § 26.4(f) provides that ''[n]o photographic or other visual or audio recording of the execution shall be permitted.'' One commenter objected to this paragraph, stating that defense counsel should be permitted to video- and audio-record executions, and alternatively recommends that the Department also record executions. The commenter states that a recording is necessary to ensure a record for review by courts and by the legislature to adjudge whether the execution method is humane. The commenter states that witness observation through the window of rooms adjacent to the execution room is insufficient.

The Department declines to make changes to the proposed rule in response to the comment. The NPRM did not propose changes to § 26.4(f) and the Department will not change this provision in response to the comment. The Department values preserving the order, privacy, and solemnity of the proceeding more than the speculative value of audio or video recording of the execution. Recording also risks revealing the identities of personnel performing tasks implementing an execution; these persons' identities are not publicly available in order to protect them from harassment and threats. Further, multiple witnesses as identified in § 26.4(c) may attend the execution to observe. The presence of these witnesses accommodates the public interest in reports and eyewitness accounts of the execution.

Accordingly, the Department adopts the rule as proposed without revising § 26.4(f).

5. § 26.5

The proposed rule proposed to extend to non-DOJ employees (including contractors) existing protections that currently apply to DOJ employees, allowing them not to be in attendance at or to participate in any execution if such attendance or participation is contrary to the moral or religious convictions of the DOJ employee. The new language was almost the exact language on this matter used in 18 U.S.C. 3597(b).

No comments were received on this proposed amendment. Therefore, the final rule adopts the amendments to § 26.5 as proposed.

6. Access to Mobile Phones

One commenter commented that attorneys for the prisoner present at the execution should be allowed to have mobile phones or immediate access to a dedicated phone line to communicate outside the facility. The commenter further stated that prisoners should be able to communicate with counsel by phone when in the execution facility.

The Department declines to make changes to the proposed rule in response to the comment. Modifying the rule to detail the manner and means of accommodating phone communication between the prisoner and his attorney, and attorney access to phone communications when inside the execution facility, is unnecessary. The current rule and the NPRM do not address phone calls and visits with attorneys. The BOP execution protocol addresses this subject and permits calls and visits between the prisoner and his attorney including during the final 24 hours leading to the execution. The Department declines to incorporate the details of the manner and means of those communications into the text of the rule.

7. References to the Director of BOP or His Designee

One commenter objected to all those provisions (§§ 26.3(a)(3), 26.4(a), 26.4(c)(1), 26.4(c)(4), 26.4(e), and 26.4(g)) in which the proposed rule proposed to add ''or his designee'' after ''Director of the Federal Bureau of Prisons'' or replace ''Warden'' with ''Director of the Federal Bureau of Prisons or his designee.'' The commenter stated that the rule fails to define who can be a designee and fails to set any limits on which designees may make the decision or take the action described in the rule. Thus, the comment recommended that the rule include a definition of ''designee'' to ensure the person entrusted with the task is competent to do so and is specifically authorized.

The Director of the Federal Bureau of Prisons is authorized to redelegate duties vested in him. *See* 28 CFR 0.97. The authority to redelegate responsibilities regarding management of Federal correctional institutions and the custody and care of persons held therein allows appropriate flexibility in managing correctional institutions, including activities related to executions. Adopting the recommendation would unnecessarily curtail flexibility. Further, to the extent the Director redelegates the duties vested in him by this rule, such delegations would be better placed in the BOP execution protocol, which sets forth internal policy and procedures for carrying out the execution of a person convicted of a capital offense. Therefore, this subject is not suited to further elaboration in the rule and there is no need to modify the rule as the commenter recommends.

V. Regulatory Review

A. Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this final rule and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities because it concerns the manner of implementing Federal death sentences on individuals convicted of capital offenses.

B. Executive Orders 12866, 13563, and 13771—Regulatory Planning and Review

This final rule has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review,'' section 1(b), ''The Principles of Regulation,'' and Executive Order 13563, ''Improving Regulation and Regulatory Review.'' The Office of Information and Regulatory Affairs has determined that the rule is a ''significant regulatory action'' under Executive Order 12866, section 3(f).

In the proposed rule, the Department stated that if finalized, the rule could entail financial costs if, at some point in the future, a prisoner is to be executed by a manner other than lethal injection. The Department would then either have to provide its own system for an execution by a manner other than lethal injection or pay for the use of State or local facilities and personnel to perform the execution. In such a circumstance, the cost would likely be the development of Federal capabilities to implement such a sentence or payment for the use of State or local facilities and personnel. No further information either in support of this analysis or in contradiction of it was received during the public comment period. The Department has therefore not changed its analysis of the impact of the rule.

This final rule is not a regulatory action for purposes of Executive Order 13771.

C. Executive Order 13132—Federalism

This final rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Section 3597 of title 18 provides that the Federal Government ''may use appropriate State or local facilities for the purpose [of implementing a sentence of death], may use the services of an appropriate State or local official or of a person such an official employs for the purpose, and shall pay the costs thereof.'' The statutory authorization and the rule to implement it are directed at the Federal Government. Neither the statute nor the final rule imposes any requirements for action or costs on States. Any actions using the services of State or local governments would be done by agreement, and with the Federal Government paying the costs thereof. As noted above, some commenters opposed the rule on federalism grounds, but those commenters misunderstood the requirements of Executive Order 13132

and the impact of the rule. Therefore, in accordance with Executive Order 13132, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

E. Executive Order 12988—Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

F. Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (adjusted for inflation), and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

G. Congressional Review Act

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

List of Subjects in 28 CFR Part 26

Law enforcement officers, Prisoners.

Accordingly, for the reasons stated in the preamble, part 26 of chapter I of title 28 of the Code of Federal Regulations is amended as follows:

PART 26—DEATH SENTENCES PROCEDURES

■ 1. The authority citation for part 26 is revised to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 4001(b), 4002, 3596, 3597; 28 U.S.C. 509, 510, 2261, 2265.

■ 2. Amend § 26.1 by:
■ a. Designating the existing language as paragraph (a); and
■ b. Adding new paragraphs (b) and (c) to read as follows:

§ 26.1 Applicability.

* * * * *

(b) Where applicable law conflicts with any provision of this part, the Attorney General may vary from that provision to the extent necessary to comply with the applicable law.

(c) Any task or duty assigned to any officer or employee of the Department of Justice by this part may be delegated by the Attorney General to any other officer or employee of the Department of Justice.

§ 26.2 [Removed and Reserved]

■ 3. Remove and reserve § 26.2.

■ 4. Amend § 26.3 by revising the section heading and paragraphs (a)(2), (3), and (4) to read as follows:

§ 26.3 Date, time, place, and manner of execution.

(a) * * *

(2) At a penal or correctional institution designated by the Director of the Federal Bureau of Prisons;

(3) Under the supervision of a United States Marshal (Marshal) designated by the Director of the United States Marshals Service, assisted by additional qualified personnel selected by the Director of the United States Marshals Service and the Director of the Federal Bureau of Prisons, or their designees, and acting at the direction of the Marshal; and

(4) By intravenous injection of a lethal substance or substances in a quantity sufficient to cause death, such substance or substances to be determined by the Director of the Federal Bureau of Prisons, or by any other manner prescribed by the law of the State in which the sentence was imposed or which has been designated by a court in accordance with 18 U.S.C. 3596(a).

* * * * *

■ 5. Amend § 26.4 by revising the introductory text, paragraphs (a), (b), (c), (e), and (g) to read as follows:

§ 26.4 Other execution procedures.

Except to the extent a court orders otherwise:

(a) The Director of the Federal Bureau of Prisons or his designee shall notify the prisoner under sentence of death of the manner of execution and the date designated for execution at least 20 days in advance, except when the date follows a postponement of fewer than 20 days of a previously scheduled and noticed execution, in which case the Director of the Federal Bureau of Prisons or his designee shall notify the prisoner as soon as possible. If applicable law provides that the prisoner may choose among multiple manners of execution, the Director or his designee shall notify the prisoner of that option.

(b) Beginning seven days before the designated date of execution, the prisoner shall have access only to his spiritual advisers (not to exceed two), his defense attorneys, members of his family, and the officers and employees of the institution designated in § 26.3(a)(2). Upon approval of the Director of the Federal Bureau of Prisons or his designee, the prisoner may be granted access to such other persons as the prisoner may request.

(c) In addition to the Marshal, the following persons shall be present at the execution:

(1) Necessary personnel selected by the Marshal and the Director of the Federal Bureau of Prisons or his designee;

(2) Those attorneys of the Department of Justice whom the Deputy Attorney General determines are necessary;

(3) Not more than the following numbers of persons selected by the prisoner:

(i) One spiritual adviser;

(ii) Two defense attorneys; and

(iii) Three adult friends or relatives; and

(4) Not more than the following numbers of persons selected by the Director of the Federal Bureau of Prisons or his designee:

(i) Eight citizens; and

(ii) Ten representatives of the press.

* * * * *

(e) The Director of the Federal Bureau of Prisons or his designee should notify those individuals described in paragraph (c) of this section as soon as practicable before the designated time of execution.

* * * * *

(g) After the execution has been carried out, qualified personnel selected by the Director of the Federal Bureau of Prisons or his designee shall conduct an examination of the body of the prisoner to determine that death has occurred and shall inform the Marshal and the Director of the Federal Bureau of Prisons or his designee of his determination. Upon notification of the prisoner's death, the Marshal shall ensure that appropriate notice of the sentence's implementation is filed with the sentencing court.

* * * * *

■ 6. Amend § 26.5 by revising the first sentence to read as follows:

§ 26.5 Attendance at or participation in executions by Department of Justice personnel.

No officer or employee of the Department of Justice or a State department of corrections, or any employee providing services to those departments under contract, shall be required, as a condition of that employment or contractual obligation, to be in attendance at or to participate in any execution if such attendance or

participation is contrary to the moral or religious convictions of the officer or employee, or, if the employee is a medical professional, if the employee considers such participation or attendance contrary to medical ethics.
* * *

Dated: November 18, 2020.

William P. Barr,

Attorney General.

[FR Doc. 2020–25867 Filed 11–25–20; 8:45 am]

BILLING CODE 4410–19–P

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 102

Rule Exempting an Amended System of Records From Certain Provisions of the Privacy Act

AGENCY: National Labor Relations Board.

ACTION: Direct final rule.

SUMMARY: The National Labor Relations Board (NLRB) exempts a new system of records, NLRB iTrak and Banned Entry List, from certain provisions of the Privacy Act of 1974, pursuant to sections (k)(1), (2), and (5) of that Act.

DATES: This rule is effective January 26, 2021 without further action, unless adverse comment is received by December 28, 2020. If adverse comment is received, the NLRB will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: All persons who desire to submit written comments for consideration by the Agency regarding the rule shall mail them to the Agency's Senior Agency Official for Privacy, National Labor Relations Board, 1015 Half Street SE, Third Floor, Washington, DC 20570–0001, or submit them electronically to *privacy@nlrb.gov.* Comments may also be submitted electronically through *http://www.regulations.gov,* which contains a copy of this rule and any submitted comments.

FOR FURTHER INFORMATION CONTACT: Prem Aburvasamy, Senior Agency Official for Privacy, National Labor Relations Board, 1015 Half Street SE, Third Floor, Washington, DC 20570–0001, (202) 273–3733, *privacy@nlrb.gov.*

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the **Federal Register**, the Agency has announced a new system of records, NLRB–34, NLRB iTrak and Banned Entry List, pursuant to the Privacy Act of 1974, 5 U.S.C. 552a.

Pursuant to subsections (k)(1), (2), and (5) of the Privacy Act, and for the reasons set forth below, the Board includes within 29 CFR 102.119 additional paragraphs (q) and (r), exempting portions of the amended system of records (NLRB–34) from subsections (c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I), and (f) of the Privacy Act.

Subsection (k)(1) of the Privacy Act authorizes the head of an agency to exempt a system of records from subsections (c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I), and (f) of the Privacy Act (5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I), (f)) (hereinafter, ''the applicable subsections'') if records are properly classified pursuant to an Executive order, within the meaning of section 552(b)(1) of the Freedom of Information Act.

Subsections (k)(2) and (5) of the Privacy Act, in combination, authorize the head of an agency to exempt a system of records from the applicable subsections if records are created or maintained for the purpose of law enforcement (other than material within the scope of subsection (j)(2) of the Privacy Act), as well as determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence. As indicated in the Agency's accompanying Privacy Act system of records notice issuing NLRB–34, this system contains information compiled by the Agency in the course of carrying out its security responsibilities.

The requirements of the applicable subsections, if applied to the system of records NLRB–34, would substantially compromise the ability of the Agency's Security Branch staff to effectively conduct investigations concerning the suitability, eligibility, and fitness for service of applicants for Federal employment and contract positions at the Agency, in addition to determining the appropriate level of access to the Agency's facilities. For instance, the disclosure requirements as set forth in the provisions for notice, access, amendment, review, and accountings could enable subject individuals to take action to jeopardize the physical safety or anonymity of confidential sources used during investigatory proceedings. Additionally, the disclosure of information gathered during a security investigation may unreasonably weaken the interests of protecting properly classified information and the objectivity of certain examination materials.

This rule relates to individuals rather than small business entities. Accordingly, pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–612, this rule will not have a significant impact on a substantial number of small business entities.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Agency has determined that this rule would not impose new recordkeeping, application, reporting, or other types of information collection requirements on the public.

The rule will not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among levels of government. Therefore, it is determined that this rule does not have federalism implications under Executive Order 13132.

In accordance with Executive Order 12866, it has been determined that this rule is not a ''significant regulatory action,'' and therefore does not require a Regulatory Impact Analysis.

List of Subjects in 29 CFR Part 102

Privacy, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the NLRB amends 29 CFR part 102 as follows:

PART 102—RULES AND REGULATIONS, SERIES 8

■ 1. The authority citation for part 102 is revised to read as follows:

Authority: 29 U.S.C. 151, 156. Section 102.117 also issued under 5 U.S.C. 552(a)(4)(A), and § 102.119 also issued under 5 U.S.C. 552a(j) and (k). Sections 102.143 through 102.155 also issued under 5 U.S.C. 504(c)(1).

Subpart K—Records and Information

■ 2. Section 102.119 is amended by revising the section heading and adding paragraphs (q) and (r) to read as follows:

§ 102.119 Privacy Act Regulations: Notification as to whether a system of records contains records pertaining to requesting individuals; requests for access to records, amendment of such records, or accounting of disclosures; time limits for response; appeal from denial of requests; fees for document duplication; files and records exempted from certain Privacy Act requirements.

* * * * *

(q) Pursuant to 5 U.S.C. 552a(k)(1), (2), and (5), the system of records maintained by the NLRB containing NLRB iTrak and Banned Entry List records shall be exempted from the provisions of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f) insofar as the system may contain:

(1) Records properly classified pursuant to an Executive order, within the meaning of 5 U.S.C. 552(b)(1);

(2) Investigatory material compiled for law enforcement purposes other than material within the scope of 5 U.S.C. 552a(j)(2); and

(3) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts or access to classified information.

(r) The Privacy Act exemptions contained in paragraph (q) of this section are justified for the following reasons:

(1)(i) 5 U.S.C. 552a(c)(3) requires an agency to make the accounting of each disclosure of records available to the individual named in the record at his/her request. These accountings must state the date, nature, and purpose of each disclosure of a record and the name and address of the recipient. 5 U.S.C. 552a(d) requires an agency to permit an individual to gain access to records pertaining to him/her, to request amendment to such records, to request a review of an agency decision not to amend such records, and to contest the information contained in such records.

(ii) iTrak and Banned Entry List records may contain properly classified information which pertains to national defense and foreign policy obtained from another Federal agency. Application of exemption (k)(1) is necessary to preclude an individual's access to and amendment of such classified information under 5 U.S.C. 552a(d), which would pose a risk of harm to national defense and foreign policy interests.

(iii) iTrak and Banned Entry List records may contain investigatory material compiled for law enforcement purposes other than material within the scope of 5 U.S.C. 552a(j)(2). Application of exemption (k)(2) is necessary to preclude an individual's access to or amendment of such records under 5 U.S.C. 552a(c)(3) and (d), which would pose a risk of harm to law enforcement interests. Specifically, this exemption is necessary to safeguard the integrity of law enforcement investigations by minimizing the threat of harm to confidential sources, witnesses, and law enforcement personnel. Additionally, this exemption reduces the risks of improper influencing of sources, the destruction of evidence, and the fabrication of testimony.

(iv) Exemption (k)(5) is claimed with respect to the requirements of 5 U.S.C. 552a(c)(3) and (d) because this system contains investigatory material compiled solely for determining suitability, eligibility, and qualifications for Federal employment. To the extent that the disclosure of material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence, the applicability of exemption (k)(5) will be required to honor promises of confidentiality should an individual request access to or amendment of the record, or access to the accounting of disclosures of the record. This exemption is necessary to safeguard the integrity of security investigations by minimizing the threat of harm to confidential sources, witnesses, and law enforcement personnel. Additionally, this exemption reduces the risks of improper influencing of sources, the destruction of evidence, and the fabrication of testimony.

(2) 5 U.S.C. 552a(e)(1) requires an agency to maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required by statute or by Executive order of the President. This requirement could foreclose investigators from acquiring or receiving information the relevance and necessity of which is not readily apparent and could only be ascertained after a complete review and evaluation of all the evidence. This system of records is exempt from this requirement because in the course of security investigations, the accuracy of information obtained or introduced occasionally may be unclear, or the information may not be strictly relevant or necessary to favorably or unfavorably adjudicate a specific investigation at a specific point in time. However, in the interests of protecting the public trust and national security, it is appropriate to retain all information that may aid in establishing patterns in such areas as criminal conduct, alcohol and drug use, financial dishonesty, allegiance, foreign preference or influence, and psychological conditions, that are relevant to future security determinations.

(3) 5 U.S.C. 552a(e)(4)(G) and (H) require an agency to publish a **Federal Register** notice concerning its procedures for notifying an individual, at his/her request, if the system of records contains a record pertaining to him/her, how to gain access to such a record, and how to contest its content. Since this system of records is being exempted from subsection (f) of the Privacy Act concerning agency rules, and subsection (d) of the Privacy Act concerning access to records, these requirements are inapplicable to the extent that this system of records will be exempt from subsections (d) and (f) of the Act. Although the system would be exempt from these requirements, the NLRB has published information concerning its notification, access, and contest procedures because, under certain circumstances, it may be appropriate for a subject to have access to a portion of that individual's records in this system of records.

(4) 5 U.S.C. 552a(e)(4)(I) requires an agency to publish a **Federal Register** notice concerning the categories of sources of records in the system of records. Exemption from this provision is necessary to protect the confidentiality of the sources of information, to protect the privacy and physical safety of confidential sources and witnesses, and to avoid the disclosure of investigative techniques and procedures. Although the system will be exempt from this requirement, the agency has published source information in the accompanying notice in broad generic terms.

(5) 5 U.S.C. 552a(f) requires an agency to promulgate rules which shall establish procedures whereby an individual can be notified in response to a request if any system of records named by the individual contains a record pertaining to that individual. The application of this provision could compromise the progress of a law enforcement investigation regarding security and impede a prompt assessment of the appropriate access to the Agency's facilities. Although this system would be exempt from the requirements of subsection (f) of the Act, the Agency has promulgated rules which establish agency procedures because, under certain circumstances, it could be appropriate for an individual to have access to all or a portion of that

individual's records in this system of records.

Dated: November 13, 2020.

Washington, DC.

By direction of the Board.

Roxanne L. Rothschild,

Executive Secretary, National Labor Relations Board.

[FR Doc. 2020–25468 Filed 11–25–20; 8:45 am]

BILLING CODE 7545–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2020–0552]

Special Local Regulation: Palm Beach Holiday Boat Parade

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation on December 5, 2020 to provide for the safety and security of certain navigable waters along the Intracoastal Waterway during the Palm Beach Holiday Boat Parade. During the enforcement period, all non-participant persons and vessels will be prohibited from entering, transiting, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami or a designated representative. The operator of any vessel in the regulated area must comply with instructions from the Coast Guard or designated representative.

DATES: The regulation in 33 CFR 100.702, Table to § 100.702, Line 9, will be enforced on December 5, 2020 from 5:30 p.m. through 8:30 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Mr. Omar Beceiro, Sector Miami Waterways Management Division, U.S. Coast Guard: Telephone: 305–535–4317, Email: *Omar.Beceiro@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a special local regulation for the Palm Beach Holiday Boat Parade published in 33 CFR 100.702, Table to § 100.702, Line 9, on December 5, 2020 from 5:30 p.m. through 8:30 p.m. This action is being taken to provide for the safety and security of certain navigable waters along the Intracoastal Waterway during this one-day event. Our regulation for marine events within the Seventh Coast Guard District, § 100.702, specifies the location of the special local regulation for the Palm Beach Holiday Boat Parade, which encompasses a moving buffer zone of 50 yards around the parade as it travels north along the Intracoastal Waterway in Palm Beach, FL. Only event sponsor designated participants and official patrol vessels will be allowed to enter the regulated area. Spectators may contact the Coast Guard Patrol Commander to request permission to pass through the regulated area. If permission is granted, spectators must pass directly through the regulated area at a safe speed without loitering.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will inform the public through Local Notice to Mariners and marine information broadcasts at least 24 hours in advance of the enforcement of the special local regulation.

Dated: November 17, 2020.

J.F. Burdian,

Captain, U.S. Coast Guard, Captain of the Port Miami.

[FR Doc. 2020–25751 Filed 11–25–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 5

RIN 2900–AQ92

Administrative Procedures: Guidance Documents; Correction

AGENCY: Department of Veterans Affairs.

ACTION: Final rule; correction.

SUMMARY: The Department of Veterans Affairs (VA) is correcting a final rule that published on November 13, 2020, establishing in regulation its processes and procedures for issuing guidance documents. This final rulemaking will implement the mandates of Executive Order 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents.

DATES: This correction is effective December 14, 2020.

FOR FURTHER INFORMATION CONTACT: Richard Murphy, Office of Policy and Interagency Collaboration, Office of Enterprise Integration, 810 Vermont Avenue NW, Washington, DC 20420, (202) 714–8507. (This is not a toll-free telephone number).

SUPPLEMENTARY INFORMATION: On November 13, 2020, at 85 FR 72569, VA published a rulemaking establishing in regulation its processes and procedures for issuing guidance documents. This final rulemaking will implement the mandates of Executive Order 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents.

Correction

In FR Doc. 2020–25121, appearing on column 3 of page 72570, in the **Federal Register** of 85 FR 72570, the following correction is made:

■ 1. On page 72570, column 3, the Signing Authority paragraph should read as follows:

''The Secretary of Veterans Affairs approved this document on November 6, 2020, for publication and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.''

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2020–25474 Filed 11–25–20; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 9

RIN 2900–AQ37

Servicemembers' Group Life Insurance—Family Servicemembers' Group Life Insurance: Member Married to Member

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations governing Servicemembers' Group Life Insurance (SGLI) and Family Servicemembers' Group Life Insurance (FSGLI) to allow a SGLI-covered member (member) who marries another SGLI-eligible member (member spouse) after January 1, 2013, or a member whose spouse becomes a member spouse after January 1, 2013, to receive FSGLI coverage on a member spouse at the maximum statutory amount or a lesser amount, or to increase existing FSGLI coverage on a member spouse. A member married to a member may elect or increase FSGLI coverage for a member spouse, without a requirement to show good health, within 240 days of: The member's marriage to another member, the member's spouse entering service, or the member's spouse separating from service. If a member does not elect or increase FSGLI coverage within this 240-day ''no

health'' period, then the member can still receive or increase FSGLI coverage by applying for such coverage and submitting proof of the member spouse's good health. The final rulemaking also states that FSGLI coverage that is in force at the time a spouse or child enters service will continue and the member is not required to elect or reapply for such coverage. Additionally, VA is making a technical amendment to the amendatory language.

DATES: This rule is effective December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Paul Weaver, Department of Veterans Affairs Insurance Service (310/290B), 5000 Wissahickon Avenue, Philadelphia, PA 19144, (215) 842–2000, ext. 4263. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

On February 11, 2020, VA published in the **Federal Register** (85 FR 7683) a proposed rule to amend its regulations governing the application process for FSGLI coverage for member spouses of SGLI-covered members. Interested persons were invited to submit written comments on or before April 13, 2020. VA received one comment concerning the submission of proof of good health for former member spouses. The commenter recommended that VA revise the rulemaking to allow a member to elect FSGLI coverage on a member spouse without submitting proof of good health for 120 days following a marriage or a former member spouse's separation from service. The commenter suggested that this grace period would minimize adverse selection and bring parity to FSGLI eligibility requirements for civilian and member spouses and is consistent with Congressional intent to avoid creating FSGLI debts for members who do not want FSGLI coverage on member spouses. Based on internal agency reconsideration of the proposed regulation and the comment received, VA is making the following revisions.

I. FSGLI Coverage for Member Spouses

Section 1969(g)(2)(B) of title 38, U.S.C., requires VA to manage FSGLI according to sound actuarial principles, and VA explained in the proposed rulemaking that this requires limiting the risk of adverse selection of FSGLI applicants. VA has determined that removing the proposed requirement for members to submit proof of their member spouse's good health for 240 days following a member's marriage to another member or a member's spouse entering service is consistent with sound actuarial principles. If a member does not elect or increase coverage on a member spouse within the 240-day period, then the member will have the opportunity to receive FSGLI coverage by applying for such coverage and submitting proof of their member spouse's good health. Although the commenter recommended a 120-day ''no health'' period for a member to elect FSGLI without submitting proof of their member spouse's good health, VA has determined that a 240-day ''no health'' period is more appropriate since it would allow for greater participation in FSGLI and would remain consistent with sound actuarial principles. This change is reflected in new § 9.24(a).

II. FSGLI Coverage for Former Member Spouses

VA is also amending our proposed rulemaking to allow a member, upon election, to initiate FSGLI coverage at the maximum statutory amount or a lesser amount, or to increase existing FSGLI coverage, on a former member spouse. A member will only be required to submit proof of good health when more than 240 days have passed following the former member spouse's separation from service. If a member does not elect FSGLI at the maximum statutory amount or a lesser amount, or increase existing FSGLI coverage, within 240 days following their former member spouse's separation from service, then the member will have the opportunity to apply for FSGLI or to increase existing FSGLI coverage by submitting proof of their former member spouse's good health. Although the commenter recommended a 120-day ''no health'' period for a member to elect or increase FSGLI without submitting proof of their former member spouse's good health, VA has determined that a 240-day ''no health'' period is more appropriate because it would allow for greater participation in FSGLI and would remain consistent with sound actuarial principles. We also note that the 240-day period is consistent with 38 CFR 9.2(c), which allows a former member to apply for Veterans' Group Life Insurance within 240 days after separating from service without submitting proof of good health. This change is reflected in new § 9.24(c).

III. Technical Amendments to 38 CFR Part 9

VA is making two technical amendments to the amendatory language in this final rule. In the proposed rulemaking, we proposed to create a new paragraph (f) in current 38 CFR 9.2 and to create a new 38 CFR 9.3. In this final rule, we are creating a new paragraph (g) because paragraph (f) was recently added by 85 FR 35562, Extension of Veterans' Group Life Insurance (VGLI) Application Period in Response to the COVID–19 Public Health Emergency (June 11, 2020) (interim final rule). We are clarifying that paragraph (g) applies to member spouses eligible for coverage under 38 U.S.C. 1967(a)(1)(A)(ii) as well as (C)(ii). We are also clarifying that § 9.2(g)(2) refers to a member-spouse covered under 38 U.S.C. 1967(a)(1)(A)(i) and who was also eligible for coverage under 38 U.S.C. 1967(a)(1)(A)(ii) or (C)(ii) but who was not so insured or was insured at a reduced amount by reason of the member's election pursuant to 38 U.S.C. 1967(a)(2)(B) or (a)(3)(B). We are also moving proposed § 9.3 to new 38 CFR 9.24 for purposes of minimizing disruption to the other regulations in part 9. We are clarifying that this section applies to member spouses eligible for coverage under 38 U.S.C. 1967(a)(1)(A)(ii) as well as (C)(ii). New § 9.2(g) and new § 9.24 reflect the changes discussed above.

For the reasons discussed above, VA is adopting the proposed rule as a final rule with the above-noted changes.

Executive Orders 12866, 13563 and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866.

VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published From FY 2004 Through Fiscal Year to Date.''

This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. There are no small entities involved with processing and/or determining eligibility for SGLI and FSGLI. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

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

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Paperwork Reduction Act

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

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance number and title for the program affected by this document is 64.103, Life Insurance for Veterans.

List of Subjects in 38 CFR Part 9

Life insurance, Military personnel, Veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Brooks D. Tucker, Assistant Secretary for Congressional and Legislative Affairs, Performing the Delegable Duties of the Chief of Staff, Department of Veterans Affairs, approved this document on November 16, 2020, for publication.

Luvenia Potts,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons stated in the preamble, VA proposes to amend 38 CFR part 9 as set forth below:

PART 9—SERVICEMEMBERS' GROUP LIFE INSURANCE AND VETERANS' GROUP LIFE INSURANCE

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

Authority: 38 U.S.C. 501, 1965–1980A, unless otherwise noted.

■ 2. Section 9.2 is amended by adding paragraph (g) to read as follows:

§ 9.2 Effective date; applications.

* * * * *

(g) Except as provided in § 9.24, the effective date of enrollment, re-enrollment, or an increase in coverage under 38 U.S.C. 1967(a)(1) shall be the date the uniformed service receives an application and proof of the insurable spouse's good health:

(1) For an insurable spouse who was eligible for coverage under 38 U.S.C. 1967(a)(1)(A)(ii) or (C)(ii) but was not so insured or was insured at a reduced rate and who became a member; and

(2) For a member-spouse covered under 38 U.S.C. 1967(a)(1)(A)(i) and who was also eligible for coverage under 38 U.S.C. 1967(a)(1)(A)(ii) or (C)(ii) but who was not so insured or was insured at a reduced amount by reason of an election made by a member.

■ 3. Add § 9.24 to read as follows:

§ 9.24 Insurable dependents who become eligible members, and eligible members who marry eligible members.

(a) A Servicemembers' Group Life Insurance-covered member (member) who marries another Servicemembers' Group Life Insurance eligible member (member spouse) after January 1, 2013, or is married to a person who becomes a Servicemembers' Group Life Insurance eligible member after January 1, 2013, shall receive Family Servicemembers' Group Life Insurance spousal coverage at the statutory maximum amount or a lesser amount, or receive increased existing spousal coverage on their member spouse, upon an election of such coverage if made within 240 days following the member's marriage to another member, or the member's spouse entering service, without having to provide proof of the member spouse's good health. If a member does not elect coverage for a member spouse within 240 days following the member's marriage to another member, or the member's spouse entering service, then the member may still receive spousal coverage at the statutory maximum amount or a lesser amount, or increase existing spousal coverage, by applying and submitting proof of the member spouse's good health.

(b) A spouse shall remain eligible to be covered by any existing Family Servicemembers' Group Life Insurance spousal coverage without the member electing such coverage or applying for such coverage with proof of the member spouse's good health in a case where the spouse is enrolled in coverage under 38 U.S.C. 1967(a)(1)(A)(ii) or (C)(ii) prior to becoming a member married to another member.

(c) A member's spouse who was insured under the member's Family Servicemembers' Group Life Insurance at the time the spouse separates from service will continue to be covered under the spousal Family Servicemembers' Group Life Insurance carried while in service, and the member will not need to elect such coverage. If a member seeks to enroll a former member spouse who did not have such spousal insurance coverage when the former member spouse separates from service, or seeks to increase existing spousal coverage on their former member spouse, the member shall receive such spousal coverage on their former member spouse, upon an election of such coverage if made within 240 days following the former member spouse's separation from service, without having to provide proof of the former member spouse's good health. If a member does not elect coverage for a former member spouse within 240 days following the former member spouse's separation from service, then the member may still receive spousal coverage at the statutory maximum amount or a lesser amount, or increase existing spousal coverage, by applying and submitting proof of the former member spouse's good health.

(d) After January 1, 2013, an insurable child who is a member at the time a parent's Servicemembers' Group Life Insurance coverage commences is not eligible for automatic dependent coverage under 38 U.S.C. 1967(a)(1)(A)(ii) or (C)(ii). Dependent coverage in effect for an insurable child prior to becoming a member shall remain in effect so long as the child remains an insurable dependent. If an insurable child was not covered prior to becoming a member, the child cannot be covered under 38 U.S.C.

1967(a)(1)(A)(ii) or (C)(ii) after the child becomes a member.

[FR Doc. 2020–25585 Filed 11–25–20; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2015–0463; FRL–10015–75–Region 8]

Approval and Promulgation of Air Quality Implementation Plans; Utah; Regional Haze State and Federal Implementation Plans

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing approval of State Implementation Plan (SIP) revisions submitted by the State of Utah on July 3, 2019, as supplemented on December 3, 2019, to satisfy certain regional haze requirements for the regional haze program's first implementation period (Utah SIP revisions). The EPA is approving the Utah SIP revision that provides an alternative to best available retrofit technology (BART) controls for nitrogen oxides (NO_X) at the PacifiCorp Hunter and Huntington power plants. The EPA finds that the NO_X BART Alternative for Hunter and Huntington achieves greater reasonable progress toward natural visibility conditions than BART, in accordance with the requirements of the Clean Air Act (CAA) and the EPA's Regional Haze Rule. In conjunction with this approval, we are withdrawing the Federal Implementation Plan (FIP) that addresses NO_X BART for the Hunter and Huntington power plants that EPA promulgated in 2016. The EPA is also approving Utah's December 3, 2019 SIP supplement that requires reporting of all deviations from compliance with the applicable requirements under particulate matter (PM) BART and the NO_X BART Alternative, including the emission limits for Hunter and Huntington. The EPA is taking these actions pursuant to sections 110 and 169A of the CAA.

DATES: This rule is effective on December 28, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2015–0463. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the website and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please call or email the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Aaron Worstell, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6073, *worstell.aaron@epa.gov.*

SUPPLEMENTARY INFORMATION:

Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

Table of Contents

I. Proposed Action and the EPA's Conclusion

On July 5, 2016, the EPA promulgated a final rule titled ''Approval, Disapproval, and Promulgation of Air Quality Implementation Plans; Partial Approval and Partial Disapproval of Air Quality Implementation Plans and Federal Implementation Plan; Utah; Revisions to Regional Haze State Implementation Plan; Federal Implementation Plan for Regional Haze,'' which approved, in part, a regional haze SIP revision submitted by the State of Utah on June 4, 2015.[1] In the July 2016 final rule, the EPA also disapproved, in part, the Utah regional haze SIP submission, including the NO_X BART Alternative (also ''BART Alternative'' or ''Alternative'') for Hunter Units 1 and 2 and Huntington Units 1 and 2, which are BART units as explained in more detail below. The BART Alternative relied on sulfur dioxide (SO_2), NO_X, and PM emission reductions from the 2015 closure of PacifiCorp's Carbon power plant, as well as NO_X reductions achieved through combustion control upgrades at Hunter Units 1, 2 and 3 and Huntington Units 1 and 2, which were installed in 2006–2014 (Hunter Unit 3 is not a BART unit). The combustion control upgrades for Hunter Units 1 and 2 and Huntington Units 1 and 2 include an Alstom TSF 2000™ low-NO_X firing system and two elevations of separated overfire air (SOFA). The combustion upgrades for Hunter Unit 3 include upgraded low-NO_X burners (LNB) and overfire air (OFA). Concurrent with disapproving the NO_X BART Alternative, EPA promulgated a FIP in the July 2016 final rule that imposed a NO_X BART emission limit of 0.07 lb/MMBtu (30-day rolling average) for each of the four BART units based on the emission reductions achievable through the installation and operation of selective-catalytic reduction (SCR) plus upgraded combustion controls.

On July 3, 2019, Utah submitted a revised SIP that, based on new technical information and a different regulatory test, seeks to demonstrate that the previously submitted NO_X BART Alternative achieves greater reasonable progress than BART. The SIP revision also includes amendments to Utah's SO_2 milestone reporting requirements under the SO_2 Backstop Trading Program pursuant to 40 CFR 51.309 such that SO_2 emission reductions resulting from the closure of the Carbon plant are not counted under both the SO_2 Backstop Trading Program and the NO_X BART Alternative. On January 22, 2020, the EPA proposed to approve the State's July 3, 2019 SIP revision based on this new information.[2] Specifically, we

[1] 81 FR 43894 (July 5, 2016).

[2] 85 FR 3558 (Jan. 22, 2020).

proposed to incorporate the following into Utah's SIP:

- A NO_X emission limit of 0.26 lb/MMBtu (30-day rolling average) each for Hunter Units 1 and 2 and Huntington Units 1 and 2.
- A NO_X emission limit of 0.34 lb/MMBtu (30-day rolling average) for Hunter Unit 3.
- A requirement to permanently close and cease operation of the Carbon power plant by August 15, 2015.
- The associated amendments to the SO_2 milestone reporting requirements.

Because approval of the NO_X BART Alternative satisfies Utah's BART obligation for Hunter Units 1 and 2 and Huntington Units 1 and 2, we also proposed to withdraw the FIP for NO_X BART at these units. In particular, we proposed to find that the NO_X BART Alternative would achieve greater reasonable progress towards natural visibility conditions than would be achieved through the installation and operation of BART at Hunter Units 1 and 2 and Huntington Units 1 and 2 under EPA's 2016 FIP.

The EPA also proposed to approve a December 3, 2019 SIP supplement to the July 3, 2019 SIP revision that includes monitoring, recordkeeping, and reporting (MRR) requirements for the units subject to the NO_X BART Alternative and PM BART. The supplement also includes amendments that require each source to submit a report of any deviation from applicable emission limits and operating practices, including deviations attributable to upset conditions, the probable cause of such deviations, and any corrective actions or preventive measures taken.

Finally, contingent on our approval of these two SIP revisions, we proposed to find that Utah's SIP fully satisfies the requirements of section 309 of the Regional Haze Rule and that, therefore, the State has fully complied with the requirements for reasonable progress, including BART, for the first implementation period.

EPA requested comment on its proposed approval of Utah's regional haze SIP elements related to the NO_X BART Alternative under 40 CFR 51.309(d)(4)(vii) and 51.308(e)(2) and (3), as well as the MRR elements for the units subject to that BART Alternative and to PM BART. EPA previously approved Utah's regional haze SIP as meeting all other requirements of 40 CFR 51.309,[3] and we neither reopened nor requested comment on previously approved elements.

[3] See 77 FR 74355 (Dec. 14, 2012); 81 FR 43894 (July 5, 2016).

The EPA conducted a public hearing for our proposed action in Price, Utah on February 12, 2020. Our public comment period closed on March 23, 2020.

Our January 2020 proposed rule provided background on the requirements of the CAA and EPA's Regional Haze Rule, a summary of Utah regional haze SIP submittals and related EPA actions, and the EPA's rationale for its proposed action. That background information and rationale will not be restated here. For the reasons stated in the proposed rule, this document, and in the accompanying Response to Comments (RTC) document, the EPA concludes that Utah's NO_X BART Alternative achieves greater reasonable progress under 40 CFR 51.308(e)(2) and (3).

II. Public Comments and EPA Responses

We received both written and oral comments at the public hearings we held in Price, Utah. We also received comments through the internet and mail. The full text of comments received from these commenters is included in the publicly posted docket associated with this action at *https://www.regulations.gov.* Our RTC document, which is also included in the docket associated with this action, provides detailed responses to all significant comments received except for those addressed below.[4] Our RTC document is organized similarly to the structure presented in this section. Therefore, if additional information is desired concerning how we addressed a particular comment, the reader should refer to the appropriate section in our RTC document.

PacifiCorp, conservation organizations (HEAL Utah, Sierra Club, National Parks Conservation Association, Utah Physicians for a Healthy Environment, and Natural Resources Defense Council), Edison Electric Institute, Ute Mountain Ute Tribe, and Salt Lake City's Capitol Hill Action Group submitted detailed written comments. Many general comments were made at the public hearing.

A. Legal Issues

Comment summary: Some commenters argued that the modeling assumptions used for comparing the BART Benchmark (the controls required by the 2016 FIP) [5] to the NO_X BART Alternative overstated emissions for non-BART units in the BART Benchmark scenario. Specifically, the commenters argued that emissions for the Carbon plant should have reflected compliance with the Mercury and Air Toxics Standards (MATS) rule, which was required by April 15, 2015. According to the commenters, compliance with MATS would have resulted in a greater than 50 percent reduction in SO_2 emissions at Carbon Units 1 and 2 compared to its historical emissions. Additionally, the commenters argued that emissions from Hunter Unit 3 in the BART Benchmark scenario should have reflected combustion controls installed in 2007. The modeling instead assumed that under this scenario, the Carbon plant and Hunter Unit 3 would emit pollutants consistent with the 2001–2003 baseline.[6] The commenters argued that such assumption overstates the emissions from these sources that would have occurred under the BART Benchmark and thus understates the visibility benefits that would occur under the BART Benchmark.

Response: Utah's modeling of emissions at Carbon and Hunter Unit 3 under the NO_X BART Alternative and the BART Benchmark is reasonable and authorized under the EPA's regulations for BART alternatives. In particular, assuming continued emissions from sources that would not be subject to BART controls in the BART Benchmark scenario, when such emissions would be eliminated under the BART Alternative, is simply a necessary analytical step for making a proper comparison of the two scenarios to determine which achieves ''greater reasonable progress.'' [7] This is authorized by the Regional Haze Rule, and it is consistent with the EPA's prior regulatory actions, EPA guidance, and case law.

[4] Most commenter citations and footnotes are excluded from this document.

[5] As described above, in the July 2016 FIP, EPA determined that NO_X BART for each of the four BART units constituted an emission limit of 0.07 lb/MMBtu (30-day rolling average) based on the emission reductions achievable through the installation and operation of SCR plus upgraded combustion controls. Utah's July 2019 SIP submittal thus refers to the BART Benchmark controls as the ''EPA FIP,'' as do many of the commenters. While the controls represented by the BART Benchmark and EPA's 2016 FIP are indeed the same, the relevant comparison for this action is between the BART Benchmark and the NO_X BART Alternative. 40 CFR 51.308(e)(2); see also 85 FR 3572. We therefore refer to the 2016 FIP as the BART Benchmark as appropriate in this document, the preamble to the proposed rule, and the RTC document.

[6] See 85 FR 3568.

[7] 40 CFR 51.308(e).

First, Hunter Unit 3 and the Carbon Units are not BART sources.[8] Accordingly, reductions from these sources should not be included in determining emissions reductions from the BART Benchmark under 40 CFR 51.308(e)(2)(i)(C). Hunter Unit 3 and the Carbon Units are covered by Utah's BART Alternative, however, and thus emissions reductions from these sources properly are attributed to the BART Alternative under 40 CFR 51.308(e)(2)(i)(D). Were the EPA to include these same emission reductions in the BART Benchmark scenario, even though there would have been no enforceable obligation that they occur under that scenario, a proper comparison of the relative degree of visibility improvement between the two scenarios would not be possible.

Furthermore, Utah properly applied a 2001–2003 baseline to calculate emissions reductions under both scenarios. Pursuant to 40 CFR 51.308(e)(2)(iv), a state's SIP must demonstrate that emissions reductions resulting from an alternative measure will be surplus to those reductions resulting from measures adopted to meet requirements of the CAA ''as of the baseline date of the SIP.'' In promulgating the Regional Haze Rule in 1999, we explained that the ''baseline date of the SIP'' in this context means ''the date of the emissions inventories on which the SIP relies,'' [9] which is defined as 2002 for regional haze purposes.[10] Any measure adopted after 2002 is accordingly ''surplus'' under 40 CFR 51.308(e)(2)(iv). Indeed, in 2002, the EPA designated the baseline date of all regional haze SIPs as 2002.[11] The EPA explained that ''[p]rogress in improving visibility is tracked from baseline conditions (established using air quality monitoring for the 2000–2004 period). If 2002 is used as the base year for planning purposes, then States can take credit for emission reductions that are achieved before the 2007–2008 SIP due date.'' [12]

In other words, for purposes of calculating emissions reductions from BART alternatives, states assume a baseline of 2002 emissions and may take credit for emissions reductions after that date, even if those reductions occur as a result of, or to comply with, other CAA requirements, so long those requirements occur after that baseline. Thus, Utah's modeling properly credited emissions reductions from Carbon's 2015 shutdown and Hunter 3's 2007 controls towards the BART Alternative. Furthermore, in order to properly compare the BART Benchmark to the NO_X BART Alternative under 51.308(e)(2) to determine if the Alternative achieves greater reasonable progress, common sense dictates that the EPA must compare emissions reductions under each scenario from the same baseline year. Thus, Utah's modeling also properly included Carbon and Hunter 3's emissions from the 2001–2003 baseline period (*i.e.,* not including any reductions from MATS compliance or 2007 controls) under the BART Benchmark because Carbon and Hunter 3 are not BART sources.

This approach is supported by case law.[13] In *Yazzie* v. *EPA,* the United States Court of Appeals for the Ninth Circuit reviewed and upheld EPA's FIP, which included a BART alternative instead of BART.[14] The petitioners argued that the EPA inconsistently credited the BART alternative, but not the BART benchmark, for emissions reductions from controls voluntarily installed in 2009–2011 for purposes of comparing the two.[15] Like here, the EPA used a 2001–2003 baseline from which to calculate emissions reductions under both scenarios for purposes of the comparison.[16] The Ninth Circuit deemed this approach reasonable under 40 CFR 51.308(e)(3).[17] Likewise, Utah's approach here with respect to Hunter 3 and Carbon is reasonable.

Commenters additionally argue that the State cannot take credit for the portion of the reductions from the Carbon shutdown that would have happened anyway had Carbon remained in operation but in compliance with the MATS rule. However, as the D.C. Circuit has recognized, EPA's regulations allow for BART alternatives even when the reductions are due to compliance with another CAA requirement. In *UARG* v. *EPA,* the United States Court of Appeals for the District of Columbia Circuit reviewed and upheld the EPA's rule finding that emission reductions attributable to the 2011 Cross-State Air Pollution Rule (CSAPR)—implemented under the ''good neighbor'' provision of the Act, CAA section 110(a)(2)(D)(i)(I)—may be treated as a BART alternative. The petitioners there argued that the EPA should not have compared BART on its own (*i.e.,* without CSAPR in place) to the BART alternative on its own (*i.e.,* CSAPR without BART in place), but should have instead compared BART *plus* CSAPR to CSAPR, because CSAPR (like the MATS rule here), was implemented under a separate provision of the CAA and would go into effect regardless of BART.[18] The D.C. Circuit rejected the petitioners' argument as effectively requiring more of BART alternatives than the EPA's rule requires. The court explained that under the Regional Haze Rule, the EPA properly compares BART without the alternative or other CAA requirements to the alternative without BART.[19] Underlying that holding is the fact that EPA's regulations authorize BART alternatives to take advantage of emission reductions achieved to meet some other CAA requirement so long as they are surplus to requirements as of the baseline.[20] Thus, as in *UARG,* the EPA here properly compared the BART Benchmark without MATS compliance at Carbon to the NO_X BART Alternative.

This approach is also consistent with other EPA actions. See, *e.g.,* 79 FR 39322, 39325 (July 10, 2014) (approving Connecticut's use of emissions reductions from post-2002 regulations as surplus that could be credited to its BART alternative); 77 FR 34218, 34219 (June 11, 2012) (approving Indiana's credit to its BART alternative for reductions from a non-BART source); 78 FR 57487, 57489–91 (Sept. 19, 2013) (approving Massachusetts' comparison of the BART benchmark and the BART alternative from a common 2002 baseline, and approving the state's use of emissions reductions from post-2002 regulations as surplus that could be credited to its BART alternative); 79 FR 33438, 33441–42 (June 11, 2014) (approving Washington's credit to its BART alternative for reductions achieved through controls installed post-2002 in order to meet other CAA requirements).

In sum, in this final action approving Utah's NO_X BART Alternative, the EPA finds that Utah properly compared the BART Benchmark to the BART Alternative, using its modeling of the emissions reductions of each without the other from the 2001–2003 baseline period, consistent with the Regional

[8] See 85 FR 3559; 81 FR 43895; Utah Air Quality Board, ''Utah State Implementation Plan Section XX,'' June 24, 2019, pages 28–29.

[9] 64 FR 35714, 35742 (July 1, 1999).

[10] 70 FR 39104, 39143 (July 6, 2005).

[11] See Memorandum dated November 18, 2002, from Lydia Wegman and Peter Tsirigotis, Subject: ''2002 Base Year Emission Inventory SIP Planning: 8-hr Ozone, $PM_{2.5}$, and Regional Haze Programs.''

[12] Id. at 3. The first regional haze SIPs were due December 17, 2007. See 40 CFR 51.308(b).

[13] See *Utility Air Regulatory Group* v. *EPA,* 885 F.3d. 714 (D.C. Cir. 2018); *Yazzie* v. *EPA,* 851 F.3d 960 (9th Cir. 2017).

[14] 851 F.3d at 975.

[15] 851 F.3d at 974.

[16] Id.

[17] See id.

[18] *UARG,* 885 F.3d at 720.

[19] See id.

[20] See 40 CFR 51.308(e)(2)(i)(C), (e)(2)(iv). See also *UARG,* 885 F.3d at 719, 720 (finding challenge to EPA's BART alternative regulations to be time-barred).

Haze Rule, its regulatory history, EPA guidance, and case law.

Comment summary: Some commenters argued that there are three legal flaws with Utah's treatment of SO_2 emissions reductions from the Carbon plant shutdown. As explained in the preamble to the proposed rule, Utah's SIP revision continues to report historical emissions for the Carbon plant in annual milestone reports for the SO_2 Backstop Trading Program to ensure that SO_2 emissions reductions from the Carbon shutdown are not double-counted towards the NO_X BART Alternative and the SO_2 Backstop Trading Program. First, the commenters argued that the approach violates 40 CFR 51.309(d)(4)(iii)'s requirement that reporting under the SO_2 Backstop Trading Program include ''actual'' emissions. Second, the commenters argued that the approach violates 40 CFR 51.309(d)(4)(i), which requires that participating states use the same compliance methodology during the first two years of the Program. Finally, the commenters argued that removing Carbon from the SO_2 Backstop Trading Program would undermine and potentially nullify the EPA's approval of that Program because the Program's inclusion of sources like Carbon was an underpinning of the EPA's approval.

Response: The EPA disagrees with this comment and the incorporated 2016 comments by the National Park Service. First, 40 CFR 51.309(d)(4)(iii)'s requirement that SIPs include provisions requiring ''annual reporting of actual stationary source SO_2 emissions'' must be read in context with the following sentence that such ''data must be sufficient to determine annually whether the milestone for each year through 2018 is achieved.'' [21] The provision goes on to require that the participating states submit the data to the EPA and the regional planning organization and that the data be kept for at least 10 years. Thus, read in context, § 51.309(d)(4)(iii) plainly is meant to require reporting that allows a determination of whether the milestones have been met.[22] Utah's approach to reporting Carbon's emissions under the SO_2 Backstop Trading Program serves this purpose because Utah will overstate actual emissions under the Program. This conservative approach ensures that the reported data are sufficient to determine whether the SO_2 milestone is achieved and is therefore consistent with and achieves the purpose of the provision, and the EPA finds it approvable.

As explained in the proposal, the participating states first achieved the 2018 milestone (the most stringent milestone) in 2011 when Carbon was fully operational. Between 2011 and Carbon's shutdown in 2015, emissions continued to stay below the 2018 milestone and decreased significantly each year. The most recent milestone report, for 2016, demonstrates that SO_2 emissions were 36 percent lower than the 2018 milestone.[23] At its highest reported SO_2 emissions level, Carbon's emissions made up only 10 percent of the participating states' three-year average SO_2 emissions (reported in 2014).[24] Thus, even with the additional emissions from Carbon, the participating states can easily achieve the 2018 milestone, and overstating Utah's emissions for purposes of the SO_2 Backstop Trading Program will not impair any determination of compliance with the milestones.

Second, Utah's approach does not violate 40 CFR 51.309(d)(4)(i). As an initial matter, the commenters selectively quote the provision. The complete sentence reads, ''*[d]uring the first two years of the program,* compliance with the milestone may be measured by a methodology of the States' choosing, so long as all States in the program use the same methodology.'' [25] The SO_2 Backstop Trading Program was approved in 2012, which is more than two years ago.[26] Thus, this sentence is no longer applicable.

Instead, after the first two years of the Program, § 51.309(d)(4)(i) requires that participating states measure compliance by comparing ''a three-year rolling average of actual emissions with a rolling average of the emissions milestones for the same three years.'' Utah's SIP revision remains consistent with this methodology. Under this methodology, each state reports its own emissions.[27] As explained above, using this methodology, the participating states achieved the 2018 milestone in 2011, and emissions are currently 36 percent below the 2018 milestone.[28] Accordingly, Wyoming and New Mexico are not prejudiced by Utah's continued reporting of the Carbon emissions, nor do they have any reason to amend their SIPs to account for Carbon's emissions. Indeed, the EPA approved a similar SIP revision for units in Wyoming in 2019.[29] Utah's approach is consistent with § 51.309(d)(4)(i) and with the other states' methodologies.

Finally, Utah's approach does not undermine or nullify the EPA's approval of the SO_2 Backstop Trading Program. In approving the Program as better than BART, the EPA relied on the fact that the Program, including the 2018 SO_2 emissions milestone, covered 63 non-BART sources, including Carbon.[30] It hardly undermines the EPA's approval that one of the sources that was included in the Program has now shut down. The Program was designed to encourage sources to reduce emissions so that the emissions milestones were and are never exceeded.[31] In any case, Utah has not removed Carbon from the Program, but rather has decided to continue counting its emissions at historical levels towards the 2018 milestone, even though the source is now actually emitting at zero. That is, emissions from Carbon remain covered by the SO_2 Backstop Trading Program. Even accounting for Carbon's historical emissions, the participating states' SO_2 emissions are far below the 2018 milestone and there is no indication that the 2018 milestone will ever be exceeded such that emissions under the Program would exceed projected emissions under BART, thereby rendering the Program less effective than BART.

Even it if was the case that Utah had removed Carbon from the SO_2 Backstop Trading Program, however, the inclusion of non-BART units like Carbon was just one of several reasons the EPA deemed the Program better than BART. Additional reasons included: (1) The trading program discouraged emissions from new sources more effectively than under BART; (2) the trading program included an aggregate cap on emissions, which decreased emissions more effectively than BART; and (3) the trading program encouraged earlier reductions than under BART.[32] The Tenth Circuit upheld the EPA's considerations as ''a reasonable basis for

[21] 40 CFR 51.309(d)(4)(iii).

[22] See 64 FR 35751–52 (''Section 51.309(d)(4) requires monitoring and reporting of stationary source emissions of SO_2 in order to assess compliance with these milestones during the period 2003 to 2018.'').

[23] 85 FR 3570.

[24] Id. at Table 6.

[25] 40 CFR 51.309(d)(4)(i) (emphasis added).

[26] See 77 FR 73926 (Dec. 12, 2012).

[27] See Utah Admin. Code R307–250–9(8); WY Rules and Regulations 020.0002.14 § 2(h)(viii); New Mexico Admin. Code 20.2.81.106(O) and 20.11.46.16(H) (all requiring quarterly and annual reports).

[28] 85 FR 3570 (Table 6).

[29] See 84 FR 22711, 22712, 22715 (May 20, 2019) (requiring Basin Electric to use inflated emission rates to calculate and report emissions from two units for the SO_2 Backstop Trading Program to ensure SO_2 emissions are not double counted for the SO_2 Program and the BART alternative).

[30] 77 FR 30953, 30965 (May 24, 2012).

[31] 77 FR 74360. Participating states must continue to meet the 2018 milestone until the Program is replaced with an EPA-approved SIP revision. See also 40 CFR 51.309(d)(4)(vi)(A).

[32] See 77 FR 30965; 77 FR 73927.

the EPA's approval of the 309 program.'' [33] Accordingly, Utah's continued accounting of the Carbon emissions in the SO_2 Backstop Trading Program, which arguably affects just one part of the EPA's rationale in a proportionally minor way (1/63), cannot possibly undermine or nullify the EPA's approval.

Finally, as noted above, Carbon has not been removed from the Program as the commenters contend. Rather, as explained above, Carbon's emissions continue to be included in the inventory of annual emissions notwithstanding the fact that it is shut down.[34] Thus, SO_2 emissions remain capped at the 2018 milestone, including Carbon's emissions. To the extent it may become necessary, future SO_2 reductions would have to come from other sources in order to allow the participating states to continue to meet the 2018 milestone.

Comment summary: Some commenters assert that the EPA may not approve the NO_X BART Alternative because the NO_X BART Alternative would allow increased emissions limits and visibility impairment without offsetting increased emissions elsewhere in Utah's SIP in violation of CAA section 110(*l*), 42 U.S.C. 7410(*l*). The commenters argue that case law supports an interpretation of CAA section 110(*l*) that prevents implementation plan revisions that would increase overall air pollution limits or worsen air quality. The commenters argue that the EPA's approval of the NO_X BART Alternative and withdrawal of the FIP would violate CAA section 110(*l*) for two specific reasons. First, the commenters assert that the NO_X BART Alternative would increase emissions limits and resulting NO_X pollution compared to the FIP. They argue that the EPA's proposed analysis and conclusion that increased NO_X emissions will not interfere with applicable CAA requirements is ''woefully insufficient to support compliance with section 110(*l*).'' Second, the commenters assert that Utah's treatment of the SO_2 emissions reductions from the Carbon plant, which continues to report Carbon's emissions under the SO_2 Backstop Trading Program so that they can be credited to the NO_X BART Alternative, violates CAA section 110(*l*). The commenters argue that such treatment eliminates an applicable requirement under the CAA that results in an increase in overall allowed emissions.

Response: The EPA disagrees with these comments. CAA section 110(*l*) states in relevant part: ''The Administrator shall not approve a revision of a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 7501 of this title), and any other applicable requirement of this chapter.'' [35] CAA section 110(*l*) applies to all requirements of the CAA and to all areas of the country, whether attainment, nonattainment, unclassifiable or maintenance for one or more of the six criteria pollutants. EPA interprets section 110(*l*) as applying to all National Ambient Air Quality Standards (NAAQS) that are in effect, including those for which SIP submissions have not been made.[36] However, the level of rigor needed for any CAA section 110(*l*) demonstration will vary depending on the nature and circumstances of the revision.

There are two possible paths for satisfying CAA section 110(*l*). First, a state may demonstrate through an air quality analysis that the revision will not interfere with attainment of the NAAQS, reasonable further progress, or any other applicable requirements. Second, a state may substitute equivalent emissions reductions to compensate for any change to a plan to ensure actual emissions to the air are not increased and thus preserve status quo air quality.[37] The second approach may be used, for example, where no attainment demonstrations are available to guide an analysis of whether the SIP revision would interfere with attainment of the NAAQS. However, nothing in the statute requires a state to rely on substitute emission reductions or alters the basic proposition that section 110(*l*) can be satisfied by an air quality analysis demonstrating that a plan revision will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable CAA requirement. As explained in greater detail below, in this case, the EPA has concluded based on an air quality analysis that the revision will not interfere with attainment of the NAAQS or any other applicable CAA requirement and is not relying on substitute emission reductions.

Before addressing comments regarding the EPA's analysis, however, we address the commenters' suggestion that CAA section 110(*l*) *per se* prohibits approval of any SIP revision that allows an increase in emissions or weakens requirements relative to the existing implementation plan.[38] Such an interpretation is not supported by the statutory language or case law. First, the plain language of the provision does not prohibit every SIP revision that allows an increase in emissions or weakens the existing plan's requirements. Rather, the language prohibits EPA approval of such a SIP revision if it *would interfere with* attainment of the NAAQS, reasonable further progress, or any other applicable requirement of the CAA.[39] Thus, the language focuses on *interference* rather than on emissions increases or changed requirements.

Second, courts have upheld EPA's interpretation that the relevant inquiry under CAA section 110(*l*) is not whether the SIP revision allows an increase in emissions or weakens requirements, but whether there has been a demonstration that the SIP revision would interfere with the NAAQS, reasonable further progress, or any other applicable CAA requirement.

For example, in *Kentucky Resources Council* v. *EPA,* the petitioners argued that a new attainment demonstration, which was not due for years after action on the SIP revision, was required in order to show noninterference under CAA section 110(*l*). Instead, the examination in that case was based on whether the area, which was designated as a nonattainment area for the relevant NAAQS, would have more difficulty attaining and maintaining the NAAQS with the SIP revision (*i.e.,* whether the SIP revision would interfere with

[33] *WildEarth Guardians* v. *EPA,* 770 F.3d 919, 935 (10th Cir. 2014).

[34] See 85 FR 3574.

[35] 42 U.S.C. 7410(*l*).

[36] In general, a section 110(*l*) demonstration should address all pollutants whose emissions and/or ambient concentrations would change as a result of a plan revision. Here, commenters allege that emissions and/or ambient concentrations of NO_X and SO_2 would change as a result of this plan revision.

[37] ''Equivalent'' emissions reductions are reductions that are equal to or greater than those reductions achieved by the control measure approved into the plan. To show that compensating emissions reductions are equivalent, adequate justification must be provided. The compensating, equivalent reductions should represent actual emissions reductions achieved in a contemporaneous time frame to the change of the existing control measure in order to preserve the status quo air quality. If the status quo is preserved, noninterference is demonstrated. In addition to being contemporaneous, the equivalent emissions reductions should also be permanent, enforceable, quantifiable, and surplus.

[38] While the EPA acknowledges that this action will allow for greater NO_X emissions than the 2016 FIP, the EPA does not concede that this action weakens regional haze requirements or allows increased visibility impairment. Instead, as is explained in the preamble to the proposed rule, this document, and in the EPA's response to comments, Utah's NO_X BART Alternative will achieve *greater* reasonable progress through combined NO_X, SO_2, and PM reductions and therefore results in a *stronger* regional haze requirement than the existing plan. See, *e.g.,* 85 FR 3566 (Table 3), 3569, 3573.

[39] See 42 U.S.C. 7410(*l*).

attainment and maintenance of the NAAQS). In upholding the EPA's interpretation and examination, the U.S. Court of Appeals for the Sixth Circuit explained, ''Congress did not intend that the EPA reject each and every SIP revision that presents some remote possibility for interference. Thus, where EPA does not find that a SIP revision would interfere with attainment, approval of the revision does no violence to the statute.'' [40] The Sixth Circuit further explained that, ''[i]n rejecting [a] strict interpretation in favor of one that allows [states] more flexibility, the EPA does service to a fundamental premise underlying the Clean Air Act scheme, which is that the states have the primary responsibility for ensuring that the NAAQS are met.'' [41] Likewise, the U.S. Court of Appeals for the Eleventh Circuit upheld the EPA's interpretation stating, ''[w]e agree that where interference is not demonstrated, approval of the state's SIP revision appropriately respects the state's choice to achieve air quality standards with 'whatever mix of emission limitations it deems best suited to its particular situation.' '' [42]

The commenters misconstrue other cases. In *El Comite Para El Bienestar de Earlimart* v. *EPA* and *WildEarth Guardians* v. *EPA,* the U.S. Court of Appeals for the Ninth Circuit dismissed petitioners' CAA section 110(*l*) challenges without addressing what is required to show that a SIP revision violates CAA section 110(*l*).[43] And contrary to the commenters' assertion, neither *Indiana* v. *EPA* nor *Kentucky Resources Council* v. *EPA* stand for the proposition that the EPA *must* require substitute emissions reductions when a SIP revision increases emissions so that overall net emissions do not increase. In those cases, the U.S. Courts of Appeal for the Sixth and Seventh Circuits simply held that the EPA reasonably concluded that CAA section 110(*l*) was not violated when substitute emissions reductions were included in the SIP revisions at issue.[44] But as explained above, the EPA has previously identified *two options* for demonstrating noninterference under CAA section 110(*l*): (1) Substitution of one measure by another with equivalent or greater emissions reductions/air quality benefit; and (2) an air quality analysis showing that removing the measure will not interfere with other applicable requirements (*i.e.,* without a substitute measure).[45] Here the SIP submission did not include substitute measures and the EPA chose to evaluate the air quality impact of the proposed revision. As we explain below, the EPA's air quality analysis shows that the Utah SIP revisions will not interfere with attainment of the NAAQS, reasonable further progress, or any other CAA requirement.

Importantly, the statute does not require any ''specific methodology'' for air quality analyses under CAA section 110(*l*).[46] In general, the level of rigor needed for any CAA section 110(*l*) demonstration will vary depending on the nature of the revision, its potential impact on emissions and air quality, and the air quality in the affected areas.

In the proposed rule, the EPA proposed to find that the SIP revisions satisfy section 110(*l*). The document explained how the proposed SIP revisions and associated FIP withdrawal will comply with and thus could not be said to interfere with applicable regional haze requirements and general implementation plan requirements such as enforceability. The proposal also addressed potential interference with requirements concerning attainment and reasonable further progress, stating that the Utah SIP revisions will allow for greater NO_X emissions at the four subject-to-BART units as compared to the 2016 FIP (which is currently judicially stayed). The proposal went on to explain that the change in these emissions compared to the FIP, however, is not anticipated to interfere with any applicable requirements under the CAA. We explained that the geographic area where the BART units are located is not part of a nonattainment area for any NAAQS. Furthermore, we explained that the approved portions of the $PM_{2.5}$ attainment demonstrations and clean data determinations (CDD) for the Salt Lake City, Provo, and Logan, UT–ID nonattainment areas (NAAs) do not rely on the installation of SCR at Hunter or Huntington to achieve attainment of the NAAQS. Similarly, we explained that the EPA recently approved Utah's PM_{10} redesignation requests and maintenance plans for Salt Lake County, Utah County, and Ogden City NAAs.[47] These PM_{10} redesignation requests and maintenance plans do not rely on the installation of SCR at Hunter or Huntington to achieve attainment of the NAAQS. Finally, we explained that there are no other approved attainment demonstrations in other areas of the State or outside of the State that rely on the installation of SCR at Hunter or Huntington to achieve attainment of any of the NAAQS.[48]

The commenters contend that the EPA's air quality analysis is inadequate but did not provide any evidence that Utah's SIP revisions will interfere with any specific applicable requirement under the CAA. Here, for the reasons explained below, the EPA now confirms the proposed conclusions from the CAA section 110(*l*) analysis in the proposal.

First, the geographic area where the Hunter and Huntington Units are located is not part of a nonattainment area for any NAAQS. Also, monitors in the geographic area do not currently show exceedances of the ozone NAAQS.[49]

Second, since the publication of the proposal on January 22, 2020, the PM_{10} areas for Salt Lake County, Utah County, and Ogden City were redesignated as attaining the PM_{10} NAAQS.[50] The areas continue to attain the PM_{10} NAAQS based on the most recent official ambient data (2017–2019).[51] This means that these areas attained the NAAQS at current emission levels, *i.e.,* the emission levels allowed by the NO_X controls installed at Hunter and Huntington between 2006 and 2014 and which will be maintained under Utah's NO_X BART Alternative. Because the FIP was judicially stayed and the NO_X emission controls required by the FIP (SCRs) were never installed, current emissions levels do not reflect emission levels that would have been achieved if the FIP had been implemented. In other words, the EPA's approval of the Utah NO_X BART Alternative will not cause an increase in NO_X emissions at Hunter

[40] 467 F.3d 986, 994 (6th Cir. 2006).

[41] Id. at 996.

[42] *Alabama Environmental Council* v. *EPA,* 711 F.3d 1277, 1293 (11th Cir. 2013) (quoting *Train* v. *NRDC, Inc.,* 421 U.S. 60, 79 (1975)). See also *Indiana* v. *EPA,* 796 F.3d 803, 811 (7th Cir. 2015) (''When deciding whether to approve Illinois's SIP revision, EPA was required to determine whether the revision would, *going forward,* interfere with attainment.'') (emphasis in original); *Galveston-Houston Ass'n for Smog Prevention* v. *EPA,* 289 Fed. Appx. 745, 754 (5th Cir. 2008) (''[C]hanges to a SIP, either dropping measures or reducing measurement requirements, are not by themselves sufficient to prove interference. Rather, one must show that the substitute measures are not at least equivalent to the previous measures in achieving attainment.'').

[43] See *El Comite Para El Bienestar de Earlimart* v. *EPA,* 786 F.3d 688, 696–97 (9th Cir. 2015); *WildEarth Guardians* v. *EPA,* 759 F.3d 1064, 1074 (9th Cir. 2014).

[44] See *Kentucky Resources Council,* 467 F.3d at 995–96; *Indiana,* 796 F.3d at 812–13.

[45] See *Indiana,* 796 F.3d at 806.

[46] *Kentucky Resources Council,* 467 F.3d at 995.

[47] The PM_{10} redesignations for Salt Lake County, Utah County, and Ogden City nonattainment areas revised 40 CFR 81.345 to signify that these areas are in attainment. Utah demonstrated maintenance of the PM_{10} standard to 2035 through the maintenance plans.

[48] 85 FR 3574.

[49] EPA, ''Air Quality System Preliminary Design Value Report,'' October 7, 2020.

[50] 85 FR 10989 (Feb. 26, 2020).

[51] EPA, ''Air Quality System Preliminary Design Value Report,'' September 15, 2020.

or Huntington compared to current conditions. Therefore, the SIP approval will not interfere with already-achieved NAAQS attainment for PM_{10}, and there is no evidence, including none provided by the commenters, to suggest that PM_{10} areas for Salt Lake County, Utah County, and Ogden City will not continue to attain the NAAQS following our approval of the SIP and concurrent withdrawal of the FIP.

Third, the Northern Wasatch Front, Southern Wasatch Front, and Uinta Basin ozone non-attainment areas were designated nonattainment for the 2015 ozone NAAQS on August 3, 2018.[52] As part of the 2018 ozone designation process, the EPA conducted a meteorological Hybrid Single-Particle Lagrangian Integrated Trajectory (HYSPLIT) analysis to determine whether sources near the monitors violating the NAAQS contribute to the Northern and Southern Wasatch Front ozone non-attainment areas. Evaluation of such meteorological data helps to assess the fate and transport of emissions contributing to ozone concentrations and to identify areas potentially contributing to the monitored violations. Results of the HYSPLIT analysis for the Northern and Southern Wasatch Front ozone nonattainment areas show that back trajectories rarely originated or passed through Carbon and Emery counties on high ozone days in the Wasatch Front (where Hunter and Huntington are located).[53] Instead, the HYSPLIT analysis indicates that emissions originating within Davis and Salt Lake Counties, the southern portion of Weber County, the northern portion of Utah County, and the eastern portion of Tooele County primarily contribute to monitor violations.[54] Furthermore, the monitors in the Southern Wasatch Front ozone nonattainment area (closest to the BART sources) are currently attaining the ozone standard using 2017–2019 and preliminary 2018–2020 data.[55]

For the Uinta Basin non-attainment area, the EPA has determined that ozone production is a highly localized phenomenon. The Uinta Basin is a winter ozone area, where violating ozone concentrations are dependent on stagnant winter conditions associated with strong temperature inversions. During the ozone designations process, the EPA used the latest data and information available to the agency (and to the states and tribes through the Ozone Designations Mapping Tool and the EPA Ozone Designations Guidance and Data web page),[56] to evaluate emissions and air quality data and other information for counties in the Uinta Basin. The EPA determined that the stagnant winter conditions associated with strong temperature inversions limit the influence of areas outside of the topographic Uinta Basin.[57] Thus, at the time of the 2018 designation, the EPA determined that sources in surrounding counties (like Hunter and Huntington) do not contribute to the violating area because of these unique geographic features and the associated winter temperature inversion meteorology.

Fourth, the Salt Lake City, Provo, and Logan, Utah-Idaho (UT–ID) $PM_{2.5}$ nonattainment areas were designated nonattainment for the 2006 24-hour $PM_{2.5}$ NAAQS on November 13, 2009.[58] On October 19, 2018, the EPA finalized a determination of attainment for the Logan, UT–ID $PM_{2.5}$ nonattainment area.[59] Based on the most recent 3 years of valid data at that time (2015–2017), the Logan, UT–ID nonattainment area attained the 2006 primary and secondary 24-hour $PM_{2.5}$ NAAQS by the attainment date of December 31, 2017. Likewise, on June 8, 2020, the EPA proposed a determination of attainment, based on the most recent 3 years of valid data (2017–2019), that the Salt Lake City and Provo nonattainment areas attained the 2006 primary and secondary 24-hour $PM_{2.5}$ NAAQS by the attainment date of December 31, 2019.[60] On January 13, 2020, Utah submitted redesignation requests for the Logan, UT–ID, Salt Lake City, and Provo $PM_{2.5}$ nonattainment areas and the EPA is actively reviewing this submittal for future action.

Because the Logan, UT–ID $PM_{2.5}$ nonattainment area is now attaining the $PM_{2.5}$ NAAQS and we proposed to find that the Salt Lake City and Provo $PM_{2.5}$ nonattainment areas are also now attaining the $PM_{2.5}$ NAAQS at *current* emission levels, which would not increase upon approval of Utah's SIP revisions, the SIP approval will not interfere with NAAQS attainment for $PM_{2.5.}$ Additionally, there is no evidence, including none provided by the commenters, to suggest that these areas will not continue to attain the NAAQS following our approval of the SIP and concurrent withdrawal of the FIP.

Fifth, contrary to the commenters' argument, the EPA demonstrated that the SIP approval will not interfere with the CAA's BART requirements, including the SO_2 Backstop Trading Program. As explained elsewhere in this document, Utah's amendments to the SO_2 Backstop Trading Program do not alter the applicable 2018 SO_2 milestone or the sources covered by the Program, and thus maintain compliance with the Program and the Regional Haze Rule. The SIP amendments to Utah's SO_2 milestone reporting requirements under the SO_2 Backstop Trading Program are merely an accounting exercise to ensure that emission reductions resulting from the Carbon plant's closure are not credited towards both the SO_2 Backstop Trading Program and the NO_X BART Alternative. The SIP amendments further do not result in an actual increase in emissions.

In summary, we find that Utah's SIP revisions will not interfere with attainment of the NAAQS, reasonable further progress, or other CAA requirements because: (1) The geographic area where the Hunter and Huntington Units are located is not part of a nonattainment area for any NAAQS; (2) the recently redesignated former PM_{10} nonattainment areas in Salt Lake County, Utah County, and Ogden City are attaining the PM_{10} NAAQS at current emission levels, which would remain unchanged with approval of Utah's SIP revisions; (3) we determined in 2018 that the Hunter and Huntington power plants do not contribute to the Northern Wasatch Front and Southern Wasatch Front ozone non-attainment areas, and that the Uinta Basin non-attainment area is a highly localized phenomenon and sources in surrounding counties, including the Hunter and Huntington power plants, do not contribute to the violating area; (4) the Logan, UT–ID $PM_{2.5}$ nonattainment area is attaining the

[52] 83 FR 25776, 25836 (June 4, 2018). At that time, the ozone monitors located closest to the two power plants, in Carbon County, did not violate the 2015 ozone standard. EPA, ''Utah: Northern Wasatch Front, Southern Wasatch Front, and Uinta Basin Intended Area Designations for the 2015 Ozone National Ambient Air Quality Standards Technical Support Document (TSD),'' page 6 (''Utah 2015 Ozone TSD''). Also found in docket EPA–HQ–OAR–2017–0548; posted January 5, 2018.

[53] Utah 2015 Ozone TSD, pages 18–25.

[54] Id. at 25.

[55] EPA, ''Air Quality System Preliminary Design Value Report,'' October 7, 2020.

[56] The EPA's Ozone Designations Guidance and Data web page can be found at *https://www.epa.gov/ozone-designations/ozone-designations-guidance-and-data.*

[57] Utah 2015 Ozone TSD, pages 29, 30.

[58] 74 FR 58688 (Nov. 13, 2009).

[59] 83 FR 52983 (Oct. 19, 2018). A nonattainment area may be issued a determination of attainment by the EPA only if monitored data demonstrate that air quality has improved enough that the NAAQS is now being achieved. These determinations are based upon complete, quality-assured data gathered at established state and local air monitoring stations and national air monitoring stations in the nonattainment area and must include a notice and comment rulemaking by the EPA determining that the area is attaining the relevant standard. Although a determination of attainment is not equivalent to a redesignation in 40 CFR part 81, a determination of attainment shows that monitored air quality no longer violates the NAAQS.

[60] 85 FR 35033 (June 8, 2020).

$PM_{2.5}$ NAAQS, and we proposed to find that the Salt Lake City and Provo $PM_{2.5}$ nonattainment areas are also attaining the $PM_{2.5}$ NAAQS, all at current emission levels that would not increase under Utah's SIP revisions; and (5) the Utah SIP revisions properly account for SO_2 emissions in accordance with applicable requirements. Furthermore, the commenters provided no analysis or information to indicate otherwise. Thus, we confirm our position in the proposed rule that Utah's SIP revisions are not anticipated to interfere with applicable requirements of the CAA and therefore CAA section 110(*l*) does not prohibit approval of this SIP and concurrent withdrawal of the FIP.

B. BART Alternative Requirements

Comment summary: Some commenters asserted that because the EPA's proposed rule would result in a significantly different distribution of emissions from BART, it fails to show ''greater reasonable progress'' under 40 CFR 51.308(e)(3) than the EPA's previously issued FIP. Specifically, the commenters assert that when alleged technical deficiencies including those in the CAMx dispersion modeling are corrected, the EPA is unable to prove ''greater reasonable progress'' because visibility will decline in one or more Class I areas and there is not an overall improvement in visibility over all affected Class I areas.

Response: We disagree with this comment. The three plants (Hunter, Huntington, and Carbon) are all located within 40 miles of each other in Central Utah and are therefore similarly situated to the affected Class I areas. But Utah chose to use CAMx dispersion modeling to assess whether the NO_X BART Alternative achieves greater reasonable progress for the worst and best 20 percent of days (*i.e.,* the two-prong test). This is the regulatory test required under § 51.308(e)(3) if the distribution of emissions *were* substantially different.[61] Thus, the question of emissions distribution is not pertinent to the EPA's approval of Utah's NO_X BART Alternative. Any influence that the respective geographic relationship of the emission reductions from BART and the NO_X BART Alternative have on visibility impacts at the Class I areas is resolved by the CAMx modeling.

We respond to specific comments related to alleged technical deficiencies in the modeling in more detail below and in the RTC document. We find that the CAMx modeling used for the greater reasonable progress demonstration was performed consistent with EPA guidance and that the model performance was similar to applications of the CAMx model that the EPA and states have used in previous actions for regional haze.[62] The CAMx modeling results showed that the NO_X BART Alternative met the requirements of the greater reasonable progress two-prong test, *i.e.,* visibility does not decline in any Class I area under the BART Alternative relative to the Baseline on both the 20% best and 20% worst days, and the average visibility improvement across all affected Class I areas is greater under the BART Alternative than under the BART Benchmark.[63]

C. BART Alternative ''Greater Reasonable Progress'' Determination

Comment summary: Some commenters asserted that the CAMx modeling supporting the Utah NO_X BART Alternative is flawed because it continues to assume that the installation and operation of SCR on Hunter Units 1 and 2 and Huntington Units 1 and 2 would achieve a NO_X emission rate of 0.07 lb/MMBtu on a 30-day rolling average, as approved by the EPA four years ago in its FIP. The commenters contend that there are several electric generating units (EGUs) that have achieved NO_X emission rates of 0.04 lb/MMBtu or lower on an annual average basis. The commenters further contend that the EPA recently adopted a BART alternative for the Laramie River Station in Wyoming and acknowledged that a 0.04 lb/MMBtu NO_X emission rate would be achieved with SCR on an annual average basis under a 0.06 lb/MMBtu NO_X limit applicable on a 30-day average basis.

The commenters further assert that while the Hunter and Huntington BART units have been achieving 0.19–0.20 lb/MMBtu NO_X rates on an annual average basis in the last two years, these units should be able to readily achieve a 0.04 lb/MMBtu annual average NO_X rate with SCR. The commenters contend that such a NO_X rate equates to a 74–80% NO_X removal efficiency across the SCR, and SCR systems are routinely designed to achieve 90% NO_X removal. The commenters therefore argue that it is improper to judge the Utah BART Alternative against a BART Benchmark that utilizes obsolete emissions information and that the EPA should not have assumed a controlled annual average NO_X rate any higher than 0.04 lb/MMBtu for the Hunter and Huntington Units in BART modeling.

Response: We disagree with this comment. By way of background, the EPA's FIP used an assumed emission rate of 0.05 lb/MMBtu on an *annual* basis, but required compliance with a 0.07 lb/MMBtu, *30-day rolling average* limit.[64] The commenters here contend that EPA should have used a lower annual limit, which would in turn lower the 30-day rolling average limit, for purposes of the BART Benchmark. As an initial matter, emission limits associated with BART do not need to meet the lowest emission rate achieved with that technology at any coal-fired power plant. The Regional Haze Rule provides that ''[t]he determination of BART must be based on an analysis of the best system of continuous emission control technology available and associated emission reductions achievable for each BART-eligible source that is subject to BART.'' [65]

Additionally, the BART Guidelines state that: ''[i]n assessing the capability of the control alternative, latitude exists to consider special circumstances pertinent to the specific source under review, or regarding the prior application of the control alternative,'' [66] and that ''[t]o complete the BART process, you must establish enforceable emission limits that reflect the BART requirements.'' [67] The five factor BART analysis described in the Guidelines is a case-by-case analysis that considers site-specific factors in assessing the best technology for continuous emission controls. After a technology is determined as BART, the BART Guidelines require establishment of an emission limit that reflects the BART requirements, but does not specify that the emission limit must represent the maximum level of control achieved by the technology selected as BART.

While the BART Guidelines and the Regional Haze Rule do not preclude selection of the maximum level of control achieved by a given technology as BART, the emission limit must be set to reflect BART which in turn must be determined based on a consideration and weighing of the five statutory BART factors. Therefore, limits set in other BART determinations, Best Available Control Technology during Prevention of Significant Deterioration review, or emission rates achieved from the operation of individual facilities under

[61] See 40 CFR 51.308(e)(3).

[62] Previous actions that relied on CAMx modeling include the Cross-State Air Pollution Rule (CSAPR) (76 FR 48208 (Aug. 8, 2011)); the FIP revision for Laramie River Station in Wyoming (84 FR 22711 (May 20, 2019)); and the SIP revision for Coronado Generating Station in Arizona (82 FR 46903 (Oct. 10, 2017)).

[63] See 85 FR 3573.

[64] 81 FR 43903.

[65] 40 CFR 51.308(e)(1)(ii)(A).

[66] 40 CFR part 51, appendix Y, section IV.D.3.

[67] 40 CFR part 51, appendix Y, section V.

an emissions trading program (*e.g.,* CSAPR) may provide important information, but should not be construed to automatically represent the most appropriate BART limit for a given technology.

Additionally, while the commenters cite actual annual emission rates found in the EPA's Air Markets Program Database (AMPD) to support their claim that an annual emission rate of 0.04 lb/MMBtu is achievable with SCR, a more thorough review of the data supports the EPA's conclusion that an annual emission rate no lower than 0.05 lb/MMBtu is representative of what can be achieved when retrofitting SCR to an existing boiler. Of the 155 coal-fired EGUs equipped with SCR operating in 2019 with actual annual emission rates below 0.10 lb/MMBtu, 135 (87.1%) had actual annual emissions greater than 0.05 lb/MMBtu, 18 (11.6%) had actual annual emissions greater than 0.04 lb/MMBtu and less than or equal to 0.05 lb/MMbtu, and only 2 (1.3%) had actual annual emissions less than or equal 0.04 lb/MMBtu.[68] The figure in our RTC document shows the number of coal-fired EGUs equipped with SCR by actual annual emission range in increments of 0.01 lb/MMbtu. Notwithstanding the site-specific nature of SCR retrofits, these data support the conclusion that an annual emission rate of 0.05 lb/MMBtu is appropriate for the Utah BART units, and confirm that the assumption is relatively conservative because the majority of EGUs equipped with SCR have actual annual emission rates that are higher.

Moreover, the lowest emission rates found in the AMPD database may not be indicative of what can be expected at the Utah BART units for a number of reasons. As noted above, the site-specific characteristic of each SCR installation must be taken into account when determining the anticipated actual annual emission rate. For example, the commenter lists Dry Fork Unit 1 in Wyoming among units that are achieving an actual annual emission rate of 0.04 lb/MMBtu.[69] However, construction on Dry Fork Unit 1 began in 2007 and SCR was integrated into the original design, and not installed as a retrofit as would be the case with the Utah BART units.

Our use of an anticipated actual annual emission rate with SCR of 0.05 lb/MMBtu here is also consistent with our 2016 FIP.[70] The EPA is unaware of, and the commenters have not cited, any advancements in SCR retrofit technology that have occurred since our July 2016 final rule. Accordingly, we have no reason to conclude that the assumptions we made at that time regarding SCR performance are now obsolete.

Finally, the commenters have incorrectly assumed that a 90% control efficiency can be achieved in all SCR applications regardless of the input NO_X emission rate or other parameters. In our July 2016 final rule, the EPA used an actual annual average emission rate for LNB/SOFA (*i.e.,* pre-SCR) at the Utah BART units of 0.20 lb/MMBtu to 0.22 lb/MMBtu.[71] A 90% reduction with SCR from these emission rates would yield annual emission rates of 0.020 lb/MMBtu to 0.022lb/MMBtu. As can be seen from the AMPD data discussed above, no EGU has achieved this level of control with SCR. Thus, because this level of control has not been achieved in practice, it is not a realistic expectation for the Utah BART units.

Comment summary: Some commenters criticized the selection of Class I areas for inclusion in the CAMx modeling domain. The commenters asserted that the modeling included Class I areas beyond 300 kilometers from the Carbon, Hunter, and Huntington power plants, and afforded equal weight to areas near and distant from the pollution sources even though there is higher confidence in the CAMx modeling at sites within 300 kilometers of the sources. The commenters further asserted that PacifiCorp included certain areas (*e.g.* San Pedro Parks Wilderness Area (New Mexico)) farther than 500km from the sources, while apparently omitting others a similar distance away (*e.g.* Craters of the Moon in Idaho; Jarbidge in Nevada; Yellowstone, Grand Teton, Washakie, Fitzpatrick, and Bridger in Wyoming; Petrified Forest and Sycamore Canyon in Arizona; and Rocky Mountain, Eagles Nest, Rawah, and Great Sand Dunes in Colorado, among others). The commenters also stated that while Utah appeared to give undue weight to visibility benefits at certain distant Class I areas, Utah gave zero weight (and did not even analyze) visibility impacts at similarly distant sites. The commenters therefore argue that the assessed Class I areas were selected in an arbitrary manner, and that the analysis does not account for visibility impacts ''over all affected Class I areas,'' as required by the Regional Haze Rule.[72] The commenters argue that if corrected, the alleged errors may flip the outcome of Utah's analysis; *i.e.,* if the Class I areas outside of 300 kilometers from the power plants are omitted, the modeling fails to demonstrate that the average visibility benefit of the BART Alternative will be greater than the 2016 FIP (BART Benchmark).

Response: The EPA disagrees with this comment. The draft modeling protocol prepared by PacifiCorp included a rectangular modeling domain that included all of the Class I areas within a distance of 300 km of the Hunter and Huntington Units that had been considered in previous CALPUFF modeling applications for these BART sources. The EPA reviewed the proposed modeling domain and recommended that the boundaries of the domain be extended farther east, north, and south to include terrain features that could affect the transport of pollutants from the BART sources.[73] PacifiCorp agreed to extend the size of the domain as requested by the EPA. Thus, for example, the domain was extended farther north to include the Uinta mountain range in northern Utah, and the domain was extended farther east such that the relevant Class I areas were fully included in the model domain and were not located close to the boundary of the domain. Because of the possibility of modeling artifacts at domain boundaries,[74] the EPA believed that the larger model domain was technically more defensible. The motivation for expanding the size of the model domain was to provide more accurate model results, not to include more Class I areas. However, given that additional Class I areas were included within the domain, the EPA determined that it was appropriate to consider visibility benefits at all Class I areas for which model results were available. The EPA determined that it would have been arbitrary to include some Class I areas

[68] See spreadsheet titled ''SCR Actual Annual Emissions by Range.xlsx'' in the docket. Note that AMPD query returned a total of 265 coal-fired EGUs equipped with SCR operating in 2019. However, many of these units had actual annual emission rates well in excess of what would be anticipated with an SCR when operated on a year-round basis. For that reason, the EPA eliminated all units with an actual annual emission rate in excess of 0.10 lb/MMBtu from consideration, leaving 155 units.

[69] AMPD data for 2019 show actual annual emissions of 0.0432 lb/MMBtu, above 0.04 lb/MMBtu.

[70] 81 FR 2034.

[71] See 81 FR 43903, Tables 2 through 5.

[72] 40 CFR 51.308(e)(3)(ii).

[73] Email dated September 20, 2017, from Aaron Worstell (EPA) to Jay Baker (UDAQ), Subject: Updated invitation: Utah Regional Haze CAMx Model Review, docket ID EPA–R08–OAR–2015–0463–0228.

[74] For example, if emissions plumes near the model domain boundaries are transported out of the model domain, those emissions are permanently lost to the model, even if meteorological recirculation patterns might cause those emissions to re-enter the domain. Selecting a large model domain reduces the possibility that emissions plumes will be transported out of the model domain.

but not to include other nearby Class I areas for which modeling results were available. The additional Class I areas (Mount Zirkel Wilderness Area [WA], Maroon Bells/Snowmass WA, West Elk WA, La Garita WA, Weminuche WA, and San Pedro Parks WA) are located close to and within the same air basins as the other Class I areas previously included in the CALPUFF modeling. While there are other Class I areas located within 500 km of the sources, prevailing wind patterns and terrain features make it less likely that emissions from Hunter and Huntington would impact those areas, and the EPA did not find that it was reasonable to recommend further expansion of the model domain to include these Class I areas. In addition, the calculation of the average difference between BART and the BART Alternative is most influenced by the Class I areas closest to and most impacted by Hunter, Huntington and Carbon. Therefore, small modeled impacts at additional distant Class I areas would likely have little or no impact on the average impact across all affected Class I areas.

We also disagree with the comment that there is higher confidence in the CAMx modeling at sites within 300 kilometers of the sources. Higher confidence in modeling for sites within 300 kilometers is a feature of the CALPUFF model. For example, the Interagency Workgroup on Air Quality Modeling report recommended the ''use of CALPUFF for transport distances of order 200 km and less. Use of CALPUFF for characterizing transport beyond 200 to 300 km should be done cautiously with an awareness of the likely problems involved.'' [75] The CAMx model is not subject to this limitation because it was developed and has been widely used and evaluated for applications at distances much greater than 300 kilometers, including modeling and regulatory analyses for interstate transport of ozone and $PM_{2.5}$. Photochemical grid models such as CAMx are recommended by the EPA in Appendix W [76] for long range transport modeling for secondary pollutants, including regional haze.

Comment summary: Some commenters asserted that the CAMx modeling cannot support the NO_X BART Alternative because it employs the wrong metric for comparison. Specifically, the commenters argue that instead of using ''the worst and best 20 percent of days'' to demonstrate greater reasonable progress under 40 CFR 51.308(e)(3), Utah should have substituted an analysis for the 20% of days in a calendar year ''with the highest amount of anthropogenic visibility impairment'' under the EPA's 2017 revisions to the Regional Haze Rule. The commenters argue that without such modeling, the EPA cannot demonstrate in accordance with the regional haze requirements that the BART Alternative would result in greater reasonable progress than BART as determined in the EPA's FIP (BART Benchmark), and the BART Alternative is not approvable.

Response: We disagree that the CAMx modeling relied on in Utah's SIP submittal employs the wrong metric for comparison of the BART Benchmark and NO_X BART Alternative. First, as explained elsewhere in the preamble to the proposed rule, the RTC document, and this document, Utah submitted its NO_X BART Alternative, and the EPA proposed to approve it, under the two-prong test in 40 CFR 51.308(e)(3)(i) and (ii). The two-prong test requires that ''the State must conduct dispersion modeling to determine differences in visibility between BART and the [alternative] for each impacted Class I area, *for the worst and best 20 percent of days.*'' [77] The 2017 revisions to the Regional Haze Rule discussed by the commenter did not change 40 CFR 51.308(e)(3).[78] Indeed, § 51.308(e)(3) is a BART provision applicable to the first regional haze planning period, and the EPA explicitly did not make any changes to the Regional Haze Rule's BART provisions in the 2017 revisions.[79] Because Utah's SIP revisions are intended to satisfy first planning period BART requirements,[80] the CAMx modeling properly employed the haziest days metric rather than the new ''most impaired days'' metric.

Comment summary: Commenters assert that the most fundamental technical deficiency in the CAMx modeling is the emissions information used by Utah for the ''typical year'' scenario (also called the 2011 reference case). Commenters assert that the EPA provided no explanation as to why the 2011 reference case was modeled with the 2001–2003 baseline period emissions at Carbon, Hunter and Huntington. Commenters note that in the interval between the baseline period and the typical year, PacifiCorp installed significant emissions control improvements at both Hunter and Huntington, which resulted in substantial SO_2 reductions.

Commenters assert that the Hunter and Huntington emission controls are important because the associated impact of such controls on visibility conditions in Class I areas in Utah and neighboring states already would be reflected in the 2009–2013 five-year average Interagency Monitoring of Protected Visual Environments (IMPROVE) data used in the CAMx modeling. Commenters claim that by using the 2001–2003 baseline emissions to describe the Hunter and Huntington plants for the 2011 reference year, the post-2003 SO_2 reductions at Hunter and Huntington are essentially double counted. Commenters conclude that Utah's approach to typical year emissions for the Hunter, Huntington and Carbon power plants presents a fundamental error with the CAMx modeling and the resulting implication is that the modeling results cannot be used to support Utah's conclusion that the Utah NO_X BART Alternative would result in greater visibility improvement compared to the EPA FIP (BART Benchmark).

Response: We disagree with this comment. As an initial matter, the commenters have not explained how the emissions data used in the 2011 Typical Year scenario results in a faulty outcome to the two-prong regulatory analysis required under 40 CFR 51.308(e)(3). Indeed, the modeling was appropriately designed to assess each prong in a reasonable and technically defensible way.[81]

As we explained in the proposed rule, CAMx was configured to simulate four modeling scenarios: the 2011 Typical Year, the 2025 Baseline, the BART Benchmark, and the Utah NO_X BART Alternative. The 2011 Typical Year scenario includes emissions for Carbon, Hunter and Huntington at 2001–2003 levels, while all other sources remain at 2011 levels. The annual NO_X and SO_2 emissions modeled for each of these scenarios are shown in Table 1 below.

[75] EPA, ''Interagency Workgroup on Air Quality Modeling (IWAQM) Phase 2 Summary Report and Recommendations for Modeling Long Range Transport Impacts,'' December 1998, pages 18 and D–11.

[76] 40 CFR part 51, appendix W.

[77] 40 CFR 51.308(e)(3) (emphasis added).

[78] See 82 FR 3078, 3124 (Jan. 10, 2017).

[79] See 81 FR 26942, 26947 (May 4, 2016) (''States undertook the BART determination process during the first implementation period. The BART requirement was a one-time requirement . . . . Consequently, we are not proposing any changes to the BART provisions in this rulemaking.'').

[80] See 85 FR 3575.

[81] See AECOM, ''Photochemical Modeling Protocol to Assess Visibility Impacts for PacifiCorp Power Plants Located in Utah,'' January 2018.

TABLE 1—ANNUAL NO_X AND SO_2 EMISSIONS BY MODELING SCENARIO

Plant	Unit	2011 Typical year		2025 Baseline		2025 BART benchmark		2025 Utah NO_X BART alternative	
		NO_X (tpy)	SO_2 (tpy)	NO_X (tpy)	SO_2 (tpy)	NO_X (tpy)	SO_2 (tpy)	NO_X (tpy)	SO_2 (tpy)
Carbon	1	1,312	2,286	1,312	2,286	1,312	2,286	0	0
	2	1,977	3,528	1,977	3,528	1,977	3,528	0	0
Hunter	1	6,380	2,535	6,380	2,535	796	1,153	3,166	1,153
	2	6,092	2,531	6,092	2,531	798	1,408	3,028	1,408
	3	6,530	1,204	6,530	1,204	6,530	1,230	4,490	1,230
Huntington	1	5,944	2,380	5,944	2,380	793	1,254	3,147	1,254
	2	5,817	12,308	5,816	12,308	753	1,201	3,366	1,201

The modeling relied on the 2011 emissions data because a robust, well-evaluated modeling platform was available only for 2011 and was not available for any other year.

The 2025 Baseline modeling scenario, which is based on the 2011 Typical Year scenario with emissions projected to 2025, also uses 2001–2003 emissions for PacifiCorp's units in order to reflect only those controls that were in place at those units in the baseline period (*i.e.,* pre-regional haze measures).[82] This allows for a straightforward comparison of the effects of the BART Benchmark versus the Utah NO_X BART Alternative relative to the 2025 Baseline (*i.e.,* relative to conditions without any regional haze measures applied to the Utah BART sources). Because measures included in the BART Alternative were installed starting in 2006, using emissions from a later year to represent the baseline would not accurately reflect the impacts of each of the two scenarios. While Utah could have chosen to use different years to represent baseline emissions from Hunter, Huntington, and Carbon, it chose to use a consistent period for these Units that is also consistent with the baseline period of the regional haze SIP, and we find this to be a reasonable approach.[83]

The 2011 Typical Year and the 2025 Baseline scenarios were used in the development of relative response factors (RRFs) that were applied to publicly available IMPROVE monitoring data in order to predict future visibility conditions in 2025 for the BART Benchmark and the NO_X BART Alternative scenarios. The BART Benchmark and BART Alternative results were then both compared to the 2025 Baseline scenario and to each other to determine whether the BART Alternative passes the two-prong test in § 51.308(e)(3).

The BART Benchmark scenario includes 2001–2003 Carbon and Hunter 3 emissions, because Carbon and Hunter 3 are not BART sources. But the BART Benchmark reflects predicted NO_X emissions reductions from the installation of SCR controls on Hunter and Huntington Units 1 and 2 because those controls were required by EPA's 2016 FIP. The BART Benchmark scenario also includes SO_2 emissions from Hunter and Huntington from 2014–2016 in order to match the BART Alternative scenario, which as explained below, is important for the comparison in § 51.308(e)(3)(ii). The BART Alternative scenario includes emissions from Hunter and Huntington from 2014–2016 to reflect all emissions controls required by the Alternative, and zero emissions from Carbon because the Alternative requires Carbon's 2015 shutdown. As described below, these modeling scenarios allow an accurate comparison between the BART Benchmark and the Utah NO_X BART Alternative under the two-prong test in § 51.308(e)(3).

The first step (prong 1) of the two-prong test requires a demonstration that the BART alternative does not result in a decline in visibility at any Class I area relative to a baseline.[84] The record clearly establishes that there is no decline in visibility under the NO_X BART Alternative when visibility impacts of the NO_X BART Alternative are compared to the 2025 Baseline scenario.[85] As we explained in the proposed rule under prong 1, while the post-2003 SO_2 reductions from Hunter and Huntington increase the apparent overall visibility benefit of the BART Alternative relative to the Baseline, there would not be an anticipated decline in visibility relative to the Baseline in the absence of those SO_2 reductions from Hunter and Huntington because the BART Alternative would still result in overall NO_X, SO_2, and PM emissions decreases compared to the Baseline.[86]

At the second step of the (e)(3) test (prong 2), the state must establish that there is ''an overall improvement in visibility, determined by comparing the average differences between BART and the alternative.'' [87] Thus, the purpose of the modeling at this step is to allow for a comparison between two control scenarios—the BART benchmark and the BART alternative—relative to a baseline. It is not critical that the baseline itself be entirely representative of what might be expected to happen in 2025 so long as the emissions and meteorological data used in the modeling allow for the comparison between the BART benchmark and BART alternative. As noted above, the commenters have not demonstrated that the 2025 Baseline scenario here does not serve that purpose.

As we explained in the proposed rule, the relative to the 2025 Baseline, the BART Benchmark and BART Alternative include actual SO_2 reductions from Hunter and Huntington that occurred after the 2001–2003 baseline due to scrubber upgrades. Thus, the CAMx modeling results for the BART Benchmark and BART Alternative shown in Tables 4 and 5 of the proposed rule reflect these SO_2 reductions. The treatment of these SO_2 reductions in the modeling does not affect the determination of greater reasonable progress under the two-prong test. Under prong 2, because the SO_2 reductions from Hunter and Huntington are equal under the BART Alternative and BART Benchmark, they do not advantage either control scenario.[88]

In other words, even if the CAMx modeling counts Huntington and

[82] Utah Regional Haze State Implementation Plan, Staff Review of Recommended Alternative to BART for NO_X, May 28, 2019, page 13.

[83] Contrary to the commenters' claim, EPA explained this approach in the proposed rule. 85 FR 3572.

[84] 40 CFR 51.308(e)(3)(i).

[85] See 85 FR 3568–69, 3573, and Tables 4 and 5 (column D).

[86] Id. at 3573.

[87] 40 CFR 51.308(e)(3)(ii).

[88] 85 FR 3572–73.

Hunter as creating an additional visibility improvement in the BART Benchmark and NO_X BART Alternative scenarios relative to the 2025 Baseline scenario, this artifact of the data is present for both the BART Benchmark and BART Alternative scenarios. Thus, it does not have a meaningful effect on the comparison in *relative* improvement in visibility *between those scenarios.* The modeling does not, and need not, purport to establish actual, absolute improvements in visibility under the two scenarios; it simply needs to allow for a comparison between the scenarios. In order to pass the second prong under § 51.308(e)(3), a BART alternative must show an overall average improvement in visibility over the BART benchmark. Here, Utah's NO_X BART Alternative demonstrated an overall average improvement over the BART benchmark of 0.00494 deciviews across all Class I areas on the 20 percent best days and 0.00058 deciviews on the 20 percent worst days.[89] Thus, Utah's NO_X BART Alternative passes the second prong of 40 CFR 51.308(e)(3).

In sum, there is no merit to commenters' assertion that the data used in the CAMx modeling cannot be used to support Utah's conclusion that the Utah NO_X BART Alternative would result in greater visibility improvement compared to the EPA FIP (BART Benchmark) under the two-prong test in § 51.308(e)(3).

III. The EPA's Final Action

For the reasons stated in the preamble to the proposed rule, in the RTC document, and in this document, we are fully approving the SIP revisions submitted by the State of Utah on July 3, 2019, as supplemented on December 3, 2019.

A. 2019 Utah Regional Haze SIP Revisions

We are approving these aspects of the 2019 Utah RH SIP revisions:

- NO_X BART Alternative, including NO_X emission reductions from Hunter Units 1, 2 and 3 and Huntington Units 1 and 2, and SO_2, NO_X and PM emission reductions from Carbon Units 1 and 2.
- A NO_X emission limit of 0.26 lb/MMBtu (30-day rolling average) each for Hunter Units 1 and 2 and Huntington Units 1 and 2.
- A NO_X emission limit of 0.34 lb/MMBtu (30-day rolling average) for Hunter Unit 3.
- A requirement to permanently close and cease operation of the Carbon power plant by August 15, 2015.
- The associated amendments to the SO_2 milestone reporting requirements.
- MRR requirements for units subject to the NO_X BART Alternative and the PM BART emission limits.

We also note that the regulatory text amendments contained in this document include incorporation of additional parts of SIP section XX (XX.B–C and XX.E–N) and section XXIII, which were not addressed in the proposed action or in this final action. The EPA approved these SIP sections as meeting the requirements of the CAA and applicable regulations in previous actions;[90] however, we inadvertently did not incorporate all approved sections in 40 CFR 52.2320(e). We are remedying this oversight and reorganizing 40 CFR 52.2320(e) to better reflect the structure of Utah's SIP submissions here. We did not reopen these previously approved SIP sections in this rulemaking.

Finally, consistent with our approval of Utah's July 2019 and December 2019 SIP submissions, we find that Utah's SIP fully satisfies the requirements of section 309 of the Regional Haze Rule and therefore the State has fully complied with the requirements for reasonable progress, including BART, for the first implementation period.

B. FIP Withdrawal

Because we find that Utah's July 2019 and December 2019 SIP submissions satisfy the NO_X BART and MRR requirements currently addressed by the EPA's 2016 FIP, we are also withdrawing in whole the Utah Regional Haze FIP at 40 CFR 52.2336 that imposes NO_X BART requirements on Hunter Units 1 and 2 and Huntington Units 1 and 2.

C. Clean Air Act Section 110(l)

As we explain in detail in section II.A of this document and in the RTC document that accompanies this action, we find that our approval of the 2019 Utah SIP revisions and concurrent withdrawal of the corresponding the FIP is consistent with CAA section 110(*l*), 42 U.S.C. 7410(*l*).

IV. Incorporation by Reference

In this document, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the SIP amendments described in section III.A of this preamble and set forth below. The EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* (refer to docket EPA–R08–OAR–2015–0463) and at the EPA Region 8 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 the EPA for inclusion in the SIP, have been incorporated by reference by the 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 the EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.[91]

V. Statutory and Executive Order Reviews

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

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866[92] and was therefore not submitted to the Office of Management and Budget (OMB) for review. This final rule applies to three facilities in the State of Utah. It is therefore not a rule of general applicability.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because it is not significant under Executive Order 12866 for the reasons stated in section V.A above. Instead, it is a *Rule of Particular Applicability* that is exempted under Executive Order 12866.

C. Paperwork Reduction Act

This action does not impose an information collection burden under the PRA. Because this rule revises regional haze reporting requirements for three facilities, the PRA does not apply.

D. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. This rule does not impose any requirements or create impacts on small

[89] Id. at 3569.

[90] 73 FR 16543 (Mar. 28, 2008); 77 FR 74355 (Dec. 14, 2012); 78 FR 4072 (Jan. 18, 2013); 81 FR 43894 (July 5, 2016).

[91] 62 FR 27968 (May 22, 1997).

[92] 58 FR 51735, 51738 (Oct. 4, 1993).

entities as no small entities are subject to the requirements of this rule.[93]

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments. Thus, Executive Order 13175 does not apply to this action.

In comments on the proposed rule, the Ute Mountain Ute Tribe requested consultation. In response, the EPA offered consultation, but the Ute Mountain Ute Tribe later waived the opportunity for consultation.

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

This action is not subject to Executive Order 13045.[94] The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not subject to Executive Order 13211[95] because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained in EPA's EJ analysis. The EPA's *Guidance on Considering Environmental Justice During the Development of Regulatory Actions*[96] is the Agency's guide for determining when environmental justice should be considered when developing regulations. In support of this guidance, the EPA used EJSCREEN[97] to identify areas of potential environmental justice (EJ) concerns associated with this rulemaking. A 300-kilometer radius zone of impact was used in the EJSCREEN analysis consistent with other regional haze actions. The results do not identify any areas of potential EJ concerns.[98] Moreover as explained in the preamble to the final rule and in response to comments, the Utah Regional Haze SIP, as revised by this action, will ensure a significant reduction in emissions compared to regional haze baseline levels (2002). Finally, the EPA's analysis under CAA section 110(*l*) shows that this action will not interfere with any applicable requirement concerning attainment and reasonable further progress or any other applicable CAA requirements. Thus, this final action will not create a disproportionately high and adverse effect on minority, low-income, and/or indigenous/tribal populations.

The availability of regulations.gov to submit written comments and a public hearing in Price, Utah provided meaningful opportunities for public participation in the proposed rulemaking. The EPA considered input received during the public comment period regarding environmental justice considerations.

L. Determination Under Section Clean Air Act Section 307(d)

Pursuant to CAA sections 307(d)(1)(B) and 307(d)(1)(V), the Administrator determines that this action is subject to the provisions of section 307(d). CAA section 307(d)(1)(B) provides that section 307(d) applies to, among other things, ''the promulgation or revision of an implementation plan by the Administrator under [CAA section 110(c)].''[99] Under section 307(d)(1)(V), the provisions of section 307(d) also apply to ''such other actions as the Administrator may determine.''[100] To the extent the approval of Utah's SIP submittals is not expressly identified under section 307(d), the Administrator hereby determines that section 307(d) applies to this aspect of this action. The agency has complied with the procedural requirements of CAA section 307(d) during the course of this rulemaking.

M. Congressional Review Act (CRA)

This rule is exempt from the CRA because it is a rule of particular applicability that only applies to three named facilities.

N. Judicial Review

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 January 26, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for 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 CAA section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Sulfur oxides.

Andrew Wheeler,

Administrator.

For the reasons set forth in the preamble, 40 CFR part 52 is to be amended as follows:

[93] See 13 CFR 121.201, Sector 22, Subsector 221.

[94] 62 FR 19885 (Apr. 23, 1997).

[95] 66 FR 28355 (May 22, 2001).

[96] *https://www.epa.gov/sites/production/files/2015-06/documents/considering-ej-in-rulemaking-guide-final.pdf*

[97] EJSCREEN: Environmental Justice Screening and Mapping Tool is available at *https://www.epa.gov/ejscreen.*

[98] Results in the EJSCREEN Report for the Hunter and Huntington Power Plants show percentiles of less than 80 for all EJ Indexes evaluated. See EJSCREEN Report in the docket.

[99] 42 U.S.C. 7607(d)(1)(B).

[100] 42 U.S.C. 7607(d)(1)(V).

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 TT—Utah

■ 2. In § 52.2320:
■ a. The table in paragraph (c) is amended by revising the entries ''R307–110–17,'' ''R307–110–28,'' and ''R307–150–03''.
■ b. The table in paragraph (e) is amended by:
■ i. Adding the entries ''Section IX.H.21. General Requirements: Control Measures for Area and Point Sources, Emission Limits and Operating Practices, Regional Haze Requirements'' and ''Section IX.H.22. Source Specific Emission Limitations: Regional Haze Requirements, Best Available Retrofit Technology'' in numerical order.
■ ii. Removing from under the center heading ''XVII. Visibility Protection'' the entries ''Progress Report for Utah's State Implementation Plan for Regional Haze,'' ''Section XX.D.6. Best Available Retrofit Technology (BART) Assessment for NO_X and PM,'' and ''Section XX.G. Long-Term Strategy for Fire Programs.''
■ iii. Adding the center heading ''XX. Regional Haze'' and the entries ''Section XX.A. Executive Summary'', ''Section XX.B. Background on the Regional Haze Rule'', ''Section XX.C. Long-Term Strategy for the Clean-Air Corridor'', ''Section XX.D. Long-Term Strategy for Stationary Sources'', ''Section XX.E. Sulfur Dioxide Milestones and Backstop Trading Program'', ''Section XX.F. Long-Term Strategy for Mobile Sources'', ''Section XX.G. Long-Term Strategy for Fire Programs'', ''Section XX.H. Assessment of Emissions from Paved and Unpaved Road Dust'', ''Section XX.I. Pollution Prevention and Renewable Energy Programs'', ''Section XX.J. Other GCVTC Recommendations'', ''Section XX.K. Projection of Visibility Improvement Anticipated from Long-Term Strategy'', ''Section XX.L. Periodic Implementation Plan Revisions'', ''Section XX.M. State Planning/Interstate Coordination and Tribal Implementation'', ''Section XX.N. Enforceable Commitments for the Utah Regional Haze SIP'', and ''Progress Report for Utah's State Implementation Plan for Regional Haze'' in numerical order and after the entry ''Section XXIII. Interstate Transport''.

The revisions and additions read as follows:

§ 52.2320 Identification of plan.

* * * * *

(c) * * *

Rule No.	Rule title	State effective date	Final rule citation, date	Comments
*	*	*	*	*
R307–110. General Requirements: State Implementation Plan				
*	*	*	*	*
R307–110–17 ...	Section IX. Control Measures for Area and Point Sources, Part H, Emission Limits.	11/25/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
*	*	*	*	*
R307–110–28 ...	Section XX. Regional Haze	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
*	*	*	*	*
R307–150. Emission Inventories				
*	*	*	*	*
R307–150–03 ...	Applicability	6/25/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
*	*	*	*	*

* * * * * (e) * * *

Rule title	State effective date	Final rule citation, date	Comments
*	*	*	*
IX. Control Measures for Area and Point Sources			
*	*	*	*
Section IX.H.21. General Requirements: Control Measures for Area and Point Sources, Emission Limits and Operating Practices, Regional Haze Requirements.	11/25/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section IX.H.22. Source Specific Emission Limitations: Regional Haze Requirements, Best Available Retrofit Technology.	11/25/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	

Rule title	State effective date	Final rule citation, date	Comments
* * *	*	* *	* *
XX. Regional Haze			
Section XX.A. Executive Summary	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.B. Background on the Regional Haze Rule.	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.C. Long-Term Strategy for the Clean-Air Corridor.	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.D. Long-Term Strategy for Stationary Sources.	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.E. Sulfur Dioxide Milestones and Backstop Trading Program.	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.F. Long-Term Strategy for Mobile Sources.	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.G. Long-Term Strategy for Fire Programs	4/7/2011	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.H. Assessment of Emissions from Paved and Unpaved Road Dust.	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.I. Pollution Prevention and Renewable Energy Programs.	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.J. Other GCVTC Recommendations	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.K. Projection of Visibility Improvement Anticipated from Long-Term Strategy.	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.L. Periodic Implementation Plan Revisions.	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.M. State Planning/Interstate Coordination and Tribal Implementation.	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Section XX.N. Enforceable Commitments for the Utah Regional Haze SIP.	8/15/2019	[INSERT **Federal Register** CITATION] 11/27/2020.	
Progress Report for Utah's State Implementation Plan for Regional Haze.	2/4/2016	85 FR 64050, 10/9/2020	
* * *	*	* *	* *

§ 52.2336 [Removed and Reserved]

■ 3. Remove and reserve § 52.2336.

[FR Doc. 2020–23994 Filed 11–25–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 2560

[LLAK940000 L14100000.HM0000 20X]

RIN 1004–AE66

Alaska Native Vietnam-Era Veterans Allotments

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Land Management (BLM) is issuing final regulations to enable certain Alaska Native Vietnam-era veterans to apply for land allotments under Section 1119 of the John D. Dingell, Jr. Conservation, Management, and Recreation Act of March 12, 2019 (Dingell Act). The Dingell Act requires the BLM to issue regulations to implement the Act's land allotment provisions. This action will enable certain Alaska Native Vietnam-era veterans to apply for an allotment who, because of their military service, were not able to do so during the late 1960s and early 1970s.

DATES: The final rule is effective on December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Paul Krabacher, Division of Lands and Cadastral, Bureau of Land Management, (907) 271–5681. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, 7 days a week, to leave a message or question with the previously mentioned point of contact. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

I. Background

On December 18, 1971, Congress enacted the Alaska Native Claims Settlement Act (ANCSA; 43 U.S.C. 1601, *et seq.*), which repealed the Alaska Native Allotment Act (34 Stat. 197, as amended). During the time leading up to the repeal of the Alaska Native Allotment Act, certain Alaska Natives who were eligible to apply for allotments were serving in the U.S. military and may have missed their opportunity to apply because of their military service.

In 1998, Congress enacted a law allowing certain Alaska Native veterans a new opportunity to apply for allotments under the Alaska Native Allotment Act, as it was in effect before its repeal (Alaska Native Veterans Allotment Act of 1998; 43 U.S.C. 1629g). Those Alaska Native veterans were able to apply for allotments from July 31, 2000 to January 31, 2002. Under the Alaska Native Veterans Allotment Act of 1998, about 250 allotments were issued to Alaska Native veterans or their heirs.

On March 12, 2019, Congress enacted Section 1119 of the Dingell Act (codified at 43 U.S.C. 1629g–1) to

provide an additional opportunity for Alaska Native veterans who have not applied for or received an allotment under prior laws to apply for an allotment. Congress required the BLM to issue regulations implementing the Dingell Act as it pertains to land allotments for Alaska Native veterans. This rule will carry out that congressional mandate.

II. Discussion of the Final Rule, Section-by-Section Analysis, and Response to Comments on the Proposed Rule

The BLM developed this rule based on the proposed rule published in the **Federal Register** on July 10, 2020 (85 FR 41495). The BLM invited public comment for 30 days and received written comments from 28 individuals and groups. In addition, the agency in collaboration with the Bureau of Indian Affairs (BIA) held public meetings in Anchorage and Fairbanks prior to the drafting of the proposed rules to give participants an opportunity to provide early input into the proposed rule. The primary purpose of these meetings was to gather input from Alaska Native entities and the State, in keeping with the requirement in the Dingell Act for consulting with State, Native corporations on available lands for selection. Oral comments were recorded in writing at each of the meetings prior to the drafting of the proposed rules. Additionally, four virtual public meetings were held during the 30-day comment period. All the meetings were open to the public and were advertised in local media. Participants included both Alaska Native and non-Native individuals. Transcripts and recordings were captured for three of the virtual meetings and are included in the administrative record for this rule.

Most of the written comments we received during the 30-day comment period addressed more than one section of the proposed rule. Comments are addressed on a section-by-section basis.

This preamble discusses the proposed rule and the comments the BLM received from the public about the rule. It explains the changes the BLM incorporated into this final rule and why the BLM made them. It also explains why the BLM did not adopt all of the changes recommended by the public.

The final rule is adopted with the changes to the proposed rule discussed in this section. In summary, the final rule establishes the requirements for participating in the Alaska Native Vietnam Veterans Land Allotment Program (Program). It contains the requirements an applicant must meet in order to qualify to apply for and receive an allotment.

The final rule establishes:

1. The types of Federal land that the BLM can and cannot convey to an allotment applicant;
2. When and how an applicant may apply for a substitute selection if the original application describes land that cannot be conveyed;
3. How a personal representative may apply for an allotment on behalf of eligible veterans or the heirs of eligible veterans; and
4. The processing of applications for allotments.

Responses to Comments

In preparing the final rule, the BLM considered each of the 171 comments received from 28 individuals and groups during the 30-day public comment period. A discussion of those comments follows. The discussion deals with changes made to the final rule resulting from comments the BLM received, as well as through internal review. The discussion also covers changes urged by the public that the BLM is not adopting. In both cases we explain the reason(s) for the decisions.

Many of the comments the BLM received were about the applicant's inability to select lands because they are currently unavailable. Section 1119(b) of the Dingell Act identifies certain Federal lands that are excluded from being allotted under this Program, including but not limited to lands within the boundary of a National Forest System Unit, a U.S. Fish and Wildlife Service (USFWS) refuge, a National Park System Unit, or a congressionally designated wilderness area. The statute also excludes lands that are subject to a withdrawal under section 17(d)(1) of the Alaska Native Claims Settlement Act, or other authority. Commenters noted that a majority of Alaska Native veterans (or heirs) who are eligible for this Program reside in the Southeast portion of Alaska where lands are not available for selection because Congress excluded the National Forest System Units, including the Tongass National Forest. As a result of these statutory exclusions, allottees and their heirs will not be able to receive ancestral lands or lands near their homes. The Dingell Act makes only vacant, unappropriated, and unreserved lands available for selection. The BLM has no authority to make lands available except pursuant to the Dingell Act, and the regulations cannot open any new lands.

Another category of comments pertained to the 60-day time periods in the proposed rule for applicants to respond to certain actions, such as notifications for correcting errors and responding to BLM decisions. Commenters were concerned that these 60-day deadlines are not long enough. We address these comments—which were directed to many different sections of the proposed rule—in the discussion of § 2569.414 that follows.

The BLM added language to some sections where commenters said the language was not clear. We are making other changes to ensure that the rule is consistent from one section to another and that the meaning of certain terms is clear.

The following is a section-by-section discussion of the comments the BLM received, and which suggestions we adopted and which suggestions we rejected and our reasons for doing each.

Section 2569.201 What terms do I need to know to understand this subpart?

Section 2569.201 contains definitions that are used in the regulations. The BLM is adding new definitions that clarify the meaning of ''error'' as it relates to the application process. Based on comments received, the BLM agrees that it should not reject an application with very minor errors and should consider it to be ''received.'' This change requires the BLM to differentiate in the regulations between errors that are very minor, major errors that are correctable, and major errors that cannot be corrected; the BLM determined it would use the terms ''technical error,'' ''substantive error,'' and ''uncorrectable defect'' respectively to define each category of errors. The discussion of how these new definitions will be applied during the application process is addressed later in this preamble (see discussion under §§ 2569.410 and 2569.411).

Specific terms addressing comments or additions for clarity include:

Allotment. Several commenters requested that the definition include language from the previous 1998 Act stating that proof of prior use and occupancy of selected lands is not required. Although the BLM agrees that such proof is not required, since the regulations only provide for what is required (and not what is not), we are not changing the text in the final rule in response to these comments.

Available Federal Lands. This term in the final rule incorporates the definition from the Dingell Act. In general, ''available Federal land'' is defined as vacant, unappropriated, and unreserved public land. One commenter requested that available lands include lands withdrawn pursuant to section 17(d)(1)

of the Alaska Native Claims Settlement Act. These lands are only available when the withdrawal is revoked. We are not changing the definition in the final rule in response to this comment.

Eligible Individual. This term is used throughout the regulations to refer to an Alaska Native veteran who is eligible to receive an allotment under the Dingell Act, or another person who is eligible to apply for an allotment on the behalf of such a veteran. One commenter requested clarity on whether a person who previously applied for, but did not receive, an allotment is eligible. An individual who previously applied for, but did not receive, an allotment does qualify for this Program. We are not changing the definition in the final rule because the definition already states that a Native Veteran who ''has not already received'' an allotment is an eligible individual.

Another commenter asked whether a pending application under the 1998 Act would disqualify an individual for this Program. The BLM found that this is a very rare situation and in the final rule has deleted a reference to ''pending applications'' from the proposed definition. If the BLM receives an application from a pending applicant, it will contact the individual and explain the options for going forward. The pending application will need to be relinquished or denied before the BLM can process an application under this Program. Therefore, the BLM removed the phrase ''and does not have a pending application'' from the definition. In so doing, there is no longer a reason to refer to prior allotment programs cited in the Dingell Act, and that reference has been removed. The BLM will change the definition in the regulation to solely refer to the Dingell Act since it is no longer modifying when an applicant is deemed to have received an allotment under the other allotment acts.

Another commenter recommended spelling out the definition as written in the Dingell Act instead of referring readers to the Act. The BLM decided to retain the reference to the Act instead of reciting the definition in the Act to ensure that the language stays consistent with the Act.

Mineral. A commenter requested that the BLM add a definition for ''minerals.'' In the proposed and final rules, the United States will reserve to itself all minerals associated with lands allotted under this Program. The commenter requested this new definition in order to limit the U.S. mineral reservation to coal, oil, and gas. The BLM agrees that providing a definition of mineral will be beneficial because the term ''mineral'' is vague. However, the commenter's requested definition is too limited considering the legislative intent behind the Dingell Act. Congress's intent was to offer Alaska Natives, who served in the military during the Vietnam era, a chance to receive an allotment similar to the one that they otherwise could have received under the Alaska Native Allotment Act of 1906. Congress also intended to eliminate historic delays related to agency review of the mineral potential for requested allotments by allowing applicants to select any available lands while reserving the mineral estate to the United States. Under the Alaska Native Allotment Act of 1906, allotments could be made only on vacant, unappropriated, and unreserved ''nonmineral'' land, which is generally defined as lands that are not known to contain any leasable, saleable, or locatable minerals, in such quantities and of such qualities as would, with reasonable prospects of success in developing a paying mine thereon, induce a person of ordinary prudence to expend the time and money necessary to such development. In 1980, however, section 905(a)(3) of the Alaska National Interest Lands Conservation Act (43 U.S.C. 1634(a)(3)) expanded the definition of ''nonmineral'' lands under the Alaska Native Allotment Act of 1906 to include lands with valuable deposits of sand or gravel. Based on this revised definition of ''nonmineral'' lands under the Alaska Native Allotment Act of 1906, ''mineral'' is properly defined for this rule as including coal, oil, natural gas, other leasable minerals, locatable minerals, and saleable minerals, other than sand and gravel.

Realty Service Provider. This term refers to the tribal and intertribal organizations that provide Trust Real Estate Services pursuant to a contract or compact with the BIA. Although § 2569.412(a) lists the website the public can use to determine which Service Provider serves a particular area for assistance with an application, one commenter recommended that the link be added to the definition as well. The BLM believes that the location of the website URL is more appropriate in § 2569.412 and did not change this definition in the final rule.

Receipt date. This term is used in the regulations to refer to the date on which an application arrives at the BLM Alaska State Office. The Receipt Date is used to determine which application will receive preference if two or more applications contain conflicting selections. A commenter suggested that a postmark be the determining factor for preference versus the date an application arrives at the BLM Alaska State Office. This situation is addressed later in this preamble in the discussion of § 2569.502. The BLM did not change this definition in the final rule as a result of this comment.

Substantive error. As discussed later in this preamble (see §§ 2569.410 and 2569.411), this new definition is added to the final rule to describe one category of errors or omissions that the BLM may find on applications and supporting documents submitted as required under § 2569.402. Substantive errors include, but are not limited to: Missing land descriptions and missing forms required under § 2569.404, if applicable. When an applicant corrects this type of error, the correction could show that the application has an uncorrectable defect, for instance, the applicant is not an Alaska Native.

Technical error. As discussed later in this preamble (see §§ 2569.410 and 2569.411), this new definition is added to the final rule to describe one category of errors or omissions that the BLM may find on applications and supporting documents submitted as required under § 2569.402. A ''technical error'' is defined as a type of error that does not rise to the level of a substantive error or uncorrectable defect. For example, not signing your application is a technical error that can easily be corrected and does not raise any new issues that would cause an application to be rejected.

Uncorrectable defect. As discussed later in this preamble (see §§ 2569.410 and 2569.411), this new definition is added to the final rule to describe one category of errors or omissions that the BLM may find on applications and supporting documents submitted as required under § 2569.402. An uncorrectable defect in an application is evidence that shows you are not qualified for an allotment. That evidence includes a lack of qualifying military service or proof of Alaska Native descent, or shows that the applicant has already received an allotment under a previous allotment program.

Valid relinquishment. The Dingell Act allows an Eligible Individual to select and receive from the BLM lands that have been selected by the State or a Native corporation if that entity ''agrees to voluntarily relinquish the selection.'' A commenter requested that the BLM clarify that for the relinquishment to be valid, the voluntary relinquishment must be signed by a person authorized by a board resolution of the Native corporation or a delegated official of the State. The BLM already included this

requirement in the definition and it will not make any changes.

The BLM has added the new definitions in alphabetic order, which requires us to redesignate the individual definitions as paragraphs (a) through (q) in the final rule. We did not receive comments on the following definitions and they have not changed in the final rule: ''Allotment,'' ''Native,'' ''Native corporation,'' ''Segregate,'' ''Selection,'' ''State,'' ''State or Native corporation selected lands,'' and ''Veteran.''

Section 2569.301 How will the BLM let me know if I am an Eligible Individual; and

Section 2569.302 What if I believe I am an Eligible Individual, but I was not notified by the BLM?

The Department of Defense (DOD) and the Department of Veterans Affairs (VA) identified and delivered to the BIA the names of veterans who served during the Vietnam Era as specified in the Act. The BIA, after subsequent review, delivered the names of Native veterans to the BLM. The BLM further reviewed the names to determine whether the Native veterans previously received an allotment of land pursuant to previous allotment Acts. As a result, the BLM has notified approximately 2,000 individuals that it believes to be eligible for the Program. There are still individuals with pending determinations.

Comments were received from several Alaska Native organizations that suggested the BLM or the BIA share the list of Eligible Individuals publicly or directly to enhance outreach. The list cannot be shared publicly due to the Privacy Act. However, when the BLM sends notification letters to Eligible Individuals, the Realty Service Provider and/or the BIA will be copied for their likely assistance with future applications. One commenter requested that the BLM notify the specific Native corporation when an application is received for lands within their specific region. When an application is considered received by the BLM, the location of the selection gets entered onto the Master Title Plat, which the public, including Native corporations, can monitor. The Privacy Act prevents the BLM from publishing or otherwise releasing the names of Eligible Individuals without their consent.

Eligible Individuals who were not identified through the process described earlier will need to provide documentation to demonstrate that they are eligible. In addition to the application, those individuals will be required to provide a Certificate of Degree of Indian Blood or other documentation from the BIA demonstrating that they meet the definition of a Native, and a Certificate of Release or Discharge from Active Duty (Form DD–214) or other documentation from the DOD or VA demonstrating that they meet the definition of a veteran. One commenter asked the BLM to allow an affidavit in place of the DOD or VA documentation for Veteran status. The BLM has a responsibility to ensure public lands are only granted to a private individual when the person qualifies under the Dingell Act. The BLM would be unable to ensure it was meeting its responsibility if it accepted an affidavit alone and will not incorporate this suggestion into the final rule.

Section 2569.303 Who may apply for an allotment under this subpart on behalf of another person?

Section 2569.303 sets out who can apply on behalf of an Eligible Individual. The BLM received many comments addressing how a personal representative is appointed. Several commenters suggest the BLM interpret the requirements of the Dingell Act at 43 U.S.C. 1629g–1(a)(2)(B) that a ''personal representative . . . has been duly appointed in the appropriate Alaska State court or a registrar has qualified'' broadly, with one specifically pointing to the phrase, ''a registrar has qualified'' as a basis for a broad interpretation. When interpreting a statute, the language of the statute is the first consideration. The BLM believes that the Dingell Act is clear. The first portion addresses a formal probate which is done by a judge for the Alaska State Court System. The second portion, regarding the registrar, addresses informal probates. The position of registrar is set out in the Alaska State statutes as the position that makes the determination on informal probates within the Alaska State Court System (AS 13.16.085). As such, the Dingell Act requires that a personal representative be appointed by an Alaska State Court System, whether by a judge in the formal probate process or by the registrar in the informal process. The BLM cannot add an alternative method for personal representatives to be appointed.

Commenters variously suggested that the BLM expand the ways a personal representative can be appointed to include those appointed by other state courts, tribal courts, affidavits from the family, and by the wills of the deceased. The BLM does not have the authority or the expertise to determine the heirs of a deceased veteran. It also does not have the authority to choose or appoint personal representatives. Often there will be multiple heirs or persons claiming to be heirs. The BLM cannot know which allotment application to process or which parcel of land to convey without a formal determination of the estate representative and the heirs who will benefit. Likewise, allowing the appointment of personal representatives from multiple jurisdictions could put the BLM in the position of deciding among competing appointments and the BLM is ill-equipped to make that determination. The lack of a formal representative would cause considerable chaos and dramatically slow down the processing of all allotment applications. Lastly, the Dingell Act is clear that only personal representatives appointed by the Alaska State Court System can apply on behalf a deceased Eligible Individual. Therefore, the BLM declines to make any of the requested changes in the regulations.

One commenter suggested a clarification be added to § 2659.303(b) that would indicate that an attorney-in-fact would not need to be appointed by a court. We are responding to the comment by changing the order of the sentence to clarify that an attorney-in-fact does not need to be court-appointed. However, we are not adopting a recommendation that the attorney-in-fact must be appointed according to Alaska State law since this restriction is not required by the Dingell Act and could cause confusion for applicants living in other states.

Section 2569.401 When can I apply for an allotment under this subpart?

As mandated under the Dingell Act, the application period begins on the effective date of this final rule and will run for a period of 5 years (43 U.S.C. 1629g–1(b)(3)(B)). Several commenters mistakenly referred to the 5 years as the period for the BLM to process an application.

Several commenters requested the five-year window be extended. The statute directs the period that the Program will be in effect, and the BLM lacks authority to extend the application period beyond the statutory deadline. Any extension of the period will require additional legislation from Congress. Therefore, no change was made to the final rule as a result of these comments.

One commenter requested an extension of the 5 years because the State of Alaska is so over-selected under the Statehood Act that there are currently limited lands available. As stated previously, the Dingell Act sets out the application period, and the BLM lacks the authority to change it. Again,

no change was made to the final rule as a result of this comment. Also, the BLM notes that State-selected lands are available for selection under this Program if the State is willing to relinquish portions of its selection.

Another commenter states it would be unfair if an application is submitted during the 5-year period and considered late because the BLM does not adjudicate it quickly enough, and then considers it to be too late to process. The amount of time it takes the BLM to adjudicate an application does not change the date for when the BLM deems an application to be received for the purposes of the 5-year application period. An application submitted prior to the end of the 5-year window will be considered timely filed.

Upon reviewing the comments received on this section as a whole, the BLM recognizes that there is a need to address the situation where an application is received in the BLM State office after the 5-year period is over, but the application is post-marked prior to the end of the application period. Under final § 2569.502, the BLM will use the receipt date for the purposes of adjudicating the application preference rights under the Dingell Act. However, in determining whether an application is timely filed, the BLM will use the post-mark date for applications that were sent by mail, as provided for under new paragraph (a)(2) of § 2569.401 of the final rule. Additionally, new paragraph (a)(1) has been added to clarify that BLM will consider applications timely filed that an applicant submits prior to the beginning of the application period, but BLM will not adjudicate the application until the application period begins on December 28, 2020.

Section 2569.404 What must I file with my application form?

One commenter proposed that proof of an applicant's valid enrollment as a citizen of a federally recognized tribe be added to the list of supporting documents that applicants must provide to the BLM to prove they are Eligible Individuals. This section already requires applicants to provide a Certificate of Degree of Indian Blood or other documentation from the BIA to prove they are eligible. The BIA has the sole authority to make a determination of whether a person is an Alaska Native. In the absence of a Certificate of Degree of Indian Blood, an individual or a tribe can work with the BIA to make sure the determination meets the definition under ANCSA (43 U.S.C. 1602) for ''Native.'' The BLM did not change the final rule in response to this comment.

Section 2569.405 What are the special provisions that apply to selections that include State or Native corporation selected land?

This section covers the special provisions that apply when an applicant applies for Federal lands within State or Native corporation selected lands. One commenter recommended that the BLM make it clear in the final rule that applicants may need to request up to three relinquishments in order to obtain an allotment. Such a situation could arise, the commenter said, when a village Native corporation has selected the surface estate and the regional Native corporation has automatically selected the subsurface estate, and the State has top-filed some of the same lands. The proposed and final rule only require one relinquishment, because when a village corporation relinquishes the surface, the subsurface selection by the Regional corporation is automatically relinquished. Paragraph (c) establishes that the applicant's selection takes precedent over the State's top-filing, and thus a relinquishment from the State is unnecessary. We did not change the final rule in response to this comment.

One commenter requested that the BLM consider an application complete even if the applicant has not received a valid relinquishment. The BLM added a new sentence to paragraph (a) that clarifies that an applicant is not required to provide the relinquishment with the application. The BLM will request a relinquishment from the State or Native corporation on behalf of the applicant if an applicant applies for selected lands and does not include a relinquishment. If the State or Native corporation is unwilling to provide a relinquishment within 60 days, the application will still be considered complete, but the applicant will need to submit a substitute selection pursuant to § 2569. 411(c).

One commenter requested that the regulations require the BLM to notify the ''appropriate Native regional and/or village corporation so that those corporations can pro-actively assist the applicant to obtain the necessary relinquishments or select alternate lands.'' The change discussed previously also addresses this comment.

Another commenter stated the regulations incentivize applicants to apply for currently available lands rather than apply for State or Native corporation selected lands because available land the applicant would otherwise select may no longer be available by the time the applicant learns the State or Native corporation will not relinquish their selected land. The Dingell Act established a first come, first served basis for the BLM to award an allotment of land. The regulations follow the same structure, which we agree does create a situation where applicants who are risk averse may choose to apply for land they know is open rather than take a chance on land that is State or Native corporation selected. This is an unavoidable trade-off that the regulations cannot change. We did not change the final rule in response to this comment.

Section 2569.406 What are the rules about the number of parcels and size of the parcel for my selection?

Several commenters had a misunderstanding that the size of the land allotment has to be less than 160 acres. This section clearly states that an allotment cannot be more than 160 acres or less than 2.50 acres. We did not change the final rule in response to this comment.

Section 2569.409 Where do I file my application?

Several commenters recommended that the BLM allow applications to be submitted online or electronically. This option was considered but found to be impracticable within the statutory timeframe for promulgating the final rules. Congress required the BLM to issue regulations implementing section 1119 of the Dingell Act no later than 18 months after March 12, 2019. The BLM's current System of Records Notice (SORN), which is a requirement under the Privacy Act of 1974 and covers the BLM's collection of information from the public for this new regulation, was established without a means to collect information electronically and would require an amendment. The process related to a SORN amendment or renewal takes a length of time which could not be completed prior to accepting applications for this Program. We did not change the final rule in response to this comment.

Section 2569.410 What will the BLM do if it finds an error in my application?

Several commenters requested additional clarification regarding the types of errors that would or would not warrant a rejection of an application. The BLM agrees with the need to ensure that minor errors do not lead to applicants losing their preferred parcels. However, some errors could lead to an applicant being unqualified, and those errors need to be addressed differently. In response to the comments, the BLM has developed a new system for the

final rule that addresses how the different types of errors will be handled.

In response to commenters' requests, this section will now explain how the BLM will review an application for errors when it is submitted. This initial review will determine whether an application can be deemed received and is not the final adjudication of whether an applicant qualifies under the Dingell Act. The BLM will review the applications to determine if there are uncorrectable defects or correctable errors in the application. An uncorrectable defect is where the application or the attached materials demonstrate that the applicant is not qualified. For instance, if a person has previously received an allotment under another allotment Act, they are not eligible under the Dingell Act. If the person indicates on their application that they have previously received an allotment, and the BLM finds that this is correct, the BLM will find that the application has an uncorrectable defect. In the case of an uncorrectable defect, the BLM will issue a decision rejecting the application and the applicant will have the right to appeal.

If the BLM finds a correctable error in an application, it will characterize the error or omission as either a technical error or a substantive error. In both cases, the BLM will send a notice to the applicant identifying the error and provide the applicant 60 days after receiving the notice to correct the error. The applicant will need to correct the error or omission by mailing the correction to the BLM postmarked by the end of the 60-day period. If the BLM does not receive a timely correction of the error, it will reject the application.

The BLM will characterize the type of error because a technical error will be treated differently than a substantive error for the purposes of the conflict provisions in § 2569.411. As defined in § 2569.201, a ''technical error'' is a minor error in the information provided on the application that will assist the BLM in adjudicating the claim. Typically, the error will be an omission such as failing to sign the application. The BLM needs the information, but this omitted information is not likely to result in the BLM rejecting the application for not meeting the statutory requirements once the missing information is provided. As such, the BLM finds it likely that such an application will be approved once the information is submitted. The BLM will treat the application as received on its original receipt date once the technical error has been corrected.

Conversely, a ''substantive error'' in the application is the type of error or omission that goes to the very substance of the requirements of the Dingell Act. The BLM needs to ensure that allotments are only awarded to those individuals qualified to receive an allotment. A substantive error would include not providing the documents required by § 2569.404 that show proof that the applicant is an Alaska Native or a veteran, if the applicant is not on the list of Eligible Individuals. This type of error is much more likely to result in the application being rejected due to the BLM finding the person does not meet the qualifications of the Act. Due to the increased likelihood of the application not meeting the requirements, the BLM will not consider an application with a substantive error as received for the purposes of the conflict provision at § 2569.411 until the corrections are submitted. Leaving out the land description or providing a description that fails to provide sufficient detail for the BLM to determine the applicant's intended selection will also be considered a substantive error because the BLM has no way to determine what land it should segregate and make unavailable for future selections.

These changes were addressed by adding paragraphs (b), (c), and (d) to this section.

Section 2569.411 When is my application considered received by the BLM?

One comment, which was also addressed in § 2569.410, requested that the BLM consider an application to be ''received'' when it has technical errors. Following the changes to § 2569.410 discussed earlier, the BLM clarifies in the final rule that an application that is free of substantive errors will be considered received on the original receipt date—that is, the date on which the application is physically received by the BLM Alaska State Office (see § 2569.201(h)). Thus, if the receipt date of an application was on Day 1, the BLM would use Day 1 as the received date even if it took the BLM until Day 15 to review the application and determine that the application is free of substantive errors. This application would have preference over any application submitted after Day 1.

If an application contains a technical or substantive error, the BLM will provide notice as set forth in § 2569.410 and require the applicant to correct the error. Once an application with only technical errors is corrected, the application will receive the preference corresponding to the date on which the BLM physically received the original application at the BLM State Office. An application with substantive errors will receive the preference corresponding to the date upon which the BLM physically receives all corrections to the substantive errors at the BLM State Office.

Changes made in § 2569.504 to the final regulations to allow applicants to amend their selections requires a change in this section as well. If the applicant chooses to file an amended selection pursuant to § 2569.504, the applicant would receive the preference corresponding to the date on which the amended selection was physically received at the BLM Alaska State Office, assuming that the amended selection is free from technical errors or conflicts. Similar to the way a substitute selection will be handled, in terms of its application date, the BLM finds that an amended selection should not retain its the original application date in order to ensure fairness to all applicants. The BLM revised paragraph (c) in this section to reflect this change by adding the phrase ''or an amended selection under § 2569.504.''

Section 2569.412 Where can I go for help with filling out an application?

The BLM received comments pertaining to Eligible Individuals getting help with filling out their applications. The proposed rule highlighted the Realty Service Provider's role as being crucial. Several commenters raised concerns regarding limited internet access and how this could affect applicants' ability to print maps from the Available Lands Map website (*https://arcg.is/1HTrrO*). Several commenters specifically requested that the BLM provide maps to the public showing lands that are available lands for selection. It would be logistically difficult for the BLM to supply maps of all the available lands for selection at a scale that would enable an individual to confidently select a parcel. Realty Service Providers will assist applicants with viewing, selecting, and printing selections from the Available Lands Map website, which includes zoom capabilities, background changes to topography or satellite views. However, the BLM will fulfill map requests from the public for a specific area or location. The BLM's contact information for requesting maps for those without internet capability is found at § 2569.412 of the regulatory text. We did not change the final rule in response to these comments.

One commenter requested that we clarify the roles for the VA and the Department of Interior (DOI) regarding proposed § 2569.412(d) which included the VA in a list of places that applicants could seek assistance in filling out their

applications. The VA does not have a role in providing assistance to applicants in completing applications; that role belongs to the BLM. The VA's role is to effectively direct inquiries about the Program that are made to the VA to the BLM or the BIA Alaska. The VA's statutory obligations to provide outreach to veterans and make referrals to the DOI regarding this Program will continue, along with its support in determining veteran eligibility. In response to this comment, in the final rule we removed proposed § 2569.412(d) to eliminate any confusion and redesignated paragraph (e) as new paragraph (d).

One commenter requested that the specific contact information for the BIA and the BLM, such as direct phone numbers or website addresses be included in the rule. The regulatory text includes the requested contact information, and no further information needs to be added to the final rule. We did not change the final rule in response to this comment.

Section 2569.413 How will I receive Notices and Decisions?

The BLM received a number of comments pertaining to how the BLM would issue Notices and Decisions, how applicants would reply to them, how applicants could update their contact information, and who the BLM should contact when it issues Notices and Decisions.

One commenter requested that the BLM clarify how applicants could update their contact information. Paragraph (c) in the proposed and final rules provides the information on how applicants can update their address of record and has been updated for the final rule to include information on how to contact the BLM via fax and email.

One commenter asked the BLM to clarify when it considers a response to be received by the BLM, especially when the response is mailed. In response, the BLM added paragraph (d) to the final rule to clarify that a response will be deemed received either on the date it is physically received at the BLM Alaska State Office; if the response is mailed, on the date it was post-marked; or, if emailed, the date the email was sent.

One commenter requested that the BLM provide additional means in the final regulations for applicants to respond to notices and decisions. Rather than making this change in the final rule, the BLM will state within the individual notices and decisions that it sends to applicants how they may respond. Generally, a response can be submitted by email or fax, but not in every case. To avoid any confusion, the methods of response will be addressed in the notice or decision. We did not change the final rule in response to this comment.

Another commenter requested that the BLM clarify the substitute method referenced in § 2569.413(b)(2) for re-delivering Notices or Decisions if they are returned to the BLM as undelivered, or if the recipient refused to sign the Return Receipt. Generally, the BLM will use first-class mail to deliver Notices and Decisions, but it may use other methods such as personal delivery or any method that the BLM determines has the highest chance of success at the time. No change was made to the rule in response to this comment.

One commenter requested that the BLM notify the Realty Service Provider and the village and regional corporation if the first delivery of a Notice or Decision is unsuccessful. By policy, the BLM will send the Realty Service Provider and/or the BIA a courtesy copy of all documents sent to an applicant. The BLM will also send the Realty Service Provider and/or the BIA a notice when a document is returned for any reason, and the BLM requests a current address from the Realty Service Provider and/or the BIA at that time. Likewise, if the land selected by an applicant is also selected by a Native corporation, the appropriate village and regional corporation will receive a courtesy copy of all documents sent to the applicant.

In preparing the final rule, the BLM found paragraphs (b)(i) through (iii) were incorrectly numbered in the proposed rule. We redesignated those paragraphs as (b)(1) through (3) for the final rule to conform with U.S. Government Publishing Office style requirements.

Section 2569.414 May I request an extension of time to respond to Notices?

In response to comments requesting that the BLM extend various deadlines for things such as responding to notifications for correcting errors on applications and responding to BLM Notices, the BLM added § 2569.414 to the final rule which expressly allows extensions of time for good cause. Several commenters recommended a longer time, up to 1 year, for applicants to respond to Notices. During the consultation process that the Department conducted in 2019 with potentially affected tribes, the proposed response time for correcting errors on applications at that time was 30 days, which participants said was too short. The BLM doubled the response time, to 60 days, for nearly all clarification issues related to the application process. For correcting technical issues, the DOI determined that it creates an unfair situation for other applicants to keep the land segregated and unavailable from other applicants to select while the original applicant makes corrections. Likewise, to extend a response time for substantive errors beyond 60 days could create an undue hardship on the applicant in that the application will not be considered received until the corrections are received, and the applicant may unwittingly lose the preference for their favored parcel.

Overall, the BLM finds that using a consistent period of 60 days to respond takes into consideration the myriad of communication difficulties that can occur in Alaska, while providing consistency throughout the regulation to avoid confusion. The time period the BLM has adopted in the rule is also fair because the 60-day response time starts when the applicant receives the Notice, and responses are considered received when postmarked. Hence, any delay in the mail would not affect the length of time the applicant has to reply. Permitting extensions to the 60-day deadline for ''good cause'' when fixing some types of errors or responding to Notices provides an additional safeguard to ensure fairness.

Section 2569.501 What will the BLM do with my application after it is received?

We received numerous comments on the steps the BLM will take to process applications after they are received. One commenter requested that the BLM send a copy of all Notices of Survey to the Realty Service Providers. As discussed earlier, the Realty Service Provider and/or the BIA will receive copies of all documents, including the Notice to Survey, that the BLM sends to applicants. We did not change the final rule in response to this comment.

Another commenter expressed confusion about what it means that the BLM will note the selection to the Master Title Plat and asked whether this is a public process that is open to public comments. The Master Title Plat is a BLM-managed, publicly available record of actions that have taken place on Federal lands. Notations to the Master Title Plat are administrative functions that do not warrant public participation or comment. The BLM did not change the final rule in response to this comment.

Several commenters requested that the BLM provide a timeline for completing each of the steps outlined in paragraphs (a) through (j) in § 2569.501. Some of the commenters suggested that

the BLM should issue an Interim Conveyance within one year of receiving an application, and then complete the survey and issue the Certificate of Allotment within two years. The Dingell Act states that it is the intent of Congress that once the application period begins the BLM will issue Certificates of Allotments within one year of receiving the applications of Eligible Individuals. While the BLM will strive to meet the intent of Congress, unforeseen complications with surveying parcels or adjudicating applications, for example, may cause delays. The expression of intent by Congress did not impose a statutory deadline. Also, unlike the ANCSA, the Dingell Act does not give the BLM authority to issue an interim conveyance. The BLM did not change the final rule in response to this comment.

One commenter requested that the BLM provide a notice to the applicant when an application is submitted. The BLM finds this is a matter better addressed by policy rather than in the regulations. The BLM will issue a notification to the applicant with a courtesy copy to the Realty Service Provider and/or the BIA when an application is submitted. If the selection involves State- or Native corporation-selected lands, that entity will also receive notification that an application has been filed. The notification will provide the results of the BLM's review for errors under § 2569.410 and specify whether the application has been deemed received. If the BLM finds errors, the notification will alert the applicant and identify exactly what information is needed and why. If the BLM finds errors in the application, the applicant will have 60 days to submit a correction. We did not change the final rule in response to this comment.

One commenter requested that paragraph (c) clearly state whether an allotment adjustment could affect the acreage. The BLM will attempt to retain the acreage requested in the selection, but the adjustment may cause a reduction or addition in the acreage by straightening the boundaries or otherwise making it easier to survey. This clarification was added to the section.

Section 2569.502 What if more than one Eligible Individual applies for the same lands?

This section addresses what happens when two applicants apply for the same land. The BLM will consider an application ''received'' even if it has technical errors. An applicant can wait for the BLM to issue a final decision pursuant to paragraph (b) before selecting a substitute selection. However, an applicant may want to select a substitute parcel if the original selection conflicts with another application that has technical errors. As such, the BLM added paragraph (c) to give applicants the option to select a substitute parcel prior to a final decision on the conflict. This fully optional provision alleviates the need for applicants to wait 60 days for parcels they are unlikely to receive. This responds to several comments received that stated that the application with minor errors should not be at a disadvantage in the conflict provision. The benefit to applicants is that they can obtain a preference right to the substitute selection earlier. The risk is being unable to choose the originally desired land later if technical errors in the conflicting application are not corrected and the original selection re-opens.

One commenter wanted confirmation that Eligible Individuals can still apply for an allotment within the five-year timeframe if their applications are rejected. This was part of the proposed rule in paragraph (c) and it is retained in the final rule. Because we are adding a new paragraph between two existing paragraphs in § 2569.502, we are renumbering the remaining paragraphs of this section in the final rule. Paragraph (c) in the proposed § 2569.502 will be paragraph (d) in the final rule.

One commenter requested that the BLM make the preference on a substitute selection based on the receipt date of their original application. While the BLM recognizes the justification for this recommendation, the logistical challenges of doing so would cause disruption throughout the adjudication process. Later applicants who had no conflict with their selection when it was made could lose out to a substitute selection made in the future. This could create a chain reaction where the applicant that is now conflicted files a substitute selection over a previous applicant as well. The delays this would cause to adjudication and the uncertainty it would cause for applicants outweigh the equitable considerations for the single applicant whose substitute selection cannot relate back to his original application receipt date. No change was made to the final rule as a result of this comment.

One commenter recommended that the first tiebreaker for determining an application's preference should be the postmark date on the application. This suggestion could cause delays as the BLM would have to wait to process any of the applications until enough time had passed for potentially conflicting applications to be received in the mail that may have an earlier postmark date. In paragraph (a)(1), the BLM chose to make the first tiebreaker the date for when the BLM receives the application in order to speed up the processing time for applications. Under paragraph (a)(2), postmarks or shipping dates would be used to break a tie if the receipt dates on multiple applications are the same. No change was made to the final rule based on this comment.

One commenter recommended that the BLM allow an applicant to include an alternative selection with their application as a backup in case there is a conflict. The BLM has considered how this recommendation would work logistically. The BLM does not believe it is sound policy to segregate the alternative selection when the application is deemed received because that would block other applicants from requesting the land, and without segregating the land, there is no guarantee that the alternative selection would remain open. As such, asking for an alternative selection would tie up lands that other Eligible Individuals could select and add complexity to an application that is of little benefit. No change was made to the final rule as a result of this comment.

Another commenter asked whether a person determined by the VA and the BIA to be an Eligible Individual pursuant to § 2569.301 would receive preference over an applicant who was not predetermined to be eligible. The conflict provision in this section rests solely on when the BLM receives a complete application, and no consideration is given to applicants who are predetermined to be Eligible Individuals. No change was made to the final rule based on this comment.

Section 2569.503 What if my application includes lands that are not available Federal lands?

One commenter requested that an application submitted on unavailable lands should be considered as received on the receipt date. The BLM will consider the date submitted for applications, even if the applicant selected unavailable lands, in determining whether an application is timely filed for purposes of the 5-year window under the Dingell Act. However, the BLM will issue the applicant a decision informing the applicant that the lands selected are not available. The applicant will then have the same choices he or she would have under § 2569.503(a). The applicant could make a substitute selection that

consists of an adjustment to his or her original selection that excludes the lands that are not available or make a new selection in a different area. For purposes of determining preference under the conflict provision, a substitute selection which describes new lands will be deemed received when the substitute selection is submitted. No change was made to the final rule as a result of this comment.

Section 2569.504 Once I file, can I change my land selection?

The BLM received several comments recommending that the BLM allow applicants to amend their selections when new lands become available. In response to these comments, the BLM re-analyzed the fairness of allowing applicants to amend their selection. Currently, the available lands are geographically restricted, primarily due to withdrawals of lands under section 17(d)(1) of the ANCSA or other authority, or because the land is within a National Wildlife Refuge or a National Forest. Actions by either the Secretary or Congress may make these lands available during the selection period. The BLM recognizes the applicants' desire to amend their application in the event land closer to their homes or places of subsistence activities become available. On the other hand, the applicant's original selection segregates the land from all other applicants and taxpayer dollars would be expended to perform surveys that would have to be redone if applicants changed their selection.

One commenter recommended that the BLM ''should allow for changes to selections up until the BLM schedules the surveys of the selected lands.'' The BLM believes that this recommendation balances the concerns of both the applicants and the BLM and has changed § 2569.504 in the final rule accordingly. Under new paragraph (a), the applicant would be able to amend their application up until their response to the Notice of Survey under § 2569.501(e) is due. This will limit the time in which a selection can block future applicants from selecting the land and ensure that the BLM does not waste resources on surveys which will not be needed. Likewise, it will give applicants a period of time to see if new lands have become available.

In making this change, the BLM recognized a similar issue may arise where an applicant has relinquished their application after BLM has already undergone the expense of the survey and decides to apply again. Therefore, the BLM added new paragraph (c) to only allow an application for new land if the original application is relinquished before the applicant responds to the Notice of Survey or where the original selection is no longer available.

Section 2569.505 Does the selection need to be surveyed before I can receive title to it?

Several comments were received related to the requirement that a selection must be surveyed before the BLM can convey it to the applicant and the timeliness of the survey. One commenter said the survey should be an immediate priority for the BLM. To the best of its ability, the BLM will follow the intent of the legislation to issue a Certificate of Allotment within one year of an application, including the survey. No change was made to the final rule as a result of these comments.

Section 2569.506 How will the BLM convey the land?

Several comments were received pertaining to the Certificate of Allotment. The Certificate of Allotment issued under the Dingell Act will have the same benefits as a Certificate of Allotment issued under the Alaska Native Allotment Act of 1906 as to being inalienable and nontaxable until otherwise provided by Congress, or until the Secretary of the Interior or the Secretary's delegate approves a deed of conveyance vesting in the purchaser a complete title to the land. No change was made to the final rule as a result of this comment.

One commenter requested that the lands not be encumbered or impeded by any Federal designation, including, but not limited to, Wild and Scenic River or Areas of Critical Environmental Concern. A Certificate of Allotment is a grant of a private title which means that the land is no longer federally managed land subject to such federal designations. No change was made to the final rule as a result of this comment.

One commenter requested clarification about how the Certificate of Allotment will be issued if there are multiple heirs, devisees, and/or assigns. They suggested that the BLM issue multiple Certificates of Allotment in the names of each heir. The BLM does not determine who the heirs, devisees and/or assigns are. There will be one Certificate of Allotment, just like the other allotment programs, which will state it is for the Heirs, Devisees and/or Assigns of (name of the Eligible Individual). The BLM added paragraph (d) to § 2569.506 to clarify how the Certificate of Allotment will be issued when the Eligible Individual is deceased.

Section 2569.507 What should I do if the Eligible Individual dies or becomes incapacitated during the application process?

In reviewing the proposed rules, the BLM found that the end of the last sentence of paragraph (d) could create confusion about how a Certificate of Allotment is issued when the Eligible Individual is deceased. To correct this, the BLM has removed the phrase: ''and will issue the Certificate of Allotment in the name of the deceased Eligible Individual'' from the final rule.

Section 2569.601 What lands are available for selection?

Many comments identified additional lands they believed should be included as available lands for selection. Lands that they identified included lands in the Tongass National Forest, non-navigable lands within the Tongass, land within State or municipal boundaries, areas around ports, and the USFWS refuge lands. As stated earlier, the Dingell Act identified the lands that are available, and the BLM lacks the authority to make any lands available for selection that are not vacant, unappropriated, or unreserved.

Additionally, several commenters identified un-patented mining claims and State or Native selections in the Southeast as lands they believed should be available for selection. These lands would not become available for selection when the mining claim is forfeited or relinquished, or after the State or Native selections are denied or relinquished, unless the underlying land is vacant, unappropriated, or unreserved and certified as free of known contaminants.

Several commenters noted that currently available lands are isolated. Some commenters cited costs related to visiting the currently available remote sites prior to making a commitment to a selection. One of the commenters questioned applicants' ability to access their newly acquired allotments. ANILCA section 1323(b) guarantees access across all the BLM land and, again, the Act defines the lands that are available to be conveyed. These rules cannot open any lands not identified by the Dingell Act.

One commenter requested that the Alaska Native Veterans Allotment Program of 2019 map show ''potentially available lands.'' The current map does show ''potentially available lands.'' The commenter also proposed subsequent legislation to release ANCSA withdrawals on individually selected

parcels. Legislative action is within the purview of Congress, not the BLM.

There were several comments suggesting that maps be printed and sent to applicants, and that applicants should be able to comment on them. The BLM is not printing maps Program-wide because of the vast area of available lands, the fact that available lands will change over time, and the significant resources required to print maps of suitable size for selections. Eligible Individuals are directed instead to use the online Available Lands Map to review and print land selections. For those without access to the internet, a physical copy of the map of available Federal lands can be requested from the agencies and offices listed in § 2569.412. Members of the public are always encouraged to provide comments on available products, such as maps, to the BLM to ensure the map is as user friendly as possible.

A commenter asked what the process is for the BLM to add additional lands as they become available. The BLM continually updates its land records with conveyances and other actions. When new lands become available, the BLM will do a contamination review and, if the lands have no known contaminants, the newly available lands will be reflected on the Available Lands Map. However, the BLM does not have the authority to add additional lands by request as the available lands are defined in the Act.

No changes were made to the final rule as a result of these comments.

Section 2569.602 How will the BLM certify that the land is free of known contamination?

One commenter requested a ''more rigorous level of effort'' to determine whether or not a land selection is free of known contaminants, to include a site visit to complete an environmental assessment. The BLM will perform a contaminated site review by reviewing the databases listed in § 2569.602 for contamination reports. The land would not be available for selection if any of the databases indicated that the land is potentially contaminated. The BLM finds that the approach outlined in § 2569.602 adheres to the statutory requirement to certify that the land is free of known contamination. The BLM will be cautious in its review, and any land found to have possible contamination based on these searches will not be available for selection. Throughout the Program, new land databases may become available to review for contamination, and the BLM will continue to seek out the most up-to-date information. The public is encouraged to suggest any other sources the BLM should review before it certifies the lands as free from contamination. No change was made to the final rule as a result of this comment.

Section 2569.603 (previously numbered 2569.604) Are lands that contain minerals available?

The proposed rules did not include a § 2569.603. In the final rule, proposed rule § 2569.604 is now designated § 2569.603. The BLM also revised the title and the regulation to provide additional clarification.

One commenter requested that the BLM clarify in the rule whether the allottee would receive royalties for minerals removed from the land. Minerals are reserved to the United States, so the allottee will not hold any interest in the minerals to acquire a royalty interest. Another commenter stated, ''The word 'you' should be replaced with 'Eligible Individuals or to the devisees and/or assigns of Eligible Individuals.' '' The BLM implemented this change to add clarity to the regulations.

Section 2569.604 (previously numbered 2569.605) What happens if new lands become available?

The proposed rules did not include a § 2569.603. Section 2569.605 in the proposed rule was changed to § 2569.604 in the final rules following the removal of the missing section.

One commenter asked how new lands would become available and suggested that the rule should include a timeframe for the BLM to review new additions and make them available. New lands may become available for selection through the revocation of ANCSA section 17(d)(1) withdrawals which have been recommended by the BLM in Resource Management Plans, or through new legislation. In both scenarios, the BLM cannot estimate a timeline because the ability to open these lands is outside of the agency's control. If new land becomes available, the BLM must certify that it is free of known contamination before making it available for selection. The BLM will then update the Available Lands Map and its records to show those additional lands as available for selection. The BLM will work quickly to complete these steps if land becomes available. No change was made to the final rule as a result of these comments.

Section 2569.701 If Congress makes lands available within a National Wildlife Refuge, what additional rules apply?

Several commenters requested the ability to change their selection if national wildlife refuge lands become available. These comments were addressed in § 2569.504, which explains the opportunity for changing a land selection. Another commenter requested that lands be made available within the Yukon Delta National Wildlife Refuge. While national wildlife refuge lands are not available for selection under this Program, the Dingell Act directs the USFWS to submit a report to Congress with its determination of which lands within the National Wildlife Refuge System should be made available for allotment selection. Such refuge lands could be made available for selection through subsequent legislation. No changes were made to the final rule as a result of these comments.

Comments on Subjects Not Included in the Proposed Rule

Some of the comments the BLM received were general in nature but did not pertain to any language that appeared in the proposed rule itself. Several commenters were appreciative of the Program, one commenter requested outreach on specific media outlets, a comment from a Native corporation stated that they will require a cultural tie to any selection before the corporation will relinquish its selection for an Eligible Individual. No changes were made to the final rule as a result of these comments.

Comments Related to Funding

Several comments requested assurance that the Realty Service Providers are funded to assist applicants. The Dingell Act did not provide funding to the BIA or the BLM for implementing the Program. The BIA has taken measures to provide one-time funding to help offset these costs, and it intends to continue assisting the Realty Service Providers to ensure the success of the Program. Another commenter suggested that funding be made available to potential applicants to perform site visits. Any costs to visit a site are the responsibility of the Eligible Individual.

The BLM received one comment suggesting that monetary compensation be offered instead of an allotment of land, especially since 43 U.S.C. 1629g–1(b) limited the types of Federal land that can be conveyed. 43 U.S.C. 1629g–1(b) does not contain any provision for monetary compensation in lieu of an

allotment of land. The BLM has no authority to include such a provision in its regulations.

No change was made to the final rule as a result of these comments.

II. Procedural Matters

Regulatory Planning and Review Executive Orders 12866 and 13563

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. These regulations are not a significant regulatory action and are not subject to review by the Office of Management and Budget under Executive Order 12866.

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

These regulations will not have an effect of $100 million or more on the economy and will not adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The effect of these regulations will be on a limited number of individuals who are qualified to apply for allotments and on the Interior Department agencies responsible for administering the allotment Program. The allotment application period is limited by law to 5 years. The regulations create simple adjudication tasks for the BLM staff to implement the Dingell Act.

For more detailed information, see the Regulatory Impact Analysis (RIA) prepared for this rule. The RIA has been posted in the docket for the rule on the Federal eRulemaking Portal: In the Searchbox, enter ''RIN1004–AE66,'' click the ''Search'' button, open the Docket Folder, and look under Supporting Documents.

Reducing Regulation and Controlling Regulatory Costs (E.O. 13771)

This rule is not a significant regulatory action under E.O. 12866, and therefore is not considered an E.O. 13771 regulatory action.

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act of 1980, as amended (5 U.S.C. 601 *et seq.*), to ensure that Government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule will have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. This rule would apply only to certain Alaska Native veterans eligible to apply for allotments and applies only to Alaska Native veterans as individuals. Therefore, the Department of the Interior certifies that this document will not have any significant impacts on small entities under the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2)). This rule:

1. Will not have an annual effect on the economy of $100 million or more.

2. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

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

The BLM is promulgating regulations to implement section 1119 of the Dingell Act, which provides an additional opportunity for Alaska Native veterans who have received allotments under prior laws to apply for allotments. This rule will have no significant economic impact. This rule will specify the procedures under which applications for allotments under section 1119 of the Dingell Act are submitted and processed. Processing of these applications by the BLM will result in the transfer of lands selected by veterans from the Federal Government to the veterans, as required by Congress. Submitting and processing these applications will result in minor costs to the applicants and to the Government.

Unfunded Mandates Reform Act

This final rule will not impose an unfunded mandate on State, local, tribal governments, or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments, or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (E.O. 12630)

This final rule will not affect a taking of private property or otherwise have taking implications under E.O. 12630. Section 2(a) of E.O. 12630 identifies policies that do not have takings implications, such as those that abolish regulations, discontinue governmental programs, or modify regulations in a manner that lessens interference with the use of private property.

Under the final rules, lands selected by an applicant must be federally owned lands in the State of Alaska that are vacant, unappropriated, and unreserved. An applicant may select, in whole or in part, land that has been selected by the State or a Native corporation, but has not yet been conveyed to that entity; however, the State or Native corporation must choose to make that land available by relinquishing their selection.

The rule will not affect private property rights. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

A Federalism assessment is not required because the rule will not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Civil Justice Reform (Executive Order 12988)

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

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

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

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

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. This final rule complies with the requirements of Executive Order 13175 and Department of the Interior Secretarial Order 3317. Specifically, while preparing this rule, the BLM initiated consultation with potentially affected tribes. Examples of consultation include written correspondence, and meetings and discussions about objectives of this rulemaking effort with representatives of tribal governments.

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

This rule contains new information collections. All information collections require approval under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). The BLM may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number.

The information collection requirements identified below associated with the Alaska Native Vietnam Veteran Land Allotment Program require approval by OMB:

(1) *Provide Proof of Eligibility (43 CFR 2569.302)*—Section 2569.302 would allow individuals who believe that they are eligible to participate in the program, but who have not been automatically notified by the BLM that they are eligible, to apply for an allotment. Such individuals would be required to provide with their application supporting documents to prove they are eligible, such as a Certificate of Degree of Indian Blood and a Certificate of Release or Discharge from Active Duty (Form DD–214).

(2) *Appointment of Personal Representative/Guardian/Attorney-in-fact (43 CFR 2569.303 and 2569.404)*—Section 2569.303 would allow another person to apply for an allotment on behalf of an Eligible Individual. A personal representative of the estate of an Eligible Individual could apply for an allotment for the benefit of the estate. The personal representative must be appointed in an appropriate Alaska State court by either a judge in the formal probate process or the registrar in the informal probate process. A court-appointed guardian or conservator or an attorney-in-fact of an Eligible Individual could apply for an allotment for the benefit of the Eligible individual. Similarly, under § 2569.507 if an applicant dies or becomes incapacitated before completing the application process, a personal representative, guardian, conservator, or attorney-in-fact could be appointed to continue to represent the applicant or the applicant's estate.

Section 2569.404 identifies the information and documents that applicants would be required to include on their initial application form under various applicant scenarios. This form would collect basic contact information, along with the Eligible Individual's date of birth, and:

- A map showing the location of the requested allotment, along with a written description of the land requested. The BLM will provide an internet-based mapping tool with the identified available Federal lands;
- Appropriate documentation proving that the Eligible Individual is an Alaska Native;
- Appropriate documentation proving that the Eligible Individual is a Veteran who served during the Vietnam Conflict (between August 5, 1964, and December 31, 1971); and
- If applicable, documentation from an Alaska State Court that shows that a personal representative, guardian/conservator, or attorney-in-fact is authorized to file the application or pursue an already-filed application on behalf of the Eligible Individual or his/her estate.

If additional time is needed for the applicant or the applicant's heirs to arrange for a personal representative, guardian, conservator, or attorney-in-fact to be appointed, the BLM would allow the applicant, an employee of the BIA, or a Realty Service Provider to request that the application be held in abeyance for 2 years.

Note: With regard to the application process, § 2569.407 specifies that if an applicant's selection contains more than 160 rods (one-half mile) of water frontage, the BLM will automatically request the Secretary to waive the 160-rod limitation contained in Section 1 of the Act of May 14, 1898 (48 U.S.C. 371).

(3) *Request for 2-year Extension of Application Deadline (43 CFR 2569.401 and 2569.507)*—Section 2569.401 would set a 5-year deadline for Eligible Individuals, their heirs, or representatives to submit initial applications. In the case of those who submit applications that are incorrect, incomplete, or conflict with other selections, Eligible Individuals would have 60 days after the BLM notifies them of these defects to submit corrected, completed, or substitute applications. This period may be extended for up to 2 years in order to allow a personal representative, guardian, conservator, or attorney-in-fact to be appointed. (see §§ 2569.410, 2569.502, and 2569.503) (This two-year extension language appears in both §§ 2569.401(b) and 2569.507(c) reg text. The preamble in the rule discusses the two-year extension under the 2569.401 discussion and includes the .507(c) citation.)

(4) *Allotment Application—Form BLM No. AK–2469 (43 CFR 2569.402 and 2569.404)*—Section 2569.402 would require applicants to fill out and sign an application form (BLM No. AK–2569). The requirements associated with § 2569.404 are specified above.

Section 2569.403 would require the BLM to directly mail a copy of the application form to those persons who have been preliminarily identified as Eligible Individuals through the process described in § 2569.301. The applications would be mailed to the most recent addresses on file with the VA, the BIA, and the BLM. This section also identifies locations where copies of the application form would be available for applicants who do not receive an application in the mail.

(5) *Multiple Applications That Include Selected State and Native Corporation Lands (43 CFR 2569.405)*—If an applicant requests land previously selected by, but not yet conveyed by the Federal Government to the State or an Alaska Native corporation, the applicant, or the BLM acting on behalf of the applicant, could request that the State or Alaska Native corporation relinquish the land to the applicant. This relinquishment would be conditioned upon the applicant successfully completing the application process. In conjunction with this rulemaking, the BLM anticipates that the State and Alaska Native corporations would also issue blanket conditional relinquishments of certain selected unconveyed lands. These blanket relinquishments also would take effect only if valid applications for these lands are successfully completed.

Upon receipt of an application requesting State or Alaska Native corporation selected, unconveyed lands, if the application does not include a relinquishment request from either the State or Naive corporation, the BLM would automatically request such relinquishment on behalf of the applicant. The BLM must receive a valid relinquishment from the State or Native corporation, agreeing to relinquish the land to the applicant before approving

the application. Following existing Alaska Conveyance Program policy, the relinquishment would be in the form of a letter from the State or Alaska Native corporation and must include the legal description of the parcel the entity is willing to relinquish. The letter must also describe the conditions, if any, for the relinquishment. If the relinquishment is by a Native corporation, the letter must be accompanied by a board resolution authorizing the relinquishment and granting the person signing the letter authority to do so.

If an application requests land covered by a blanket State or Alaska Native corporation relinquishment, a relinquishment letter and an Alaska Native corporation board resolution would not be required.

(6) *Correcting Technical Errors on Applications (43 CFR 2569.410)*—If the BLM finds a technical error in an application, such as an incomplete or unsigned application, it would notify the applicant. The applicant would then have 60 days after receiving notification to correct the error.

(7) *Correcting Errors in Survey-related Documents (43 CFR 2569.501)*—After receiving an application, reviewing the legal description of the land requested, and making minor boundary adjustments, if needed, the BLM would send the applicant a Notice of Survey, informing the applicant of the shape and location of the lands the BLM planned to survey. The applicant would have an opportunity to challenge, in writing, the draft Plan of Survey within 60 days of receipt of the BLM's notice.

(8) *Substitute Selections—Multiple Applications on Same Lands (43 CFR 2569.502)*—If two or more Eligible Individuals select the same lands, in whole or in part, the BLM would decide which application would be given preference based on either submission dates and times, or a lottery. The non-preferred applicants could, within 60 days of receipt of the BLM's decision, either provide the BLM a new substitute selection or request that the BLM continue to adjudicate the non-conflicting portion of the selection.

If a non-preferred applicant does not respond to the BLM's decision within 60 days, the BLM would reject the application and the Eligible Individual could file a new application for different lands before the end of the five-year program.

Upon completion of the survey, the BLM would mail the applicant a document titled Conformance to Plat of Survey. If the applicant found an error in the way the BLM surveyed the land, based on the Plan of Survey, the applicant could dispute the survey in writing within 60 days of receipt of the Conformance of Plat of Survey.

(9) *Substitute Selections and Requests for Partial Adjudication (43 CFR 2569.502 and 2569.503)*—If an Eligible Individual's selection includes lands that are not available Federal lands, the BLM would issue a decision informing the applicant that the land is unavailable. The applicant could, within 60 days of receipt of the BLM's decision either provide the BLM a new substitute selection or request that the BLM continue to adjudicate the portion of the selection that is within available Federal lands.

If the applicant fails to respond within 60 days of receipt of the BLM's decision, the BLM will reject the initial application and the Eligible Individual could file a new application for different lands before the end of the five-year application period.

(10) *Appeals of BLM Decisions (43 CFR 2569.502, 2569.503, and 2569.801)*—Applicants would be allowed to appeal any of the BLM's Decisions regarding their applications to the Interior Board of Land Appeals as provided for under 43 CFR part 4. If the applicant is a non-preferred applicant under 43 CFR 2569.502, the losing applicant could select a substitute selection under § 2569.502(b).

Title of Collection: Alaska Native Vietnam Era Veterans Land Allotment.

OMB Control Number: 1004–0216.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Individuals and State/Local/Tribal governments.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Estimated Annual Nonhour Burden Cost: $55,000 (associated with court fees and miscellaneous expenses).

Requirement	Estimated annual number of responses	Estimated annual hours per response	Estimated total annual burden hours *
Provide Proof of Eligibility (43 CFR 2569.302):			
Individuals/Households	50	2	100
Appointment of Personal Representative/Guardian/Attorney-in-fact (43 CFR 2569.303 and .404):			
Individuals/Households	200	2.5	500
Request for 2-year Extension of Application Deadline (43 CFR 2569.401 and 2569.507):			
Individuals/Households	20	.5	10
Allotment Application (43 CFR 2569.402 and 2569.404:			
Individuals/Households	500	4.5	2,250
State/Native Corporation Relinquishments (43 CFR 2569.405):			
State/Local/Tribal Governments	75	2	150
Correcting Technical Errors on Applications (43 CFR 2569.410):			
Individuals/Households	175	2	350
Correcting Errors in Survey-related Documents (43 CFR 2569.501):			
Individuals/Households	20	2	40
Substitute Selections—Multiple Applications on Same Lands (43 CFR 2569.502):			
Individuals/Households	150	2	300
Substitute Selections and Requests for Partial Adjudication (43 CFR 2569.502 and 2569.503):			
Individuals/Households	15	.5	8
Appeals of BLM Decisions (43 CFR 2569.502, 2569.503, 2569.801):			
Individuals/Households	60	2	120
Totals	*1,265*	.....	*3,828*

* Rounded.

On July 10, 2020, we published a proposed regulation (RIN 1004–AE66, ''*Alaska Native Vietnam-Era Veterans Allotments*'' 85 FR 41495). The proposed rule solicited comments on the information collections for a period of 30 days, ending on August 10, 2020. We received the following comment related to information collection in response to the proposed rule:

Comment: Department of Veterans Affairs—Veterans Benefits Administration (VA–VBA), received August 10, 2020:

The VA–VBA commented on both the proposed rule, which is addressed earlier in the preamble, and on the application form. VA requested BLM clarify question 8 on the Alaska Native Vietnam-Era Veterans Allotment application as to the specific service requirement or whether BLM will consider character of discharge as part of qualifying service.

Agency Response to Comment: In response to this comment, the BLM has added the language, ''(e.g. Form DD214 or other official documentation),'' to the end of question 8 to clarify the proof an applicant should submit to demonstrate they meet the definition of veteran. Similarly, the BLM has added, ''(e.g. Certificate of Degree of Indian Blood or other official documentation),'' to the end of question 9 to clarify the proof an applicant should submit to demonstrate they meet the definition of Native. In accordance with the PRA, the information collection requirements included in this final rule have been submitted to OMB for approval under control number 1004–0216.

National Environmental Policy Act

A detailed statement under the National Environmental Policy Act (NEPA) is not required because the rule is categorically excluded from NEPA review. This final rule is excluded from the requirement to prepare a detailed statement because it is a regulation entirely procedural in nature. (For further information see 43 CFR 46.210(i)). We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA. Therefore, the BLM has issued a categorical exclusion for this final rule. Documentation of the reliance upon a categorical exclusion has been prepared and is available for public review with the other supporting documents for this rule.

Effects on the Energy Supply (Executive Order 13211)

This rule is not a significant energy action under the definition in E.O. 13211. Therefore, a Statement of Energy Effects is not required.

Author

The principal authors of this final rule are: Paul Krabacher and Candy Grimes, Division of Lands and Cadastral Survey; assisted by the Office of the Solicitor.

Dated: November 4, 2020.

David L. Bernhardt,

Secretary of the Interior.

List of Subjects in 43 CFR Part 2560

Alaska, Homesteads, Indian lands, Public lands—sale, and Reporting and recordkeeping requirements.

For the reasons set out in the preamble, the BLM amends 43 CFR part 2560 as follows:

PART 2560—ALASKA OCCUPANCY AND USE

■ 1. The authority citation for part 2560 continues to read as follows:

Authority: 43 U.S.C. 1201, 1740.

■ 2. Add subpart 2569 to read as follows:

SUBPART 2569—ALASKA NATIVE VIETNAM-ERA VETERANS LAND ALLOTMENTS

General Provisions

Sec.

Applying for an Allotment

Processing the Application

Available Federal Lands—General

National Wildlife Refuge System

Appeals

SUBPART 2569—ALASKA NATIVE VIETNAM-ERA VETERANS LAND ALLOTMENTS

Authority: 43 U.S.C. 1629g–1(b)(2).

General Provisions

§ 2569.100 What is the purpose of this subpart?

The purpose of this subpart is to implement section 1119 of the John D. Dingell, Jr. Conservation, Management, and Recreation Act of March 12, 2019, Public Law 116–9, codified at 43 U.S.C. 1629g–1, which allows Eligible Individuals to receive an allotment of a single parcel of available Federal lands in Alaska containing not less than 2.5 acres and not more than 160 acres.

§ 2569.101 What is the legal authority for this subpart?

The legal authority for this subpart is 43 U.S.C. 1629g–1(b)(2).

§ 2569.201 What terms do I need to know to understand this subpart?

(a) *Allotment* is an allocation to an Alaska Native of land which shall be deemed the homestead of the allottee and his or her heirs in perpetuity, and shall be inalienable and nontaxable except as otherwise provided by Congress;

(b) *Available Federal lands* means land in Alaska that meets the requirements of 43 U.S.C. 1629g–1(a)(1) and that the BLM has certified to be free of known contamination.

(c) *Eligible Individual* means a Native Veteran who meets the qualifications listed in 43 U.S.C. 1629g–1(a)(2) and has not already received an allotment pursuant to the Act of May 17, 1906 (34 Stat. 197, chapter 2469) (as in effect on December 17, 1971); or section 14(h)(5) of the Alaska Native Claims Settlement Act (43 U.S.C. 1613(h)(5)); or section 41 of the Alaska Native Claims Settlement Act (43 U.S.C. 1629g);

(d) *Mineral* means coal, oil, natural gas, other leasable minerals, locatable minerals, and saleable minerals other than sand and gravel.

(e) *Native* means a person who meets the qualifications listed in section 3(b) of the Alaska Native Claims Settlement Act (43 U.S.C. 1602(b));

(f) *Native corporation* means a regional corporation or village corporation as defined in sections 3(g) and (j) of the Alaska Native Claims Settlement Act (43 U.S.C. 1602);

(g) *Realty Service Provider* means a Public Law 93–638 ''Contract'' or Public Law 103–413 ''Compact'' Tribe or Tribal organization that provides Trust Real Estate Services for the Bureau of Indian Affairs;

(h) *Receipt date* means the date on which an application for an allotment is physically received by the BLM Alaska State Office, whether the application is delivered by hand, by mail, or by delivery service;

(i) *Segregate* has the same meaning as in 43 CFR 2091.0–5(b);

(j) *Selection* means an area of land that has been identified in an application for an allotment under this part;

(k) *State* means the State of Alaska;

(l) *State or Native corporation selected land* means land that is selected, as of the receipt date of the allotment application, by the State of Alaska under the Statehood Act of July 7, 1958, Public Law 85–508, 72 Stat. 339, as amended, or the Alaska National Interest Lands Conservation Act (ANILCA) of December 2, 1980, 94 Stat. 2371, or by a Native corporation under the Alaska Native Claims Settlement Act of December 18, 1971, 43 U.S.C. 1611 and 1613, and that has not been conveyed to the State or Native corporation;

(m) *Substantive error* means an error or omission in an application of information that is immediately necessary to determine if you are eligible to apply for an allotment. Substantive errors include, but are not limited to, missing land descriptions, missing name or inability to contact the applicant, and missing forms required under § 2569.404, if applicable. When a person corrects this type of error, the correction could show the applicant has an uncorrectable defect like not being an Alaska Native.

(n) *Technical error* means types of errors that do not rise to the level of substantive error or uncorrectable defect. For instance, not signing your application is an easily correctable error and correcting the error by signing the application cannot raise any new issues which could cause an application to be rejected.

(o) *Uncorrectable defect* means information provided with an application which provides obvious evidence that you are not qualified to receive an allotment. That evidence includes a lack of qualifying military service or proof of Alaska Native decent.

(p) *Valid relinquishment* means a signed document from a person authorized by a board resolution from a Native corporation or the State that terminates its rights, title and interest in a specific area of Native corporation or State selected land. A relinquishment may be conditioned upon conformance of a selection to the Plat of Survey and the identity of the individual applicant; and

(q) *Veteran* means a person who meets the qualifications listed in 38 U.S.C. 101(2) and served in the U.S. Army, Navy, Air Force, Marine Corps, or Coast Guard, including the reserve components thereof, during the period between August 5, 1964, and December 31, 1971.

Who Is Qualified for an Allotment

§ 2569.301 How will the BLM let me know if I am an Eligible Individual?

The Bureau of Land Management (BLM), in consultation with the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the Bureau of Indian Affairs (BIA), has identified individuals whom it believes to be Eligible Individuals. If the BLM identifies you as a presumed Eligible Individual, it will inform you by letter at your last address of record with the BIA or the VA. Even if you are identified as presumptively eligible, you still must certify in the application that you do meet the criteria of the Dingell Act.

§ 2569.302 What if I believe I am an Eligible Individual, but I was not notified by the BLM?

If the BLM has not notified you that it believes that you are an Eligible Individual, you may still apply for an allotment under this subpart. However, as described in § 2569.404(b), you will need to provide evidence with your application that you are an Eligible Individual. Supporting evidence with your application must include:

(a) A Certificate of Degree of Indian Blood or other documentation from the BIA to verify you meet the definition of Native; and

(b) A Certificate of Release or Discharge from Active Duty (Form DD–214) or other documentation from DoD to verify your military service.

§ 2569.303 Who may apply for an allotment under this subpart on behalf of another person?

(a) A personal representative of the estate of an Eligible Individual may apply for an allotment for the benefit of the estate. The personal representative must be appointed in an appropriate Alaska State court by either a judge in the formal probate process or the registrar in the informal probate process. The Certificate of Allotment will be issued in the name of the heirs, devisees, and/or assigns of the deceased Eligible Individual.

(b) An attorney-in-fact, a court-appointed guardian, or a court-appointed conservator of an Eligible Individual may apply for an allotment for the benefit of the Eligible Individual. The Certificate of Allotment will be issued in the name of the Eligible Individual.

Applying for an Allotment

§ 2569.401 When can I apply for an allotment under this subpart?

(a) You can apply between December 28, 2020 and December 29, 2025.

(1) If an application is submitted prior to the beginning of the application period, it will be held until the application period begins and considered timely filed.

(2) If an application is submitted by mail after the application period, the BLM will use the post-mark date to determine if the application was timely filed.

(b) Notwithstanding paragraph (a) of this section, in the case of a corrected or completed application or of an application for a substitute selection for resolution of a conflict or an unavailable

land selection, you can submit a corrected, completed, or substitute application within 60 days of receiving the notice described in § 2569.410, § 2569.502(b), or § 2569.503(a), respectively. This period may be extended for up to two years in order to allow a personal representative, guardian, conservator, or attorney-in-fact to be appointed, as provided in § 2569.507(c).

(c) Except as set forth in paragraphs (a) and (b) of this section, the BLM will issue a decision rejecting any application received after December 29, 2025.

§ 2569.402 Do I need to fill out a special application form?

Yes. You must complete and sign the BLM Form No. AK–2569–1004–0216, ''Alaska Native Vietnam-Era Veteran Land Allotment Application.''

§ 2569.403 How do I obtain a copy of the application form?

The BLM will mail you an application form if you are determined to be an Eligible Individual under § 2569.301. If you do not receive an application in the mail, you can also obtain the form at the BIA, a Realty Service Provider's office, the BLM Public Room, or on the internet at *https://www.blm.gov/alaska/2019AKNativeVetsLand.*

§ 2569.404 What must I file with my application form?

(a) You must include the following along with your signed application form:

(1) A map showing the selection you are applying for:

(i) Your selection must be drawn on a map in sufficient detail to locate the selection on the ground.

(ii) You must draw your selection on a map that is either a topographic map or a printout of a map that shows the section lines from the BLM mapping tool, available at *https://www.blm.gov/alaska/2019AKNativeVetsLand.*

(2) A written description of the lands you are applying for, including:

(i) Section, township, range, and meridian; and

(ii) If desired, additional information about the location. The submitted map will be given preference if there is a conflict between the written description and the submitted map, unless you specify otherwise.

(b) In addition to the materials described in paragraph (a) of this section, you must also provide the following materials, under the circumstances described in paragraphs (b)(1) through (4) of this section:

(1) If you, or the person on whose behalf you are applying, are an Eligible Individual as described in § 2569.301, and were not notified by the BLM of your eligibility, you must provide proof that you, or the person on whose behalf you are applying, are an Eligible Individual, consisting of:

(i) A Certificate of Degree of Indian Blood or other documentation from the BIA to verify that you (or the person on whose behalf you are applying) are an Alaska Native; and

(ii) A Certificate of Release or Discharge from Active Duty (Form DD–214) or other documentation from DoD to verify that you (or the person on whose behalf you are applying) are a Veteran and served between August 5, 1964 and December 31, 1971.

(2) If you are applying on behalf of the estate of an Eligible Individual who is deceased, you must provide proof that you have been appointed by an Alaska State court as the personal representative of the estate, and an affidavit stating that the appointment has not expired. The appointment may have been made before or after the enactment of the Act, as long as it has not expired.

(3) If you are applying on behalf of an Eligible Individual as that individual's guardian or conservator, you must provide proof that you have been appointed by a court of law, and an affidavit stating that the appointment has not expired.

(4) If you are applying on behalf of an Eligible Individual as that individual's attorney-in-fact, you must provide a legally valid and current power of attorney that either grants a general power-of-attorney or specifically includes the power to apply for this benefit or conduct real estate transactions.

(c) You must sign the application, certifying that all the statements made in the application are true, complete, and correct to the best of your knowledge and belief and are made in good faith.

(d)

§ 2569.405 What are the special provisions that apply to selections that include State or Native corporation selected land?

(e)

(a) If the selection you are applying for includes State or Native corporation selected land, the BLM must receive a valid relinquishment from the State or Native corporation that covers all of the lands in your selection that are State or Native corporation selected lands. If the application does not include a valid relinquishment, the BLM will contact the State or Native corporation to request a relinquishment. This requirement does not apply if all of the State or Native corporation selected land included within your selection consists of land for which the State or Native corporation has issued a blanket conditional relinquishment as shown on the mapping tool available at *https://www.blm.gov/alaska/2019AKNativeVetsLand.*

(b) No such relinquishment may cause a Native corporation to become underselected. See 43 U.S.C. 1621(j)(2) for a definition of underselection.

(c) An application for Native corporation or State selected land will segregate the land from any future entries on the land once the BLM receives a valid relinquishment.

(d) (d) If the State or Native corporation is unable or unwilling to provide a valid relinquishment, the BLM will issue a decision finding that your selection includes lands that are not available Federal lands and then follow the procedures set out at § 2569.503.

§ 2569.406 What are the rules about the number of parcels and size of the parcel for my selection?

(a) You may apply for only one parcel.

(b) The parcel cannot be less than 2.5 acres or more than 160 acres.

§ 2569.407 Is there a limit to how much water frontage my selection can include?

Generally, yes. You will normally be limited to a half-mile along the shore of a navigable water body, referred to as 160 rods (one half-mile) in the regulations at 43 CFR part 2090, subpart 2094. If you apply for land that extends more than 160 rods (one half-mile), the BLM will treat your application as a request to waive this limitation. As explained in 43 CFR 2094.2, the BLM can waive the half-mile limitation if the BLM determines the land is not needed for a harborage, wharf, or boat landing area, and that a waiver will not harm the public interest. If the BLM determines it cannot waive the 160-rod (one half-mile) limitation, the BLM will issue a decision finding your selection includes lands that are not available Federal lands and then follow the procedures set out at § 2569.503.

§ 2569.408 Do I need to pay any fees when I file my application?

No. You do not need to pay a fee to file an application.

§ 2569.409 Where do I file my application?

You must file your application with the BLM Alaska State Office in Anchorage, Alaska, by one of the following methods:

(a) Mail or delivery service: Bureau of Land Management, ATTN: Alaska Native Vietnam-era Veterans Land

Allotment Section, 222 West 7th Avenue, Mail Stop 13, Anchorage, Alaska 99513–7504; or

(b) In person: Bureau of Land Management Alaska, Public Information Center, 222 West 7th Avenue, Anchorage, Alaska 99513–7504.

§ 2569.410 What will the BLM do if it finds an error in my application?

(a) If an error is found, the BLM will send you a notice identifying any correctable errors or omissions and whether the error is substantive or technical.

(1) You will have 60 days from the date you received the notice to correct the errors or provide the omitted materials.

(2) If you do not submit the corrections to the BLM within the 60-day period, the BLM will issue a decision rejecting your application and require you to submit a new application.

(b) If the error is a substantive error, your application will not be deemed received until the corrections are made.

(c) If the error is a technical error, your application will be deemed received as of the receipt date. However, the application may still be rejected if the BLM does not receive the corrections within 60 days from the date you received the notice to correct the errors.

(d) If you have uncorrectable defect, then the BLM will issue a decision rejecting your application.

§ 2569.411 When is my application considered received by the BLM?

(a) An application that is free from substantive errors, as described in § 2569.410, will be deemed received on the receipt date, except that if such an application is received before December 28, 2020, the application will be deemed received on December 28, 2020.

(b) An application that contains substantive errors will be deemed received on the receipt date of the last required correction.

(c) (c) In the case of a substitute selection for conflict resolution under § 2569.502, for correction of an unavailable lands selection under § 2569.503, or an amended selection under § 2569.504, the substitute application will be deemed received on the receipt date of the substitute selection application.

§ 2569.412 Where can I go for help with filling out an application?

You can receive help with your application at:

(a) The BIA or a Realty Service Provider for your home area or where you plan to apply. To find the list of the Realty Service Providers, go to *https://www.bia.gov/regional-offices/alaska/real-estate-services/tribal-service-providers* or call 907–271–4104 or 1–800–645–8465.

(b) The BLM Public Rooms:

(1) The Anchorage Public Room located at 222 West 7th Avenue, Anchorage, Alaska 99513–7504, by email at *AK_AKSO_Public_Room@blm.gov,* by telephone at 907–271–5960, Monday through Friday from 8 a.m. to 4 p.m. excluding Federal Holidays.

(2) The Fairbanks Public Room located at 222 University Ave, Fairbanks, Alaska 99709, by email at *BLM_AK_FDO_generaldelivery@blm.gov* or by telephone at 907–474–2252 or 2200, Monday through Friday from 7:45 a.m. to 4:30 p.m. excluding Federal Holidays.

(c) The following BLM Field Offices:

(1) Anchorage Field Office located at 4700 BLM Road, Anchorage, Alaska, by email at *blm_ak_afo_general_delivery@blm.gov,* by phone 907–267–1246, Monday through Friday from 7:30 a.m. to 4 p.m. excluding Federal Holidays.

(2) Glennallen Field Office located at Mile Post 186.5 Glenn Highway, by email at *blm_ak_gfo_general_delivery@blm.gov,* by phone 907–822–3217, Monday through Friday 8 a.m. to 4:30 p.m. excluding Federal Holidays.

(3) Nome Field Station located at the U.S. Post Office Building, by phone 907–443–2177, Monday through Friday excluding Federal holidays.

(d) (d) Online at the BLM website which gives answers to frequently asked questions and a mapping tool which will show the available Federal lands and provide online tools for identifying and printing your selection: *https://www.blm.gov/alaska/2019AKNativeVetsLand.*

§ 2569.413 How will I receive Notices and Decisions?

(a) The BLM will provide all Notices and Decisions by Certified Mail with Return Receipt to your address of record.

(b) Where these regulations specify that you must take a certain action within a certain number of days of receiving a notice or decision, the BLM will determine the date on which you received the notice or decision as follows:

(1) If you sign the Return Receipt, the date on which you received the notice or decision will be the date on which you signed the Return Receipt.

(2) If the notice or decision is returned as undelivered, or if you refuse to sign the Return Receipt, the BLM will make a second attempt by an alternative method. If the second attempt succeeds in delivering the notice or decision, the BLM will deem the notice or decision to have been received on the date when the notice or decision was delivered according to the mail tracking system.

(3) If the notice or decision is returned as undelivered following the second attempt, the BLM may issue a decision rejecting your application.

(c) You have a duty to keep your address up to date. If your mailing address or other contact information changes during the application process, please notify the BLM by mail at the address provided in § 2569.409(a), or by telephone at 907–271–5960, by fax at 907–271–3334, or by the email address provided in the received notice or decision. If you notify the BLM by mail, fax, or email, please prominently include the words ''Change of Contact Information'' in your correspondence.

(d) Any responses to Notices or Decisions will be deemed received when it is physically received at the BLM Alaska State Office; if the response is mailed, on the date it was post-marked; or, if emailed, the date the email was sent.

§ 2569.414 May I request an extension of time to respond to Notices?

The BLM will allow reasonable extensions of deadlines in Notices for good cause. The request for the extension must be received from the Eligible Individual prior to the end of the 60-day period and provide the reason an extension is needed.

Processing the Application

§ 2569.501 What will the BLM do with my application after it is received?

After your application is deemed received in accordance with § 2569.411, the BLM will take the following steps:

(a) The BLM will enter your selection onto the Master Title Plat (MTP) to make the public aware that the land has been segregated from the public land laws.

(b) The BLM will then determine whether the selection includes only available Federal lands or if the selection conflicts with any other applicant's selection. The BLM will also review its records and aerial imagery to identify, to the extent it can, any valid existing rights that exist within the selection.

(c) The BLM may make minor adjustments to the shape and description of your selection to match existing property boundaries, roads, or meanderable waterbodies, or to reduce the number of corners or curved boundary segments. The BLM will attempt to retain the acreage requested in the selection, but the adjustment may

cause a reduction or addition in the acreage (not to exceed 160 acres).

(d) After any adjustments have been made, the BLM will send you a Notice of Survey to inform you of the shape and location of the lands the BLM plans to survey. The Notice of Survey will include:

(1) Your original land description;

(2) The adjusted land description plotted onto a Topographic Map and a MTP;

(3) Imagery of your original land description with the adjusted land description projected onto it;

(4) a Draft Plan of Survey; and

(5) A list of valid existing rights that the BLM has identified within the selection.

(e) The Notice of Survey will provide you an opportunity to challenge, in writing, the Draft Plan of Survey of the adjusted land description within 60 days of receipt of the BLM's notice. If no challenge is received within 60 days, the BLM will deem the Draft Plan of Survey to have been accepted.

(f) The BLM will finalize the Plan of Survey based on the Draft Plan of Survey in the Notice of Survey or the adjustment you provide pursuant to paragraph (e) of this section.

(g) The BLM will survey the selection based on the Plan of Survey.

(h) After survey, the BLM will mail you a document titled Conformance to Plat of Survey. That document will:

(1) Show the selection as actually surveyed;

(2) Plot the survey onto imagery; and

(3) If you found an error in the way the BLM surveyed the selection based on the Plan of Survey, provide an opportunity to dispute the survey in writing within 60 days of receipt of the Conformance of Plat of Survey. If no notice of dispute is received within 60 days, the BLM will deem the survey to have been accepted.

(i) The BLM will issue a Certificate of Allotment. No right or title of any sort will vest in the selection until the Certificate of Allotment is issued.

(j) (j) If an application is rejected for any reason, the BLM will remove the corresponding selection from the MTP to make the public aware that the land is no longer segregated from the public land laws.

§ 2569.502 What if more than one Eligible Individual applies for the same lands?

(a) If two or more Eligible Individuals select the same lands, in whole or part, the BLM will:

(1) Give preference to the application bearing the earliest receipt date;

(2) If two or more applications bear an identical receipt date, and one or more application bears a legible postmark or shipping date, give preference to the application with the earliest postmark or shipping date; or

(3) Assign to any applications for the same land that are still tied after the criteria in paragraphs (a)(1) and (2) of this section are applied a number in sequence, and run a random number generator to pick the application that will receive preference.

(4) For purposes of paragraphs (a)(1) and (2) of this section, an application received, postmarked, or shipped before December 28, 2020 will be deemed to have been received, postmarked, or shipped on December 28, 2020.

(b) The BLM will issue a decision to all applicants with conflicting selections setting out the BLM's determination of preference rights. Applicants who do not have preference must make one of the following choices:

(1) Provide the BLM a substitute selection within 60 days of receipt of the BLM's decision. The substitute selection may consist of either an adjustment to the original selection that avoids the conflict, or a new selection located somewhere else. The substitute selection will be considered a new application for purposes of preference, as set forth in § 2569.411(c), but the applicant will not need to resubmit any portions of the application other than the land description and map; or,

(2) If only a portion of the selection is in conflict, the applicant may request that the BLM continue to adjudicate the portion of the selection that is not in conflict. The BLM must receive the request within 60 days of your receipt of the BLM's decision. Each applicant is allowed only one selection of land under this act and will not be allowed to apply for more acreage later.

(c) If the BLM finds your application conflicts with an application which has technical errors, the BLM will provide you the option of selecting a substitute parcel prior to that application being corrected under the procedures of paragraph (b)(1) of this section.

(d) If you receive a decision finding your application does not have preference under paragraph (b) of this section and the BLM does not receive your choice within 60 days of receipt of the notice, the BLM will issue a decision rejecting your application. If your application is rejected, you may file a new application for different lands before the end of the five-year application period.

§ 2569.503 What if my application includes lands that are not available Federal lands?

(a) If your selection includes lands that are not available Federal lands, the BLM will issue you a decision informing you of the unavailable land selection and give you the following choices:

(1) Provide the BLM a substitute selection within 60 days of your receipt of the decision. The substitute selection may consist of either an adjustment to your original selection that avoids the unavailable lands, or a new selection located somewhere else. Your substitute selection will be considered a new application for purposes of preference, as set forth in § 2569.411(c), but you will not need to resubmit any portions of your application other than the land description and map; or,

(2) If only a portion of your selection is unavailable, you may request that the BLM continue to adjudicate the portion of the selection that is within available Federal lands. The BLM must receive your request within 60 days of your receipt of the BLM's decision. You are allowed only one parcel of land under this act, and you will not be allowed to apply for more acreage later.

(b) If you receive a decision finding your selection includes unavailable lands under paragraph (a) of this section and the BLM does not receive your choice within 60 days of receipt of the notice, the BLM will issue a decision rejecting your application. If your application is rejected, you may file a new application for different lands before the end of the five-year application period.

§ 2569.504 Once I file, can I change my land selection?

(a) Once your application is received in accordance with § 2569.411, you will only be allowed to amend your selection until 60 days after you receive the Notice of Survey as set forth in § 2569.501(e). Your amended selection will be considered a new application for purposes of preference, as set forth in § 2569.411(c), but you will not need to resubmit any portions of your application other than the land description and map.

(b) Otherwise, you will not be allowed to change your selection except as set forth in § 2569.502 or § 2569.503.

(c) If an applicant relinquishes their application more than 60 days after they receive the Notice of Survey as set forth in § 2569.501(e), the applicant will only be able to submit a new application for a new selection if their original selection is no longer available.

§ 2569.505 Does the selection need to be surveyed before I can receive title to it?

Yes. The land in your selection must be surveyed before the BLM can convey it to you. The BLM will survey your

selection at no charge to you, as set forth in § 2569.501(g).

§ 2569.506 How will the BLM convey the land?

(a) The BLM will issue a Certificate of Allotment which includes language similar to the language found in Certificates of Allotment issued under the Act of May 17, 1906 (34 Stat. 197, chapter 2469), providing that the land conveyed will be deemed the homestead of the allottee and his or her heirs in perpetuity, and will be inalienable and nontaxable until otherwise provided by Congress or until the Secretary of the Interior or his or her delegate approves a deed of conveyance vesting in the purchaser a complete title to the land.

(b) The Certificate of Allotment will be issued subject to valid existing rights.

(c) The United States will reserve to itself all minerals in the Certificate of Allotment.

(c) If the Eligible Individual is deceased, the Certificate of Allotment will be issued in the name of the heirs, devisees, and/or assigns of the deceased Eligible Individual.

§ 2569.507 What should I do if the Eligible Individual dies or becomes incapacitated during the application process?

(a) If an Eligible Individual dies during the application process, another individual may continue the application process as a personal representative of the estate of the deceased Eligible Individual by providing to the BLM the materials described in § 2569.404(b)(2).

(b) If an Eligible Individual becomes incapacitated during the application process, another individual may continue the application process as a court-appointed guardian or conservator or as an attorney-in-fact for the Eligible Individual by providing to the BLM the materials described in § 2569.404(b)(3) or (4).

(c) If a deceased or incapacitated Eligible Individual has received a notice from the BLM that requires a response within 60 days, as described in § 2569.410, § 2569.501(e), § 2569.501(h)(3), § 2569.502(b), or § 2569.503(a), and no personal representative, guardian, or conservator has been appointed, or no attorney-in-fact has been designated, the individual who receives the notice, or an employee of the BIA or a Realty Service Provider, may respond to the notice in order to request that the BLM extend the 60-day period to allow for a personal representative, guardian, or conservator to be appointed. The BLM will extend a 60-day period under this paragraph (c) for up to two years.

(d) If the BLM has completed a Draft Plan of Survey as described in § 2569.501(d) or a survey as described in § 2569.501(g), and the estate of the deceased Eligible Individual does not wish to dispute the Draft Plan of Survey as described in § 2569.501(e) or the results of the survey as described in § 2569.501(h), then the BLM will not require a personal representative to be appointed. The BLM will continue to process the application.

(e) Other than as provided in paragraphs (b), (c), and (d) of this section, the BLM will not accept any correspondence on behalf of a deceased or incapacitated Eligible Individual from an individual who has not provided the materials described in § 2569.404(b)(2), (3), or (4).

Available Federal Lands—General

§ 2569.601 What lands are available for selection?

You may receive title only to lands identified as available Federal land. You can review the available Federal lands on the mapping tool available at *https://www.blm.gov/alaska/2019AKNativeVetsLand.* If you do not have access to the internet, a physical copy of the map of available Federal lands can be requested by either:

(a) Calling the BLM Alaska Public Room, the BIA Regional Realty Office or Fairbanks Agency Office, or your local Realty Service Provider. The map will be current as of the date it is printed and mailed to the mailing address provided at the time of request; or

(b) Requesting a physical copy in person at any of the offices listed in paragraph (a) of this section.

§ 2569.602 How will the BLM certify that the land is free of known contaminants?

The BLM will review land for contamination by using current contaminated site database information in the Alaska Department of Environmental Conservation database, the U.S. Army Corps of Engineers Formerly Used Defense Sites database, the U.S. Air Force database, and the Federal Aviation Administration database, or any equivalent databases if any of these databases are no longer available. Any land found to have possible contamination based on these searches will not be available for selection.

§ 2569.603 Are lands that contain minerals available?

Yes the lands are available for selection, however, the minerals will be reserved to the United States and will not be conveyed to Eligible Individuals or to the devisees and/or assigns of Eligible Individuals.

§ 2569.604 What happens if new lands become available?

(a) New lands may become available during the application period. As additional lands become available, the BLM will review the lands to determine whether they are free of known contaminants as described in § 2569.602.

(b) After review, the BLM will update the online web maps of available Federal lands to include these additional lands during the five-year application period.

National Wildlife Refuge System

§ 2569.701 If Congress makes lands available within a National Wildlife Refuge, what additional rules apply?

Any Certificate of Allotment for lands within a National Wildlife Refuge will contain provisions that the lands remain subject to the laws and regulations governing the use and development of the Refuge.

Appeals

§ 2569.801 What can I do if I disagree with any of the Decisions that are made about my allotment application?

(a) You may appeal all Decisions to the Interior Board of Land Appeals under 43 CFR part 4.

(b) On appeals of Decisions made pursuant to § 2569.502(b):

(1) Unless the BLM's decision is stayed on appeal pursuant to 43 CFR 4.21, the BLM will continue to process the conflicting applications that received preference over your application.

(2) Within 60 days of receiving a decision on the appeal, the losing applicant may exercise one of the two options to select a substitute parcel pursuant to § 2569.502(b).

(c) On appeals of Decisions which reject the application or of a decision made pursuant to § 2569.503(a):

(1) Unless the BLM's decision is stayed on appeal pursuant to 43 CFR 4.21, the BLM will lift the segregation of your selection and the land will be available for all future entries.

(2) If you win the appeal and the decision was not stayed, your selection will be considered received as of the date of the Interior Board of Land Appeals decision for purposes of preference under § 2569.502(a).

[FR Doc. 2020–24954 Filed 11–25–20; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A

Policy on Redundant, Overlapping, or Inconsistent Regulations

AGENCY: Immediate Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Policy statement.

SUMMARY: The Immediate Office of the Secretary (IOS) is issuing this policy regarding redundant, overlapping, or inconsistent regulations.

DATES: November 27, 2020.

SUPPLEMENTARY INFORMATION: The Department believes that its decision-making ought to be transparent, rational, and well-honed to achieve legitimate government objectives with minimum transaction costs to the affected sector. This policy furthers those objectives and the objectives of the Richardson Waiver (see 36 FR 2532 (Feb. 5, 1971)), and various Executive Orders by requiring that all regulations issued by this Department are necessary, understandable, and provide clear guidance to the public and regulated entities regarding the standards to be met and procedures to be followed. Redundant, overlapping, or inconsistent regulations undermine these goals by injecting uncertainty, creating potentially conflicting regulatory regimes, and increasing transactions costs with no discernible benefit to the public.

Effective immediately, all agencies and offices of the Department that prepare regulations must ensure that any rule is not inconsistent with, and does not overlap with, any regulation that has already been issued through an agency within the Department. In the event an agency proposing that the Secretary issue a rule discovers that such rule is inconsistent or overlaps with another Department rule, the proposing agency shall not recommend issuance until it also recommends to the Secretary the steps to be taken to avoid duplicative or overlapping regulations.

Collection of information requirements: This document does not impose information collection requirements.

Brian Harrison,

Chief of Staff, Department of Health and Human Services.

[FR Doc. 2020–26023 Filed 11–24–20; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Subtitle A

Public Access to Materials Underlying Impact Analyses; Statement of Policy

The Department believes that its decision-making ought to be as transparent as appropriate to better enable the citizenry to comment on its proposed rules and demonstration projects. This document furthers that objective and the objectives of the Richardson Waiver (*see* 36 FR 2532 (Feb. 5, 1971)) by requiring that all assumptions, working papers, models, and other information used as part of any impact analysis (*e.g.,* economic, actuarial) associated with a rule (including ratemakings) or demonstration project (hereinafter, ''analyses'') are posted on the Department's website at the time the results of the analysis are publicly disclosed, subject to the limitations set forth below. This document also applies to rules issued or demonstration projects approved by this Department jointly with one or more other Departments, but only after consultation with such other Departments and only with respect to the analyses performed by this Department.

The Department's regulations and demonstration projects involving federal healthcare programs, the Affordable Care Act, the Food, Drug, and Cosmetic Act, or the Public Health Service Act are amongst the most economically significant actions undertaken by any Federal agency. The Office of the Assistant Secretary for Planning and Evaluation, the Office of Economics and Analysis within the Office of Policy, Legislation, and International Affairs at the Food and Drug Administration, the Office of the Actuary at the Centers for Medicare & Medicaid Services, and other applicable agencies and offices all undertake impact analyses that assess or seek to predict the wide range of economic and other impacts and burdens associated with each rule or demonstration project.

The Office of Management and Budget (''OMB'') Circular A–4 requires agencies to make their impact analyses reproducible by third-party evaluators. Disclosing the information underlying such analyses, to the extent permitted by law and consistent with robust privacy protections, will promote an informed public comment process that in turn advances both the quality and accountability of the Department's important programs. Implementing this policy will allow the public to review and evaluate the methodologies and assumptions that underlie the impact analysis. This transparency should enable a more accurate calculation of anticipated effects because the public will be better positioned to analyze and provide formal comment upon the models and data to identify and correct faulty assumptions or other errors.

Effective for any rulemaking or demonstration project proposed after November 30, 2020, all agencies and offices of the Department which issue analyses, whether economic, actuarial or otherwise, as part of a proposed or final rulemaking or demonstration project must post for public viewing on the Department's website all data and assumptions underlying any such analysis, including all working papers, all calculations, all references, and all other information necessary to allow a third-party to replicate the agency's analytic work. For purposes of this Notice, a rulemaking or demonstration project is deemed to have started with the publication in the **Federal Register** of a notice of proposed rulemaking or proposed demonstration projection, advanced notice of proposed rulemaking or final rule (whether interim or otherwise) or demonstration project, whichever occurs first.

The disclosure must occur no later than 3 days after the date when the results of such analyses are publicly released and are to be posted in-full on the Department's website notwithstanding Exemption 5 of the Freedom of Information Act (5 U.S.C. 552(b)(5)), except as noted below. This Notice does not contemplate the release of information that would otherwise be exempt from disclosure under the Freedom of Information Act, other than Exemption 5 as noted in the preceding sentence, or the Privacy Act of 1974.

The disclosure requirements in this Notice do not apply to analyses undertaken for settlement or litigation purposes or to communications with the Executive Office of the President, OMB, or other departments or agencies that are not part of a published analysis for a rulemaking or demonstration project, or to information that is deemed to fall within the attorney-client privilege, or to privileges that inure to officials outside this Department. Whether an exception contained in this paragraph applies shall be determined by the Office of the General Counsel in consultation with the relevant division within the Department.

Nothing in this policy shall be construed to impair or otherwise affect the functions of the Director of OMB

relating to budgetary or administrative proposals. The effect of regulations on estimates of budget baseline spending will continue to be developed separately using the budget's economic and technical assumptions according to OMB Circular A–11.

Alex M. Azar II,

Secretary.

[FR Doc. 2020–25957 Filed 11–24–20; 8:45 am]

BILLING CODE P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 51

[WC Docket No. 18–156; FCC 20–143; FR ID 17154]

8YY Charge Reform

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission takes definitive steps to address the arbitrage and fraud that have increasingly undermined the system of intercarrier compensation that currently underpins toll free calling. Those steps include transitioning 8YY end office originating charges to bill-and-keep over approximately three years and creating a single charge for 8YY tandem switching and transport services and capping it at a lower, uniform rate. The order caps rates for the database queries necessary to route toll free calls, reduces them to a national uniform rate over approximately three years, and limits such database query charges to one per call. Finally, the Commission allows carriers to use existing mechanisms to recover lost revenue. The measures will reduce the incentives for carriers to engage in 8YY access arbitrage and lower the costs of 8YY services overall.

DATES: The amendments in this document shall be effective December 28, 2020, except for §§ 51.907(i) through (k) (instruction 4), 51.909(l) through (o) (instruction 5), and 51.911(e) (instruction 6.b.), which are delayed. The FCC will publish a document in the **Federal Register** announcing the effective date for those sections.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW, Washington, DC 20554.

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SUPPLEMENTARY INFORMATION: This a final rule summary for the Commission's report and order released October 9, 2020. A full text copy of this document can be accessed at the following internet address: *https://www.fcc.gov/document/fcc-modernizes-rules-toll-free-calls.*

I. Background

1. 8YY services have long been a prominent fixture of the telecommunications landscape. Calls to 8YY numbers differ from other calls carried over the public switched telephone network in that the party receiving the call—not the party placing the call—pays the toll charges. When long-distance calls were expensive, allowing consumers to call businesses and other institutions without worrying about the cost of toll service was a benefit to consumers and to the companies receiving their calls. Reductions in toll rates and the rise of unlimited, all-distance calling plans have largely eliminated separate toll charges for consumers, yet 8YY services continue to have significant value, as evidenced by the persistently high demand for toll free numbers. Businesses and other institutions increasingly use 8YY numbers to support branding efforts, and to facilitate and evaluate marketing efforts—by, for example, assigning specific numbers to individual advertising campaigns to track the effectiveness of those campaigns.

2. The record indicates that the percentage of originating traffic attributable to 8YY has grown significantly over the years and currently accounts for the vast majority of originating access traffic. According to AT&T, for example, in 2008, 8YY originating minutes accounted for 64% of all AT&T originating access minutes (including minutes from AT&T affiliates) and by 2019, they accounted for 83% of all originating access minutes. Increased demand for toll free numbers has led the Commission to authorize a half a dozen additional toll free codes beyond the original 800 code, including the 888, 877, 866, 855, 844, and 833 codes.

A. 8YY Routing and Intercarrier Compensation

3. To understand intercarrier compensation for 8YY calls, it is first necessary to understand how toll free calls are routed and how that differs from the routing of non-toll free calls. When a caller dials an 8YY number, the originating carrier does not simply pass the call to the customer's pre-subscribed interexchange carrier, as it would for a non-toll free call. Instead, to determine how to route a toll free call, the originating carrier typically queries an industrywide database operated by the Toll Free Number Administrator (the 8YY Database) to determine the 8YY provider for the dialed number. Typically, for calls routed over time-division multiplexing (TDM) based networks, to query the 8YY Database a carrier must route the 8YY call through a switch, equipped with a ''service switching point.'' The service switching point ''suspends'' routing of the call and, during this suspension, sends a query over the signaling system 7 (SS7) channel to a service control point. Service control points are ''regional databases that contain routing instructions for the toll free numbers located in . . . particular geographic regions.'' 8YY calls from customers served by local exchange carrier end offices that are not connected to a service control point can be routed to one of the local exchange carrier's tandem switches that is equipped with a service control point, and the call is processed from there. Local exchange carriers that do not own a service control point can purchase database query services from carriers that do.

4. A database query produces a carrier identification code, which tells the local exchange carrier to route the call to the 8YY provider, typically an interexchange carrier, associated with that carrier identification code. The originating carrier then uses its own or an intermediate carrier's transport and switching facilities to route the call to the designated 8YY provider.

5. Carriers assess intercarrier compensation somewhat differently for 8YY calls than for other calls. When a caller places a regular long-distance call from a landline telephone, the caller's local exchange carrier routes that call to the long-distance carrier (interexchange carrier) used by the caller through pre-arranged direct connections with the interexchange carrier or through a nearby tandem switch and the interexchange carrier pays the local exchange carrier for originating the call. The interexchange carrier is then responsible for routing the call to its final destination and for paying any charges associated with its decisions about how to route the call. For its part, the interexchange carrier is paid by the customer that placed the call.

6. By contrast, when a caller makes a toll free call from a landline telephone, the 8YY provider pays the caller's local exchange carrier for originating the call and for performing the 8YY Database query. The 8YY provider also pays tandem switching and transport charges

to intermediate carriers in the call path between the local exchange carrier and the 8YY provider. The 8YY customer compensates the 8YY provider for completing the call. The rates paid by 8YY providers for various access charges typically are tariffed rates which vary widely depending on where an 8YY call originates and how it is routed.

7. The situation is slightly different for 8YY calls placed using a wireless carrier. The Commission's rules prohibit wireless carriers from tariffing terminating or originating access charges. As a result, a wireless carrier cannot assess 8YY providers for originating end office charges, database query charges, or tandem switching or transport charges.

B. Impact of the 2011 USF/ICC Transformation Order

8. In the 2011 *USF/ICC Transformation Order* (76 FR 73830, Nov. 29, 2011), finding that the intercarrier compensation system had become ''riddled with inefficiencies and opportunities for wasteful arbitrage,'' the Commission undertook comprehensive reform of the intercarrier compensation system by adopting bill-and-keep ''as the default methodology for all intercarrier compensation traffic.'' As a first step in moving intercarrier compensation toward bill-and-keep, the Commission established a plan to transition all terminating end office rates and some terminating tandem switching rates to bill-and-keep over six years for price cap carriers and competitive local exchange carriers that benchmark to price cap carriers and nine years for rate-of-return carriers and the competitive local exchange carriers that benchmark to them.

9. As part of the intercarrier compensation reforms adopted in the *USF/ICC Transformation Order,* the Commission created a transitional Eligible Recovery mechanism to mitigate revenue reductions wrought by the transition of terminating end office charges to bill-and-keep. The Commission defined as ''Eligible Recovery'' the amount of intercarrier compensation revenue reductions that price cap and rate-of-return incumbent local exchange carriers would be eligible to recover. An incumbent local exchange carrier's Eligible Recovery is based on a percentage of the reduction in intercarrier compensation revenues resulting from the reforms adopted in the *USF/ICC Transformation Order.* After calculating Eligible Recovery, incumbent local exchange carriers may recover that amount through Access Recovery Charges, subject to caps and, where eligible, Connect America Fund Intercarrier Compensation support. The Commission adopted a rebuttable presumption that these revenue recovery mechanisms would allow carriers to earn a reasonable return on their investment, and also adopted a Total Cost and Earnings Review to allow individual carriers to demonstrate that the rebuttable presumption is incorrect and that additional recovery is needed to prevent a taking.

10. In the *USF/ICC Transformation Order,* the Commission found that ''originating charges for all telecommunications traffic subject to [its] comprehensive intercarrier compensation framework should ultimately move to bill-and-keep.'' It declined, however, to move originating access to bill-and-keep immediately. Instead, it capped most originating access charges as ''a first step'' in a ''measured transition toward comprehensive reform.'' The Commission capped all interstate originating access charges and intrastate originating access charges for price cap carriers at their then current rates. The Commission also capped interstate originating access charges for rate-of-return carriers. But, it declined to cap intrastate originating rates for rate-of-return carriers to ''control the size'' of the Connect America Fund and to ''minimize burdens on consumers.'' The Commission further specified that the access charge reforms undertaken in the *USF/ICC Transformation Order* would ''generally apply to competitive [local exchange carriers (LECs)] via the [competitive local exchange carrier (CLEC)] benchmarking rule,'' which allows competitive local exchange carriers to tariff interstate access charges ''at a level no higher than the tariffed rate for such services offered by the incumbent LEC serving the same geographic area.''

11. In the *USF/ICC Transformation Further Notice of Proposed Rulemaking (FNPRM)* (76 FR 78384, Dec. 16, 2011), the Commission committed to transition originating access charges to bill-and-keep and sought further comment on how to make that transition. It also specifically sought comment on the appropriate treatment of 8YY originating access, including the ''need for a distinct 8YY resolution.'' There was wide variation in 8YY originating access charges when the Commission capped most 8YY originating access charges at their 2011 rates in the *USF/ICC Transformation Order.* As a result, such rates continue to vary widely among carriers. Database query charge rates, for example, range from $0.0015 to $0.015 per query.

C. 8YY Arbitrage and Abuse

12. The unique routing of, and compensation for, 8YY calls have created opportunities for arbitrage and other abuse of the intercarrier compensation system. As AT&T describes it, ''originating access charges for 8YY calls inherently invite fraud and abuse, because they create a mismatch in pricing signals'' and carriers ''are increasingly exploiting this arbitrage opportunity, and . . . increasingly focusing their efforts on 8YY calling now that most terminating access charges have gone to bill-and-keep.'' Moreover, as the Commission observed in the *USF/ICC Transformation FNPRM,* ''because the calling party chooses the access provider but does not pay for the toll call, it has no incentive to select a provider with lower originating access rates.'' Because 8YY originating access charges have not yet transitioned to bill-and-keep, neither the originating carrier nor any intermediate provider that performs tandem switching and transport has an incentive to use the lowest cost means of routing the call since both may collect access charges. Incentives for 8YY abuse are further enhanced by the fact that 8YY access and 8YY Database query rates vary significantly, creating incentives for some providers to use carriers with higher rates to increase their revenues. Commenters identify four types of abuse associated with 8YY calls: traffic pumping, benchmarking abuse, mileage pumping, and database query abuse.

13. 8YY traffic pumping, or ''robocalling,'' occurs when an access-stimulating entity enters into a revenue sharing agreement with a local exchange carrier and then uses auto-dialing equipment to generate significant amounts of 8YY traffic that the carrier passes on to the interexchange carrier for payment. This kind of abuse involves the generation of 8YY traffic that has no legitimate purpose and exists solely for the purpose of obtaining intercarrier compensation. As AT&T explains, ''these fraudulent calling schemes cause a wide variety of harms'' including inundating ''8YY customers with unwanted calls that increase the 8YY customer's expense,'' and affect ''the ability of legitimate calls to be completed or cause other systems to be disrupted.'' As a result, 8YY customers ''must pay for the traffic pumpers' calls to their numbers, for the time wasted by congested incoming lines and lost employee productivity, and for the procurement of remedial services.'' 8YY robocallers have become very sophisticated and are able to display a different spoofed telephone number for

each call they place to elude easy detection of their illegitimate calls.

14. A second type of benchmarking abuse occurs when an originating carrier in one part of the country sends its toll free calls to a competitive local exchange carrier located in a different part of the country where the incumbent local exchange carrier serving that geographic area has relatively high access charges. As AT&T explains, some competitive local exchange carriers ''have set themselves up as 8YY 'aggregators,' agreeing to handle 8YY calls from many originating providers.'' The aggregating competitive local exchange carrier hands off its aggregated 8YY traffic to interexchange carriers in these more remote areas, thereby allowing the competitive local exchange carrier to charge higher access charges ''relative to what the provider would have been able to charge in the incumbent LEC area where the call was actually placed.''

15. As Bandwidth further explains, toll free aggregators ''that are inserted into the call path by the originators of Toll Free traffic routinely ignore the routing instructions in the SMS 800 database.'' These toll free aggregators chosen by the originating carriers route 8YY calls to ''whichever IXC or tandem is willing to pay the highest rate.'' This kind of arbitrage ''increases the amount of revenue to be shared, often adds additional hops, and can result in failed calls . . . driving up costs and disrupting [carriers'] ability to properly manage their networks.'' These practices can also affect network management, causing unnecessary network congestion and ultimately distorting network investment.

16. A third type of 8YY arbitrage is mileage pumping, which occurs when a carrier artificially inflates the distance it routes an 8YY call to increase the transport revenues it receives when it hands off an 8YY call to the interexchange carrier that serves as the 8YY provider. Mileage pumping occurs when ''a CLEC tariffs a per-mile charge for transport and then either (i) bills the IXC for transport it does not actually provide (because it is provided by a different provider) or (ii) inefficiently routes traffic long distances—sometimes more than a hundred miles—to inflate the number of miles applied to the per-mile transport charge.''

17. Finally, there is 8YY Database query abuse, which results from relatively high and varied database query charges and the fact that often more than one carrier assesses a database query charge in the course of routing an 8YY call (*i.e.,* double dipping). A significant portion of 8YY origination revenues are derived from assessing database query charges. The ability to assess high database query charges provides an additional incentive and revenue source for carriers engaged in other forms of 8YY arbitrage.

D. Recent Procedural History

18. In 2016, the Commission sought comment on a petition filed by AT&T which, in relevant part, sought forbearance from rules related to pricing regulation and tariffing of 8YY Database query charges. AT&T subsequently moved to withdraw its petition and the Commission granted its motion.

19. In 2017, the Wireline Competition Bureau (Bureau) issued a Public Notice seeking to update the record in the *USF/ICC Transformation Order* dockets on 8YY access charges, in part in response to an *ex parte* letter filed by Ad Hoc Telecommunications Users Committee (Ad Hoc). In its letter, Ad Hoc alleges that there has been an increase in 8YY-related arbitrage and asks the Commission to reduce or eliminate incentives for that arbitrage.

20. In 2018, the Commission adopted a further notice of proposed rulemaking (*8YY FNPRM*) (83 FR 31099, July 3, 2018) seeking comment on a proposal to move all 8YY originating access charges to bill-and-keep, impose a nationwide cap on 8YY Database query charges, and impose a limit of one query charge per 8YY call. The *8YY FNPRM* also invited commenters to ''propose additional, or alternative, methods for reforming originating 8YY access charges'' in ways that ''would reduce abusive practices related to 8YY calls.'' It also sought comment on potential sources of revenue recovery.

II. Discussion

21. In this document, we take the next steps toward transitioning intercarrier compensation to bill-and-keep by adopting rules aimed at curtailing abuse of the 8YY intercarrier compensation regime and preserving the value of toll free services. As an initial step, and to avoid further opportunities for arbitrage or rate increases during the transitions, we cap all originating 8YY end office, tandem switching and transport, and database query charges at their current rates as of the effective date of this *Order.* We then transition each of these rate elements. We reduce originating 8YY end office charges to bill-and-keep over three further steps beginning July 1, 2021 and ending July 1, 2023. We also adopt a single uniform nationwide rate cap of $0.001 per minute for originating 8YY tandem switching and transport access charges as of July 1, 2021. We reduce database query charges to a cap of $0.0002 per query in three steps ending July 1, 2023, and as of the effective date of this *Order,* we end double dipping by prohibiting carriers from charging for more than one query per call. These changes, which are consistent with recommendations in the USTelecom industry consensus proposal, will lower 8YY calling costs by removing inefficiencies, reducing incentives for carriers to use TDM networks and thereby encouraging the adoption of IP-based networks, and diminishing 8YY intercarrier compensation disputes. In making these changes to intercarrier compensation for 8YY traffic we continue our progress toward moving our intercarrier compensation system toward a bill-and-keep end state and drastically reduce the incentives that have led to the proliferation of 8YY arbitrage schemes.

E. Transitioning Originating 8YY End Office Charges

22. As proposed in the *8YY FNPRM* we transition originating 8YY end office charges to bill-and-keep. We agree with those commenters that argue that moving 8YY originating end office charges to bill-and-keep is the best way to remove the underlying incentives to route calls inefficiently and generally inflate the charges imposed on 8YY providers created by the existence of originating access charges for 8YY traffic. We also agree with those commenters that propose a three-year transition period as one that will give carriers sufficient time to adjust to this new regime.

23. As the initial step, we cap all intrastate originating 8YY end office rates not previously capped at their current levels as of the effective date of this *Order.* As the Commission explained when it capped most originating access rates, capping rates ''ensures that no rates increase during reform'' and also ''minimize disruption to consumers and service providers by giving parties time, certainty, and stability'' as they adjust to the changes we make in this document.

24. Then, effective July 1, 2021, we require all local exchange carriers to bring any intrastate originating 8YY end office access rates that exceed the comparable interstate rates into parity with the comparable interstate rates. As the Commission has recognized, intrastate rates that vary from interstate rates create ''incentives for arbitrage and pervasive competitive distortions within the industry.'' By bringing intrastate rates into parity with comparable interstate rates, this initial step will ''minimize opportunities for arbitrage

that could be presented by disparate intrastate rates.''

25. In the *USF/ICC Transformation Order,* the Commission declined to cap intrastate originating rates for rate-of-return carriers because it wanted to ''minimize[ ] the burden intercarrier compensation reform [would] place on consumers and . . . help manage the size of the access replacement mechanism.'' The Commission sought comment on whether to ''initially defer the transition to bill-and-keep for originating access to the states to implement.'' Some state commissions have urged the Commission to proceed cautiously, if at all, and to allow an additional time period to transition originating access to bill-and-keep. In the nine years since the Commission adopted the *USF/ICC Transformation Order,* the industry has transitioned the majority of interstate and intrastate terminating charges to bill-and-keep without disrupting carriers' ability to operate and update their networks. Thus, the Pennsylvania Public Utilities Commission's argument that it would be premature for the Commission to proceed with any further intercarrier compensation reform because ''the Commission has not yet fully implemented the initial rate transition for terminating access charges that it adopted in 2011'' is now moot. Likewise, the Pennsylvania Public Utilities Commission's concern that a ''notice to refresh the record is not the proper vehicle to consider and adopt any comprehensive proposals'' to reform intercarrier compensation is no longer relevant. We only revise originating access for 8YY services, not other aspects of intercarrier compensation, and we do so after the Commission released a further notice of proposed rulemaking (*8YY FNPRM*) and a rigorous examination of the record we have received in response to that FNPRM. We find no reason to further delay the transition of intrastate originating 8YY access charges for rate-of-return carriers. To the contrary, we find that bringing some rate-of-return carriers' intrastate originating 8YY end office access rates to parity and capping them all will reduce arbitrage with minimal disruption, and will provide an appropriate starting point for the multiyear transition of these rates to bill-and-keep that we adopt herein.

26. Although the Commission capped price cap carriers' interstate and intrastate originating rates in the *USF/ICC Transformation Order,* the Commission did not require those carriers to bring originating intrastate rates to parity with the comparable originating interstate rates. If a price cap carrier's capped originating intrastate end office rates are above the comparable interstate rates, that carrier is required to reduce its intrastate rates to interstate levels on July 1, 2021.

27. After reducing or capping intrastate 8YY end office rates, we next transition all intrastate and interstate originating 8YY end office charges from their capped amounts to bill-and-keep in two equal reductions. Effective July 1, 2022, we reduce all originating 8YY end office rates to half of their capped levels. Then, effective July 1, 2023, we reduce all originating 8YY end office rates to bill-and-keep.

28. Moving originating 8YY end office charges to bill-and-keep is consistent with the Commission's long-held determination that bill-and-keep will be the end state for all access charges, including originating access. It therefore aligns with the Commission's adoption of bill-and-keep for local exchange carriers' terminating end office access charges in the 2011 *USF/ICC Transformation Order* as well as the Commission's decision that wireless providers cannot impose access charges. Indeed, as Ad Hoc observes, ''[t]he legitimacy of the use of bill-and-keep as a mechanism for access traffic has not been the subject of serious debate for some time.''

29. We also agree with those commenters that argue that moving to bill-and-keep is the best approach to reducing (or eliminating) incentives for 8YY arbitrage and other abuse. Under our existing rules, the interexchange carrier is unable to choose the originating call path and must pay the local exchange carrier's charges to originate the call, and there is evidence that carriers routinely ignore the routing direction provided by the 8YY provider in the 8YY Database. This mismatch in incentives is ''what *inherently* creates the opportunity for arbitrage and fraud,'' as originating local exchange carriers not only lack incentives to minimize intercarrier compensation charges but actually have an incentive to inflate those charges. As Ad Hoc explains, ''[b]ecause the choosing party has no incentive to select the provider with the lowest access charges, there is no competitive pressure on those charges. But there are powerful incentives for unscrupulous actors to take advantage of this broken market by generating traffic to 8YY numbers for no purpose other than to inflate the access charge revenues that are ultimately paid by toll free service customers.'' Bill-and-keep, by contrast, ''will incentivize efficient call routing and will benefit the public interest,'' as the originating ''LEC would recover its costs from its end user''—or from existing recovery mechanisms—and will face competitive pressure to make cost-efficient routing decisions.

30. The Commission previously adopted bill-and-keep as the default methodology for all intercarrier compensation traffic and recognized that adopting bill-and-keep ''imposes fewer regulatory burdens and reduces arbitrage and competitive distortions inherent in the current [intercarrier compensation] system, eliminating carriers' ability to shift network costs to competitors and their customers.'' We find no merit to arguments that 8YY traffic should be excluded from our actions to move intercarrier compensation to bill-and-keep. Contrary to some commenters' claims, apart from the obligation of 8YY providers to pay the long-distance costs, there is nothing unique about 8YY traffic that militates in favor of exempting such traffic from a bill-and-keep regime. Bill-and-keep itself remains ''competitively neutral, treating all carriers equally.'' And, moving end office charges to bill-and-keep will significantly reduce 8YY arbitrage, given that end office charges represent a majority of all originating access charges. In sum, we agree that adopting bill-and-keep for 8YY end office charges ''fosters competition, is simple to establish and administer, and addresses arbitrage,'' and ''the 'competitive distortions' 8YY access charges create.''

31. Some commenters argue against moving to bill-and-keep and instead urge us to adopt narrower, more targeted rules to prohibit specific 8YY arbitrage or abusive practices or simply pursue enforcement through the Commission's Enforcement Bureau or the courts. Targeted enforcement actions are important, but insufficient because enforcement under our current rules for the provision of 8YY services would not be able to address the underlying incentives that drive 8YY arbitrage and abuse. While adopting rules narrowly targeting specific practices would likely result in parties revising their arbitrage schemes to circumvent the specific prohibitions, adopting narrower solutions would also be ''impractical and unworkable as a matter of day-to-day implementation,'' and would continue to place the burden of detection and enforcement on 8YY providers, rather than on the carriers that are abusing the current access charge regime. We also agree with AT&T that there is a risk that ''*ex ante* prohibitions will not deter bad actors from pursuing traffic-pumping or other arbitrage schemes, and the result of any such system will inevitably be extensive *ex post* litigation and billing disputes.''

And despite requests for targeted enforcement against, for example, ''robocalling-enabled arbitrage or other bad practices,'' commenters do not provide specifics that would allow us to identify these ''bad practices,'' or what specific measures we should take to curtail them. Without eliminating the financial incentives to engage in arbitrage, the Commission would continually find itself reacting to new arbitrage schemes designed to exploit our rules, given the creativity and adaptability of entities engaging in arbitrage. We conclude that focusing on the next steps in transitioning 8YY access rates to ''bill-and-keep eliminates the financial incentives'' for 8YY arbitrage and is more likely to eliminate these practices than targeted measures.

32. For similar reasons, we also decline to adopt Aureon's proposal that instead of modifying our intercarrier compensation rules we adopt a blanket prohibition against ''8YY abuse as an unjust and unreasonable practice.'' Aureon offers no details about the types of conduct it would have us prohibit, let alone how we could effectively enforce such a prohibition. Further, nothing in Aureon's submission or in the record supports its assertion that merely adopting an amorphous prohibition against 8YY abuse would lead industry to ''work cooperatively and take the legal and technical actions necessary to prevent unlawful 8YY calls.'' Aureon's contention that the Commission's ''indirect approaches, which have so far focused upon financial incentives and modifications to intercarrier compensation, have not stopped access arbitrage'' is not supported by the facts. In 2011, before the *USF/ICC Transformation Order* took effect, terminating access arbitrage was estimated to cost carriers and their customers as much as $330 million to $440 million annually. By 2019, that estimate declined to $60 million to $80 million, a dramatic reduction that we believe was largely the result of the Commission's reform efforts. The rules we adopted last year in the access arbitrage proceeding appear to be further reducing the costs of terminating access arbitrage. The rules we adopt in this document are another step in the Commission's ''comprehensive intercarrier compensation reform,'' and continue our effort to address, over time, carriers' incentives and ability to abuse our intercarrier compensation rules.

33. We find unnecessary suggestions that we adopt rules requiring local exchange carriers to offer direct connections to interexchange carriers. AT&T, for example, proposes that we adopt a rule requiring that local exchange carriers either offer direct connections to interexchange carriers for originating 8YY access or, if the originating carrier refuses to do so, require the local exchange carrier to assume financial responsibility for delivering the call to the interexchange carrier. AT&T argues that its proposal would alleviate concerns that tandem providers would be unable to charge for their services if the Commission moved tandem switching and transport to bill-and-keep because tandem providers have no end users. But the non-zero rate cap we adopt for tandem switching and transport as we continue our transition ultimately to bill-and-keep will allow intermediate tandem providers to charge for their services, obviating any need to adopt AT&T's proposal. Moreover, we agree with Aureon that AT&T's proposal would not accomplish the goals of this proceeding.

34. Other, more detailed direct connection proposals are both unnecessary to achieve the objectives of this proceeding and create additional challenges. For example, West's proposal that we require all carriers to negotiate bilateral direct connections in good faith would require us to determine whether such negotiations were undertaken in good faith, a factual question which would be difficult to resolve. O1's proposal that we mandate that carriers offer direct connections ''to requesting carriers that send or receive at least four T–1s of originating/terminating traffic per month'' extends to issues beyond the scope of this proceeding and the current record does not provide a sufficient basis for us to evaluate the impact these proposals would have on the industry.

35. We likewise decline requests that we undertake other broad changes to our intercarrier compensation system in this proceeding, such as transitioning all originating access charges to bill-and-keep or addressing ''all of the remaining intercarrier compensation transition issues'' stemming from the *USF/ICC Transformation Order* holistically rather than in a piecemeal fashion. Such broad changes would be inconsistent with the incremental approach the Commission has taken to intercarrier compensation reform and the transition to bill-and-keep, which is designed to provide carriers the necessary time and flexibility to adapt their businesses to the changes we adopt without undue disruption. Those proposals would also ''fail[] to account in *any* way for the differences between 8YY originating access functionality and terminating access functionality,'' most notably network functions, such as database queries, that are particular to 8YY traffic.

36. We also decline suggestions to issue a second further notice of proposed rulemaking to seek comment on ''more refined proposals'' for combating 8YY abuses. Issuing another further notice would only create uncertainty and unnecessarily delay our ability to address 8YY arbitrage schemes and eliminate the harms such schemes continue to inflict on both consumers and on 8YY subscribers.

37. We also disagree with parties that suggest the record contains insufficient data to justify adopting new rules to combat 8YY arbitrage. According to AT&T, for example, ''arbitrage and fraud in connection with 8YY calling have become widespread and are growing.'' In quantifying that growth, AT&T specifies that in 2008, 8YY traffic was 64% of all originating traffic and by 2019, it had grown to 83% of all originating traffic. Verizon echoes AT&T's claims, alleging that 8YY abuse is ''proliferating since terminating access rates have transitioned to bill-and-keep.'' Given AT&T and Verizon's role as 8YY providers and the relatively comprehensive market data they have access to, we find their characterizations of the 8YY market to be an acceptable basis for the actions we take. Furthermore, 8YY subscribers concur in this assessment. The record also makes clear that 8YY subscribers ''have seen an increase in the number of fraudulent calls terminating to their toll free numbers'' and that ''fraudulent access stimulation in the 8YY market is not an isolated problem.'' 8YY customers have had to ''pay for the traffic pumpers' calls to their numbers, for the time wasted by congested incoming lines and lost employee productivity, and for the procurement of remedial services from companies that provide voice network security services . . . .'' And in a 2016 survey conducted by the Toll Free Number Administrator, 35% of all Toll Free Responsible Organizations reported that traffic pumping was a ''key obstacle facing the industry.'' The Toll Free Number Administrator estimates that up to 20% of toll free minutes for some carriers could be the result of traffic pumping. This and other evidence convince us of the pressing need to reform the 8YY access charge regime. Reducing the costs of 8YY arbitrage is more than sufficient justification for the rules we adopt in this *Order,* and the record regarding the burdens 8YY arbitrage imposes on carriers, toll free subscribers, and consumers is extensive. Various carriers describe a ''wide variety of harms'' that 8YY schemes cause ranging from unwanted calls and

increased expenses to call completion issues. While Ad Hoc explains that its members have seen an increase in the number of fraudulent calls terminating to their toll free numbers, resulting in tied up lines, lost productivity, and the need for unnecessary remedial expenses such as voice network security services. Critics of the record in this proceeding set too high an evidentiary threshold for Commission action; have not submitted data in the record to support their position; and fail to acknowledge the prevalence of 8YY arbitrage or the harms caused by such arbitrage.

38. We are also unpersuaded by commenters arguing that moving originating end office charges to bill-and-keep would enable IXCs to reap windfall profits. Instead, we agree with GCI that ''[e]liminating the implicit subsidies in the current system cannot fairly be described as a 'windfall'; rather, it will incentivize efficient call routing and will benefit the public interest.'' In fact, the Commission rejected similar arguments when it moved terminating end office charges to bill-and-keep, finding that a significant proportion of interexchange carriers' reduced access expenses were likely to be passed through to benefit consumers. We expect that the cost savings resulting from our new rules will flow through to interexchange carriers' customers, in the form of lower prices or better service or both, and we therefore decline to require interexchange carriers to pass through the benefits they receive as some commenters have suggested.

39. We disagree with Public Knowledge that the approach we take in this document ''will allow IXCs to 'double dip' by charging 8YY subscribers fees to own an 8YY number as well as charging LECs that route the 8YY calls'' resulting in a ''windfall'' for interexchange carriers. The rules we adopt in this document do not allow an interexchange carrier to charge a local exchange carrier for originating a call. To the contrary, moving originating 8YY end office charges to bill-and-keep will foreclose *any* carrier's ability to assess those intercarrier charges. Indeed, the premise of bill-and-keep is that carriers rely on their own end users, rather than other carriers, to recover their costs. At the same time, 8YY providers will continue to be responsible for the long-distance charges for calls placed to their 8YY numbers.

40. There is also no reason to believe that moving 8YY end office access charges to bill-and-keep will lead to an appreciable increase in rates for local service. As Ad Hoc points out, ''in wireless markets, the bill-and-keep framework has been in place for years and no separate, toll free specific charges have been imposed on callers.'' In fact, charges for wireless calling plans declined even as access charges for wireless calls moved to bill-and-keep. There is no reason to expect a different outcome here.

41. Relatedly, we are unpersuaded by commenters' unsupported assertions that moving to bill-and-keep will somehow hamper rural local exchange carriers' ability to meet the broadband needs of their customers. Our rules provide a revenue recovery system for lost interstate 8YY revenue for the rate-of-return local exchange carriers and we leave it to the states to handle the substantially smaller impact on intrastate 8YY revenue. Furthermore, as important as we find broadband deployment, we continue to reject the suggestion that we should preserve inefficiencies in our intercarrier compensation regime to implicitly subsidize carriers' efforts to deploy broadband.

42. Contrary to the views expressed by some commenters that appear to profit as middlemen in the existing intercarrier compensation regime, we find that interexchange carriers' customers, and consumers in general, will benefit from our efforts to address 8YY abuses. By reducing the incentives for local exchange carriers to engage in 8YY arbitrage, we expect to see a reduction in, or elimination of, such arbitrage. As AT&T points out, bill-and-keep ''shifts originating costs to end user charges, where they can be disciplined by competition.'' This will result in inflated costs being ''competed away, which will make the overall system more efficient and permit 8YY calling to occur at efficient (and still robust) levels.''

43. The reforms we adopt here do not alter the fact that the toll portion of an 8YY call will still be paid by the called party, not the calling party, thereby preserving the *toll free* nature of 8YY calls. Thus, arguments by some parties that 8YY calls would no longer be ''free'' with the imposition of bill-and-keep are misplaced. For the same reason, we find that concerns that Teliax and others have raised about potential false advertising claims related to 8YY calling are groundless; the calls will remain toll free to consumers even after this *Order* takes effect. It is also worth noting that consumers have always paid for service from their local provider as a component of any toll free call.

44. With respect to issues of self-help that some commenters have raised, we reiterate our previous statements cautioning parties to be mindful of ''their payment obligations under the tariffs and contracts to which they are a party.'' We continue to discourage providers from engaging in self-help except to the extent that such self-help is consistent with the Communications Act of 1934, as amended (the Act), our regulations, and applicable tariffs. Disallowing self-help, whether in the access stimulation context or not, would be inconsistent with existing tariffs, some of which permit customers to withhold payment under certain circumstances.

45. *Transition.* We find that the multiyear transition period that we adopt for moving originating 8YY end office access charges to bill-and-keep ''affords a reasonable period [for carriers to] make adjustments'' to reduce these rates to bill-and-keep. We amend §§ 51.907 and 51.909 of our rules to effectuate this transition for price cap and rate-of-return carriers and rely on the application of the existing benchmark requirements in §§ 51.911(c) and 61.26 of our rules to apply this same transition to tariffed rates charged by competitive local exchange carriers. We begin by capping all intrastate and interstate originating 8YY end office rates that are not already capped as of the effective date of this *Order.* Next, we require carriers to bring their intrastate originating 8YY end office rates that exceed their interstate originating 8YY end office rates into parity with their interstate rates as of July 1, 2021. In doing so, we ''balance the importance of starting the first step of reform as quickly as possible with the practical realities that billing system implementation and tariff revisions'' will take some time. This step of our transition provides a ''gradual rate reduction of intrastate to interstate charges,'' followed by a 12-month period before the next rate reduction to enable carriers to ''appropriately adjust and phase in revenue changes.'' Additionally, these rate reductions and those scheduled for July 1, 2022 and July 1, 2023 are timed to coincide with annual access tariff filing dates, minimizing administrative burdens on filing entities and on the Commission. The transition period exceeds the two-year transition for originating 8YY access rates on which the Commission sought comment in the *USF/ICC Transformation FNPRM.* It also closely parallels the transition proposed in the *8YY FNPRM* by reducing rates in three steps over a three-year transition. Several commenters support transitions of similar duration, and we find that a three-year transition with rate changes

tied to the annual access tariff filings benefits both carriers and consumers.

46. Some commenters advocate for a shorter transition period, or even for no transition at all. They suggest that the costs of 8YY arbitrage are significant enough to justify a more rapid transition. However, we find that allowing no transition or only a single year would not give providers adequate time to adapt their business plans to accommodate the move to bill-and-keep. Other commenters argue for a longer transition, some as long as the transition provided to move terminating end office charges to bill-and-keep. We agree, however, with those commenters that argue that a six- or nine-year transition, like the one the Commission adopted for terminating end office access charges, would inappropriately ''perpetuate incentives for the originating . . . carriers involved to engage in traffic pumping and other arbitrage schemes,'' and ''allow perpetrators of fraud and traffic pumping to eke out [additional] years of access revenues.'' In 2011, transitioning to bill-and-keep was a relatively untested concept. By now, carriers have had over eight years to adapt to bill-and-keep and have successfully accomplished that transition for terminating end office rates. Carriers have also been on notice since at least 2011 that the Commission plans to move all intercarrier compensation to bill-and-keep. The multiyear transition we adopt today for originating access charges means that carriers will have had eleven years to prepare for the elimination of 8YY originating end office rates. We find that the transition period we adopt strikes the appropriate balance between providing carriers adequate lead time to adjust to the new rules, ''while still moving quickly to the desired end state of bill-and-keep.''

47. Our decision is also influenced by the fact that the revenues affected by this *Order* are likely to be smaller than those affected as a result of the *USF/ICC Transformation Order.* In the *USF/ICC Transformation Order,* the Commission reduced most terminating intrastate rates to interstate rates, capped most originating intrastate and interstate charges for price cap carriers and originating interstate charges for rate-of-return carriers at 2011 levels, and reduced carriers' Eligible Recovery by 10% annually for price cap carriers and 5% annually for rate-of-return carriers. By contrast, according to NTCA estimates, rural local exchange carriers' (RLECs) total originating 8YY access revenues for the 12 months from July 2019 through June 2020 were approximately $30.3 million. In addition, the record shows that while 8YY arbitrage has increased in recent years as a percentage of originating traffic, overall originating traffic and therefore originating access revenues have declined. Thus, we find that moving originating end office access charges for 8YY calls to bill-and-keep will have a smaller relative impact on carriers than did the rules the Commission adopted in the *USF/ICC Transformation Order.* Accordingly, we find that a multiyear transition ending July 1, 2023 is reasonable for moving originating 8YY end office charges to bill-and-keep.

F. Adopting a Joint Tandem Switched Transport Access Service Rate Cap for Originating 8YY Traffic

48. Next, to reduce incentives for arbitrage with respect to 8YY originating tandem switching and transport rates while preserving the role of independent tandem providers, we move rates for these services toward bill-and-keep by adopting the proposal made by USTelecom that we impose a single nationwide tariffed joint tandem switched transport access service rate cap of $0.001 per minute for originating 8YY traffic. We amend §§ 51.907 and 51.909 of our rules to effectuate this transition for price cap and rate-of-return carriers and rely on the application of the existing benchmark requirements in §§ 51.911(c) and 61.26 of our rules to apply this same transition to tariffed rates charged by competitive local exchange carriers. In the interest of reducing administrative burdens, we allow carriers to implement any necessary changes as part of their next set of annual tariff revisions, and make the cap effective July 1, 2021. To prevent gamesmanship in the interim, we cap all intrastate and interstate originating toll free tandem switching and transport rates at their current levels as of the effective date of this *Order.*

49. Although the Commission proposed moving these rates to bill-and-keep in the *8YY FNPRM,* we agree with commenters that doing so at this stage would leave uncompensated those intermediate providers that do not serve end customers. We remain committed to moving all intercarrier compensation to bill-and-keep and by taking this interim step toward that goal, we leave for further consideration questions of the network edge and how intermediate providers will be compensated when we reach a full bill-and-keep-regime. Allowing carriers to charge for tandem switching and transport service under a uniform nationwide rate cap will preserve independent tandem service providers' role in routing originating 8YY traffic until we complete the transition of these rates to bill-and-keep.

50. In the meantime, we find that instituting a single uniform tandem switching and transport rate cap ''will immediately remove the largest incentive to create [8YY] arbitrage schemes.'' Because originating carriers and intermediate providers currently charge interexchange carriers for transport on a distance-sensitive, per-minute, per-mile basis, they have an incentive to engage in ''mileage pumping, inefficient routing and aggregation of 8YY traffic to high rate areas.'' AT&T, for example, describes mileage pumping schemes in which ''a CLEC tariffs a per-mile charge for transport and then either (i) bills the IXC for transport it does not actually provide . . . or (ii) inefficiently routes traffic long distances—sometimes more than a hundred miles—to inflate the number of miles applied to the per-mile transport charge.'' As Verizon explains, ''as long as 8YY tandem-switched transport rates remain high, and continue to vary from LEC to LEC, there will be strong incentives for carriers to engage in such arbitrage schemes.'' We agree with USTelecom that, because ''the lack of uniformity in current rate structures tend[s] to distort the market by incenting 8YY call origination and aggregation in remote areas,'' setting a nationwide cap on originating 8YY tandem switching and transport rates will reduce 8YY arbitrage, particularly abuses related to 8YY benchmarking. Although they do not necessarily agree with the level of the rate cap, several intermediate providers agree that we should cap the rate for tandem switching and transport. Inteliquent, for example, ''emphasized its agreement with USTelecom that the Commission should adopt a nationwide tandem rate to address any abuses in tandem charges assessed for 8YY-related costs.''

51. In addition to eliminating incentives for 8YY benchmarking and mileage pumping, a single nationwide tandem switching and transport rate cap for 8YY traffic constitutes another transitional step in the process of achieving the Commission's longer term goal of moving all intercarrier compensation to bill-and-keep. Furthermore, if we transition 8YY originating end office charges to bill-and-keep without also taking action to begin the transition of originating 8YY tandem switching and transport charges toward bill-and-keep by reducing those rates, we could create incentives for carriers to shift the focus of their 8YY arbitrage schemes to tandem switching and transport charges. Such a shift

would not be unlike the shift in arbitrage practices that occurred when the Commission moved terminating end office rates to bill-and-keep but left certain terminating tandem switching and transport rates in place.

52. We agree with commenters that it is premature to move originating toll free tandem switching and transport charges to full bill-and-keep, as proposed in the *8YY FNPRM.* As commenters including AT&T, CenturyLink, and independent tandem providers argue, because intermediate tandem providers generally do not serve end-user customers, moving tandem switching rates to bill-and-keep—which is premised on carriers obtaining compensation from their end users—could strand them without a clear source of revenue. Commenters observe that the result could be to ''disincentivize investment in tandem facilities,'' and ''limit[] the benefits tandem services provide to the entire public switched network.'' We agree that independent tandem services add important ''network redundancy and alternative routing options,'' and ''are a fundamental component of today's telecommunications network.'' Mindful of the importance of these attributes, our institution of an interim national rate cap retains ''an IXC payment obligation for tandem functionality utilized for originating 8YY traffic,'' and preserves independent tandem providers' ability to receive compensation for the services they provide.

53. Some parties claim that today's reforms will shift financial incentives to engage in 8YY traffic stimulation to interexchange carriers, or allege that interexchange carriers are responsible for the increase in access charges they must pay because IXCs have encouraged their 8YY customers to increase their use of toll free services. These assertions are unsupported by the record. Commenters provide no explanation as to how interexchange carriers either drive or would engage in such arbitrage, nor do they offer any evidence that such schemes exist. These commenters also fail to acknowledge that by moving 8YY end office charges to bill-and-keep and moving to a uniform nationwide tandem switched transport access service rate cap, we reduce incentives for *all* carriers to engage in 8YY arbitrage.

54. FailSafe Communications, Inc., (FailSafe) requests that we provide an indefinite exemption from bill-and-keep for 8YY access traffic associated with small and medium-sized business end users with less than 24 phone lines, arguing that the ''loss of the [carrier access billing] contribution'' would upset its current business model targeted at small and medium-sized businesses. We do not find that such an exemption is justified. FailSafe fails to recognize that to the extent that its clients are the recipients of 8YY calls, they will benefit from lower access prices paid by their 8YY provider. To the extent FailSafe's business model relies on intermediate carriers being paid for tandem switching and transport, we provide a uniform tariffed rate for those services. Furthermore, FailSafe does not offer a justification for the broad waiver it requests for access traffic associated with small and medium-sized business end users, nor does it explain how such a waiver could be operationalized.

55. We also decline to adopt the alternative proposal the Commission sought comment on in the *8YY FNPRM* that would have imposed mileage limitations on 8YY transport charges and would have transitioned originating 8YY tandem switching and transport rates to bill-and-keep, but only where the ''originating carrier also owns the tandem.'' There is no basis in the record for treating some tandem and transport providers owned by originating providers differently than independent tandem providers. Further, this proposal would allow abuse by independent tandem providers to continue unchecked.

56. Upon review of the record, we now reject proposals to impose specific distance-based mileage caps such as a ten-mile flat distance cap, mileage limits that ''vary by the type of market,'' or a cap based on the ''shortest practicable direct route.'' We find these and other suggestions in the record concerning tandem switching and transport overly narrow and therefore unlikely to be as successful in curtailing abuse as adopting a single, uniform rate cap. Any attempt to cap just 8YY transport mileage would only create incentives to abuse other aspects of the rate. In addition, commenters that recommend a mileage cap have provided insufficient data to allow us to determine the appropriate distance for a mileage cap, if we were to adopt one. Alternatively, ITTA recommends that we require competitive local exchange carriers to benchmark tandem and transport rates to the ''charges of the ILEC in the market where 8YY traffic originates.'' We find this approach would be administratively burdensome and potentially unworkable given the difficulties inherent in determining ''where [an 8YY] call originates,'' difficulties that will only increase with the evolution of new technologies.

57. Instead, we find that the most workable interim solution to addressing arbitrage of toll free tandem switching and transport rates in connection with intercarrier compensation for 8YY traffic is to set a single nationwide joint tandem switched transport access service rate cap of $0.001 per minute as an interim step toward moving these services toward bill-and-keep. USTelecom proposes this rate as part of its consensus proposal and states that this rate ''would address negative incentives that currently exist in the market while allowing legitimate cost recovery and providing a level competitive playing field for all market participants.'' USTelecom explains that ''$0.001 remains an 'above cost' rate' '' and that ''rates at and below $0.001 exist today and CLECs currently provide service in those areas at those rates due to the ILEC benchmarking rule.'' According to USTelecom, a rate of $0.001 per minute is approximately at the midpoint of rates currently assessed by its larger members. In addition, USTelecom members that own tandem switches ''agree to provide service at this rate'' and find no reason to charge higher existing rates given their agreement.

58. Bandwidth, a facilities-based competitive local exchange carrier that operates an interexchange network to provide 8YY service, agrees with the USTelecom proposal, explaining that, in Bandwidth's experience ''without revenue sharing, a tandem charge of $0.001 should be sufficient to recover an IP tandem provider's costs of delivering the traffic to the [Responsible Organization].'' According to Bandwidth the $0.001 per minute rate ''is likely high enough to enable a revenue share of $0.0005–7,'' suggesting that costs to provide tandem switching may in fact be lower than $0.001 per minute. As Bandwidth also explains, adopting a higher rate could retard the transition to IP networks by perpetuating a high rate for TDM switching. Indeed, although independent tandem providers may be more reliant than other carriers on revenues from these services, their filings in the record of this proceeding also make clear that they rely principally on lower-cost IP-based switching and transport to provide service and are therefore likely to have lower costs than carriers that operate legacy TDM-based networks. Given this record evidence, we find that a cap of $0.001 per minute will allow carriers, including intermediate tandem providers, a reasonable level of compensation for providing 8YY tandem switching and transport services as we transition all 8YY access rates

ultimately to bill-and-keep. Allowing carriers to charge as much as $0.001 per minute for tandem switching and transport also addresses concerns that intermediate providers would not receive compensation for 8YY traffic routed over their networks. Given the support for a uniform nationwide rate cap in general, particularly from intermediate providers such as Inteliquent and Bandwidth, we concur that a uniform cap is suitable, notwithstanding the potentially variable nature of transport service.

59. Unsurprisingly, even among carriers that support a uniform rate cap, not all carriers support the $0.001 per minute rate for joint tandem switched transport access services. In particular, Inteliquent proposes a nationwide uniform rate cap of $0.0017 per minute, which it describes as a national average tandem usage rate it calculated using its own internal traffic data. Inteliquent claims its proposed rate is ''based on those charged by the largest ILECs, which in turn were based originally on cost studies.'' Yet, Inteliquent fails to acknowledge that those cost studies are almost three decades old and, given the generally declining costs of providing telecommunications service, those dated cost-based rates almost certainly overstate carriers' current costs. Moreover, the fact that a broad consensus of USTelecom member companies is willing to accept a lower rate would appear to confirm that Inteliquent's average rate is unlikely to reflect the USTelecom member companies' current costs. Inteliquent also argues that ''picking an arbitrary, unweighted number that might be sufficiently compensatory to *some* carriers in *some* circumstances is not a form of 'averaging' '' accepted by courts. But, of course, there is nothing arbitrary about the rate cap of $0.001 that we adopt.

60. Inteliquent's preferred approach, however, would be the adoption of a higher rate cap of $0.002814/minute that would include tandem switching, transport, and what it refers to as ''dedicated tandem charges'' as the ''best method'' to avoid harming competitive tandem providers like Inteliquent. Our rules governing tandem-switched transport access services currently exclude flat rated charges for transport of traffic over dedicated transport facilities. We similarly exclude such dedicated charges from the rules we adopt here for joint tandem switched transport access services. The Commission sought comment on the possible inclusion of ''fixed charges'' in the *8YY FNPRM* but, apart from Inteliquent's suggestion, the record is devoid of any discussion of the potential implications of including dedicated transport services in our rate cap. Inteliquent's claim that if we do not incorporate dedicated tandem charges into the uniform tandem switching and transport rate, incumbent LECs will simply increase the rates for those charges is misplaced. Those charges were capped by the *USF/ICC Transformation Order* at their 2011 levels, with the exception of rate-of-return carriers' intrastate traffic, which represents a small minority of all 8YY traffic. We also have some concern that setting a toll free tandem switching and transport rate cap inclusive of dedicated transport charges could overcompensate at least some competitive tandem providers. If, as Inteliquent explains, dedicated tandem charges are ''disproportionally levied by incumbent LECs,'' then adopting a higher unified rate for tandem switching, transport and dedicated transport would offer a windfall to the competitive carriers that do not typically charge for those services and increase, rather than decrease, the cost of 8YY services. As we continue to proceed incrementally in the implementation of bill-and-keep for 8YY traffic, we will monitor the impact of this *Order* on toll free dedicated transport charges and will revisit the issue if our actions in this *Order* adversely impact competition for these services.

61. After careful review of the record, we find that a rate cap of $0.001 will reasonably compensate providers for tandem switching and transport access services while we consider how best to move all intercarrier compensation to a bill-and-keep regime. As we make that transition, there is no legal requirement that we establish purely cost-based rates. The rate cap we adopt here is not intended primarily to reflect carriers' costs but is instead intended to ensure a reasonable transitional rate as part of our transition of originating toll free tandem switching and transport rates to bill-and-keep. The Commission has previously delineated the merits of bill-and-keep as a rate methodology and affirms those benefits here. Carriers that believe this cap provides insufficient revenue recovery may seek a Total Cost and Earnings Review provided for in this *Order.*

62. *Implementation.* To achieve this nationwide uniform cap, effective July 1, 2021, we require that tandem providers eliminate existing tandem switching charges and transport charges for originating 8YY traffic, and instead subsume charges for both tandem switching and transport into a single joint tandem switched transport access service rate element not to exceed $0.001 per minute. The new rate structure we adopt will compensate the tandem provider for the use of its facilities whenever it provides either or both elements of a joint tandem switched transport access service. We find that requiring carriers to combine their tandem switching and transport rates into a single per minute rate element is ''simpler to implement'' than an approach that keeps the two separate, reducing the burden on carriers that must implement the new rules.

63. To give tandem providers adequate time to implement our rate cap, we require carriers to file tariffs that comply with the interim rate cap for originating 8YY tandem switching and transport rates effective July 1, 2021. We find that this period of time provides carriers with a reasonable timeframe in which to transition their rates to the $0.001 per minute cap, and allows for implementation of necessary changes to billing systems and the filing of required tariff changes as part of carriers' annual tariff revisions. At the same time, to avoid gamesmanship before July 1, 2021, we cap all existing toll free tandem switching and transport rates as of the effective date of this *Order.*

64. A longer transition, such as the one we adopt for moving originating 8YY end office charges to bill-and-keep, is unnecessary in this instance because tandem switching accounts for a smaller proportion of total originating access charges, and carriers will still be able to charge intercarrier compensation for toll free tandem switching and transport and will not need to find alternative sources of revenue for their tandem switching and transport costs during this transition. Adopting a longer transition, on the other hand, would unnecessarily prolong carriers' incentives to engage in 8YY arbitrage and could delay carriers' transition to IP-enabled services.

65. *Network edge.* In response to a request in the *8YY FNPRM* for comment on whether a distinct approach to determining the network edge is necessary in the 8YY context, T-Mobile proposes that we require carriers to interconnect at ''no more than a few dozen POIs for the entire country'' instead of at ''hundreds, or even thousands of POIs across the country.'' It describes existing interconnection arrangements as an inefficient system that is ''slowing the transition from legacy transmission platforms and services to those based fully on internet Protocol.'' NTCA opposes the T-Mobile proposal, claiming that ''the shift of all financial responsibility to RLECs serving relatively small customer bases

in remote rural areas for transport to reach distant points would undermine universal service and the ability to maintain reasonably comparable rates.'' NTCA also argues that ''moving from existing network edges would introduce a much greater degree of uncertainty and exacerbate the potential for confusion or disruption as underlying network technologies change.'' We decline to implement T-Mobile's proposal in this proceeding. Mandating such fundamental changes to carriers' interconnection obligations would have unpredictable consequences for a wide range of interconnection arrangements and are best dealt with in a comprehensive fashion in the separate proceedings where the Commission previously sought comment on issues relating to intercarrier compensation and the network edge.

66. GCI proposes a four-part plan for determining the default network edge for 8YY traffic in Alaska. But the record does not provide any information on the financial implications of its proposal for other Alaska carriers or the impact of its proposal on carriers' network build-out and rates, let alone provide other parties sufficient opportunity to comment on its financial or operational implications. All of which underscores the need to address GCI's proposal in the broader context of our network edge proceeding. We therefore decline to adopt GCI's proposed approach to the network edge for 8YY traffic in Alaska here.

67. Finally, NTCA raises concerns that if larger providers are no longer responsible for 8YY transport costs, they may attempt to ''leverage such changes to demand rearrangement of existing interconnection arrangements and to move the network edges . . . from existing locations in rural areas to points that may be [great distances] from the rural areas where those calls originate or terminate.'' Contrary to NTCA's concerns, although our rules transition 8YY transport and tandem switching access charges incrementally toward bill-and-keep, they do not alter the fact that interexchange carriers and wireless carriers continue to be responsible for those charges. Furthermore, we affirm that nothing we do in this *Order* is intended to affect or alter existing network edge arrangements. To address NTCA's concerns, it requests that we adopt a default rule specifying that: ''(1) The RLECs will be able to choose the point of interconnection in its service area; and (2) in no event will an RLEC be financially responsible for transport of calls beyond its service area.'' We decline to adopt NTCA's proposal as unnecessary, but at NTCA's request, we take this opportunity to remind all stakeholders that a carrier has no legal obligation to agree to unilateral attempts to change network interconnection points. And, on several occasions the Commission has found that unilateral attempts by a carrier to change its interconnection point with another carrier that results in increased costs or inefficient routing of traffic is unjust and unreasonable under section 201(b) of the Act.

G. 8YY Database Query Charges

68. To continue our transition of all intercarrier compensation to bill-and-keep, to remove the incentive for arbitrage created by the existing wide disparity in rates charged for 8YY Database queries, and to put an end to abuse of the intercarrier compensation system created by multiple carriers charging for 8YY Database queries for a single call, we adopt an interim nationwide cap of $0.0002 per 8YY Database query and limit 8YY Database query charges to a single charge per call to be assessed by the carrier that originates the call (*i.e.,* no double dipping). Finally, we adopt a multistep transition to the rate cap of $0.0002 per query for intrastate and interstate 8YY Database queries to ensure carriers have sufficient time to adapt their businesses to the new rate.

1. Preventing Arbitrage by Capping 8YY Database Query Rates Nationwide

69. In response to the negative incentives created by the wide variety of 8YY Database query charges, and general agreement that there should be a nationwide database query rate, we transition 8YY Database query charges to a single, nationwide rate cap of $0.0002. Current database query rates are widely disparate, ranging from $0.0015 to $0.015 per query, because of the disparities that existed when the Commission capped most 8YY Database query charges as part of the intercarrier compensation reforms it adopted in the *USF/ICC Transformation Order.* Although some commenters suggest that the different query rates may be based in carriers' differing rate structures, none provide examples of those different structures. This high degree of variability in rates strongly suggests that some, possibly many, of these rates do not reflect the costs carriers incur in providing these services, creating opportunities for 8YY arbitrage. Generating 8YY Database query charges has become one of the principal reasons driving the increase in 8YY arbitrage. Additionally, there is nothing currently stopping more than one carrier in a call path from querying the 8YY Database and charging the interexchange carrier for the query. As a result, database query charges make up a disproportionately high proportion of intercarrier compensation paid by IXCs. AT&T, for example, reports that 8YY Database query charges represent 20% of all of its originating access expenses. As AT&T emphasizes ''[t]he cost to perform an 8YY database dip is very low, and therefore one would not expect database query charges to represent such a high percentage of AT&T's overall originating access expense.''

70. We are persuaded that a cap of $0.0002 per database query, as proposed by USTelecom, is a reasonable nationwide rate cap and will further our goals of ultimately transitioning all access charges to bill-and-keep, minimizing access costs, and routing 8YY traffic as efficiently as possible. USTelecom describes this rate as ''the estimated cost of performing a database dip.'' Additionally, the fact that this cap represents the ''agreed upon amount'' by USTelecom's members, which include companies that range from the largest to some of the smallest incumbent local exchange carriers, competitive local exchange carriers, and interexchange carriers, all with widely varying business models and cost characteristics makes it likely that it will be sufficient for carriers to recover their costs.

71. We considered suggestions that we adopt a higher rate cap, including the proposal that we cap database queries at different rates, for example, the ''national average'' rate of $0.004248 per query. We agree that ''the Commission should not adopt a higher cap, such as the national average, because such a cap would simply lock in the excessive, unregulated rates that many carriers charge today,'' perpetuating opportunities for continued arbitrage.

72. We also considered suggestions that we move 8YY Database query charges to bill-and-keep. As the Commission recognized in the *8YY FNPRM,* ''the database query is a cost a LEC must incur in order to route an 8YY call to the proper IXC, either by maintaining its own SCP database or by paying a third-party SCP for the database query.'' USTelecom agrees that ''providers incur costs associated with the [database query] function'' and therefore ''does not propose to reduce the rate to zero.'' The payment of a query charge ultimately supports the existence of the 8YY Database, which is essential to competition in the provision of toll free services. That said, such charges nonetheless remain a component part of access charges generally, to which the Commission's

commitment to bring all such charges to a bill-and-keep methodology applies. In the interim, as USTelecom explains, by setting the transitional query rate cap at a low, ''near-zero rate'' we will remove most incentives to engage in 8YY Database query charge abuse while still allowing carriers to recover their costs. Setting the cap at this level will also ensure that 8YY customers and, ultimately consumers, will not bear the burden of unreasonable query charges. As proposed in the *8YY FNPRM* and consistent with our goal of addressing fraud and arbitrage that affects all 8YY charges, this transition applies to both interstate and intrastate 8YY Database query charges. Carriers that can demonstrate higher costs may seek a waiver of the cap pursuant to the Commission's waiver processes.

2. Adopting a Multistep Transition to the Nationwide Rate Cap

73. To avoid a flash cut in revenue received by carriers for database queries, as proposed by USTelecom, we implement the nationwide rate cap for 8YY Database query charges over a multistep transition period. First, we cap all 8YY Database query charges not previously capped at their current levels as of the effective date of the *Order.* Capping all 8YY Database query rates will serve as an important step in curbing the arbitrage that currently exists for database query charges. It will also prevent carriers from gaming our reform efforts by changing or modifying existing rates in anticipation of the adoption of the first interim query rate for 8YY Database queries.

74. Second, effective July 1, 2021, we cap 8YY Database query rates for each carrier at the national average query rate of $0.004248. (Capped 8YY Database query rates from step one of the transition that are lower than $0.004248 must remain at those lower capped rates.) Several commenters supported setting the initial cap at this level. But, consistent with the USTelecom proposal we make this the second step of the transition. Setting July 1, 2021 as the effective date for this step will allow carriers ample time to prepare to transition higher rates to the cap. We find that adopting an implementation date of July 1, 2021 for this transitional step will ensure that carriers have ample time to reduce the ''excessive, unregulated rates that many carriers charge today'' and therefore ''mitigate this form of arbitrage.'' Third, effective July 1, 2022, all database query rates will be transitioned half of the way to the final target rate of $0.0002. So, if a carrier's database query rate is capped at $0.004248 in the second step, its cap would be $0.002224 on July 1, 2022. If a carrier's rate cap is below $0.004248, then it will use its capped rate to arrive at its rate effective July 1, 2022. Finally, effective July 1, 2023, carriers may not charge more than $0.0002 for an 8YY Database query.

75. Adopting a multistep, multiyear transition period to implement the 8YY Database query rate cap is consistent with the prior Commission's actions and will ''provide [the] industry with certainty and sufficient time to adapt to a changed regulatory landscape'' and help minimize disruption to consumers and service providers. Accordingly, we agree with parties that favor a reasonable transition period to avoid the negative effects that might have resulted from imposing a ''flash cut'' to the new nationwide cap.

76. Implementation of the database query rate cap and transition will occur through application of amendments to § 51.907 of our rules for price cap carriers, § 51.909 of our rules for rate-of-return carriers, and § 51.911 of our rules for competitive local exchange carriers.

77. Nearly two decades ago, the Commission declined to subject competitive local exchange carrier database query charges to the benchmarking rules because of the dearth of information about such carriers' query charges in the proceeding before it. This proceeding by contrast includes robust discussion of competitive providers' database query charges and we find that given our adoption of a nationwide rate cap for all database query charges, the simplest and most administrable manner to implement that change for competitive local exchange carriers is by applying our benchmark rules to competitive local exchange carrier database query charges. The competitive local exchange carrier benchmark rule in § 61.26 of our rules and the benchmarking requirements for access reciprocal compensation rates in § 51.911(c) of our rules already applies to competitive local exchange carrier interstate charges, except database query charges. We now amend § 51.911 of our rules to make clear that beginning July 1, 2021, a competitive local exchange carrier providing interstate or intrastate switched exchange access services for use in the delivery of a Toll Free Call shall not have a tariffed interstate or intrastate Toll Free Database Query Charge rate that exceeds the rate charged by the competing ILEC.

3. Limiting 8YY Database Query Charges to One Per 8YY Call, To Be Assessed by the Originating Carrier

78. To further reduce the abuse of the 8YY Database query, as of the effective date of this *Order,* we will eliminate double dipping and allow only one carrier in a call path to charge a single database query for each 8YY call. If the originating carrier is unable to conduct the 8YY query or transmit the results of the query, the next carrier in the call path that is able to do so may conduct the single query and assess the charge. We agree with the Toll Free Number Administrator that ''multiple dip charges are unnecessary and increase the cost of a call to a[n 8YY number].'' There is broad support in the record for this action, with many commenters agreeing that ''there is no legitimate reason why an IXC should be expected to pay for multiple database queries.'' We agree that ''a single dip could allow [a] call to be correctly routed'' and that ''routing information should be carried with that call until it is terminated.'' Allowing only one query per call will eliminate an obvious source of 8YY arbitrage and encourage efficient routing.

79. In the typical 8YY call path, it is the originating carrier that conducts the query because the query is a necessary prerequisite to routing the call to the proper 8YY provider. Some commenters support allowing the originating carrier to assess the database query charge, while others support allowing the carrier that hands the call off to the 8YY provider to assess the charge. We find that allowing the originating carrier to assess the 8YY Database query charge or, if that carrier is unable to conduct the query or transmit the results of the 8YY query, allowing the next carrier in the call path to assess the charge, is consistent with long-standing industry practice and fosters efficient routing of 8YY calls from their inception. Conducting the database query at the point of initiation of the call, allows the originating carrier and all subsequent carriers in the call path to use the correct call routing information to transmit the call. In contrast, allowing the last carrier that hands the call off to the 8YY provider to assess the query charge would necessarily entail inefficient routing up to the point where the final carrier conducts the query.

80. Commenters suggest that some originating carriers' networks may lack the requisite signaling functionality to pass the results of an 8YY Database query, necessitating an additional query by the next carrier in the call path. In the very limited instances where an

originating carrier cannot pass the results of an 8YY Database query, that carrier is not required to perform a query, and may not charge for an 8YY Database query. In this circumstance, we allow the next carrier in the call path to conduct the query and assess the single charge. Carriers other than the next carrier in the call path after the originating carrier remain free to perform their own database queries but may not assess a charge for them. Not allowing intermediate carriers to assess a second 8YY Database query charge per call should have a *de minimis* impact on those carriers' bottom lines generally. Although the record does not allow us to quantify the number of carriers that lack these basic signaling capabilities, this likely involves a subset of rural carriers which are likely to serve a relatively small fraction of customers and a similarly small fraction of 8YY calls overall. Intermediate providers that are affected by this restriction transport such traffic pursuant to voluntary agreements and can decide whether to renegotiate their contractual arrangements. In fact, the record shows that competitive local exchange carriers and interconnected Voice over internet Protocol providers partner with other providers, including intermediate tandem providers, to perform the database queries needed ''to determine the IXC serving the dialed toll free number . . . and then route[] the call to the IXC through an unaffiliated carrier's tandem switch that is interconnected with the serving IXC.''

H. Relying on Existing Mechanisms for Revenue Recovery

81. We find that our existing revenue recovery mechanisms are sufficient to facilitate incumbent local exchange carriers' reasonable recovery needs as we move originating 8YY end office charges to bill-and-keep and move to national rate caps for 8YY joint tandem switched transport service and 8YY Database query charges. Consistent with the principles of bill-and-keep, competitive local exchange carriers, which are not subject to prescriptive rate regulation, can decide whether to recover from their end users any revenues they ''lose'' as a result of this *Order.* Accordingly, we decline requests to adopt new recovery mechanisms specifically tailored to 8YY.

82. The Commission adopted the current rules for Eligible Recovery as part of the intercarrier compensation reforms it undertook in the *USF/ICC Transformation Order.* The Commission designed those rules to enable price cap and rate-of-return carriers to recover a portion of the revenues they lost as terminating end office access rates transitioned to bill-and-keep. Our existing recovery mechanisms reflect ''the differences faced by price cap and rate-of-return carriers.'' Rate-of-return carriers, ''which are generally smaller and less able to respond to changes in market conditions than are price cap carriers'' require a ''greater degree of certainty'' in connection with intercarrier compensation reforms. We therefore conclude that it is reasonable and appropriate to rely on these mechanisms here, especially insofar as commenters have not demonstrated that they are unable to recover all or part of their lost revenues through existing federal and state recovery mechanisms and insofar that these mechanisms permit rate-of-return carriers to obtain some recovery from explicit universal service support through Connect America Fund Intercarrier Compensation. As the Commission provided for in the *USF/ICC Transformation Order,* we continue here to provide an opportunity for carriers to request additional support if needed through a petition for a Total Cost and Earnings Review. In addition, carriers retain the option of seeking a waiver of any provision of the Commission's rules.

1. Rate-of-Return Carriers

83. Rate-of-return carriers will continue to calculate their Eligible Recovery using the methodology adopted in the *USF/ICC Transformation Order* and pursuant to § 51.917(d) of our rules. The Eligible Recovery calculation will allow rate-of-return carriers to account for most of their total lost 8YY revenues. Because the Eligible Recovery calculation requires rate-of-return carriers to subtract expected interstate switched access revenues from Base Period Revenue, adjusted downward 5% annually, a decline in originating 8YY interstate switched access revenues resulting from the reforms we make today means that less revenue will be subtracted from the adjusted Base Period Revenue. This will increase rate-of-return carriers' Eligible Recovery. Thus, the Eligible Recovery calculation will reflect rate-of-return carriers' lost interstate end office and tandem switching and transport access revenues and allow recovery of those revenues.

84. Consistent with the Commission's rules, and the recommendation of ITTA, WTA, and USTelecom, rate-of-return carriers will continue to recover Eligible Recovery through the same two-step process set forth in the *USF/ICC Transformation Order:* first through the Access Recovery Charge, subject to the current caps, and then through Connect America Fund Intercarrier Compensation, as permitted by the Commission's rules. In the *USF/ICC Transformation Order,* the Commission explained that carriers—especially rate-of-return carriers—likely would not be able to recover all of their lost revenues through Access Recovery Charges alone, given the constraints imposed by our caps on permissible Access Recovery Charges and by the Residential Rate Ceiling. Accordingly, the Commission allowed incumbent local exchange carriers to rely on Connect America Fund Intercarrier Compensation to recover Eligible Recovery that they could not recover through permitted Access Recovery Charges.

85. Consistent with the concept of moving to bill-and-keep, rate-of-return carriers will continue to look first to their end users for recovery through the Access Recovery Charge. Some commenters suggest that we modify the Access Recovery Charge caps for rate-of-return carriers, but do not offer any specifics on how those caps should be modified. Rate-of-return carriers can rely on Connect America Fund Intercarrier Compensation support to recover at least some of the revenues that they cannot recover through their Access Recovery Charges.

86. Rate-of-return carriers will recover any Eligible Recovery permitted by § 51.917(f) of our rules through Connect America Fund Intercarrier Compensation pursuant to § 54.304 of our rules. We agree with ITTA that using Connect America Fund Intercarrier Compensation support in this manner is consistent with the Commission's mandate under section 254 of the Act to advance universal service through ''specific, predictable and sufficient'' mechanisms and the Commission's use of universal service funding as a component of prior intercarrier compensation reforms.

87. We conclude that concerns that allowing rate-of-return carriers to continue receiving support from Connect America Fund Intercarrier Compensation will limit the funds available under the Alaska Plan are unfounded. As GCI concedes, the Alaska Plan provides ''fixed amounts of support to participating ILECs and CMRS providers in exchange for specific, tailored obligations to deploy broadband over a ten-year period.'' Nothing we do in this *Order* alters Alaska Plan support. Accordingly, the rules that we adopt today will not ''upend the carefully calibrated commitments'' made as part of that Plan.

88. Our rules for calculating rate-of-return Eligible Recovery will consider

reductions in originating interstate revenue but not any reductions in originating intrastate revenue. Although the recovery mechanism established in the *USF/ICC Transformation Order* adopted a formal mechanism for terminating intrastate revenue recovery for rate-of-return carriers, we adopt a different approach here for several reasons. The hundreds of millions of dollars in rate-of-return carriers' annual intrastate revenues potentially affected by the *USF/ICC Transformation Order*'s reforms dwarf the intrastate revenues at issue here, which NTCA estimates will be approximately $6.5 million per year. Further, even the recovery mechanism in the *USF/ICC Transformation Order* declined to ensure revenue-neutrality, and we are not persuaded to go further here, particularly given the comparatively limited revenues at stake. In addition, in contrast to interstate rate regulation, intrastate revenue recovery largely is a matter of state control, presenting a real risk of over-recovery if we were to establish a formal recovery mechanism for intrastate 8YY origination charges here. For one, many states have granted local exchange carriers a significant amount of flexibility regarding intrastate rates. In addition, in contrast to our regulation of price cap carriers, we have left rate-of-return carriers' intrastate originating access rates uncapped—and continue to do so, except with specific respect to 8YY originating charges as reformed in this *Order.* Furthermore, we anticipate that our reform of 8YY originating charges will reduce billing disputes, leading to some cost savings for local exchange carriers. The record thus does not demonstrate that a formal recovery mechanism genuinely is needed here for intrastate 8YY origination charges above and beyond the recovery possible under state law.

89. We find it unnecessary to adopt ITTA's proposal to ''restart the timeline'' of the 5% annual reductions in rate-of-return carriers' Baseline Adjustment Factor or to otherwise adjust the Eligible Recovery calculation for rate-of-return carriers to accommodate our changes to the 8YY access charge regime. ITTA fails to provide a basis for changing the 5% annual reductions which were instituted to approximate the rate of line losses rate-of-return carriers were experiencing at the time of the adoption of the *USF/ICC Transformation Order.* We therefore decline to modify the 5% annual reduction.

2. Price Cap Carriers

90. Like rate-of-return carriers, we find that price cap carriers should look to the existing rules to determine how to adjust to the changes we make today to our intercarrier compensation system. We decline to adopt the suggestion of some commenters that we revise our Eligible Recovery rules to allow price cap carriers to include 8YY originating access revenues in their Eligible Recovery calculations. Instead, consistent with our move to bill-and-keep, price cap carriers may increase their Subscriber Line Charges or their Access Recovery Charges, to the extent they are otherwise able to do so. There is no compelling evidence in the record that further change to our recovery mechanisms is warranted. In fact, parties have not provided any meaningful data regarding the amount of revenue price cap carriers as a whole derive from 8YY originating access charges, or how such revenues should be considered as part of the Eligible Recovery calculations. Without actionable data regarding the revenues price cap carriers might lose as a result of our reform, and their ability to recover that revenue from their end users absent rule changes, we are unable to justify amending the Eligible Recovery calculation. The Commission has concluded that ''[p]rice cap carriers generally are less dependent than rate-of-return carriers on interstate access charge revenues and universal service support, and better able to use various economies of scale to generate cost-saving efficiencies, thereby reducing the relative impact of any revenue reductions.'' These same considerations lead us to conclude that price cap carriers will be able to accommodate changes in 8YY originating access revenues without the need for new universal service support. We also find that the transitions we adopt for today's reforms will give price cap carriers adequate time to adapt to these changes.

91. We also decline to implement proposals to freeze the annual 10% reduction in the Price Cap Carrier Traffic Demand Factor or to offset that annual 10% reduction by the amount of revenues lost as a result of our reform of 8YY access charges. Although we sought ''quantifiable data or evidence'' to help us determine what proportion of originating access revenues are attributable to 8YY calls and, more broadly, the need for originating local exchange carriers to replace the revenues they currently obtain from 8YY-related access charges, parties failed to submit the data we would need to quantify the revenues that price cap carriers might lose as a result of our reforms. Without that data, we are unable to justify amending the Eligible Recovery calculation. Commenters also do not attempt to explain how our reforms to 8YY originating access charges are related to the Commission's mechanism designed to estimate line loss for price cap carriers, which is reflected in the 10% annual reduction. Nor do they claim that the 10% annual reduction has somehow ceased to reasonably predict line loss trends. Furthermore, the 10% reduction is applied only to the revenue reductions included in the Eligible Recovery calculation—required reductions to a price cap carrier's terminating access revenues.

92. We also decline to adopt suggestions by CenturyLink and ITTA that we amend our existing revenue recovery rules to allow price cap carriers to receive Connect America Fund Intercarrier Compensation support to recover revenues lost as the result of today's reform. In the *USF/ICC Transformation Order,* the Commission allowed price cap carriers to seek recovery from Connect America Fund Intercarrier Compensation on a transitional basis and phased out such support over time. The Commission chose to phase out this support for price cap carriers in part because it adopted measures allowing price cap carriers the opportunity to receive additional universal service support through other mechanisms. The same logic applies today. With the new support mechanisms now phased in, there is no basis to revisit the phase-out of Connect America Fund Intercarrier Compensation support ''designed to reflect the efficient costs of providing service over a voice and broadband network.'' Since the adoption of the *USF/ICC Transformation Order,* price cap carriers that have chosen to receive high-cost universal service support have been able to maintain and improve their networks using universal service support they receive through the phased-in Connect America Fund mechanisms apart from the phased-out Connect America Fund Intercarrier Compensation. Therefore, we decline to extend Connect America Fund Intercarrier Compensation support to price cap carriers to recover lost 8YY access revenues at this time.

93. Although we do not adopt a specific revenue recovery mechanism for price cap carriers, we also do not foreclose those carriers from recovering reduced revenues through lawful end-user charges such as the Subscriber Line Charge. Indeed, such end-user recovery is one of the central tenets of bill-and-keep. Some price cap carriers claim they are unable to bill their end users to offset reduced 8YY access charge

revenues given the Commission's limits on end user charges. We note, however, that certain price cap carriers' tariffs contain end user charges that are below the Commission's caps on these charges, which would enable a measure of recovery of reduced 8YY revenues.

94. At the same time, we decline proposals to allow price cap carriers to pursue recovery through increases in the caps on Subscriber Line Charges and Access Recovery Charges, or through an increase in the Residential Rate Ceiling. In regulating end-user charges, the Commission has always had to account for important consumer interests, including ''ensuring that all consumers have affordable access to telecommunications services.'' To ensure that increases in end-user charges do ''not impact the affordability of rates'' the Commission has routinely capped such increases. USTelecom does not provide any justification for its proposed increases of as much as $12 per line per year to the Subscriber Line Charge after two years. Frontier and Windstream fail to justify their proposal for two annual increases of $0.15 per line per month in Subscriber Line Charges for price cap carriers. Windstream offers no data in support of that proposal. Frontier justifies the proposal based loosely on the amount of interstate and intrastate revenue it estimates it would lose should we adopt the USTelecom proposal without any new revenue recovery mechanism for price cap carriers. Frontier's estimates, however, appear not to take into account the extent it can offset 8YY revenue reductions through remaining room under the existing Access Recovery Charge or Subscriber Line Charge caps. Moreover, Frontier's proposal would be applicable to all price cap carriers, and no other price cap carriers have offered data estimating their anticipated revenue losses. The very fact that different parties representing price cap carriers make two such widely varying proposals for Subscriber Line Charge increases in this proceeding underscores the arbitrary and unsupported nature of both proposals. Proposals to increase the caps on Access Recovery Charges are cursory, lack supporting evidence or analysis, and fail to address the impact of such increases on affordability. Because we are concerned about affordability, we reject those proposals and the USTelecom proposal to increase the Residential Rate Ceiling by $1.00 a month to $31.00 per month. USTelecom offers no information to demonstrate that there is a meaningful relationship between the revenue reductions carriers will face as a result of this *Order* and the ability of some carriers to recover more revenue through Access Recovery Charges should we raise the residential rate ceiling by $1 per month. We also agree with NTCA that USTelecom's proposal to raise the residential rate ceiling makes no sense with respect to rate-of-return carriers which have a different revenue recovery mechanism than price cap carriers. None of these proposals provide an adequate basis for us to adopt industry-wide pricing rules. Absent adequate justification, we are also unable to analyze the potential effects on end users of increases in the Subscriber Line Charge, Access Recovery Charges or the Residential Rate Ceiling and whether the increases and timing are reasonable.

3. Case-by-Case Requests for Additional Revenue Recovery

95. We provide an opportunity for revenue recovery through existing mechanisms to promote an orderly transition in the reform of 8YY originating access charges. As explained in the *USF/ICC Transformation Order,* we do not have a legal obligation to ensure that carriers recover access revenues lost as a result of reform, absent a showing of a taking. In that Order, the Commission established a rebuttable presumption that the revenue recovery mechanisms it adopted would allow incumbent local exchange carriers to earn a reasonable return on their investment and established a ''Total Cost and Earnings Review,'' through which a carrier may petition the Commission to rebut that presumption and request additional support. The Commission identified factors that it could consider in analyzing requests for additional support and predicted that the limited recovery permitted would be more than sufficient to provide carriers reasonable recovery for regulated services, both as a matter of the constitutional obligations underlying rate regulation and as a policy matter of providing a measured transition away from incumbent local exchange carriers' historical reliance on intercarrier compensation revenues to recovery that better reflects competitive markets. Nonetheless, the Commission adopted a Total Cost and Earnings Review to allow individual carriers to demonstrate that this rebuttable presumption is incorrect and that additional recovery is needed to prevent a taking. We take the same approach here and adopt a rebuttable presumption that the existing revenue recovery mechanisms will allow incumbent local exchange carriers to earn a reasonable return on investment. We also continue to make the Total Cost and Earnings Review available to carriers affected by the 8YY originating access reforms we adopt today.

96. To show that the existing recovery mechanisms are legally insufficient, a carrier faces a ''heavy burden,'' and must demonstrate that the regime ''threatens the financial integrity of [the carrier] or otherwise impedes [its] ability to attract capital.'' As the Supreme Court has long recognized, when a regulated entity's rates ''enable the company to operate successfully, to maintain its financial integrity, to attract capital, and to compensate its investors for the risks assumed,'' the company has no valid claim to compensation under the Takings Clause, even if the current scheme of regulated rates yields ''only a meager return'' compared to alternative rate-setting approaches. We believe that our existing recovery mechanisms provide recovery well beyond any constitutionally required minimum, and we find no convincing evidence in the record that those mechanisms will yield confiscatory results.

97. As we seek to protect consumers from undue rate increases or increases in contributions to universal service funding, we will conduct the most comprehensive review of any requests for additional support allowed by law. Our existing recovery mechanisms go beyond what might strictly be required by the constitutional takings principles underlying historical Commission regulations. Therefore, although our recovery mechanisms do not seek to precisely quantify and address all considerations relevant to resolution of a takings claim, carriers will need to address these considerations to the extent that they seek to avail themselves of the Total Cost and Earnings Review procedure based on a claim that recovery is legally insufficient.

I. The Benefits of Our Actions Far Outweigh the Costs

98. The record is clear that the benefits of the actions we take today to move 8YY access charges toward bill-and-keep far outweigh the costs. By eliminating 8YY arbitrage opportunities based on high and varying originating end office access rates, tandem switching and transport rates, and database query rates, we reduce the incidence of 8YY robocalls, incent more efficient (and therefore lower cost) routing of 8YY calls, and encourage greater competition among 8YY providers on the basis of quality and price.

1. The Benefits of Our Actions

99. Carriers, 8YY customers, and consumers will all benefit from better

quality, lower-priced 8YY services as a result of the actions we take to move 8YY charges to or toward bill-and-keep. We conclude that there are at least four ways in which our actions benefit consumers and firms and enhance the public interest. *First,* by transitioning interstate and intrastate end office originating access rates for 8YY calls to bill-and-keep, moving 8YY tandem switching and transport services and database query charges to nationally capped low rates, and limiting database queries to one charge per call, we discourage inefficient routing designed to maximize 8YY access revenues. Consistent with the Commission's findings in the *USF/ICC Transformation Order,* moving originating 8YY end office access rates to bill-and-keep will move prices closer to being cost reflective and, as a consequence, ''carrier decisions to invest in, develop, and market communications services will increasingly be based on efficient price signals.'' Taken together, these actions will reduce the access charge and network operation costs carriers incur, and will provide better investment incentives. Additionally, reducing 8YY robocalls will mitigate network congestion, lower the costs of access for 8YY providers and help ensure that legitimate callers can reach their intended destinations. We expect some of the carriers' cost savings that will arise from more efficient network use to be passed on to their 8YY customers in the form of better service and/or lower prices. Ultimately, this will lead businesses using 8YY services to provide better service and/or lower prices to their own customers.

100. *Second,* our actions will reduce the 8YY originating access rates paid by interexchange carriers for legitimate 8YY calls. We estimate that originating end office charges for 8YY services exceed $56 million annually, and are possibly many times this. Because of our actions, these end office access expenses will fall to zero over the next three years. Establishing nationally uniform rate caps for 8YY tandem switching and transport charges and 8YY Database queries and reducing the number of queries per call to one will further reduce interexchange carriers' costs of providing 8YY services. These declines in access charges will further lower 8YY prices and/or increase innovation.

101. *Third,* our actions will encourage carriers to efficiently transition to IP services. Under the current system of intercarrier compensation, access revenues can be inflated by inefficiently exchanging traffic over TDM facilities. Reducing those revenues will reduce incentives to route traffic inefficiently and to use TDM facilities which will further encourage the transition to IP services. As the Commission previously found, taking steps to foster the transition to IP-based and other advanced communications technologies ''can dramatically reduce network costs and lead to the development of new and innovative services, devices, and applications, and can also result in improvements to existing product offerings and lower prices.''

102. *Finally,* our reforms will reduce intercarrier compensation disputes. Carriers will no longer need to devote as many resources to monitor their 8YY call traffic and dispute 8YY invoices. For end office switching, billing will not be necessary. Although some of these benefits are difficult to quantify, together they will be substantial.

2. The Costs of Our Actions

103. The impact of our rule changes on the intercarrier compensation revenue and expenses of carriers will vary by carrier. To the extent one carrier's losses are gains to another, for example, because the amount of access revenue losses on call origination services for one carrier constitute reduced access expenses for another carrier, these changes are transfers, and therefore do not of themselves impact economic efficiency. As such, transfers are not directly relevant to a cost-benefit analysis. In any case, except to the extent that there may be some carriers for which 8YY arbitrage is the core of a narrow business plan, relative to the scale of most carriers' operations, the impact of our action on any carrier's revenues will be small, and we expect carriers may make ameliorating adjustments to their business plans. Despite the fact that some commenters have sought approval to raise their end user charges in conjunction with this rulemaking, we expect that robust competitive pressure for voice services nationwide will limit the extent to which carriers of all types respond to our rule changes by raising their end user charges. In any case, the rule changes will provide more efficient incentives for carriers' pricing decisions, product offerings, and investments.

104. It is possible that small price increases could occur due to our actions. Rate-of-return incumbent local exchange carriers may recover a portion of their lost revenue through a combination of Access Recovery Charges and Connect America Fund Intercarrier Compensation. We estimate that the total Universal Service Fund program collection will increase at most by approximately 0.3% due to our actions. Increases in Access Recovery Charges will be paid by rate-of-return carriers' end user customers and increased Connect America Fund Intercarrier Compensation support will require increases in Universal Service Fund contributions, partially offsetting the benefits of the price declines generated by our actions. The costs of higher contributions arise because they raise prices for end users and hence distort efficient consumption of interstate services. However, we expect this loss of efficiency will be small relative to the benefits our actions will bring, primarily because the inefficiency brought about by higher contribution rates is small relative to the substantial inefficiency created by current 8YY arbitrage, and because the revenue impacts of lower 8YY access charges will only be partially offset by contribution increases. Moreover, meeting universal service obligations from contributions is simpler and more transparent than the existing opaque implicit subsidy system under which carriers pay to support other carriers' network costs through origination charges.

105. We estimate the costs necessary to update the relevant carrier's billing systems to be approximately $6 million. We estimate billing costs as follows. We use a labor cost per hour to implement billing system changes of $70. We estimate the hourly wage for this work to be $47, equivalent to the hourly pay for a General Schedule 12, step 5 employee of the federal government. This rate does not include non-wage compensation. To capture this, we markup wage compensation by 46%. The result is an hourly rate of $68.62 [= $47 × 1.46], which we round up to $70. As many as 859 carrier holding companies may be impacted by our actions. In 2018 on Form 499 filings, 859 holding companies reported non-zero revenue from per-minute charges for originating or terminating calls provided under state or federal access tariff (based on aggregated data from Form 499, line 304.1). These holding companies vary significantly in size and therefore likely face varying costs to implement billing system changes. We assume that at most 100 hours of work is required to adjust billing systems for the largest holding companies and the most complicated systems, and conservatively use that figure as the estimate for every holding company. Thus, our estimate of the costs for billing adjustment is approximately $6 million [= 859 x $70 × 100]. We acknowledge the limits of our attempt to

estimate these costs but believe this approach yields a reasonable estimate for the purposes of this cost-benefit analysis.

3. On Balance, Benefits Exceed Costs

106. On balance, the benefits of our actions outweigh their costs. Consumers, 8YY customers, and carriers will benefit as we transition 8YY access charges toward bill-and-keep, reducing the inefficiencies inherent in 8YY arbitrage, lowering 8YY access charges, causing prices of 8YY services to fall and innovation to increase, reducing 8YY congestion, encouraging network modernization, and reducing intercarrier compensation disputes. Our actions will also reduce ''competitive distortions inherent in the current system, eliminating carriers' ability to shift network costs to competitors and their customers.'' There will be some costs imposed, largely due to the need to collect additional Universal Service Fund contributions to fund rate-of-return carriers who face losses in 8YY originating access charges. Nonetheless, the costs of higher retail rates due to any increase in Access Recovery Charges are likely to be *de minimis,* and compliance costs are a small transitional expense. The significant benefits of our actions more than compensate for the necessary, yet small costs they impose.

J. Legal Authority

107. In this *Order* we correct the perverse incentives the current rules create for local exchange carriers to choose expensive and inefficient call paths for 8YY traffic. We also continue to advance the goals and objectives the Commission articulated in the *USF/ICC Transformation Order* and take further steps toward the Commission's goal of adopting a bill-and-keep regime for all intercarrier compensation.

108. As in the *USF/ICC Transformation Order,* our statutory authority to implement changes to the pricing methodology governing the exchange of traffic with local exchange carriers flows directly from sections 201(b), 251(b)(5), and 251(g) of the Act. Section 201(b) permits us to ''prescribe such rules and regulations as may be necessary in the public interest to carry out the provisions of this chapter,'' including the provision requiring the ''charges, practices, classifications, and regulations'' for interstate communications to be just and reasonable. The new rules we adopt in this *Order* will help ensure originating 8YY rates are just and reasonable as required by section 201(b) and should end the abuse of these charges, including the artificial inflation of originating access charges.

109. Section 251(b)(5) specifies that local exchange carriers have a ''duty to establish reciprocal compensation arrangements for the transport and termination of telecommunications.'' In the *USF/ICC Transformation Order* the Commission ''br[ought] all traffic within the section 251(b)(5) regime.'' In finding that it had the authority to comprehensively reform intercarrier compensation and move all interstate and intrastate access charges to bill-and-keep, the Commission explained that its authority to implement bill-and-keep as the default framework for the exchange of traffic with local exchange carriers flows directly from sections 251(b)(5) and 201(b) of the Act. This comprehensive reform approach necessarily includes originating access charges. Indeed, the Commission has long held that the absence of any reference to originating traffic in section 251(b)(5) means that—apart from access charge rules temporarily preserved by section 251(g)—the originating carrier is barred from charging another carrier for delivery of traffic that falls within the scope of section 251(b)(5). Section 251(g) of the Act—which preserves existing ''originating access until the Commission adopts rules to transition away from that system''—provides additional legal authority for our regulation of origination charges and our continuation of the measured transition away from historical access charge regimes that the Commission began in the *USF/ICC Transformation Order.* Relying on those sections of the Act, the Commission confirmed that originating charges for all telecommunications traffic should ultimately move to bill-and-keep, but capped interstate and certain intrastate originating access charges in the *USF/ICC Transformation Order* pending more comprehensive reform.

110. In considering challenges to the *USF/ICC Transformation Order,* the Tenth Circuit held that the Commission's inclusion of originating access charges in its reform effort was ''reasonable'' and entitled to deference. The Court also expressly affirmed the Commission's authority over intrastate originating access charges. The Commission's authority to take such action for interstate and intrastate originating charges is thus well settled. Arguments that we lack authority over such charges or the methodology that should apply to those charges are entirely without merit.

111. This statutory authority also allows us to establish a transition plan to reform 8YY originating access charges. We agree with CenturyLink that ''the Commission can rely on (*inter alia*) sections 4(i) and 201 through 205 of the Act, which together afford the Commission broad discretion in establishing carrier rates.'' As the Commission concluded in the *USF/ICC Transformation Order,* ''although the [Act] provides that each carrier will have the opportunity to recover its costs, it does not entitle each carrier to recover those costs from another carrier, so long as it can recover those costs from its own end users and through explicit universal service support where necessary. We continue this framework today by allowing end user recovery and, where permitted, explicit universal service support.

II. Procedural Matters

112. *Paperwork Reduction Act Analysis.* This document contains modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the modified information collection requirements contained in this proceeding. In addition, we note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198; *see* 44 U.S.C. 3506(c)(4), we previously sought specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees.

113. In this *Report and Order,* we have assessed the effects of transitioning inter- and intrastate originating 8YY end office and transport rates to bill-and-keep, and of adopting a single national rate for originating 8YY tandem switching and transport charges and database query charges and find that the tariff modifications required by our rules are both necessary and not overly burdensome. We believe that many carriers affected by this *Report and Order* will be small businesses and may employ less than 25 people. However, we find the benefits that will be realized by a decrease in the problematic consequences associated with 8YY abuse outweigh any burden associated with the changes (such as making tariff or billing revisions) required by this *Report and Order.*

114. *Congressional Review Act.* The Commission has determined, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, concurs that this rule is ''non-major''

under the Congressional Review Act, 5 U.S.C. 804(2). The Commission will send a copy of this *Report and Order* to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A).

115. *Final Regulatory Flexibility Analysis.* The Regulatory Flexibility Act as amended (RFA) requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' Accordingly, the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) concerning the possible impact of the rule changes contained in this *Report and Order* on small entities. The FRFA is set forth below.

Final Regulatory Flexibility Analysis

116. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *8YY FNPRM* in this proceeding released in June 2018. The Commission sought written public comments on the proposals in the *8YY FNPRM,* including comment on the IRFA. The Commission did not receive comments specifically directed as a response to the IRFA. However, the Commission did receive comments from NTCA–The Rural Broadband Association (NTCA), Iowa Network Services, Inc. d/b/a Aureon Network Services (Aureon), Public Knowledge, and FailSafe Communications, Inc., (FailSafe) relating to small entities. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

A. Need for, and Objectives of, the Report and Order (Order)

117. Arbitrage and fraud have a significant and increasing effect that undermines the intercarrier compensation system for 8YY calls. This arbitrage takes on a variety of forms, including traffic pumping schemes generating large numbers of illegitimate calls to toll free numbers, so-called benchmarking abuses where competitive local exchange carriers aggregate other carriers' 8YY traffic to hand it off to 8YY providers in areas where they can charge higher rates, and ''double dipping'' schemes where multiple Toll Free Database query charges are assessed when only one is needed. This 8YY arbitrage results in higher costs for 8YY providers and customers alike, and ultimately burdens consumers. Left unchecked, 8YY arbitrage threatens to undermine the broad array of useful toll free services on which consumers, businesses and other organizations commonly rely.

118. In the *Order,* the Commission takes steps to address these problems by, in some cases, reducing and, in others, eliminating, over time, most of the 8YY originating access charges that provide the underlying incentive for 8YY arbitrage schemes, consistent with the Commission's previous commitment to move all intercarrier compensation to bill-and-keep. The Commission moves 8YY originating end office access charges to bill-and-keep over three years, caps 8YY originating transport and tandem switching charges at a combined rate of $0.001 per minute, caps 8YY Database query charges needed to route 8YY calls and transitions these query charges to $0.0002 over three years, and prohibits carriers from assessing more than one query charge per 8YY call. We allow carriers to recover lost revenues from these 8YY access charge reductions to the extent existing mechanisms such as Access Recovery Charges and Connect America Fund Intercarrier Compensation allow. By striking at the root of these practices, we eliminate carriers' incentives to engage in arbitrage for 8YY calls. Our actions reduce the cost of 8YY calling overall, decrease inefficiencies in 8YY call routing and compensation, encourage the transition to IP-based networks, and diminish the frequency and costs of 8YY intercarrier compensation disputes. Additionally, the policies adopted in the *Order* will preserve the value of toll free services for both consumers and businesses.

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

119. No comments were filed in response to the IRFA. However, parties did file comments addressing the impact of proposals in the *8YY FNPRM* on small entities. NTCA, for example, expresses concern that the approach proposed by the Commission in the *8YY FNPRM* would shift financial responsibility to rural local exchange carriers (LECs) serving relatively small customer bases in remote rural areas for transport to reach distant points undermining universal service and maintaining reasonably comparable rates. NTCA urges the Commission to ensure that ''any such reforms in the future will not have a negative precedential impact on reasonable cost recovery otherwise and critical universal service objectives.'' NTCA also raises interconnection and ''network edge'' issues arising out of a transition to bill-and-keep. In addition, NTCA expresses concern that a move to bill-and-keep without default interconnection rules could create new opportunities for arbitrage and allow providers to dictate unilateral shifts in ''edges'' aimed at reducing their relative financial responsibilities for transport and thereby shift such costs instead on interconnecting carriers—and that rural local exchange carriers, serving small rural customer bases, were at particular risk of suffering serious harm from such arbitrage. As set forth in the *Order,* though our rules transition 8YY transport and tandem switching access charges incrementally toward bill-and-keep, interexchange carriers continue to be responsible for the payment of access charges during the transition. In addition, our rules provide a recovery mechanism for rate-of-return local exchange carriers' interstate revenue reduction. Further, we affirm that nothing we do in the *Order* is intended to affect or alter existing network edge arrangements, and as suggested by NTCA, we clarify that unilateral attempts by carriers to change network interconnection points may be unjust and unreasonable in violation of the Act, and carriers have no obligation to agree to such unilateral attempts to change interconnection points.

120. Aureon, a provider of centralized equal access (CEA) service in Iowa, argues that moving tandem switching and transport to bill-and-keep, as proposed in the *8YY FNPRM,* would not be ''just and reasonable'' under section 201(b) of the Communications Act of 1934, as amended (the Act) because bill-and-keep would amount to ''zero compensation'' for intermediate access providers that do not serve end users. Our adoption of a universal nationwide rate cap for originating 8YY tandem switching and transport obviates this concern by providing intermediate carriers with a regulated intercarrier compensation rate for 8YY calls, rather than moving to full bill-and-keep at this time. Public Knowledge argues that the increased cost and reduced revenues will make it harder for small rural local exchange carriers to meet the needs of rural customers, and would have a detrimental impact on the digital divide.

121. As explained in the *Order,* however, our rules provide a revenue recovery system for lost interstate 8YY revenue for the rate-of-return local exchange carriers about which Public Knowledge expresses concern and we leave it to the states to handle the substantially smaller impact on intrastate 8YY revenue. In addition, by tying 8YY-related rate changes to annual access tariff filings we minimize the cost

of implementing 8YY-related tariff revisions.

122. FailSafe, a provider of disaster recovery telecommunications solutions, for emergency response providers and a wide variety of enterprise customers, argues that ''[a]n overly-broad Order would destroy the only Disaster Recovery option available to millions of [small and medium-sized businesses]. At a minimum, it would price [small and medium-sized businesses] out of a Disaster Recovery/call overflow solution due to loss of the [carrier access billing] contribution'' and requests (1) an indefinite exemption from bill-and-keep for access traffic associated with small and medium-sized business end users with less than 24 phone lines and (2) a three-year transition to bill-and-keep for ''other services related to emergency communications.'' As the *Order* explains, to the extent that FailSafe's clients are the recipients of 8YY calls, they will benefit from lower access prices paid by their 8YY provider. To the extent FailSafe's business model relies on intermediate carriers being paid for tandem switching and transport, the *Order* provides a uniform tariffed rate for those services. Furthermore, FailSafe does not offer a justification for the broad waiver it requests for access traffic associated with small and medium-sized business end users, nor does it explain how such a waiver could be operationalized. As to FailSafe's request for a three-year transition to bill-and-keep for some services related to emergency communications, the *Order* provides for a three-year transition to bill-and-keep for all originating 8YY end office access charges.

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

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

124. The Chief Counsel did not file any comments in response to this proceeding.

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

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

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

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

128. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2017 Census of Governments indicate that there were 90,075 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number there were 36,931 general purpose governments (county, municipal and town or township) with populations of less than 50,000 and 12,040 special purpose governments—independent school districts with enrollment populations of less than 50,000. Accordingly, based on the 2017 U.S. Census of Governments data, we estimate that at least 48,971 entities fall into the category of ''small governmental jurisdictions.''

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

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

131. *Incumbent Local Exchange Carriers.* Neither the Commission nor the SBA has developed a small business size standard specifically for incumbent local exchange services. The closest applicable NAICS Code category is Wired Telecommunications Carriers. Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 indicate that 3,117 firms operated the entire year. Of this total,

3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses that may be affected by our actions. According to Commission data, one thousand three hundred and seven (1,307) incumbent local exchange carriers reported that they were incumbent local exchange service providers. Of this total, an estimated 1,006 have 1,500 or fewer employees. Thus, using the SBA's size standard the majority of incumbent local exchange carriers can be considered small entities.

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

133. We have included small incumbent local exchange carriers in this RFA analysis. As noted above, a ''small business'' under the RFA is one that, *inter alia,* meets the pertinent small business size standard (*e.g.,* a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent local exchange carriers are not dominant in their field of operation because any such dominance is not ''national'' in scope. We have therefore included small incumbent local exchange carriers in this RFA analysis, although we emphasize that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

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

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

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

137. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a definition for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable NAICS Code category is for Wired Telecommunications Carriers, as defined above. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. The applicable SBA size standard consists of all such companies having 1,500 or fewer employees. U.S. Census Bureau data for 2012 indicate that 3,117 firms operated during that year. Of that number, 3,083 operated with fewer than 1,000 employees. Thus, under this category and the associated small

business size standard, the majority of Other Toll Carriers can be considered small. According to internally developed Commission data, 284 companies reported that their primary telecommunications service activity was the provision of other toll carriage. Of these, an estimated 279 have 1,500 or fewer employees. Consequently, the Commission estimates that most Other Toll Carriers are small entities that may be affected by the rules proposed in the Notice.

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

139. *Wireless Telecommunications Carriers (except Satellite).* This industry is comprised of establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The appropriate size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. For this industry, U.S. Census Bureau data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms had employment of 999 or fewer employees and 12 had employment of 1,000 employees or more. Thus under this category and the associated size standard, the Commission estimates that the majority of Wireless Telecommunications Carriers (except Satellite) are small entities.

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

141. *Wireless Communications Services.* This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission defined ''small business'' for the wireless communications services (WCS) auction as an entity with average gross revenues of $40 million for each of the three preceding years, and a ''very small business'' as an entity with average gross revenues of $15 million for each of the three preceding years. The SBA has approved these small business size standards. In the Commission's auction for geographic area licenses in the WCS there were seven winning bidders that qualified as ''very small business'' entities, and one winning bidder that qualified as a ''small business'' entity.

142. *Wireless Telephony.* Wireless telephony includes cellular, personal communications services, and specialized mobile radio telephony carriers. The closest applicable SBA category is Wireless Telecommunications Carriers (except Satellite). Under the SBA small business size standard, a business is small if it has 1,500 or fewer employees. According to Commission data, 413 carriers reported that they were engaged in wireless telephony. Of these, an estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees. For this industry, U.S. Census Bureau data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms had fewer than 1,000 employees and 12 firms had 1,000 employees or more. Thus under this category and the associated size standard, the Commission estimates that a majority of these entities can be considered small. According to Commission data, 413 carriers reported that they were engaged in wireless telephony. Of these, an estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees. Therefore, more than half of these entities can be considered small.

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

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

144. *Recordkeeping and Reporting.* We take definitive steps to address the problems that plague 8YY intercarrier compensation by reducing or eliminating, over time, the intercarrier compensation charges that provide the underlying incentive for 8YY arbitrage schemes. We expect the requirements we adopt in the *Order* will impose some

additional compliance obligations on small entities. In the *Order,* the Commission adopts new rules for originating toll free access charges that will involve reduced 8YY originating access charges, the adoption of bill-and-keep, and the adoption of nationwide rate caps associated with 8YY traffic. Some of the changes involve a transitional period to complete implementation and will require modification of existing tariffs and filing of these tariff revisions. For small entities that may be affected, their compliance obligations may also include certain reporting and recordkeeping requirements to determine and establish their eligibility to receive revenue recovery from other sources as 8YY originating access revenue is reduced. The Commission believes the impacts of reporting, recordkeeping, and/or other compliance obligations on small entities will be mitigated by the greater certainty and reduced litigation that should occur as a result of the reforms adopted.

145. In the *Order,* the Commission moves 8YY originating end office access charges to bill-and-keep over approximately three years, caps 8YY originating transport and tandem switching charges at a combined rate of $0.001 per minute, caps 8YY Database query charges nationwide and transitions these query charges to $0.0002 over approximately three years, and prohibits carriers from assessing more than one query charge per 8YY call. Carriers are allowed to recover lost revenues from these 8YY calls to the extent existing mechanisms such as Access Recovery Charges and the Connect America Fund Intercarrier Compensation allow. By adopting policies that strike at the root of these practices, we eliminate carriers' incentives to engage in arbitrage for 8YY calls, thereby preserving the value of toll free services for both consumers and businesses.

146. The rule changes adopted in this *Order* will require affected carriers to revise their existing tariffs and internal billing systems. More specifically, carriers involved in originating toll free calls will be required to file tariff revisions to remove or revise their existing tariffs. Affected carriers will also need to file tariff revisions to modify toll free originating transport charges as these charges move to bill-and-keep. Tariff revisions will likewise be needed for the three-year transition period to bill-and-keep for toll free end office access charges. Similarly, carriers will need to file tariff revisions to implement the nationwide cap on 8YY Database queries and the three-year transition of these query charges to $0.0002 per query, as well as the rule change that allows only one carrier to assess the toll free database query charge per call. Carriers will also need to make tariff revisions to recover lost revenues from toll free calls to the extent existing mechanisms such as Access Recovery Charges and the Connect America Fund Intercarrier Compensation allow. Nevertheless, the Commission believes that with the changes to originating 8YY access charges and 8YY Database query charges, carriers' recordkeeping burdens may be reduced given the simplification of tariffing and billing that the *Order* entails. In particular, the three-year transition adopted by the Commission is timed to coincide with the annual access tariff filing dates to minimize the administrative burdens on small entities as well as other entities that are required to make such filings. These changes will require carriers to employ the same types of professional skills they typically employ whenever they file tariffs or make billing changes, including legal, accounting, and/or tariffing expertise.

147. With regard to the internal billing system changes that will be necessary for compliance with our *Order,* the cost of compliance will vary by carrier. Overall, the Commission estimates the costs necessary to update the affected carriers' billing systems will be approximately $6 million. This estimate is conservative since it is based on costs incurred by the largest carrier holding companies and the costs of modification of the most complicated systems. The $6 million industry-wide estimate results in approximately $7,000 of expense per carrier holding company. Since the Commission is not in a position to determine the actual costs for small entities, or for any specific entity for that matter, we have applied our conservative estimate to every holding company that may be impacted by decision. As we mention above, our estimate is based on requirements for the largest carrier holding companies, and thus the actual expense will likely be lower for small entities.

148. Notwithstanding the compliance costs that small entities will incur, on balance the Commission believes the benefits of its actions outweigh their costs. Consumers, 8YY customers, and carriers will benefit as we transition 8YY access charges toward bill-and-keep, thereby reducing the inefficiencies inherent in 8YY arbitrage, lowering 8YY access charges, causing prices of 8YY services to fall and innovation to increase, reducing 8YY congestion, encouraging network modernization, and reducing intercarrier compensation disputes. The ''competitive distortions inherent in the current system, eliminating carriers' ability to shift network costs to competitors and their customers,'' will also be reduced. Thus, the significant benefits of our actions more than compensate for the necessary costs imposed on small entities and other carriers.

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

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

150. As a general matter, actions taken as a result of our actions should benefit small entities as well as other service providers by reducing the inefficiencies inherent in 8YY arbitrage, providing greater regulatory certainty, and moving toward the Commission's goal of bill-and-keep for all access charges. Our tailored approach to allowing carriers different transition timeframes to implement our different rate changes is designed to balance the circumstances facing different carrier types and provide all carriers with the necessary predictability, certainty, and stability to transition from the current intercarrier compensation system.

151. *Transition Periods.* To minimize the impact of the changes to 8YY intercarrier compensation adopted in the *Order* on affected small entities, as well as other affected service providers we adopt multistep transition periods for transitioning originating 8YY end office access rates to bill-and-keep and 8YY Database query charges to no more than $0.0002 for an 8YY Database query. For end office access charges, we initially cap all intrastate originating 8YY end office rates not previously capped at their current levels as of the effective date of the *Order.* This first step will ensure against any rate increases during the transition and will benefit small entities and other service providers by giving parties time,

certainty, and stability as they adjust to the changes. Then, effective July 1, 2021, we require all local exchange carriers to bring any intrastate originating 8YY end office access rates that exceed the comparable interstate rates into parity with the comparable interstate rates. After reducing or capping intrastate 8YY end office rates, we will transition all intrastate and interstate originating 8YY end office charges from their capped amounts to bill-and-keep in two equal annual reductions. Effective July 1, 2022, we reduce all originating 8YY end office rates to half of their capped levels. Then, effective July 1, 2023, we reduce all originating 8YY end office rates to bill-and-keep.

152. In a similar fashion, small entities will benefit from the multistep, multiyear transition period to implement the 8YY Database query rate cap. Specifically, small entities will avoid the negative economic effects that might have resulted from imposing a ''flash cut'' to the new nationwide cap. Our actions which are consistent with prior Commission actions, will provide small entities with certainty and sufficient time to adapt to a changed regulatory landscape and will help minimize service disruptions. First, we cap all 8YY Database query charges not previously capped at their current levels as of the effective date of the *Order.* Second, we cap 8YY Database query rates for each carrier at the national average query rate of $0.004248 for those carriers whose capped database query rates are not already at or below $0.004248 or the rate capped in step one of the transition, if lower than $0.004248, effective July 1, 2021. This step will allow small entities and other carriers ample time to prepare to transition higher rates to the cap. Third, all 8YY Database query rates will be transitioned halfway to the final target rate of $0.0002. If a carrier's cap rate is below $0.004248, then it will use its capped rate to arrive at its rate effective July 1, 2022. Finally, effective July 1, 2023, carriers will not be allowed to charge more than $0.0002 for an 8YY Database query.

153. While the Commission proposed moving 8YY originating tandem switching and transport rates to bill-and-keep in the *8YY FNPRM,* we instead move rates for these services toward bill-and-keep by adopting a nationwide tariffed tandem switched transport access service rate cap of $0.001 per minute for originating 8YY traffic effective July 1, 2021. This approach avoids the economic hardship for small and other intermediate providers that do not serve end customers, and who would be uncompensated under bill-and-keep. Making the cap effective July 1, 2021 will reduce the administrative burdens for small entities and other carriers by allowing carriers to implement any necessary changes as part of their next set of annual tariff revisions. Further, the Commissions finds the adopted effective date will provide carriers with a reasonable timeframe in which to transition their rates to the $0.001 per minute cap and will allow for implementation of necessary changes to their billing systems. To avoid gamesmanship before July 1, 2021, however, we cap all existing toll free tandem switching and transport rates as of the effective date of the *Order.*

154. The multistep transition periods will allow carriers sufficient time to adapt to our new rules for 8YY calling and to spread the financial impact of these changes over three years. By gradually implementing these changes, we will avoid burdening small entities, and provide small carriers, as well as other carriers, with adequate time to adjust to the new rates, while at the same time minimizing existing arbitrage. We considered adopting shorter transitions or even no transitions as proposed in the record and rejected them because these proposed options would not allow carriers sufficient time to implement the changes we adopt to our system of 8YY intercarrier compensation rules. We also considered proposals in the record to allow longer transitions but rejected them since they would unnecessarily perpetuate the problem of 8YY arbitrage and the burdens it imposes on all carriers involved in 8YY calling.

155. Finally, as discussed in Section E, we recognize that carriers involved in providing toll free service may need to revise their internal billing systems to reflect the rate changes related to the actions in this *Order* and to file tariff revisions as necessary. Although we believe that internal billing system changes will be not be overly burdensome to make, we reiterate that the transitions we adopt today will ensure that small entities as well as other carriers have sufficient time, predictability, and certainty to transition their tariffs and billing systems to reflect the rates required by our new rules.

Report to Congress

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

III. Ordering Clauses

157. Accordingly, *it is ordered* that, pursuant to sections 1, 2, 4(i), 201–206, 251, 252, 254, 256, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 201–206, 251, 252, 254, 256, 303(r), 403, and § 1.1 of the Commission's rules, 47 CFR 1.1, this *Report and Order* is adopted.

158. *It is further ordered* that part 51 of the Commission's rules, 47 CFR part 51, *Is Amended* as set forth in the Final Rules, and that such rule amendments *shall be effective* thirty (30) days after publication of this *Report and Order* in the **Federal Register**, except for §§ 51.907(i)–(k), 51.909(l)–(o), and 51.911(e), which contain information collections that require approval by the Office of Management and Budget under the Paperwork Reduction Act. The Commission directs the Wireline Competition Bureau to announce the effective date for those information collections in a document published in the **Federal Register** after OMB approval, and directs the Wireline Competition Bureau to cause §§ 51.907, 51.909, and 51.911 of the Commission's rules to be revised accordingly.

159. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *Shall Send* a copy of this *Report and Order,* including the Final Regulatory Flexibility Analysis, to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

160. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *Shall Send* a copy of this *Report and Order,* including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 51

Communications common carriers, Telecommunications.

Federal Communications Commission.

Marlene Dortch,

Secretary.

Final Rules

For the reasons set forth above, the Federal Communications Commission amends part 51 of title 47 of the Code of Federal Regulations as follows:

PART 51—INTERCONNECTION

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 47 U.S.C. 151–55, 201–05, 207–09, 218, 225–27, 251–52, 271, 332 unless otherwise noted.

■ 2. Effective December 28, 2020, amend § 51.903 by adding paragraphs (n) through (p) to read as follows:

§ 51.903 Definitions.

* * * * *

(n) *Toll Free Database Query Charge* is a per query charge that is expressed in dollars and cents to access the Toll Free Service Management System Database, as defined in § 52.101(d) of this subchapter.

(o) *Toll Free Call* means a call to a Toll Free Number, as defined in § 52.101(f) of this subchapter.

(p) *Joint Tandem Switched Transport Access Service* is the rate element assessible for the transmission of toll free originating access service. The rate element includes both the transport between the end office and the tandem switch and the tandem switching. It does not include transport of traffic over dedicated transport facilities between the serving wire center and the tandem switching office.

■ 3. Effective December 28, 2020, amend § 51.905 by revising paragraph (b)(2) and adding paragraph (d) to read as follows:

§ 51.905 Implementation.

* * * * *

(b) * * *

(2) With respect to Transitional Intrastate Access Services, originating access charges for Toll Free Calls, and Toll Free Database Query Charges governed by this subpart, LECs shall follow the procedures specified by relevant state law when filing intrastate tariffs, price lists or other instruments (referred to collectively as ''tariffs'').

* * * * *

(d) Beginning July 1, 2021, and notwithstanding any other provision of the Commission's rules in this chapter, only the originating carrier in the path of the Toll Free Call may assess a Toll Free Database Query Charge for a Toll Free Call. When the originating carrier is unable to transmit the results of the Toll Free Database Query to the next carrier or provider in the call path, that next carrier or provider may instead assess a Toll Free Database Query Charge.

■ 4. Delayed until publication of a document announcing the effective date, amend § 51.907 by adding paragraphs (i) through (k) to read as follows:

§ 51.907 Transition of price cap carrier access charges.

* * * * *

(i) *8YY Transition—Step 1.* Beginning July 1, 2021, and notwithstanding any other provision of the Commission's rules in this chapter, each Price Cap Carrier shall:

(1) Establish separate rate elements for interstate and intrastate toll free originating end office access service and non-toll free originating end office access service. Rate elements reflecting fixed charges associated with originating End Office Access Service shall be treated as non-toll free charges.

(2) Reduce its intrastate toll free originating end office access service rates to its interstate toll free originating end office access service rates as follows:

(i) Calculate total revenue from End Office Access Service, excluding non-usage-based rate elements, at the carrier's interstate access rates in effect on June 30, 2020, using intrastate switched access demand for each rate element for the 12 months ending June 30, 2020.

(ii) Calculate total revenue from End Office Access Service, excluding non-usage based rate elements, at the carrier's intrastate access rates in effect on June 30, 2020, using intrastate switched access demand for each rate element for the 12 months ending June 30, 2020.

(iii) If the value in paragraph (i)(2)(ii) of this section is less than or equal to the value in paragraph (i)(2)(i) of this section, the Price Cap Carrier's intrastate End Office Access Service rates shall remain unchanged.

(iv) If the value in paragraph (i)(2)(ii) of this section is greater than the value in paragraph (i)(2)(i) of this section, the Price Cap Carrier shall reduce intrastate rates for End Office Access Service so that they are equal to the Price Cap Carrier's functionally equivalent interstate rates for End Office Access Rates and shall be subject to the interstate rate structure and all subsequent rate and rate structure modifications.

(v) Except as provided in paragraph (i)(2) of this section, nothing in this section allows a Price Cap Carrier that has intrastate rates lower than its functionally equivalent interstate rates to make any intrastate tariff filing or intrastate tariff revisions to increase such rates. If a Price Cap Carrier has an intrastate rate for an End Office Access Service rate element that is below the comparable interstate rate for that element, the Price Cap Carrier may, if necessary as part of a restructuring to reduce its intrastate rates for End Office Access Service down to parity with functionally equivalent interstate rates, increase the rate for an intrastate rate element that is below the comparable interstate rate for that element to the interstate rate in effect on July 1, 2021.

(3) Establish separate rate elements for interstate and intrastate non-toll free originating transport services for service between an end office switch and the tandem switch and remove its rate for intrastate and interstate originating toll free transport services consistent with a bill-and-keep methodology (as defined in § 51.713).

(4) Establish separate rate elements respectively for interstate and intrastate non-toll free originating tandem switching services.

(5) Establish transitional interstate and intrastate Joint Tandem Switched Transport Access Service rate elements for Toll Free Calls that are respectively no more than $0.001 per minute.

(6) Reduce its interstate and intrastate rates for Toll Free Database Query Charges to no more than $0.004248 per query. Nothing in this section obligates or allows a Price Cap Carrier that has Toll Free Database Query Charges lower than this rate to make any intrastate or interstate tariff filing revision to increase such rates.

(j) *8YY Transition—Step 2.* Beginning July 1, 2022, and notwithstanding any other provision of the Commission's rules in this chapter, each Price Cap Carrier shall:

(1) Reduce its interstate and intrastate rates for all originating End Office Access Service rate elements for Toll Free Calls in each state in which it provides such service by one-half of the maximum rate allowed by paragraph (a) of this section; and

(2) Reduce its rates for intrastate and interstate Toll Free Database Query Charges by one-half of the difference between the rate permitted by paragraph (i)(6) of this section and the transitional rate of $0.0002 per query set forth in paragraph (k)(2) of this section.

(k) *8YY Transition—Step 3.* Beginning July 1, 2023, and notwithstanding any other provision of the Commission's rules in this chapter, each Price Cap Carrier shall:

(1) In accordance with a bill-and-keep methodology, refile its interstate switched access tariff and any state tariff to remove any intercarrier charges for intrastate and interstate originating End Office Access Service for Toll Free Calls; and

(2) Reduce its rates for all intrastate and interstate Toll Free Database Query Charges to a transitional rate of no more than $0.0002 per query.

■ 5. Delayed until publication of a document announcing the effective date, amend § 51.909 by adding paragraphs (l) through (o) to read as follows:

§ 51.909 Transition of rate-of-return carrier access charges.

* * * * *

(l) *8YY Transition—Step 1.* As of December 28, 2020, each rate-of-return carrier shall cap the rate for all intrastate originating access charge rate elements for Toll Free Calls, including for Toll Free Database Query Charges.

(m) *8YY Transition—Step 2.* Beginning July 1, 2021, and notwithstanding any other provision of the Commission's rules in this chapter, each Rate-of-Return Carrier shall:

(1) Establish separate rate elements for interstate and intrastate toll free originating end office access service and non-toll free originating end office access service. Rate elements reflecting fixed charges associated with originating End Office Access Service shall be treated as non-toll free charges.

(2) Reduce its intrastate toll free originating end office access service rates to its interstate toll free originating end office access service rates as follows:

(i) Calculate total revenue from End Office Access Service, excluding non-usage-based rate elements, at the carrier's interstate access rates in effect on June 30, 2020, using intrastate switched access demand for each rate element for the 12 months ending June 30, 2020.

(ii) Calculate total revenue from End Office Access Service, excluding non-usage based rate elements, at the carrier's intrastate access rates in effect on June 30, 2020, using intrastate switched access demand for each rate element for the 12 months ending June 30, 2020.

(iii) If the value in paragraph (m)(2)(ii) of this section is less than or equal to the value in paragraph (m)(2)(i) of this section, the Rate-of-Return Carrier's intrastate End Office Access Service rates shall remain unchanged.

(iv) If the value in paragraph (m)(2)(ii) of this section is greater than the value in paragraph (m)(2)(i) of this section, the Rate-of-Return Carrier shall reduce intrastate rates for End Office Access Service so that they are equal to the Rate-of-Return Carrier's functionally equivalent interstate rates for End Office Access Rates and shall be subject to the interstate rate structure and all subsequent rate and rate structure modifications.

(v) Except as provided in paragraph (m)(2) of this section, nothing in this section allows a Rate-of-Return Carrier that has intrastate rates lower than its functionally equivalent interstate rates to make any intrastate tariff filing or intrastate tariff revisions to increase such rates. If a Rate-of-Return Carrier has an intrastate rate for an End Office Access Service rate element that less than the comparable interstate rate for that element, the Rate-of-Return Carrier may, if necessary as part of a restructuring to reduce its intrastate rates for End Office Access Service down to parity with functionally equivalent interstate rates, increase the rate for an intrastate rate element that is below the comparable interstate rate for that element to the interstate rate on July 1, 2021.

(3) Establish separate rate elements for interstate and intrastate non-toll free originating transport services for service between an end office switch and the tandem switch and remove its rate for intrastate and interstate originating toll free transport services consistent with a bill-and-keep methodology (as defined in § 51.713).

(4) Establish separate rate elements respectively for interstate and intrastate non-toll free originating tandem switching services.

(5) Establish transitional interstate and intrastate Joint Tandem Switched Transport Access rate elements for Toll Free Calls that are respectively no more than $0.001 per minute.

(6) Reduce its interstate and intrastate rates for Toll Free Database Query Charges to no more than $0.004248 per query. Nothing in this section obligates or allows a Rate-of-Return carrier that has Toll Free Database Query Charges lower than this rate to make any intrastate or interstate tariff filing revision to increase such rates.

(n) *8YY Transition—Step 3.* Beginning July 1, 2022, and notwithstanding any other provision of the Commission's rules in this chapter, each Rate-of-Return Carrier shall:

(1) Reduce its interstate and intrastate rates for all originating End Office Access Service rate elements for Toll Free Calls in each state in which it provides such service by one-half of the maximum rate allowed by paragraph (a) of this section; and

(2) Reduce its rates for intrastate and interstate Toll Free Database Query Charges by one-half of the difference between the rate permitted by paragraph (m)(6) of this section and the transitional rate of $0.0002 per query set forth in paragraph (o)(2) of this section.

(o) *8YY Transition—Step 4.* Beginning on July 1, 2023, and notwithstanding any other provision of the Commission's rules in this chapter, each Rate-of-Return Carrier shall:

(1) In accordance with a bill-and-keep methodology, refile its interstate switched access tariff and any state tariff to remove any intercarrier charges for all intrastate and interstate originating End Office Access Service for Toll Free Calls; and

(2) Reduce its rates for all intrastate and interstate Toll Free Database Query Charges to a transitional rate of no more than $0.0002 per query.

■ 6. Amend § 51.911 by:

■ a. Effective December 28, 2020, adding paragraphs (d); and

■ b. Delayed until publication of a document announcing the effective date, adding paragraph (e).

The additions read as follows:

§ 51.911 Access reciprocal compensation rates for competitive LECs.

* * * * *

(d) *Cap on Database Query Charge.* A Competitive Local Exchange Carrier assessing a tariffed intrastate or interstate Toll Free Database Query Charge shall cap such charge at the rate in effect on December 28, 2020.

(e) *Transition of cap on Database Query Charge.* Beginning July 1, 2021, notwithstanding any other provision of the Commission's rules in this chapter, a Competitive Local Exchange Carrier assessing a tariffed intrastate or interstate Toll Free Database Query Charge shall revise its tariffs as necessary to ensure that its intrastate and interstate Toll Free Database Query Charges do not exceed the rates charged by the competing incumbent local exchange carrier, as defined in § 61.26(a)(2) of this chapter.

[FR Doc. 2020–24624 Filed 11–25–20; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 141107936–5399–02; RTID 0648–XA653]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; 2020 Commercial Closure for South Atlantic Gray Triggerfish

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure for the commercial sector of gray triggerfish in the South Atlantic exclusive economic zone (EEZ). NMFS projects commercial landings of gray triggerfish will reach the commercial annual catch limit (ACL) for the July through December season by November 29, 2020. Therefore, NMFS is closing the commercial sector for gray triggerfish in the South Atlantic EEZ on November 29, 2020. This closure is necessary to protect the gray triggerfish resource.

DATES: This temporary rule is effective at 12:01 a.m., local time, on November 29, 2020, through December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes gray triggerfish and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. All weights in this temporary rule are given in round weight.

The commercial ACL (equivalent to the commercial quota) for gray triggerfish in the South Atlantic is divided into two 6-month fishing seasons. The total commercial ACL of 312,324 lb (141,668 kg) is allocated 50 percent to each commercial fishing season, or 156,162 lb (70,834 kg) for January through June, and the same amount for July through December, as specified in 50 CFR 622.190(a)(8)(i) and (ii).

After the January through June 2020 fishing season, 25,468 lb (11,552 kg) of the gray triggerfish commercial quota remained unharvested. As specified in 50 CFR 622.190(a)(8)(iii), NMFS added this unused portion of the gray triggerfish commercial quota to the commercial quota for the July through December 2020 fishing season. Therefore, the gray triggerfish commercial quota for the July through December 2020 fishing season is 181,630 lb (82,385 kg). Any unused commercial quota for the July through December fishing season becomes void and will not be added to any subsequent quota (622.190(a)(8)(iii)).

Under 50 CFR 622.193(q)(1)(i), NMFS is required to close the commercial sector for gray triggerfish when the commercial quota specified in 50 CFR 622.190(a)(8)(ii) is reached or is projected to be reached by filing a notification to that effect with the Office of the Federal Register. NMFS has determined that the commercial quota for South Atlantic gray triggerfish for the July through December 2020 fishing season will be reached by November 29, 2020. Accordingly, the commercial sector for South Atlantic gray triggerfish is closed effective at 12:01 a.m., local time, on November 29, 2020, and remains closed until the start of the next January through June fishing season on January 1, 2021.

The operator of a vessel with a valid Federal commercial vessel permit for South Atlantic snapper-grouper with gray triggerfish on board must have landed and bartered, traded, or sold such gray triggerfish prior to 12:01 a.m., local time, on November 29, 2020. During the commercial closure, the recreational bag limit specified in 50 CFR 622.187(b)(8), and the recreational possession limits specified in 50 CFR 622.187(c), apply to all harvest or possession of gray triggerfish in or from the South Atlantic EEZ. Also during the commercial closure, the sale or purchase of gray triggerfish taken from the South Atlantic EEZ is prohibited. The prohibition on the sale or purchase does not apply to gray triggerfish that were harvested, landed ashore, and sold prior to 12:01 a.m., local time, on November 29, 2020, and were held in cold storage by a dealer or processor.

For a person on board a vessel for which a valid Federal commercial or charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, the bag and possession limits and sale and purchase prohibitions for gray triggerfish apply regardless of whether the fish are harvested in state or Federal waters, as specified in 50 CFR 622.190(c)(1)(ii).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 622.193(q)(1)(i), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment as such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the regulations associated with the commercial quota for South Atlantic gray triggerfish have already been subject to notice and comment, and all that remains is to notify the public of the commercial closure for the remainder of the July through December 2020 fishing season. Prior notice and opportunity for public comment on this action is contrary to the public interest because of the need to immediately implement the commercial closure to protect South Atlantic gray triggerfish, since the capacity of the fishing fleet allows for rapid harvest of the commercial quota. Prior notice and opportunity for public comment would require time and would potentially result in a harvest that exceeds the commercial quota.

For the aforementioned reasons, there is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in the effective date of this action.

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

Dated: November 23, 2020.

Jennifer M. Wallace,

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

[FR Doc. 2020–26233 Filed 11–24–20; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02]

RTID 0648–XA652

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS is transferring 19.5 metric tons (mt) of Atlantic bluefin tuna (BFT) quota from the Reserve category to the General category. This action is intended to provide additional opportunities for General category fishermen to participate in the December General category fishery, which is scheduled to reopen on December 1, 2020, and is based on consideration of the regulatory determination criteria regarding inseason adjustments. This action would affect Atlantic tunas General category (commercial) permitted vessels

and Highly Migratory Species (HMS) Charter/Headboat category permitted vessels with a commercial sale endorsement when fishing commercially for BFT.

DATES: Effective December 1, 2020, through December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin or Nicholas Velseboer, 978–281–9260, or Larry Redd, 301–427–8503.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and amendments. NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.

The current baseline General and Reserve category quotas are 555.7 mt and 29.5 mt, respectively. See § 635.27(a). Each of the General category time periods (January, June through August, September, October through November, and December) is allocated a ''subquota'' or portion of the annual General category quota. The baseline subquotas for each time period are as follows: 29.5 mt for January; 277.9 mt for June through August; 147.3 mt for September; 72.2 mt for October through November; and 28.9 mt for December. Any unused General category quota rolls forward from one time period to the next and is available for use in subsequent time periods. To date for 2020, NMFS has taken several actions that resulted in adjustments to the General and Reserve category quotas, leaving 20 mt of quota currently available in the Reserve category (85 FR 17, January 2, 2020; 85 FR 6828, February 6, 2020; 85 FR 43148, July 16, 2020; 85 FR 59445, September 22, 2020; 85 FR 61872, October 1, 2020; 85 FR 64411, October 13, 2020; and 85 FR 68798, October 30, 2020).

For the January 2020 subquota period, NMFS transferred 19.5 mt of BFT quota from the December 2020 subquota period, and transferred 51 mt from the Reserve category, resulting in an adjusted subquota of 100 mt for the January 2020 period and a subquota of 9.4 mt for the December 2020 period (85 FR 17, January 2, 2020, and 85 FR 6828, February 6, 2020). The General category fishery is currently closed and reopens December 1, 2020.

Transfer of 19.5 mt From the Reserve Category to the General Category

Under § 635.27(a)(9), NMFS has the authority to transfer quota among fishing categories or subcategories, after considering regulatory determination criteria provided under § 635.27(a)(8). NMFS has considered all of the relevant determination criteria and their applicability to this inseason quota transfer. These considerations include, but are not limited to, the following:

Regarding the usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock (§ 635.27(a)(8)(i)), biological samples collected from BFT landed by General category fishermen and provided by BFT dealers continue to provide valuable data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. Additional opportunity to land BFT in the General category would support the collection of a broad range of data for these studies and for stock monitoring purposes.

NMFS also considered the catches of the General category quota to date (including during the summer/fall and winter fisheries in the last several years), and the likelihood of closure of that segment of the fishery if no adjustment is made (§ 635.27(a)(8)(ii) and (ix)). Preliminary landings data as of November 16, 2020, indicate that the General category has landed approximately 818 mt this year, which is also the total of the adjusted subquotas for the January through November time period. Absent a transfer, the December General category fishery would reopen on December 1 with an available quota of 9.4 mt, which, depending on BFT availability and fishing conditions, could be harvested quickly. Transferring 19.5 mt of BFT quota from the Reserve category would result in 28.9 mt being available to the General category in December, restoring the December subquota to its base amount prior to the January 2, 2020 action (85 FR 17), and would leave 0.5 mt in the Reserve category to account for any BFT mortalities associated with research.

Regarding the projected ability of the vessels fishing under the particular category quota (here, the General category) to harvest the additional amount of BFT quota transferred before the end of the fishing year (§ 635.27(a)(8)(iii)), NMFS considered General category landings over the last several years and landings to date this year. Landings are highly variable and depend on access to commercial-sized BFT and fishing conditions, among other factors. NMFS anticipates that General category participants will be able to harvest the 19.5 mt of transferred BFT quota by the end of the fishing year.

NMFS also considered the estimated amounts by which quotas for other gear categories of the fishery might be exceeded (§ 635.27(a)(8)(iv)) and the ability to account for all 2020 landings and dead discards. In the last several years, total U.S. BFT landings have been below the available U.S. quota such that the United States has carried forward the maximum amount of underharvest allowed by ICCAT from one year to the next. NMFS will need to account for 2020 landings and dead discards within the adjusted U.S. quota, consistent with ICCAT recommendations, and anticipates having sufficient quota to do that, even with this 19.5 mt transfer to the General category. Thus, this quota transfer would allow fishermen to take advantage of the availability of fish on the fishing grounds to the extent consistent with the available amount of transferrable quota and other management objectives, while avoiding quota exceedance.

NMFS also considered the effects of the adjustment on the BFT stock and the effects of the transfer on accomplishing the objectives of the FMP (§ 635.27(a)(8)(v) and (vi)). This transfer would be consistent with the current quotas, which were established and analyzed in the 2018 BFT quota final rule (83 FR 51391, October 11, 2018), and with objectives of the 2006 Consolidated HMS FMP and amendments and is not expected to negatively impact stock health or to affect the stock in ways not already analyzed in those documents. Another principal consideration is the objective of providing opportunities to harvest the full annual U.S. BFT quota without exceeding it based on the goals of the 2006 Consolidated HMS FMP and amendments, including to achieve optimum yield on a continuing basis and to optimize the ability of all permit categories to harvest their full BFT quota allocations (related to

§ 635.27(a)(8)(x)). Specific to the General category, this includes providing opportunity equitably across all time periods.

Based on the considerations above, NMFS is transferring 19.5 mt from the Reserve category to the General category. Therefore, NMFS adjusts the General category December 2020 subquota quota to 28.9 mt and adjusts the Reserve category quota to 0.5 mt. The General category fishery reopens December 1, 2020, and will remain open until December 31, 2020, or until the adjusted General category quota is reached, whichever comes first.

Monitoring and Reporting

NMFS will continue to monitor the BFT fishery closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustment, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat category vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing *hmspermits.noaa.gov* or by using the HMS Catch Reporting app, or calling (888) 872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional action (*e.g.,* closure) is necessary to ensure available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281–9260, or access *hmspermits.noaa.gov,* for updates on quota monitoring and inseason adjustments.

NMFS reminds General category participants that when the fishery reopens December 1, 2020, the BFT General category daily retention limit will be one large medium or giant BFT per vessel per day/trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 635, which was issued pursuant to section 304(c), and is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason quota transfers to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Affording prior notice and opportunity for public comment to implement the quota transfer for the December 2020 subquota period at this time is impracticable and contrary to the public interest as NMFS could not have proposed this action earlier, as it needed to consider and respond to updated landings data in deciding to transfer a portion of the Reserve quota to the General category quota. If NMFS was to offer a public comment period now, after having appropriately considered that data, it could preclude fishermen from harvesting BFT that are legally available consistent with all of the regulatory criteria. This action does not raise conservation and management concerns. Transferring quota from the Reserve category to the General category does not affect the overall U.S. BFT quota, and available data shows the adjustment would have a minimal risk of exceeding the ICCAT-allocated quota. NMFS notes that the public had an opportunity to comment on the underlying rulemakings that established the U.S. BFT quota and the inseason adjustment criteria. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: November 23, 2020.

Jennifer M. Wallace,

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

[FR Doc. 2020–26218 Filed 11–25–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 201119–0308]

RIN 0648–BI04

Fisheries Off West Coast States; West Coast Salmon Fisheries; Rebuilding Chinook Salmon Stocks

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

ACTION: Final rule.

SUMMARY: NMFS issues a final rule under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) to approve and implement rebuilding plans recommended by the Pacific Fishery Management Council (Council) for two overfished salmon stocks: Klamath River fall-run Chinook salmon (KRFC) and Sacramento River fall-run Chinook salmon (SRFC). NMFS determined in 2018 that these stocks were overfished under the MSA, due to spawning escapement falling below the required level for the three-year period 2015–2017. The MSA requires overfished stocks to be rebuilt, generally within 10 years.

DATES: This final rule is effective December 28, 2020.

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

SUPPLEMENTARY INFORMATION:

Background

In June 2018, NMFS determined that two stocks of Chinook salmon managed under the Council's Pacific Coast Salmon Fishery Management Plan (FMP) met the overfished criteria of the FMP and the MSA. Overfished is defined in the FMP to be when the three-year geometric mean of a salmon stock's annual spawning escapements falls below the reference point known as the minimum stock size threshold (MSST). The three-year geometric mean of spawning escapement fell below MSST for both KRFC and SRFC salmon stocks for the period 2015–2017. In response to the overfished determination, the Council developed rebuilding plans for these stocks, which were transmitted to NMFS for approval and implementation. NMFS published a proposed rule (85 FR 6135, February 4, 2020) describing the rebuilding plans and soliciting comments from the public on the proposed rule and on the draft environmental assessments (EA) that were prepared under the National Environmental Policy Act (NEPA).

Response to Comments

NMFS published a proposed rule on February 4, 2020 (85 6135) and related draft EAs for public comment. The comment period ended on March 5, 2020. NMFS received four public comment submissions from individuals on the proposed rule and no comments on the draft EA. The comments and responses are below.

Comment 1: One person objected to NOAA's management of salmon stocks

and said NOAA failed to protect salmon from exploitation in commercial fisheries.

Response: NOAA's NMFS disagrees that there was a failure to protect salmon from exploitation in commercial fisheries. NMFS is responsible for implementing the MSA to manage the nation's fisheries in a sustainable manner, including rebuilding overfished stocks. NMFS works with the Council to manage West Coast salmon stocks according to conservation objectives and status determination criteria specified in the FMP. It is through these measures that NMFS and the Council recognized the overfished situation for KRFC and SRFC and are managing fisheries to rebuild these stocks consistent with the provisions of the MSA. Annual management measures for ocean salmon fisheries are informed by annual stock abundance projections using the best available science, including analyses by the Council's Salmon Technical Team and Scientific and Statistical Committee. The management measures apportion the ocean harvest equitably among treaty Indian, non-treaty commercial, and recreational fisheries. The measures are also intended to allow a portion of the salmon runs to escape the ocean fisheries in order to provide for spawning escapement and to provide fishing opportunity in state waters.

Comment 2: One person wrote to support ''replenishing of the fish stocks'' and hopes for sustainable populations for the future.

Response: Sustainability is key to NMFS' mission and the cornerstone of the MSA. These rebuilding plans have been prepared to be consistent with the provisions of the MSA, and the Council and NMFS assess salmon stocks annually to assure fisheries are being managed in a sustainable manner.

Comment 3: One person supported the regulation of fisheries and acknowledged that environmental factors which contribute to fish mortality complicate fishery management. This person supports banning or highly regulating fisheries during rebuilding and additional research into salmon mortality from environmental causes and possible solutions.

Response: NMFS does not support banning fisheries in response to the current overfished status of KRFC and SRFC at this time. The Council and NMFS considered a no-fishing alternative. The estimated time to rebuild either of these Chinook salmon stocks under a no-fishing scenario was only one year shorter than under the Council's recommended alternative. The MSA requires the Secretary of Commerce to consider the needs of fishing communities in implementing a rebuilding plan. A no-fishing scenario, for either KRFC or SRFC, would include a total closure of ocean salmon fisheries from Cape Falcon, OR to the U.S./Mexico border, resulting in an estimated loss of $46 million per year to fishing communities. NMFS can only regulate fisheries in the exclusive economic zone (3 to 200 nmi—5.6 to 370.4 km—offshore) and does not have regulatory authority over fisheries shoreward of 3 nmi and in-river fisheries; therefore, NMFS does not have the authority to implement a rebuilding plan that would have no fishing-related mortality on the overfished Chinook salmon stocks since in-river freshwater fishing-related mortality would likely continue. Therefore, in consideration of these factors, NMFS is approving the Council's recommendation as the rebuilding plan that will rebuild the stocks in the shortest amount of time while taking into consideration the needs of fishing communities.

Comment 4: One person objected strongly to the use of the term ''overfished.'' This person called on NMFS to identify lack of coordination among various agencies on water discharge to benefit salmon as the cause of salmon decline.

Response: NMFS understands the concern regarding the term overfished. Under the MSA, a stock or stock complex is considered overfished when its biomass has declined below MSST (50 CFR 600.310(e)(2)(i)(E)), irrespective of the cause of the decline. NMFS supports coordination among agencies to improve salmon productivity. The Council and NMFS considered several possible factors in the decline of the overfished Chinook salmon stocks and, as stated in the proposed rule (85 FR 6135, February 4, 2020), found that the overfished condition was due to: (1) Low flows and high water temperatures in the freshwater environment which resulted in low smolt survival for both stocks, disease issues in the Klamath River, and pre-spawn mortality of migrating adults in the Sacramento River; (2) warm, unproductive ocean conditions that compromised survival in the marine environment for both stocks; (3) hatchery practices in the Sacramento River that resulted in straying of migrating salmon which lead to higher than expected in-river fishing mortality for SRFC; and (4) stock assessment errors that resulted in over-forecasting of SRFC and underpredictions of both ocean and in-river fishery mortality rates.

Changes From Proposed Rule

There are no substantive changes made to the regulatory text from the proposed rule, beyond nonsubstantive editorial changes.

Classification

Pursuant to section 304(b)(1)(A) of the MSA, the NMFS Assistant Administrator has determined that this final rule is consistent with the FMP, other provisions of the MSA, and other applicable law.

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

This proposed rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

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

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

This final rule was developed after meaningful collaboration with the tribal representative on the Council who has agreed with the provisions that apply to tribal vessels.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: November 19, 2020.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, 50 CFR part 660 is amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 773 *et seq.,* and 16 U.S.C. 7001 *et seq.*

■ 2. Add § 660.413 to read as follows:

§ 660.413 Overfished species rebuilding plans.

For each overfished salmon stock with an approved rebuilding plan, annual management measures will be established using the standards in this section, specifically the target date for rebuilding the stock to its maximum sustainable yield (MSY) level (generally expressed as S_{MSY}) and the harvest control rule to be used to rebuild the stock.

(a) *Klamath River Fall-run Chinook Salmon (KRFC).* KRFC was declared overfished in 2018. The target year for rebuilding the KRFC stock is 2020. The harvest control rule during the rebuilding period for the KRFC stock is the *de minimis* control rule specified in the FMP and at § 660.410(c), which allows for limited fishing impacts when abundance falls below S_{MSY}. The control rule describes maximum allowable exploitation rates at any given level of abundance. The control rule is presented in Figure 1 of subpart H of this part.

(1) The KRFC control rule uses reference points F_{ABC} MSST, S_{MSY}, and two levels of *de minimis* exploitation rates, F = 0.10 and F = 0.25. The maximum allowable exploitation rate, F, in a given year, depends on the pre-fishery ocean abundance in spawner equivalent units, N. At high abundance, the control rule caps the exploitation rate at $F_{ABC\geqq}$ at moderate abundance, the control rule specifies an F that results in S_{MSY} spawners; and at low abundance (*i.e.* when expected escapement is below S_{MSY}), the control rule allows for *de minimis* exploitation rates with the abundance breakpoints defined as: A = MSST/2; B = (MSST + S_{MSY})/2; C = S_{MSY}/(1—0.25); D = S_{MSY}/(1—F_{ABC}), as shown in Figure 1 of subpart H of this part. For N between 0 and A, F increases linearly from 0 at N = 0, to 0.10 at N = A. For N between A and MSST, F is equal to 0.10. For N between MSST and B, F increases linearly from 0.10 at N = MSST, to 0.25 at N = B. For N between B and C, F is equal to 0.25. For N between C and D, F is the value that results in S_{MSY} spawners. For N greater than D, F is equal to F_{ABC}.

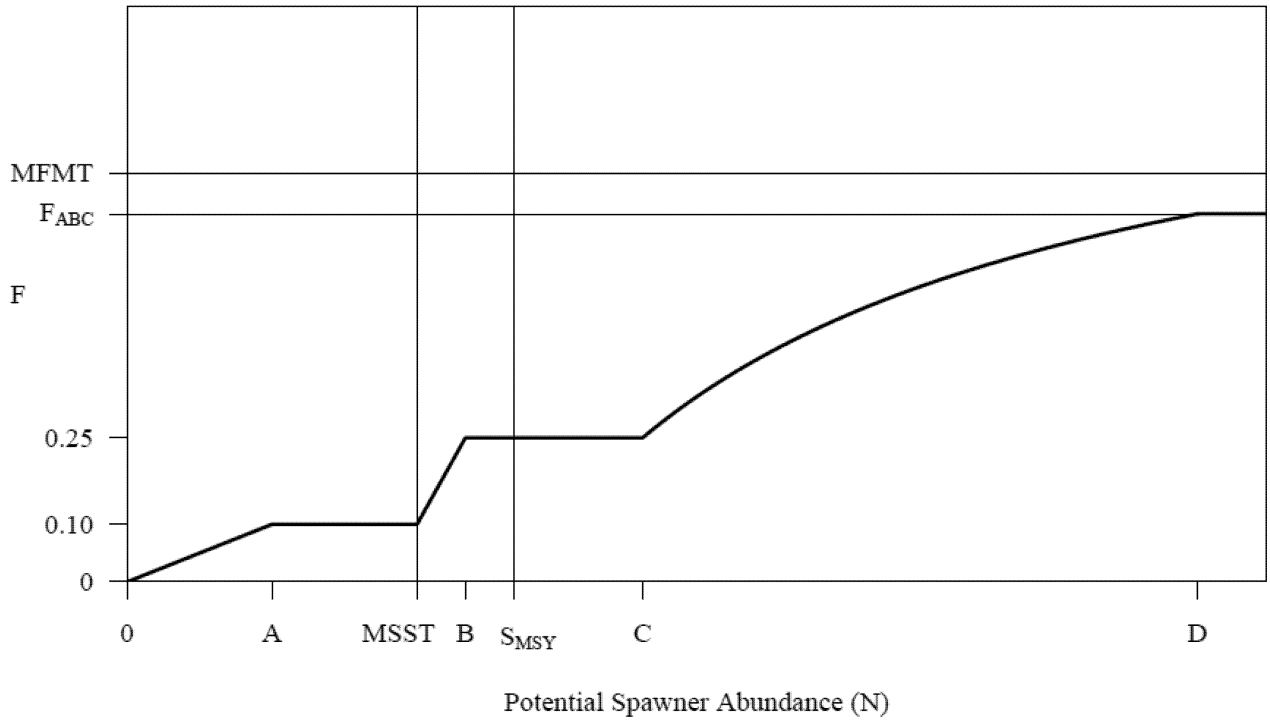
(2) [Reserved]

(b) *Sacramento River Fall-run Chinook Salmon (SRFC).* SRFC was declared overfished in 2018. The target year for rebuilding the SRFC stock is 2021. The harvest control rule during the rebuilding period for the SRFC stock is the *de minimis* control rule specified in the FMP and at § 660.410(c), which allows for limited fishing impacts when abundance falls below S_{MSY}. The control rule describes maximum allowable exploitation rates at any given level of abundance.

(1) The SRFC control rule uses the reference points F_{ABC}, MSST, S_{MSY}, and two levels of *de minimis* exploitation rates, F = 0.10 and F = 0.25. The maximum allowable exploitation rate, F, in a given year, depends on the pre-fishery ocean abundance in spawner equivalent units, N. At high abundance, the control rule caps the exploitation rate at $F_{ABC\geqq}$ at moderate abundance, the control rule specifies an F that results in S_{MSY} spawners; and at low abundance (*i.e.* when expected escapement is below S_{MSY}), the control rule allows for *de minimis* exploitation rates with the abundance breakpoints defined as: A = MSST/2; B = (MSST + S_{MSY})/2; C = S_{MSY}/(1—0.25); D = S_{MSY}/(1—F_{ABC}), as shown in Figure 1 of subpart H of this part. For N between 0 and A, F increases linearly from 0 at N = 0, to 0.10 at N = A. For N between A and MSST, F is equal to 0.10. For N between MSST and B, F increases linearly from 0.10 at N = MSST, to 0.25 at N = B. For N between B and C, F is equal to 0.25. For N between C and D, F is the value that results in S_{MSY} spawners. For N greater than D, F is equal to F_{ABC}.

(2) [Reserved]

Figure 1 to § 660.413 – Harvest Control Rule for Klamath River Fall-Run Chinook Salmon and Sacramento River Fall-Run Chinook Salmon



[FR Doc. 2020–26042 Filed 11–25–20; 8:45 am]
BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 200227–0066]

RTID 0648–XA676

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific ocean perch in the Eastern Aleutian district (EAI) of the Bering Sea and Aleutian Islands management area (BSAI) by vessels participating in the BSAI trawl limited access sector fishery. This action is necessary to prevent exceeding the 2020 total allowable catch (TAC) of Pacific ocean perch in the EAI allocated to vessels participating in the BSAI trawl limited access sector fishery.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), November 23, 2020, through 2400 hrs, A.l.t., December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2020 TAC of Pacific ocean perch, in the EAI, allocated to vessels participating in the BSAI trawl limited access sector fishery was established as a directed fishing allowance of 938 metric tons by the final 2020 and 2021 harvest specifications for groundfish in the BSAI (85 FR 13553, March 9, 2020).

In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch in the EAI by vessels participating in the BSAI trawl limited access sector fishery. While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA) finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such a requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of the Pacific ocean perch directed fishery in the EAI for vessels participating in the BSAI trawl limited access sector fishery. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 19, 2020.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: November 23, 2020.

Jennifer M. Wallace,

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

[FR Doc. 2020–26217 Filed 11–23–20; 4:15 pm]
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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 200227–0066]

RTID 0648–XA675

Fisheries of the Exclusive Economic Zone Off Alaska; Atka Mackerel in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Atka mackerel in the Bering Sea subarea and Eastern Aleutian District (BS/EAI) of the Bering Sea and Aleutian Islands management area (BSAI) by vessels participating in the BSAI trawl limited access sector fishery. This action is necessary to prevent exceeding the 2020 total allowable catch (TAC) of Atka mackerel in the BS/EAI allocated to vessels participating in the BSAI trawl limited access sector fishery.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), November 23, 2020, through 2400 hrs, A.l.t., December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2020 TAC of Atka mackerel, in the BS/EAI, allocated to vessels participating in the BSAI trawl limited access sector fishery was established as a directed fishing allowance of 2,100 metric tons by the final 2020 and 2021 harvest specifications for groundfish in the BSAI (85 FR 13553, March 9, 2020).

In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Atka mackerel in the BS/EAI by vessels participating in the BSAI trawl limited access sector fishery. While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA) finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such a requirement is impracticable and contrary to the public interest. This requirement is

impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Atka mackerel directed fishing in the BS/EAI for vessels participating in the BSAI trawl limited access sector fishery. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 19, 2020.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: November 23, 2020.

Jennifer M. Wallace,

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

[FR Doc. 2020–26213 Filed 11–23–20; 4:15 pm]

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Proposed Rules

Federal Register
Vol. 85, No. 229
Friday, November 27, 2020

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

DEPARTMENT OF JUSTICE

Executive Office for Immigration Review

8 CFR Parts 1003 and 1240

[EOIR 19–0410; Dir. Order No. 02–2021]

RIN 1125–AB03

Good Cause for a Continuance in Immigration Proceedings

AGENCY: The Executive Office for Immigration Review, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Justice (''Department'' or ''DOJ'') is proposing to define ''good cause,'' in the context of continuances, adjournments, and postponements, in its immigration regulations.

DATES: Written or electronic comments must be submitted on or before December 28, 2020. Written comments postmarked on or before that date will be considered timely. The electronic Federal Docket Management System will accept comments until midnight Eastern Time on that date.

ADDRESSES: If you wish to provide comment regarding this rulemaking, you must submit comments, identified by the agency name and reference RIN 1125–AB03 or EOIR Docket No. 198–0410, by one of the two methods below.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the website instructions for submitting comments.
- *Mail:* Paper comments that duplicate an electronic submission are unnecessary. If you wish to submit a paper comment in lieu of electronic submission, please direct the mail/shipment to: Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2616, Falls Church, VA 22041. To ensure proper handling, please reference the agency name and RIN 1125–AB03 or EOIR Docket No. 19–0410 on your correspondence. Mailed items must be postmarked or otherwise indicate a shipping date on or before the submission deadline.

FOR FURTHER INFORMATION CONTACT: Lauren Alder Reid, Assistant Director, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2616, Falls Church, VA 22041, telephone (703) 305–0289 (not a toll-free call).

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of this rule via the one of the methods and by the deadline stated above. All comments must be submitted in English, or accompanied by an English translation. The Department also invites comments that relate to the economic, environmental, or federalism effects that might result from this rule. Comments that will provide the most assistance to the Department in developing these procedures will reference a specific portion of the rule; explain the reason for any recommended change; and include data, information, or authority that support such recommended change.

Please note that all comments received are considered part of the public record and made available for public inspection at *www.regulations.gov.* Such information includes personally identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. If you want to submit personally identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONALLY IDENTIFIABLE INFORMATION'' in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must prominently identify the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *www.regulations.gov.*

Personally identifying information located as set forth above will be placed in the agency's public docket file, but not posted online. Confidential business information identified and located as set forth above will not be placed in the public docket file. The Departments may withhold from public viewing information provided in comments that they determine may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.* To inspect the agency's public docket file in person, you must make an appointment with the agency. Please see the **FOR FURTHER INFORMATION CONTACT** paragraph above for agency contact information.

II. Executive Summary

The Department of Justice proposes to amend its regulations in title 8 to provide a clearer definition of ''good cause'' and the situations in which it is shown to warrant a postponement, continuance, or adjournment in immigration proceedings. Existing regulations do not provide guidance as to what qualifies as ''good cause,'' but only provide that ''good cause'' is the standard to be applied when determining whether a postponement, continuance, or adjournment is appropriate. *Cf.* 8 CFR 1003.29. This ambiguity has left the Board of Immigration Appeals (the ''Board'' or ''BIA'') and federal courts to interpret the term on a case-by-case basis. Over time, the Board has articulated standards applicable to continuance requests arising in various contexts. Some aspects of these standards, however, would benefit from further clarification, as the Board's case law does not address every context where continuance requests typically arise. Moreover, it would simplify matters to have the applicable standards for continuances located in a single regulation. To address continuances in a more comprehensive and systematic manner, this proposed rule would revise 8 CFR 1003.29 and codify standards for what constitutes ''good cause'' in different scenarios, including many of the factors the case law defines.

First, the proposed rule at 8 CFR 1003.29(b)(1) would define ''good

cause'' to require the requesting party to demonstrate a particular and justifiable need for a continuance, and to make clear that the burden is on the requesting party. It would further provide that immigration judges should consider five specified non-exhaustive factors when determining whether good cause exists.

Second, the proposed rule at 8 CFR 1003.29(b)(2) would codify scenarios in which ''good cause'' is not shown. These would include where the continuance: Would not materially affect the outcome of the proceedings; is requested by a party who has not demonstrated a likelihood of obtaining relief in a collateral matter, where such relief is the basis for the request; is in order to seek parole, deferred action, or the exercise of prosecutorial discretion by the Department of Homeland Security (''DHS''); or would cause the immigration court to exceed a statutory or regulatory deadline, unless an exception applies or the movant demonstrates good cause.

Third, the rule would further build on the general standards regarding good cause and codify standards or guidelines for adjudicating requests for continuances in four common situations: Continuances related to collateral immigration applications outside of the Executive Office for Immigration Review's (''EOIR'') jurisdiction; continuances related to an alien's representation; continuances on an immigration judge's own motion; and continuances of a merits hearing.

III. Background

An immigration judge ''may grant a motion for continuance for good cause shown.'' 8 CFR 1003.29. The ''continuance for good cause shown'' language was initially added to the regulations in 1987 to codify existing practices and to ''restate[ ] in simpler terms the discretionary authority of Immigration Judges to grant continuances for good cause shown found in 8 CFR 242.13.'' Aliens and Nationality; Rules of Procedure for Proceedings Before Immigration Judges, 52 FR 2931, 2934 (Jan. 29, 1987); [1] *see also* Orders To Show Cause and Warrants of Arrest, 28 FR 9504, 9504–05 (Aug. 30, 1963) (codifying 8 CFR 242.13 (postponement and adjournment of hearing in exclusion proceedings)); *Matter of Sibrun,* 18 I&N Dec. 354, 355–58 (BIA 1983) (discussing factors for consideration regarding a motion for continuance in exclusion proceedings).

Although the ''good cause'' standard has been used for over 100 years, *see, e.g., Rice* v. *Ames,* 180 U.S. 371, 376 (1901) (discussing an Illinois statute that authorized justices of the peace and examining magistrates to grant continuances ''on consent of the parties or on any good cause shown.'') (internal quotation marks omitted)), and is a standard applied in the Immigration and Nationality Act (''INA'' or the ''Act''), INA 243(a)(3), 8 U.S.C. 1253(a)(3) (authorizing district courts to, for good cause, suspend the sentence and order the release of an alien who has failed to comply with a removal order),[2] the term does not have a settled meaning in law. *See Matter of L–A–B–R–,* 27 I&N Dec. 405, 412 (A.G. 2018) (comparing *Johnson* v. *Mammoth Recreations, Inc.,* 975 F.2d 604, 610 (9th Cir. 1992) (''extraordinary circumstances [are] a close correlate of good cause''), with *Hall* v. *Sec'y of Health, Educ. & Welfare,* 602 F.2d 1372, 1377 (9th Cir. 1979) (''Good cause is . . . not a difficult standard to meet.'')).

Neither the INA nor its implementing regulations presently define ''good cause''or how the standard may be met in immigration proceedings.[3] Absent such a statutory or regulatory definition, the parameters of ''good cause'' for continuances have developed over time through case law. *See, e.g., Matter of L–N–Y–,* 27 I&N Dec. 755, 759–60 (BIA 2020) (a speculative and indefinite continuance request due to uncertainty surrounding when a collateral visa request will be resolved does not demonstrate good cause); *Matter of L–A–B–R–,* 27 I&N Dec. at 413–19 (clarifying framework for ''good cause standard'' when a respondent requests a continuance to pursue collateral relief); *Matter of Hashmi,* 24 I&N Dec. 785, 790 (BIA 2009) (setting forth factors for consideration when determining whether there is ''good cause'' for a continuance so that an alien may pursue adjustment of status before the United States Citizenship and Immigration Services (''USCIS'')); *Matter of Rajah,* 25 I&N Dec. 127, 130, 135–38 (BIA 2009) (extending the *Hashmi* good cause framework to respondents seeking employment-based visas and related relief); In general, case law sets forth multi-factor balancing approaches to the good cause standard for motions for a continuance under 8 CFR 1003.29.[4] This rule proposes to codify those parameters and add requirements and clarifications where needed.

In *Matter of Sibrun,* the Board noted that there was little guidance on standards for motions to continue in immigration proceedings and turned to standards for continuances in federal criminal procedure at that time. 18 I&N Dec. at 355–356. The BIA determined that ''an alien at least must make a reasonable showing that the lack of preparation occurred despite a diligent good faith effort to be ready to proceed and that any additional evidence he seeks to present is probative, noncumulative, and significantly favorable to the alien.'' *Id.* The BIA also concluded that ''[b]are, unsupported allegations'' would not be sufficient to establish good cause and that the alien was responsible for ''specifically articulat[ing] the particular facts involved or evidence which he would have presented and otherwise fully explain how denial of his motion fundamentally changed the result reached.'' *Id.* at 357.

After *Matter of Sibrun,* many published decisions evaluating the good cause standard in immigration proceedings involved continuances to afford an alien with the time and opportunity to pursue collateral relief. *See, e.g., Matter of Sanchez Sosa,* 25 I&N Dec. 807, 812–13 (BIA 2012) (outlining factors for consideration in evaluating whether a continuance

[1] In 1987, the relevant regulation was codified at 8 CFR 3.27. *See* 52 FR at 2934. DOJ subsequently redesignated 8 CFR 3.27 as 8 CFR 3.29 in 1992. *See* Executive Office for Immigration Review; Rules of Procedures, 57 FR 11568, 11569 (Apr. 6, 1992). Following the creation of the Department of Homeland Security in 2003 after the passage of the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, EOIR's regulations were moved from chapter I of title 8 of the CFR to chapter V, and 8 CFR 3.29 was accordingly redesignated as 8 CFR 1003.29. *See* Aliens and Nationality; Homeland Security; Reorganization of Regulations, 68 FR 9824, 9830 (Feb. 28, 2003).

[2] ''Good cause'' also is used as a standard for evaluating the appropriateness of actions elsewhere in EOIR's regulations. *See, e.g.,* 8 CFR 1003.3 (extension of briefing schedule); 8 CFR 1003.20 (change of venue); 8 CFR 1003.25 (waiver of the presence of the parties).

[3] One provision of the INA does provide a multi-factor definition of ''good cause'' in the context of a district court's authority to suspend a criminal sentence imposed after a conviction of an alien for failing to take steps to execute a removal order. *See* INA 243(a)(3), 8 U.S.C. 1253(a)(3). Although that particular definition is not applicable to immigration proceedings and its factors have little bearing on whether good cause exists for a continuance in such proceedings, it does demonstrate the default approach courts have taken when evaluating ''good cause'' as the relevant standard without a precise definition. *See Matter of L–A–B–R–,* 27 I&N Dec. at 412–13.

[4] Additionally, the Attorney General has recognized that the same multi-factor test set forth by case law for continuances applies in the context of adjournments or postponements requested by the parties. *See Matter of L–A–B–R–,* 27 I&N Dec. at 407 n.1 (''The Board and the parties agree that the same good cause standard governs continuances under section 1240.6. I operate on the same understanding . . . .''); 8 CFR 1240.6 (''After the commencement of the hearing, the immigration judge may grant a reasonable adjournment either at his or her own instance or, for good cause shown, upon application by the respondent or the Service.''); *see also* 8 CFR 1240.45 (adjournments or postponements in the context of exclusion proceedings).

request to await the adjudication of a U-visa application demonstrates good cause); *Matter of Rajah,* 25 I&N Dec. at 135–38 (applying the factors in *Matter of Hashmi* to evaluation of whether a continuance request to await the adjudication of an employment-based immigrant visa petition demonstrates good cause); *Matter of Hashmi,* 24 I&N Dec. at 790 (outlining factors for consideration in evaluating whether a continuance request to await the adjudication of a family-based immigrant visa petition demonstrates good cause). In *Matter of Hashmi,* the BIA set forth six non-exhaustive factors for determining whether there is good cause for a continuance to accommodate a collateral matter, including: The DHS response to the motion to continue; whether the underlying visa petition is prima facie approvable; the respondent's statutory eligibility for adjustment of status; whether the respondent's application for adjustment of status merits a favorable exercise of discretion; the reason for the continuance; and any other relevant procedural factors. 24 I&N Dec. at 790.

Specifically, in *Matter of Hashmi,* the respondent had requested a continuance so that USCIS could have additional time and opportunity to adjudicate the Form I–130, Petition for Alien Relative, filed on the respondent's behalf, which, if granted, would have rendered the respondent prima facie eligible for adjustment of status. *See id.* at 787; *see also Matter of Garcia,* 16 I&N Dec. 653, 657 (BIA 1978) (stating that an immigration judge should favorably exercise discretion where a prima facie approvable visa petition and adjustment application have been submitted in the course of removal hearings), *modified on other grounds by Matter of Arthur,* 20 I&N Dec. 475 (BIA 1992); *see generally* INA 245(a), 8 U.S.C. 1255(a) (requiring, in part, that an applicant be eligible to receive an immigrant visa).

The BIA later extended the *Hashmi* framework to continuance requests related to other types of collateral proceedings, such as employment-based visas and U-visas. *See Matter of Sanchez Sosa,* 25 I&N Dec. at 812–13; *Matter of L–N–Y–,* 27 I&N Dec. at 757; *Matter of Rajah,* 25 I&N Dec. at 130. Notably, in *Matter of Sanchez Sosa,* the BIA determined that the movant must demonstrate that the requested continuance is ''for a reasonable period of time.'' 25 I&N Dec. at 815.

In *Matter of L–A–B–R–,* the Attorney General clarified the framework governing continuances to accommodate a collateral matter. Specifically, the Attorney General determined that where a provision uses the term ''good cause,'' but does not define it, immigration judges and the BIA should conduct a multi-factor balancing analysis. *See* 27 I&N Dec. at 413. The Attorney General stated that ''[t]he good-cause standard [for continuances] requires consideration and balancing of all relevant factors in assessing a motion for continuance to accommodate a collateral matter'' and noted that such an approach ''comports with both the INA and the prevailing treatment of good-cause standards, and has received the approval of several federal courts of appeals.'' *Id.* (collecting cases).

The Attorney General further explained, however, that not all factors relevant to the ''good-cause assessment'' in the context of continuances should be weighted equally. *Id.* Rather, the adjudicator ''must focus principally on two factors'' including ''the likelihood that the alien will receive the collateral relief'' and ''whether the relief will materially affect the outcome of the removal proceedings.'' *Id.* Additionally, the Attorney General directed that the adjudicator should consider ''whether the alien has exercised reasonable diligence in pursuing [collateral] relief, DHS's position on the motion, the length of the requested continuance, and the procedural history of the case.'' *Id.* The Attorney General elaborated that ''[i]t may also be appropriate to consider the length of the continuance requested, the number of hearings held and continuances granted previously, and the timing of the continuance motion . . . .'' *Id.* at 415. The Attorney General further stated that the burden to establish good cause is on the party seeking the continuance. *See id.* at 413.

Recently, the BIA has stressed that overall prima facie eligibility for relief is not dispositive regarding a motion for continuance where other factors weigh against continuing the proceedings. *See Matter of L–N–Y–,* 27 I&N Dec. at 758. Specifically, the BIA determined that an alien who had demonstrated prima facie eligibility for a U visa did not demonstrate good cause for a continuance where the alien did not exercise due diligence in applying for the U visa, DHS opposed the continuance, and a continuance would undermine administrative efficiency. *See id.* When evaluating administrative efficiency, the BIA considered the uncertainty as to when the U visa would be approved or become available. *See id.* at 759. The BIA also directed immigration judges to ''consider whether an alien is detained in determining the length and number of continuances that are appropriate'' in light of the alien's liberty interest and the Government's interest ''to reasonably limit the expense of detention.'' *Id.*

Notably, almost every approach to defining ''good cause,'' in the context of an alien awaiting a collateral adjudication by DHS or for a visa to become current, highlights the importance of visa availability in assessing ''good cause.'' *See, e.g., Matter of L–A–B–R–,* 27 I&N Dec. at 418 (''Similarly, because adjustment of status typically requires an immediately available visa, INA 245(a), 8 U.S.C. 1255(a), good cause does not exist if the alien's visa priority date is too remote to raise the prospect of adjustment of status above the speculative level.''); *Matter of Rajah,* 25 I&N Dec. at 136 (''A respondent who has a prima facie approvable I–140 and adjustment application may not be able to show good cause for a continuance because visa availability is too remote.'').[5] This approach comports with longstanding Board case law. *See Matter of Quintero,* 18 I&N Dec. 348, 350 (BIA 1982) (''In any case, the fact that the respondent has an approved visa petition does not entitle him to delay the completion of deportation proceedings pending availability of a visa number.''), *aff'd*

[5] Although *Matter of Hashmi* did not address visa availability per se because the respondent in that case would have a visa immediately available upon approval of a Form I–130, the Board did note that statutory eligibility for adjustment of status was an important element to consider in evaluating a continuance request, *see Matter of Hashmi,* 24 I&N Dec. at 792, and an immediately-available visa at the time an adjustment of status application is filed is a statutory requirement to adjust status. *See* INA 245(a)(3), (i)(2)(B), 8 U.S.C. 1255(a)(3), (i)(2)(B). Similarly, the BIA had no occasion to address visa availability in *Matter of Sanchez Sosa* because the annual statutory cap on U visas had not been reached at the time of the decision in June 2012, and a U visa appears to have been available to the respondent at that time. *Compare* INA 214(p)(2)(A), 8 U.S.C. 1184(p)(2)(A) (establishing an annual limit of 10,000 U visas per fiscal year), *with* USCIS, *Victims of Trafficking Form I–914 (T) and Victims of Crime Form I–918 (U) Visa Statistics (FY 2002–August 2012),*Oct. 4, 2012, *available at https://www.uscis.gov////USCIS//%20and%20Studies/Immigration%20Forms%20Data//I914T-I918U-visastatistics-2012-aug.csv (last visited Nov. 18, 2020)* (reflecting the approval of 5825 U visa applications in fiscal year 2009, 10,073 U visa applications in fiscal year 2010, 10,088 U visa applications in fiscal year 2011, and 8688 U visa applications through the end of June 2012). The Department notes that in accordance with applicable law, USCIS approves no more than 10,000 principal petitions for U nonimmigrant status each year. Previously reported data suggesting a higher number of principal petition approvals may be due to system error, duplicate counting of replacement employment authorization documents, or other systems processing error. *See* USCIS, *Number of Form I–198, Petition for U Nonimmigrant Status By Fiscal Year, Quarter, and Case Status: Fiscal Years 2009–2020* Apr. 2020, *available at https://www.uscis.gov/sites/default/files/document/data/I918u_visastatistics_fy2020_qtr2.pdf (last visited Nov. 18, 2020).*

sub nom. Quintero-Martinez v. *INS,* 745 F.2d 67 (9th Cir. 1984) (unpublished). It has also been endorsed by federal courts. *See, e.g., Chacku* v. *U.S. Att'y Gen.,* 555 F.3d 1281, 1286 (11th Cir. 2008) (finding that no good cause was shown for a continuance where the alien's priority date was years in advance of current visa availability). No case law, however, defines how close or remote visa availability must be to establish good cause.

IV. Proposed changes

A. General Considerations

As many stakeholders and experts have recognized, improper uses of continuances lead to unnecessary case delays that do not benefit a respondent with a valid claim,[6] DHS, or EOIR. *See, e.g.,* U.S. Government Accountability Office, *Immigration Courts: Actions Needed to Reduce Case Backlog and Address Long-Standing Management and Operational Challenges* 27, June 2017, *available at https://www.gao.gov/assets/690/685022.pdf* (last visited Nov. 18, 2020) (''DHS attorneys, experts, and other stakeholders we spoke with stated that immigration judges' frequent use of continuances resulted in delays and increased case lengths that contributed to the backlog.''). Consequently, the Department believes it is of critical importance to ensure that continuances in immigration court proceedings are granted only for actual good cause in a consistent and coherent manner, and it is proposing to amend its regulations accordingly.

As neither the INA nor 8 CFR 1003.29 articulate a clear definition of ''good cause,'' the Board and the Attorney General have pronounced multi-factored tests for adjudicators to use to determine whether to grant or deny a motion for a continuance. *See, e.g., Matter of L–N–Y–,* 27 I&N Dec. at 758; *Matter of L–A–B–R–,* 27 I&N Dec. at 413–19; *Matter of Rajah,* 25 I&N Dec. at 130, 135–38; *Matter of Hashmi,* 24 I&N Dec. at 790; *Matter of Sibrun,* 18 I&N Dec. at 355–58. In these decisions, the Board and the Attorney General sought to articulate or expound upon a standard by which ''good cause'' could be judged.

The proposed rule adopts the essence of this standard while clarifying the instances in which a continuance would or would not be warranted in the exercise of discretion. Further, it retains many of the primary considerations of previous agency policies. For example, in accordance with *Matter of L–A–B–R–,* the proposed rule would have decisionmakers consider the likelihood that the alien would obtain collateral relief and whether the relief would materially affect the outcome of the proceeding as primary considerations for whether good cause is shown, and establishes that good cause has not been shown where the relief sought would not materially affect the outcome. *Compare Matter of L–A–B–R–,* 27 I&N Dec. at 413–19 (indicating that immigration judges must ''focus principally on two factors: (1) The likelihood that the alien will receive the collateral relief, and (2) whether the relief will materially affect the outcome of the removal proceedings[,]'' among other considerations), *with* 8 CFR 1003.29(b)(2)(i) (proposed).

The proposed rule would also establish a non-exhaustive list of factors for an immigration judge to consider whether a particular and justifiable need for a continuance has been met, using many of the factors applied by the Board in *Matter of Hashmi* and by the Attorney General in *Matter of L–A–B–R–. Compare Matter of Hashmi,* 24 I&N Dec. at 790 (laying out six factors, including but not limited to: (1) DHS's response to the motion to continue; (2) whether the underlying visa petition is prima facie approvable; (3) the respondent's statutory eligibility for adjustment of status; (4) whether the respondent's application for adjustment of status merits a favorable exercise of discretion; (5) the reason for the continuance; and (6) any other relevant procedural factors), *and Matter of L–A–B–R–,* 27 I&N Dec. at 413 (''The immigration judge should also consider whether the alien has exercised reasonable diligence in pursuing that relief, DHS's position on the motion, the length of the requested continuance, and the procedural history of the case.''), *with* 8 CFR 1003.29(b)(1)(i)–(iv) (proposed).

Further, the proposed rule maintains the general ''due diligence'' standard, as well as the movant's burden of proof, as factors for an immigration judge to consider. *Compare Matter of Sibrun,* 18 I&N Dec. at 355–57 (stating that ''an alien at least must make a reasonable showing that the lack of preparation occurred despite a diligent good faith effort to be ready to proceed and that any additional evidence he seeks to present is probative, noncumulative, and significantly favorable to the alien'' and that the alien is responsible for ''specifically articulat[ing] the particular facts involved or evidence which he would have presented, and otherwise fully explain[ing] how denial of his motion fundamentally changed the result reached''), *with* 8 CFR 1003.29(b)(1), (b)(1)(i) (proposed).

Also, the provision of the proposed rule which limits a good cause determination where the continuance relates to collateral immigration applications is in line with precedent stating that if visa availability is too remote, a continuance may not be warranted. *Compare* 8 CFR 1003.29(b)(3)(i)(A), (ii) (proposed), *with Matter of L–A–B–R–,* 27 I&N Dec. at 418 (''Similarly, because adjustment of status typically requires an immediately available visa, INA § 245(a), 8 U.S.C. 1255(a), good cause does not exist if the alien's visa priority date is too remote to raise the prospect of adjustment of status above the speculative level.''), *Matter of Rajah,* 25 I&N Dec. at 136 (''A respondent who has a prima facie approvable I–140 and adjustment application may not be able to show good cause for a continuance because visa availability is too remote.''), *and Matter of Quintero,* 18 I&N Dec. at 350 (''Likewise, the immigration judge's refusal to continue the hearing until a visa number was available was proper because he may neither terminate nor indefinitely adjourn the proceedings in order to delay an alien's deportation.''). Thus, the elements of the proposed rule are grounded in previous agency rulings and precedents regarding continuances for good cause in immigration proceedings.

In addition, the Attorney General recognized in *Matter of L–A–B–R–* that the good cause standard is often misapplied or misconstrued in immigration proceedings, leading to the overuse of continuances. *See* 27 I&N Dec. at 411. Whereas continuances may '''promote efficient case management,''' *see id.* at 407 (quoting *United States* v.

[6] As the Supreme Court has recognized, ''[o]ne illegally present in the United States who wishes to remain . . . has a substantial incentive to prolong litigation in order to delay physical deportation for as long as possible.'' *INS* v. *Rios-Pineda,* 471 U.S. 444, 450 (1985). Thus, many aliens obtain a perverse benefit from the delays in immigration proceedings. Nevertheless, unnecessary delays do harm aliens with valid claims. *See* Human Rights First, *The U.S. Immigration Court: A Balooning Backlog that Requires Action* 5, Mar. 15, 2016, *available at https://www.humanrightsfirst.org/sites/default/files/HRF-Court-Backlog-Brief.pdf* (''Some unauthorized migrants may benefit from the delays and remain longer in the country than they should, but those with legitimate grounds for relief from removal, such as many asylum seekers, remain in limbo for unnecessarily long periods.'') (quoting Institute for the Study of International Migration, Georgetown University, *Detention and Removal: What now and What Next?: Report on an experts' roundtable Georgetown University, Washington DC,* at 13 (2014)) *available at https://isim.georgetown.edu/wp-content/uploads/sites//2019/08/DetentionRemovalv10-1.pdf* (last visited Nov. 18, 2020). In short, unnecessary delays harm the government's interest in efficient adjudications and the enforcement of the laws, an alien's interest in the timely resolution of his or her case, especially if the alien has a valid claim for relief, and the public's interest in the prompt administration of justice.

Tanner, 544 F.3d 793, 795 (7th Cir. 2008)), the overuse of continuances undercuts their purpose and leads to the unnecessary delay of immigration proceedings, *see id.* at 411. By articulating a clearly-defined good cause standard, the Department believes that it will be less likely to be misapplied or misconstrued.

Finally, an amorphous standard invites inconsistent practices among immigration judges and inconsistent results among similarly-situated aliens. EOIR currently has over 500 immigration judges *see* EOIR, *Immigration Judge Hiring* (Oct. 2020), *available at https://www.justice.gov/eoir/page/file/1242156/download (last visited Nov. 18, 2020),* and currently there is no consistent practice among them regarding many types of frequently-requested continuances. Thus, aliens and their representatives seeking similar types of continuances—*e.g.,* time to seek representation or preparation time—often receive varying decisions on both the length and number of continuances they receive based upon each individual immigration judge's own personal understanding of good cause. Further, the current—and comparatively inefficient—case-by-case nature of determining good cause, the lack of a clear definition of the term, and its consideration through an open-ended and largely subjective lens by immigration judges, and the necessarily interlocutory posture for addressing continuances that were incorrectly granted, all make the subject of good cause for a continuance ripe for rulemaking. *See Lopez* v. *Davis,* 531 U.S. 230, 244 (2001) (observing that agency ''is not required continually to revisit 'issues that may be established fairly and efficienctly in a single rule making proceeding''' (quoting *Hecker* v. *Campbell,* 461 U.S. 458, 467 (1983))); *Marin-Rodriguez* v. *Holder,* 612 F.3d 591, 593 (7th Cir. 2010) (''An agency may exercise discretion categorically, by regulation, and is not limited to making discretionary decisions one case at a time under open-ended standards.'').

For these reasons and concerns, the Department proposes, within its authority and discretion, a new rule more clearly defining when continuances are warranted in immigration court proceedings—and when such requests warrant denial in the exercise of discretion—because it believes it is of critical importance to ensure that continuances are granted only for actual good cause in a consistent and coherent manner.

While federal courts have discussed current 8 CFR 1003.29, no federal court has limited the reading of the current regulation to one specific interpretation of ''good cause'' or ruled out particular interpretations of that term as inconsistent with the INA. In fact, courts have, when discussing whether good cause existed, often cited the Department's existing frameworks favorably. *See, e.g., Toure* v. *Barr,* 926 F.3d 403, 407–08 (7th Cir. 2019) (discussing and using both the *Matter of L–A–B–R–* and *Hashmi* frameworks); *Flores* v. *Holder,* 779 F.3d 159, 164 (2d Cir. 2015) (discussing and using the *Hashmi* factors); *Ferreira* v. *U.S. Att'y Gen.,* 714 F.3d 1240, 1243 (11th Cir. 2013) (discussing and using the Board-proposed factors from *Hashmi* and *Rajah*).

Even where courts have considered their own multi-factor tests, those courts have not expressly indicated that their framework is intended to be the only way to analyze whether good cause exists, indicating instead that ''there are no bright-line rules . . . .'' *Cui* v. *Mukasey,* 538 F.3d 1289, 1295 (9th Cir. 2008). *See also, e.g., Ahmed* v. *Holder,* 569 F.3d 1009, 1012 (9th Cir. 2009); *Baires* v. *INS,* 856 F.2d 89, 92–93 (9th Cir. 1988). Further, all courts continue to maintain the general proposition that although certain factors may be considered, ''[t]he decision to grant or deny the continuance is within 'the sound discretion of the judge and will not be overturned except on a showing of clear abuse','' indicating that decisions evaluating good cause do not purport to make definitive interpretations that would otherwise leave no room for agency discretion. *Ahmed,* 569 F.3d at 1012 (quoting *Sandoval-Luna* v. *Mukasey,* 526 F.3d 1243, 1247 (9th Cir. 2008)); *see also C.J.L.G.* v. *Barr,* 923 F.3d 622, 629 (9th Cir. 2019); *Cruz Rendon* v. *Holder,* 603 F.3d 1104, 1110 (9th Cir. 2010). In short, no court has proclaimed a definitive and comprehensive interpretation of when good cause exists under 8 CFR 1003.29.

B. The Proposed Rule

In *Matter of L–A–B–R–,* the Attorney General recognized that the ''good cause'' standard is often misapplied in immigration proceedings, resulting in the overuse of continuances. *See* 27 I&N Dec. at 411 (''The overuse of continuances in the immigration courts is a significant and recurring problem.''). Continuances are an ''important management tool for adjudicators,'' intended to promote efficiency by allowing for more time in a case where ''it [would] be wasteful and inefficient to plow ahead immediately'' due to certain developments in the case, such as illness of a key participant. *Id.* at 407. However, the overuse of continuances undermines their purpose and may result in needless delay of immigration proceedings. *See id.* at 411 (''Far from being minor procedural matters, unnecessary continuances undermine the detailed statutory and regulatory scheme established under the INA.'').

Additionally, the Attorney General recognized that good cause imposes a clear limitation on the immigration judge's discretion. *Id.* at 407 (stating that ''[t]he good-cause standard is not a mere formality that permits immigration judges to grant continuances for any reason or no reason at all.''). The ''good cause'' standard provides ''an important check on immigration judges' authority that reflects the public interest in expeditious enforcement of the immigration laws, as well as the tendency of unjustified continuances to undermine the proper functioning of our immigration system.'' *Id.* at 406.

In light of the unnecessary delays caused by the improper use of continuances, the past misinterpretations and misapplications of the ''good cause'' standard with respect to continuances, and the limiting effect of good cause on an immigration judge's discretion, the Department proposes a clearer, more uniform standard to be applied when considering good cause for continuances in immigration proceedings. Under the proposed rule, good cause generally could be shown when a party demonstrates a particular and justifiable need for a continuance. The proposed rule would provide immigration judges and the BIA with a clear standard by which to determine whether a continuance is warranted based on good cause. The Department proposes to place this standard in 8 CFR 1003.29, which contains the current ''good cause'' provision.

Paragraph (a) of the proposed rule's changes to 8 CFR 1003.29 would expand upon the language of the current regulation, permitting an immigration judge to grant a motion for a continuance for good cause shown, provided that the requirements of paragraph (b) are met and that the continuance would not cause the adjudication of an asylum application by an immigration judge to exceed 180 days in the absence of exceptional circumstances. Paragraph (b) of 8 CFR 1003.29, as proposed, would provide the minimum standard that must be met in order for good cause to exist to grant a motion for a continuance. Consistent with current practice, the proposed standard would make clear that the burden of demonstrating good cause is

on the party who is requesting that the court take action or that the court excuse a prior action. *See id.; see also Matter of L–A–B–R–,* 27 I&N Dec. at 413 (''In assessing these factors, the immigration judge should also remain mindful that as the party seeking the continuance, the alien bears the burden of establishing good cause.'').

The proposed standard would require that, to establish good cause, a requesting party must be able to offer a particular reason for his or her request under the ''particular . . . need for the continuance'' requirement of paragraph (b). This requirement would codify the specificity contemplated by the existing good cause framework. *See Matter of Sibrun,* 18 I&N Dec. at 357 (''[T]he alien must specifically articulate the particular facts involved or evidence which he would have presented . . . . Finally, all three reasons which counsel advances suffer a common defect: They are but bare, unsupported allegations lacking the required specific articulation of particularized facts and evidence.''). In other words, a party who seeks an action that requires a demonstration of good cause would be required to show a specific basis for the requested action and not merely a generalized desire.

In addition, the proposed standard would require that, to establish good cause, a requesting party's reason for making the request must be ''justifiable.'' Whether a reason for a request is ultimately justifiable would depend on specific fairness and efficiency considerations at issue in the particular context, *see Matter of L–N–Y–,* 27 I&N Dec. at 759 (''Considering and balancing the relevant primary and secondary factors in this case, we agree with the Immigration Judge that there was no 'good cause' to continue the respondent's proceedings to further await the adjudication of his U nonimmigrant visa petition.''). The immigration judge should lay out such considerations on the record, keeping with current practices. *See, e.g., id.* at 757–60. Thus, although the proposed definition would set forth a generally applicable standard for good cause in the context of continuances, adjournments, and postponements (collectively ''continuances'' [7]), an immigration judge's or the BIA's determination of whether or not an action is justifiable would ultimately be decided on a case-by-case basis. *See Matter of L–A–B–R–,* 27 I&N Dec. at 412 (''I conclude that under 8 CFR 1003.29, immigration courts should continue to apply a multifactor test to assess whether good cause exists for a continuance for a collateral proceeding . . . .''). Further, the justifiability requirement would be in keeping with existing practice. *See, e.g., id.* at 415 (''Because a delay in an immigration proceeding imposes a burden on the immigration judge, DHS, and other aliens pursuing prompt hearings, the respondent seeking to avoid a disposition must demonstrate that he has a well-founded justification for such relief.'').

Moreover, in some instances, an alien remains eligible for relief even after a removal order has been entered, *see e.g.,* 8 CFR 214.14(c)(1)(ii), or removal has been effectuated, *see e.g., Matter of L–N–Y–,* 27 I&N Dec. at 760 (''Moreover, as the Immigration Judge noted, the respondent may continue to pursue his U visa, even after he is removed.''). *See also Garcia* v. *Dep't of Homeland Sec.,* No. 19–01265, 2019 WL 7290556, at *6 (N.D. Ill. Dec. 30, 2019) (unpublished) (''The governing regulations anticipate that petitioners for U-visas may not be present in the United States when their petitions are adjudicated or could be removed from the United States during the pendency of the petitions.''); *accord Alvarez-Espino* v. *Barr,* 959 F.3d 813, 818 (7th Cir. 2020) (''USCIS will process the [U visa] application whether or not Alvarez-Espino has a final order of removal against him. . . . Because Alvarez-Espino can continue to pursue every immigration benefit he seeks, the Board did not abuse its discretion in denying his motion for remand or for a continuance.''). In such instances, the mere conceivability of relief prior to the issuance of a removal order would hardly establish good cause for delaying the proceedings, because no continuance would be necessary to preserve the alien's ability to pursue the collateral matter with another agency. Thus, an alien in such circumstances could not demonstrate a particular and justifiable need for the continuance because the alien could continue to pursue whatever collateral matter he seeks regardless of whether the continuance is granted.

To demonstrate good cause for a continuance under the proposed rule, an alien who seeks a continuance would first have to clearly specify his or her reason for requesting it. *See Matter of Sibrun,* 18 I&N Dec. at 357 (''[T]he alien must specifically articulate the particular facts involved or evidence which he would have presented . . . .''). Next, the alien would have to show that the continuance is warranted by a particular and justifiable need. *See id.* at 356–57 (''Second, for purposes of appeal, even where an alien has made this minimum required showing, an immigration judge's decision denying the motion for continuance will not be reversed unless the alien establishes that that denial caused him actual prejudice and harm and materially affected the outcome of his case.''); *cf. Matter of Garcia-Reyes,* 19 I&N Dec. 830, 832 (BIA 1988) (no good cause for a continuance to demonstrate rehabilitation when ''[t]here was no showing that the respondent was eligible for any form of relief from deportation for which rehabilitation would be relevant'').

With over 1.2 million cases currently pending, EOIR, *Pending Cases, New Cases, and Total Completions* (July 14, 2020), *available at https://www.justice.gov/eoir/page/file/1242166/download (last visited Nov. 18, 2020),* it is imperative that the Department ensures that immigration cases are completed in a timely manner. *See also* EOIR, Memorandum from the Attorney General to the EOIR, *Renewing Our Commitment to the Timely and Efficient Adjudication of Immigration Cases to Serve the National Interest,* at 2 (Dec. 5, 2017), *available at https://www.justice.gov/eoir/file/1041196/download (last visited Nov. 18, 2020)* (''The timely and efficient conclusion of cases serves the national interest. Unwarranted delays and delayed decision making do not.''). Because continuances place stress on one of EOIR's scarcest resources—docket time—and in light of the growing pressures created by new cases driven by continued influxes of illegal immigration, the Department believes it is essential to ensure that continuances are used properly and in a consistent manner. *See* U.S. Government Accountability Office, *Immigration Courts: Actions Needed to Reduce Case Backlog and Address Long-Standing Management and Operational Challenges* (June 1, 2017) at 27, 68, 69 *available at https://www.gao.gov/assets/690/685022.pdf* (last visited Nov. 18, 2020) (''DHS attorneys, experts, and other stakeholders we spoke with stated that immigration judges' frequent use of continuances resulted in delays and increased case lengths that contributed

[7] The regulations use the terms continuances, adjournments, and postponements largely interchangeably, and the same ''good cause'' standard governs both continuances under 8 CFR 1003.29 and postponements and adjournments under 8 CFR 1240.6 and 1240.45. *Matter of L–A–B–R–,* 27 I&N Dec. at 407 n.1. To eliminate any residual confusion, the proposed rule consolidates the location of this standard into one regulation, 8 CFR 1003.29, and makes conforming edits to 8 CFR 1240.6 and 1240.45 accordingly. Further, the proposed rule is not intended to define good cause as it is used in any other context outside of 8 CFR 1003.29.

to the backlog. . . . Our analysis . . . showed that the use of continuances has grown over time and that, on average, cases that experience more continuances take longer to complete. . . . We also found that the percentage of completed cases which had multiple continuances increased . . . and that, on average, cases with multiples continuances took longer to complete than cases with no or fewer continuances.'').

The Department does not foresee circumstances under which a continuance would be justifiable if an alien is unlikely to receive the collateral relief requested or, if granted, the collateral relief would not materially affect the outcome of the removal proceedings, and these two factors would continue to serve as important considerations for adjudicators.[8] *See Matter of L–A–B–R–,* 27 I&N Dec. at 413.

However, a continuance would most likely not be justifiable solely because a collateral matter ''could conceivably provide relief from removal.'' *Matter of L–A–B–R–,* 27 I&N Dec. at 414. Indeed, if this were the standard for good cause, then every continuance request for a collateral matter would demonstrate good cause, because most such requests posit at least a theoretical possibility of obtaining relief. The standard in proposed paragraph (b)(2)(i) comports with the recent direction of the Attorney General that motions for continuances should be granted only sparingly. *See Matter of L–A–B–R–,* 27 I&N Dec. at 407 (asserting that, in the course of ordinary litigation, the burden placed on proceedings ''counsels against continuances except for compelling reasons'') (citing *Morris* v. *Slappy,* 461 U.S. 1, 11 (1983)). Although these two factors are important, most continuance requests to allow for collateral matters allege a likelihood of obtaining the collateral relief, and nearly all such requests posit that the collateral matter would materially impact the proceedings—otherwise there would be no need to seek the collateral matter. Thus, the proposed rule notes that although these two factors are significant, adjudicators should also consider other factors: ''(i) The amount of time the movant has had to prepare for the hearing and whether the movant has exercised due diligence to ensure preparedness for that hearing; (ii) The length and purpose of the requested continuance, including whether the reason for the requested continuance is dilatory or contrived; (iii) Whether the motion is opposed and the basis for the opposition, though the opponent does not bear the burden of demonstrating an absence or lack of good cause; (iv) Implications for administrative efficiency; and (v) Any other relevant factors for consideration.'' *Compare id., with Matter of L–A–B–R–,* 27 I&N Dec. at 413 (''The immigration judge should also consider whether the alien has exercised reasonable diligence in pursuing that relief, DHS's position on the motion, the length of the requested continuance, and the procedural history of the case.'').

A continuance would most likely not be justifiable where the alien ''appears to be seeking interim relief as a way of delaying the ultimate disposition of the case'' or has not taken practicable measures to proceed at the scheduled hearing, such as ''pursuing collateral relief in advance of the noticed hearing date.'' *Matter of L–A–B–R–,* 27 I&N Dec. at 413. A continuance would also not likely be justifiable where the alien expresses an intention to file for collateral relief at a future date or where the alien has unreasonably delayed filing for collateral relief. *Id.* at 416. Through the proposed rule, the Department indicates that, subject to an exception, a request for a continuance in order to later apply for a visa generally would not constitute good cause. To the contrary, an alien should generally exercise diligence in any activity that forms the basis of the continuance request, and a lack of such diligence undermines a putative showing of good cause. *Cf. Mazariegos-Paiz* v. *Holder,* 734 F.3d 57, 66 (1st Cir. 2013) (''Parties have an obligation to exercise due diligence in marshaling evidence. Viewed in this light, the IJ's denial of the petitioner's mid-trial request for a continuance was not an abuse of discretion.''); *Perez-Mirachal* v. *Att'y Gen.,* 275 F. App'x 141, 144 (3d Cir. 2008) (unpublished) (''We conclude that the Immigration Judge did not abuse his discretion in denying the motion for a continuance. At the time the motion for continuance was filed, Perez-Mirachal had not yet filed any motions challenging his conviction in the criminal court.''); *Matter of Sibrun,* 18 I&N Dec. at 357–58 (''Accordingly, we find that counsel has failed to establish that after more than 3 months of representing the applicant she reasonably could not have been prepared to proceed . . . .'').

The proposed rule also would clarify that seeking collateral action in the form of an exercise of prosecutorial discretion, which is solely within the purview of DHS and is beyond the authority of the immigration judge to grant, does not warrant continuing the proceedings. *See* 8 CFR 1003.29(b)(2)(ii). There is no need to continue a case in order to seek parole, deferred action, or the exercise of prosecutorial discretion by DHS, because such actions are far beyond the authority of an immigration judge to grant and may be granted by DHS at any time regardless of whether immigration proceedings are pending. *See also Matter of W–Y–U–,* 27 I&N Dec. 17, 19 (BIA 2017) (''The role of the Immigration Courts and the Board is to adjudicate whether an alien is removable and eligible for relief from removal in cases brought by the DHS. We lack the authority to review the DHS's decision to institute proceedings, which involves the exercise of prosecutorial discretion.'') (citing *Matter of G–N–C–,* 22 I&N Dec. 281, 284 (BIA 1998)), *overruled by Matter of Castro-Tum,* 27 I&N Dec. 271 (A.G. 2018);[9] *see,*

[8] ''As with any balancing analysis requiring consideration of multiple factors, a respondent's strength on certain factors may compensate for a weaker showing on others.'' *Matter of L–A–B–R–,* 27 I&N Dec. at 417. For example, ''[a] respondent who makes a compelling case that he will receive collateral relief and successfully adjust status may receive a continuance even if, for instance, he has already received previous continuances.'' *Id.* However, ''because the respondent's likelihood of success in the collateral matter is paramount, a truly weak showing on that front may be dispositive.'' *Id.* Additionally, ''[i]n some cases, it will be impossible or too uncertain that the respondent will succeed in the collateral proceeding itself.'' *Id.* Consistent with the idea that a ''compelling'' case that an alien will receive collateral relief may warrant a continuance, *Matter of L–A–B–R–,* 27 I&N Dec. at 417, the Department proposes to apply a ''clear and convincing'' evidentiary standard in assessing whether a respondent has made a sufficient showing of the likelihood of obtaining collateral relief in order to obtain a continuance based on a collateral matter. Such a standard recognizes that neither a prima facie showing of eligibility for relief, *Matter of L–N–Y–,* 27 I&N Dec. at 757–58, nor the mere conceivability of possible relief, *Matter of L–A–B–R–,* 27 I&N Dec. at 414, is dispositive regarding whether a continuance should be granted. It is also consistent with the statutory standard for eligibility for one of the most common collateral matters arising in immigration proceedings, a request to continue the case of an alien who has married a United States citizen or lawful permanent resident while in removal proceedings in order to await the adjudication of an immigrant visa petition based on the marriage. *See* INA 245(e), 8 U.S.C. 1255(e) (requiring proof by ''clear and convincing evidence'' of a bona fide marriage during removal proceedings between an alien and a United States citizen or lawful permanent resident in order for the alien to avoid having to reside outside the United States for two years before the immigrant visa petition can be approved).

[9] *Matter of Castro-Tum* itself has been abrogated within the Fourth and Seventh Circuits, though it continues to apply to immigration proceedings outside those circuits. *See Romero* v. *Barr,* 937 F.3d 282, 292–94 (4th Cir. 2019); *Morales* v. *Barr,* 963 F.3d 629, 639–40 (7th Cir. 2020). The Department also recently proposed rulemaking to codify the principle, consistent with both *Matter of Castro-Tum* and other regulations, that immigration judges and appellate immigration judges lack free-floating authority to administratively close cases. *See*

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e.g., Matter of Quintero, 18 I&N Dec. at 350 (''Furthermore, since the respondent can request deferred action status at any stage in the proceedings, the immigration judge did not err in refusing to adjourn the hearing to allow him to pursue that relief.''); *cf. Matter of Yazdani,* 17 I&N Dec. 626, 630 (BIA 1981) (same). Since the exercise of prosecutorial discretion is a matter within the exclusive jurisdiction of the DHS, it follows that in considering administrative closure, an immigration judge cannot review whether an alien falls within the DHS's enforcement priorities or will actually be removed from the United States. *See Matter of Quintero,* 18 I&N Dec. at 350 (stating that ''deferred action status is a function of the District Director's prosecutorial authority,'' which neither Immigration Judges nor the Board can review); *cf. Matter of P–C–M–,* 20 I&N Dec. 432, 434 (BIA 1991) (stating that the likelihood that an alien will be deported is not a factor to be considered in a bond determination), *overruled on other grounds by Matter of Castro-Tum,* 27 I&N Dec. 271 (A.G. 2018); *Matter of Ramirez-Sanchez,* 17 I&N Dec. 503, 505 (BIA 1980) (''Once deportation proceedings are commenced, the immigration judge must order deportation if the evidence supports the charge.'').

Further, the Department remains committed to ensuring that adjudicators follow statutory directives, including relevant timelines reflecting clear Congressional expectations that certain types of cases would be adjudicated within clear time parameters. *See, e.g.,* INA 208(d)(5)(A)(iii), 8 U.S.C. 1158(d)(5)(A)(iii) (stating that ''in the absence of exceptional circumstances, final administrative adjudication of the asylum application, not including administrative appeal, shall be completed within 180 days after the date an application is filed''). To that end, the proposed rule would clarify that good cause is not established when a continuance request would cause an immigration court to exceed a statutory or regulatory adjudication deadline, unless the request meets any exception to those deadlines.

The proposed rule also addresses common contexts for continuance requests in order to provide adjudicators with clearer standards and guidance. For instance, the proposed rule discusses continuances based on collateral immigration applications, proposing that ''a continuance request to allow an alien or a petitioner to apply for an immigrant visa or to wait for an immigrant visa for which the alien is the beneficiary to become available'' generally would not demonstrate good cause.

This default standard is in line with the current framework, which provides that because adjustment of status generally requires an immediately available visa, good cause does not exist if the alien's priority date or visa eligibility is too remote. *See, e.g., Matter of L–A–B–R–,* 27 I&N Dec. at 418 (''Similarly, because adjustment of status typically requires an immediately available visa, INA 245(a), 8 U.S.C. 1255(a), good cause does not exist if the alien's visa priority date is too remote to raise the prospect of adjustment of status above the speculative level.''); *Matter of Quintero,* 18 I&N Dec. at 350 (''[T]he fact that the respondent has an approved visa petition does not entitle him to delay the completion of deportation proceedings pending availability of a visa number.'').

Notwithstanding the general rule, the Department recognizes there may be situations in which it is appropriate to continue a case to await the adjudication of an immigrant visa petition by USCIS. Consequently, the proposed rule contains an exception that may establish good cause. To fall within the exception, the motion for a continuance would need to satisfy the three elements of that exception. *Id.*

First, the proposed rule requires the approval of the visa application or petition to provide ''an immediately-available visa to the alien'' or ''a visa to the alien with a priority date six months or less from the immediate action application date provided in the Visa Bulletin published by the Department of State for the month in which the continuance request is made,'' in recognition that an application for adjustment of status generally requires an immediately available visa at the time an application is filed. *See, e.g.,* INA 245(a)(3), (i)(2)(B), 8 U.S.C. 1255(a)(3), (i)(2)(B).

Acknowleding that certain circumstances the likelihood of an immigrant visa being available is no longer remote or speculative, even if it is not quite immediately available. Case law has not defined how near or remote visa availability should be to support a finding of good cause, however. *Matter of L–A–B–R–,* 27 I&N Dec. at 418 (''Similarly, because adjustment of status typically requires an immediately available visa, INA 245(a), 8 U.S.C. 1255(a), good cause does not exist if the alien's visa priority date is too remote to raise the prospect of adjustment of status above the speculative level.''); *Matter of Rajah,* 25 I&N Dec. at 136 (''A respondent who has a prima facie approvable I–140 and adjustment application may not be able to show good cause for a continuance because visa availability is too remote.''); *Matter of Quintero,* 18 I&N Dec. at 350 (''In any case, the fact that the respondent has an approved visa petition does not entitle him to delay the completion of deportation proceedings pending availability of a visa number.''). Consequently, individual adjudicators may take different views regarding how remote is too remote to warrant a continuance, which in turn may lead to inconsistent results for otherwise similarly-situated aliens. Thus, the proposed rule would establish a clear, uniform boundary for remoteness based on the Visa Bulletin published every month by the Department of State. *See* 22 CFR 42.51(b) (providing for the allocation of immigrant visa numbers by the Department of State). Although the priority dates in the Visa Bulletin do not always move at predictable intervals, the Department believes that using a date six months or less from the priority date reflected in the Visa Bulletin for filing visa applications [10] for the month in which the continuance request is made represents the clearest and most appropriate boundary for assessing remoteness for purposes of determining whether good cause exists. In particular, using a date no later than six months after the priority date calculated by the Department of State ''justifying immediate action in the application process,'' *see, e.g.,* U.S. Department of State, *Visa Bulletin for September 2020, No. 38 vol. X, available at https://travel.state.gov/content/travel/en/legal/visa-law0/visa-bulletin/2020/visa-bulletin-for-september-2020.html (last visited Oct. 26, 2020),* as the cutoff for assessing remoteness strikes the right balance between providing a reasonable opportunity for an alien to obtain visa-based relief and avoiding indeterminate

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[10] The Visa Bulletin contains two charts of priority dates for each broad category of visas, family-based and employment-based. *See, e.g.,* U.S. Department of State, *Visa Bulletin for September 2020, No. 38 vol. X, available at https://travel.state.gov/content/travel/en/legal/visa-law0/visa-bulletin/2020/visa-bulletin-for-september-2020.html* (last visited Oct. 26, 2020). The first chart lists final action dates, *i.e.,* visas with a priority date earlier than the date on the final action chart are available. The second chart reflects dates for filing visa applications within a timeframe justifying immediate action in the application process. The dates in the second chart are generally later than the first, and applicants for immigrant visas who have a priority date earlier than the application date in the second chart may assemble and submit required documents to the Department of State's National Visa Center.

delays based on visas that may not be current for a significant period of time.

Second, to establish good cause for a continuance related to an immigrant visa, an alien would need to demonstrate a *prima facie* eligibility for that visa and, if applicable, for adjustment of status and any necessary waiver(s) based on the visa approval, including establishing reason, as a matter of discretion, for adjustment of status and granting of any necessary waivers. This requirement is in line with the Department's past frameworks, which considered ''whether the underlying visa petition [wa]s prima facie approvable.'' *Matter of L–A–B–R–,* 27 I&N Dec. at 414 (''Three of the five main good-cause factors enumerated in *Hashmi* and *Rajah* pertained to the likelihood of these efforts' success: 'whether the underlying visa petition is prima facie approvable[.]' ''); *see also Matter of Rajah,* 25 I&N Dec. at 130 (citing the factors in *Matter of Hashmi,* including prima facie approvability of the underlying visa petition, in assessing whether a continuance is warranted to await the adjudication of a pending employment-based visa petition); *Matter of Hashmi,* 24 I&N Dec. at 790 (''In determining whether to continue proceedings to afford the respondent an opportunity to apply for adjustment of status premised on a pending visa petition, a variety of factors may be considered, including . . . whether the underlying visa petition is prima facie approvable[.]'').

Third, to establish good cause for a continuance related to an immigrant visa, the request must establish that the immigration judge has jurisdiction over any application for adjustment of status, including any necessary waivers in conjunction with that application, based on approval of the underlying visa. This requirement recognizes both the futility and the waste of scarce resources associated with continuing a case for an issue over which an immigration judge ultimately lacks any authority to provide relief, as well as the reality, discussed *supra,* that many forms of relief remain available to aliens even if their removal proceedings have concluded. *See, e.g., Alvarez-Espino,* 959 F.3d at 818 (''USCIS will process the [U-visa] application whether or not Alvarez-Espino has a final order of removal against him. . . . Because Alvarez-Espino can continue to pursue every immigration benefit he seeks [outside of removal proceedings], the Board did not abuse its discretion in denying his motion for remand or for a continuance.'').

The Board has previously recognized that many reasons militate against granting a motion to reopen based on an underlying application over which an immigration judge and the Board lack jurisdiction:

> As a practical matter, Immigration Judges and the Board have limited and finite adjudicative and administrative resources, and those resources are best allocated to matters over which we do have jurisdiction. Among the costs of reopening final proceedings in cases such as the one before us, where we have no [authority] over the underlying relief requested, are the practical and administrative difficulties associated with maintaining open cases that would rely on outside considerations and would become part of already-crowded dockets. Immigration Judges, for example, would be required to schedule and oversee matters over which they play no substantive role, because the cases would once again be on their docket. If the application is ultimately denied, the Immigration Judge is placed in the position of having to enter a further order or decision that simply sets forth information provided by others, assuming such information is actually provided to the Immigration Judge in a timely manner. There would be nothing to preclude the respondent from filing an appeal to the Board from such an order, unnecessarily adding to our pending case load, and despite the fact that we would have no review authority over aspects of that decision.

Matter of Yauri, 25 I&N Dec. 103, 110–11 (BIA 2009).[11]

Although the Board recognized that these considerations may be different for pending proceedings, it did so, in part, with the understanding that the Department would engage in rulemaking on the issue, which the proposed rule now does. *Id.* at 111 n.8.

[11] The Department notes that in *Singh* v. *Holder,* 771 F.3d 647 (9th Cir. 2014), the Ninth Circuit held that the Board possessed sua sponte authority to reopen a proceeding involving an application over which it lacked jurisdiction and to effectively grant a stay of removal, notwithstanding its decision in *Matter of Yauri. See Singh,* 771 F.3d at 652. *Singh,* however, did not address the Board's determination in *Yauri* that it would not exercise its discretion—even with its sua sponte authority—to reopen cases involving applications over which it lacked authority. *Compare id.* at 653 (''Because the BIA denied Singh's motion only for lack of authority, we grant the petition and remand to the BIA.''), *with Matter of Yauri,* 25 I&N Dec. at 110 (''Finally, and separately from any question of jurisdiction, with regard to untimely or number-barred motions to reopen, we conclude that sua sponte reopening of exclusion, deportation, or removal proceedings pending a third party's adjudication of an underlying application that is not itself within our [authority] ordinarily would not be warranted as a matter of discretion.''')). *Singh* also did not address the availability of a stay of removal from DHS in circumstances in which DHS has sole authority over the application at issue. *See generally* 8 CFR 241.6. *Singh* is binding only within the Ninth Circuit, and its jurisdictional holding regarding the Board is inapplicable to the proposed rule. Moreover, the Department does not find its reasoning persuasive enough to graft onto the proposed rule so as to establish immigration judge authority to indefinitely stay removal proceedings. Consequently, it did not purport to settle the issue of the appropriateness of continuances in situations in which the immigration judge lacks jurisdiction over the underlying application. *Id.* (''Thus, while we acknowledge the arguments raised surrounding the question whether proceedings can or should be continued when an arriving alien's adjustment application is pending with the USCIS, our decision in this case does not resolve that issue.''). Moreover, as the Board noted, an alien with an application pending before DHS may request a stay of removal, if necessary, to await the adjudication of a collateral application. *See id.* at 112; 8 CFR 241.6(a). The potential availability of a stay of removal from DHS further diminishes any need to keep immigration proceedings open in circumstances in which an immigration judge or the Board can take no action on a collateral application.

Allowing immigration judges to continue cases for applications over which they lack jurisdiction—and, thus, for which they can take no action other than to continue proceedings for an uncertain and unknown amount of time—is also tantamount to granting either deferred action, an indefinite continuance, an exercise of prosecutorial discretion, or an indefinite stay of proceedings, especially because there is no prohibition on an alien filing repeated applications. Such action is contrary to established case law. *See Matter of Silva-Rodriguez,* 20 I&N Dec. 448, 449–50 (BIA 1992) (undue delay by an immigration judge may frustrate or circumvent statutory purpose of prompt immigration proceedings); *Matter of Quintero,* 18 I&N Dec. at 350 (an immigration judge ''may neither terminate nor indefinitely adjourn the proceedings in order to delay an alien's deportation'' and ''[o]nce deportation proceedings have been initiated by the District Director, the immigration judge may not review the wisdom of the District Director's action, but must execute his duty to determine whether the deportation charge is sustained by the requisite evidence in an expeditious manner.''); *Matter of Roussis,* 18 I&N Dec. 256, 258 (BIA 1982) (''It has long been held that when enforcement officials . . . choose to initiate proceedings against an alien and to prosecute those proceedings to a conclusion, the immigration judge is obligated to order deportation if the evidence supports a finding of deportability on the ground charged.''); *see also Matter of Yazdani,* 17 I&N Dec. 626, 630 (BIA 1991) (''However, so long as the enforcement officials . . . choose

to initiate proceedings against an alien and to prosecute those proceedings to a conclusion, the immigration judge and the Board must order deportation if the evidence supports a finding of deportability on the ground charged.''). It also infringes on DHS's authority to enforce the immigration laws, *see generally* INA 103(a)(1), 8 U.S.C. 1103(a)(1), and DHS's prosecutorial discretion to determine which cases should proceed and which ones should be terminated or paused for a significant amount of time. *See Matter of Quintero,* 18 I&N Dec. at 350 (''Consequently, the prosecutorial discretion exercised in granting deferred action status is committed exclusively to [now DHS] enforcement officials. . . . Inasmuch as deferred action status is a function of the District Director's prosecutorial authority, neither the immigration judge nor the Board may grant such status or review a decision of the District Director to deny it.''); *cf. Lopez-Telles* v. *INS,* 564 F.2d 1302, 1304 (9th Cir. 1977) (''Rather, these decisions plainly hold that the immigration judge is without discretionary authority to terminate deportation proceedings so long as enforcement officials . . . choose to initiate proceedings against a deportable alien and prosecute those proceedings to a conclusion. The immigration judge is not empowered to review the wisdom of the [now DHS] in instituting the proceedings. . . . This division between the functions of the immigration judge and those of [now DHS] enforcement officials is quite plausible and has been undeviatingly adhered to by the [now DHS].'').

In short, the Department finds that the practical resource concerns associated with reopening proceedings for applications over which an immigration judge lacks jurisdiction apply equally to continuance requests in the same circumstances and that those concerns outweigh any minimal potential benefit to an alien in seeking a stay of pending proceedings from an immigration judge, particularly because aliens may seek a stay of removal from DHS if necessary.[12] *Cf. Matter of Yauri,* 25 I&N Dec. at 111 (''Given our lack of jurisdiction over this category of adjustment applications, and because a process exists for requesting a stay from the DHS, the administrative and practical costs of reopening weigh heavily in our discretionary analysis.'').

The proposed rule discusses other restrictions related to this general rule for immigrant visas and the noted exception. For instance, the approval of a visa petition or application contemplated in the general rule and the exception does not include interim relief, *prima facie* determinations, parole, deferred action, bona fide determinations or any similar dispositions short of final approval of the visa application or petition because these are examples of disposition[s] short of final approval that do not demonstrate good cause. These restrictions are in line with the general admonition against continuances based on relief that is speculative. *See, e.g., Matter of L–A–B–R–,* 27 I&N Dec. at 418 (''Similarly, because adjustment of status typically requires an immediately available visa, INA 245(a), 8 U.S.C. 1255(a), good cause does not exist if the alien's visa priority date is too remote to raise the prospect of adjustment of status above the speculative level.''); *Matter of Quintero,* 18 I&N Dec. at 350 (''[T]he fact that the respondent has an approved visa petition does not entitle him to delay the completion of deportation proceedings pending availability of a visa number'').

Further, the proposed rule would also provide that an immigration judge may not grant a continuance to an alien in removal proceedings based on a visa application or petition based on a marriage entered into during any pending administrative or judicial proceedings regarding the alien's right to be admitted or remain in the United States, including during the pending removal proceedings, unless the alien establishes by clear and convincing evidence that the marriage was entered into in good faith and in accordance with the laws of the place where the marriage took place and the marriage was not entered into for the purpose of procuring the alien's admission as an immigrant and no fee or other consideration was given (other than a fee or other consideration to an attorney for assistance in preparation of a lawful petition) for the filing of the petition or application. This restriction, which reflects the statutory prohibition in section 245(e) of the Act, 8 U.S.C. 1255(e), on granting adjustment of status based on marriages entered into during immigration proceedings unless the alien establishes, *inter alia,* that the marriage was entered into in good faith, also adheres to precedent regarding the need to establish prima facie eligibility for relief in order to obtain a continuance for a collateral matter related to that relief. *See Matter of L–A–B–R–,* 27 I&N Dec. at 413–18; *cf. Matter of Velarde-Pacheco,* 23 I&N Dec. 253, 256 (BIA 2002) (''[A] properly filed motion to reopen may be granted, in the exercise of discretion, to provide an opportunity to pursue an application for adjustment where . . . the motion presents clear and convincing evidence indicating a strong likelihood that the respondent's marriage is bona fide . . . .''), *modified on other grounds by Matter of Lamus-Pava,* 25 I&N Dec. 61 (BIA 2009). It would further acknowledge that potential fraud or dilatory tactics go to the viability of the visa petition and the ultimate discretionary consideration of any subsequent application, such that a continuance may be unwarranted because the relief is too speculative or even prohibited outright. *See Matter of Hashmi,* 34 I&N Dec. at 792 (''If other visa petitions filed on the respondent's behalf have been denied, those petitions and the USCIS's determinations could also be presented and considered. These prior filings or other evidence of potential fraud or dilatory tactics may impact the viability of the visa petition underlying the motion.''); *see also Pedreros* v. *Keisler,* 503 F.3d 162, 166 (2d Cir. 2007) (finding no abuse of discretion when a continuance was denied because there was ''no basis to conclude that the denial of the I–130 petition had any likelihood of being overturned on appeal''); *Morgan* v. *Gonzales,* 445 F.3d 549, 552 (2d Cir. 2006) (finding that there was no abuse of discretion when a continuance was denied for the adjudication of a second visa petition when the first ''stemm[ed] from a marriage that had already been determined to lack *bona fides*'').

In addition to the general rule and exception regarding continuances based on immigrant visa applications or petitions, the proposed rule contains a similar general rule and exception for non-immigrant visas, such as a U visa, premised on similar concerns. A continuance request to apply for a non-immigrant visa or to wait for a non-immigrant visa to become available, including any applicable waiver, would not demonstrate good cause unless the receipt of the non-immigrant visa, including any applicable waiver, vitiates or would vitiate all grounds of removability with which the alien has been charged and the alien demonstrates that final approval of the visa application or petition and receipt

[12] The Department notes that an immigration judge's decision is generally subject to appeal, 8 CFR 1003.1(b)(3), that the current median time to decide a typical appeal is 323 days, *see Appellate Procedures and Decisional Finality in Immigration Proceedings; Administrative Closure,* 85 FR 52491, 52508 n.39 (Aug. 26, 2020), and that most aliens who are not in custody during their removal proceedings are not immediately detained by DHS once those proceedings conclude. Thus, even without a continuance from an immigration judge, most, if not all, aliens will have ample time to obtain a decision on any collateral application before even needing to seek a stay of removal.

of the actual visa, including approval and receipt of any applicable waiver, has occurred or will occur within six months of the request for a continuance. As with continuance requests based on immigrant visas, the receipt of interim relief, prima facie determinations, parole, deferred action, bona fide determinations or any similar dispositions short of approval of the actual visa application or petition would not constitute receipt of the actual visa or evidence that the actual visa will be received within six months of the request for a continuance. These provisions also align with the general admonition against continuances to await collateral matters that are speculative or remote. *See Matter of L–A–B–R–,* 27 I&N Dec. at 418.[13]

The proposed rule also would address continuance requests regarding discrete collateral non-visa adjudications by DHS—*e.g.,* the adjudication of an asylum application filed with DHS by an alien who has been determined to be a genuine unaccompanied alien child in proceedings pursuant to section 208(b)(3)(C) of the Act, 8 U.S.C. 1158(b)(3)(C), the adjudication of a Form I–751 waiver filed with DHS under *Matter of Stowers,* 22 I&N Dec. 605 (BIA 1999),[14] or the adjudication of an application for Temporary Protected Status (''TPS'') by an alien in removal proceedings at the time a country is designated for TPS unless the charging document, if established, would render the alien ineligible for TPS, 8 CFR 1244.7(d). In these circumstances, DHS has initial jurisdiction over the application at issue for an alien in immigration proceedings, and if DHS does not grant it, it can be renewed before the immigration judge. Consequently, an immigration judge may grant such a continuance if (A) the alien has been found removable as charged; (B) the alien has established prima facie eligibility for the underlying benefit; (C) the alien has provided evidence that the application has been filed with DHS and remains pending with DHS; (D) DHS has initial jurisdiction over the application at issue even for an alien in immigration proceedings; (E) there are no other applications pending before the immigration judge; and (F) the non-approval of the application would transfer jurisdiction to the immigration judge to review and adjudicate the application. This part of the proposed rule would not only recognize the existence of various applications over which DHS and the Department share jurisdiction, but also that DHS exercises initial jurisdiction even while the alien is in removal proceedings before the Department, and it promotes the efficient movement of cases on EOIR's docket. It also exemplifies a situation where ''an impending factual development [would] alter the course of the case,'' such that it would be ''wasteful and inefficient to plow ahead immediately.'' *Matter of L–A–B–R–,* 27 I&N Dec. at 407. If an alien has established prima facie eligibility for a non-visa benefit application over which DHS has original jurisdiction, but which may be renewed before an immigration judge if not approved by DHS, then the Department has an interest in having the non-visa benefit adjudicated before proceeding on its own.

The proposed rule also addresses another context for continuance requests, those related to matters of an alien's representation. Nearly two-thirds of all respondents in removal proceedings have representation, and nearly ninety percent of those seeking asylum have representation, *see* EOIR, *Current Representation Rates* (Apr. 15, 2020), *available at https://www.justice.gov/eoir/page/file/1062991/download;* thus, it is important for the Department to ensure that representation does not undermine the orderly procedure of the immigration courts and is not a hindrance to fair and timely adjudications. Moreover, just as a criminal defendant ''may not manipulate his right to counsel to undermine the orderly procedure of the courts or subvert the administration of justice,'' *United States* v. *Thibodeaux,* 758 F.2d 199, 201 (7th Cir. 1985), so, too, an alien in civil immigration proceedings cannot manipulate his statutory right to counsel at no expense to the government, INA 292, 8 U.S.C. 1362, or any associated due process rights recognized by circuit courts to delay proceedings or subvert the administration of justice by immigration courts, *cf. Gomez-Medina* v. *Holder,* 687 F.3d 33, 38 (1st Cir. 2012) (''There is also a strong interest in not allowing manipulations of the [immigration] system in order to cause delay.''); *United States* v. *Poston,* 902 F.2d 90, 96 (D.C. Cir. 1990) (Thomas, J.) (''[T]he right to counsel cannot be insisted upon in a manner that will obstruct an orderly procedure in courts of justice, and deprive such courts of the exercise of their inherent powers to control the same. The public has a strong interest in the prompt, effective, and efficient administration of justice; the public's interest in the dispensation of justice that is not unreasonably delayed has great force.'' (citations and internal quotation marks omitted)). To that end, the proposed rule would lay out six contexts for guiding adjudicators in determining whether a continuance related to representation establishes good cause.

First, the proposed rule provides, ''[a]n immigration judge is not required to grant a continuance to any alien in removal proceedings to secure representation if the time period described in section 239(b)(1) of the [INA] has elapsed and the alien has failed to secure counsel.'' Second, an immigration judge, would be able to, in his or her discretion, grant one continuance for not more than 30 days to allow an alien to secure representation if the date of the alien's initial hearing occurs less than 30 days after the Notice to Appear's service date and the alien demonstrates that dilidgence in seeking representation since that date. Consistent with section 239(b) of the Act, 8 U.S.C. 1229(b), those two proposed provisions contemplate that the Act already grants respondents a reasonable amount of time to secure counsel prior to the first hearing, but that additional time may be necessary in discrete instances.[15] *Cf. Hidalgo-Disla* v.

[13] As discussed *supra, Matter of Sanchez Sosa,* 25 I&N Dec. 807, had no occasion to consider the impact of the remoteness of a non-immigrant visa on the alien's continuance request. The other factors considered by the Board in *Matter of Sanchez Sosa* in determining the appropriateness of a continuance to await a non-immigrant visa are generally subsumed within the proposed rule. Accordingly, the proposed rule does not deviate from *Matter of Sanchez Sosa,* but rather clarifies it in the context of non-immigrant visas whose availability is remote.

[14] Aliens who receive lawful permanent resident status on a conditional basis pursuant to section 216 of the Act, 8 U.S.C. 1186a, are required to file a petition on Form I–751 to remove the conditions within two years of the anniversary of obtaining that status. INA 216(d)(2)(A), 8 U.S.C. 1186a(d)(2)(A). Aliens who cannot meet the petition requirements may file for a waiver of them under certain circumstances, which is also filed on Form I–751. *Id.;* 1186a(c)(4). DHS has initial jurisdiction over the waiver application, and if DHS does not approve it, it may be renewed before an immigration judge. Longstanding Board case law holds that where an alien is prima facie eligible for a Form I–751 waiver, the alien's proceedings should be continued to allow DHS to adjudicate it. *See Matter of Stowers,* 22 I&N at 613–14.

[15] These proposed rule also adopts a feature of a prior regulation that governed immigration court proceedings for approximately 30 years and limited aliens to one continuance to seek representation unless ''sufficient cause'' for more time was shown. *See* 8 CFR 242.13 (1986) (''A continuance of the hearing for the purpose of allowing the respondent to obtain representation shall not be granted more than once, unless sufficient cause for the granting of more time is shown.''). No reason was given for departing from that limitation in the mid-1980s, and there is no indication that it was unworkable. *See Aliens and Nationality; Rules of Proceedings Before Immigration Judges,* 50 FR 51693 (Dec. 19, 1985) and 52 FR 2931 (Jan. 29, 1987) (proposing and then finalizing, without substantive discussion,

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INS, 52 F.3d 444, 447 (2d Cir. 1995) (finding an immigration judge's decision to proceed with a hearing after providing an alien 26 days to seek counsel was not erroneous and dismissing as frivolous an appeal asserting that it was); *Ghajar* v. *INS,* 652 F.2d 1347, 1348–49 (9th Cir. 1981) (''Ghajar's assertion that she was denied due process because she was not granted a second continuance to allow her attorney further time to prepare for the deportation hearing is without merit. . . . One full month elapsed between the date of the show cause order and the date on which the hearing ultimately took place. . . . The immigration judge did not abuse his discretion in refusing to grant a second continuance.'').

Indeed, nothing in that part of the Act prohibits ''the Attorney General from proceeding against an alien pursuant to section 240 [8. U.S.C. 1229a] if the time period described in paragraph (1) [*i.e.* ten days between the service of a Notice to Appear and the first hearing] has elapsed and the alien has failed to secure counsel.'' INA 239(b)(3), 8 U.S.C. 1229(b)(3). Thus, although aliens possess a statutory right to representation at no expense to the government, *see* INA 292, 8 U.S.C. 1362, that right is qualified by Congress's further determination that a period of ten days after an alien has been served with a Notice to Appear is a sufficient time to allow the alien to seek such representation before the intial hearing date in removal proceedings, *see* INA 239(b), 8 U.S.C. 1229(b). Although Congress's determination in INA 239(b)(3), 8 U.S.C. 1229(b)(3), may have been overlooked in litigation regarding the denial of further continuances for an alien to seek representation, the Department declines to ignore the clear statutory text of that section in the instant NPRM.

Currently, aliens in removal proceedings generally have ample time to seek representation if they exercise diligence.[16] For a detained case, the median time between service of the NTA on an alien and filing it with an immigration court is 11 days and the median time between the receipt of the NTA by an immigration court and the first hearing is 27 days; for a non-detained case, the comparable medians are 41 and 226 days, respectively. Thus, most aliens already have a reasonable and realistic amount of time to obtain representation. *Cf. Matter of C–B-,* 25 I&N Dec. 888, 889–90 (BIA 2015) (aliens should receive a fair opportunity to secure counsel).[17] Nevertheless, the Department recognizes that in limited circumstances, an alien exercising diligence may need additional time.[18] Thus, if an alien's hearing occurs less than 30 days after the service of the Notice to Appear, and the alien demonstrates that he or she was diligent in securing counsel, the proposed rule provides that a continuance of up to 30 days may be warranted.[19]

Third, the proposed rule would provide that good cause may not be found on the basis of a representative's assertion that his or her workload or obligations in other cases prevent preparation because professional responsibility obligations require that representatives do not take on no more cases than they can handle. *See* Operating Policies and Procedures Memorandum (OPPM) 17–01, *Continuances* (Jul. 31, 2017) at 5–6 (''In addition, frequent or multiple requests for additional preparation time based on a practitioner's workload concerns related to large numbers of other pending cases should be rare and warrant careful review.''). The regulations already require representatives to provide competent and diligent representation for their clients, and it would not constitute good cause if a representative is not abiding by those requirements. *See, e.g.,* 8 CFR 1003.102(o) (deeming the failure to provide competent representation to a client grounds for discipline), 1003.102(q) (deeming the failure to act with reasonable diligence and promptness in representing a client grounds for discipline).

Fourth, under the proposed rule, an immigration judge will not be permitted to grant more than one continuance in removal proceedings for preparation time that is separate from the normal preparation time between hearings. Further, any such continuance solely for preparation may be granted prior to pleading to the allegations and charges in a Notice to Appear, but will not be granted for more than 14 days. This proposed rule recognizes that a significant amount of preparation time is already built into immigration proceedings, especially between a master calendar hearing and an individual merits hearing. *See, e.g.,*

a change to the language in 8 CFR 242.13 to eliminate the general limitation of only one continuance for an alien to seek representation). Moreover, in light of the subsequent enactment of section 239(b)(3) of the Act, 8 U.S.C. 1229(b)(3), the Department believes returning to a variation of the prior system best effectuates the intent and purpose of the representation-related provisions of the Act by recognizing that the Act grants a reasonable amount of time to secure representation but that additional time may be necessary in limited circumstances.

[16] The Department recognizes that not all aliens will obtain representation even though they have ample time to seek it. For example, some aliens do not secure representation because they do not wish to pay the fee charged by a potential representative. *Cf. Al Khouri* v. *Ashcroft,* 362 F.3d 461, 464 (8th Cir. 2004) (''It would be nonsensical to recognize a constitutional entitlement to a continuance based on counsel's withdrawal when petitioners themselves are responsible for the withdrawal [due to failing to pay counsel].''). Further, many representatives, due to ethical or professional responsibility obligations, will not take cases of aliens who are ineligible for any relief or protection from removal (*e.g.,* an alien with an aggravated felony drug trafficking conviction who has no fear of persecution or torture in his or her home country) because they do not wish to charge money for representation when representation will not affect the outcome of the proceeding. These situations illustrate only that some aliens may not ultimately secure counsel for reasons common to issues of representation in all civil cases—*i.e.,* the cost of the representation and the strength of the case—not that aliens do not generally have ample time to seek representation. *See United States* v. *Torres-Sanchez,* 68 F.3d 227, 231 (8th Cir. 1995) (''Although Torres-Sanchez expressed some frustration over his attempt to obtain counsel, that frustration, in our view of the record, stemmed from his realization that he faced the inevitable consequence of deportation, not from a lack of opportunity to retain counsel. In any event, the mere inability to obtain counsel does not constitute a violation of due process.'').

[17] The Board has not defined what a reasonable and realistic amount of time is for purposes of obtaining representation, and the respondent in *Matter of C–B-* was given only eight days between the issuance of an NTA and his first hearing, in apparent contravention of section 239(b)(1) of the Act, 8 U.S.C. 1229(b)(1). *See Matter of C–B-,* 25 I&N Dec. at 889. Nevertheless, *Matter of C–B-* cannot be interpreted to contradict the Act, and the Act clearly indicates that 10 days between the service of an NTA and the first hearing is a sufficient amount of time to obtain representation. *See* INA 239(b)(3), 8 U.S.C. 1229(b)(3). Accordingly, the proposed rule is not in tension with *Matter of C–B-* and does not deviate from recognizing the statutory parameters for providing time for a respondent to obtain representation.

[18] The rule does not countenance additional time, however, in situations where an alien initially chooses to proceed without counsel and then belatedly reconsiders that decision after being found removable. *See Michel* v. *INS,* 206 F.3d 253, 259 (2d Cir. 2000) (''We cannot require the IJ to postpone a proceeding every time a party believes that the hearing is going badly, and, as a result, seeks to re-think his or her decision to forego representation.'').

[19] There is no current, consistent practice among immigration judges regarding either the number or length of continuances to seek representation. Accordingly, the proposed rule would also standardize motions practice in this area based on a recognition that most aliens have already received a significant amount of time to seek counsel prior to their first hearing but that in discrete instances, additional time may be necessary. Such standardization will benefit both practitioners and adjudicators by making procedural expectations both clear and consistent across all cases in removal proceedings. It will also ensure that aliens are not dilatory in seeking representation. Moreover, the Department believes an additional continuance of up to 30 days constitutes a reasonable amount of additional time for diligent aliens to continue seeking representation, because it would give a diligent alien potentially up to 40 days total to seek representation after being served with an NTA, which is in line with the minimum median total amount of time currently, 38 days.

Paris-Mendez v. *Barr,* 814 F. App'x 247, 250 (9th Cir. 2020) (unpublished) (''First, [respondent's] counsel decided not to prepare for an individualized hearing on September 20, 2016 until a few days prior, when she had five months to do so. Clearly, this did not justify a continuance.''); *Islam* v. *U.S. Att'y Gen.,* 748 F. App'x 961, 963 (11th Cir. 2018) (unpublished) (''The morning of Islam's removal hearing, attorney Zubaida Iqbal moved for a continuance on the ground that she had been hired the day before and needed time to prepare, but Iqbal had entered a notice of appearance in Islam's proceeding [two months earlier] and represented him at his bond hearing. And Iqbal's motion to continue was identical to the one she filed before Islam's bond hearing. The immigration judge did not abuse his discretion by refusing to further delay Islam's removal hearing when Iqbal failed to appear at the hearing or to explain in her motion why a continuance was necessary when she was familiar with Islam's case and the documents relating to his applications for relief.''); *Aguilar Delgado* v. *Gonzales,* 139 F. App'x 851, 853 (9th Cir. 2005) (unpublished) (''The agency did not abuse its discretion by denying a continuance, however, as it had given him fourteen months from his initial hearing where he appeared with counsel to prepare his case, and Aguilar Delgado chose to fire his attorney immediately preceding the hearing.'').

Consistent with an attorney's ethical duties of competence and diligence, 8 CFR 1003.102(o) and (q), additional time for putative and generalized ''preparation'' contributes to unnecessary delay and raises questions about the true purpose of the requested delay. Moreover, many instances of an alleged lack of preparation are actually due to the respondent's behavior, and the withholding of information by a respondent from his or her representative leading to that representative's lack of preparedness does not demonstrate good cause. *See, e.g., Paris-Mendez,* 814 F. App'x at 250–51 (''Second, with respect to the assertion that the petitioner's counsel learned for the first time on the morning of the hearing that the petitioner identified himself as a Jehovah's Witness and that he allegedly suffered persecution in Mexico because of his religion, it is puzzling that the petitioner's counsel was so informed at the last minute, when she had previously helped the petitioner with completing his Form I–589 . . . .''); *Ahmed* v. *Gonzales,* 185 F. App'x 665, 666 (9th Cir. 2006) (unpublished) (''Moreover, it was Ahmed's fault that his new attorney was not prepared. He hired her just before the hearing and did not inform her that the INS had revoked his visa.''); *see also Ghajar* v. *INS,* 652 F.2d at 1348–49 (''Ghajar's assertion that she was denied due process because she was not granted a second continuance to allow her attorney further time to prepare for the deportation hearing is without merit'').

Nevertheless, the Department recognizes that in rare cases, an attorney may need additional time to prepare to plead to the charges in the NTA, and the proposed rule would allow a continuance of up to 14 days to do that.[20]

Fifth, the proposed rule would provide that good cause will not be found due to a representative's scheduling conflict in another court if that conflict that existed at the time the immigration judge scheduled the hearing in open court and the representative did not raise it at the time. This change supports the standard that a practitioner's workload must be controlled and managed so that each matter can be handled competently, 8 CFR 1003.102(q). If the representative's scheduling conflict in another court arises after the immigration hearing in removal proceedings was scheduled, an immigration judge may grant a continuance (of no more than 14 days) only if that conflict involves the court appointment of a representative to a case and the immigration judge was notified of the conflict in a timely manner.

The proposed rule recognizes that in certain jurisdictions representatives may be appointed as criminal defense attorneys through a panel process in furtherance of a criminal defendant's constitutional right to representation. *See, e.g.,* 18 U.S.C. 3006A. Understanding that the constitutional rights of criminal defendants outweigh the inconvenience to the civil nature of immigration proceedings occasioned by a scheduling conflict and that criminal trials, especially of detained defendants, generally take precedence over civil proceedings, *see, e.g.,* United States Courts, *FAQs: Filing a Case, https://www.uscourts.gov/faqs-filing-case#faq-When-will-the-court-reach-a-decision-in-my-case*? (last visited Nov. 5, 2020) (the scheduling of criminal cases is assigned a higher priority than the scheduling of civil cases in federal court), the proposed rule would contain an exception such that good cause may be found for a conflict that arises after an immigration hearing is scheduled due to the appointment of a respondent's representative in a criminal case, provided that the attorney timely notifies the immigration court of the conflict.[21]

This proposed rule recognizes the disregard shown to immigration courts by practitioners who either misleadingly inform the immigration judge that they do not have a conflict when scheduling a future hearing or take on cases in other courts after the immigration court hearing has been scheduled knowing that a conflict exists. Such disregard for the time of an immigration judge and the resources of the immigration court

[20] The proposed rule recognizes that substantial preparation time is already built into the current framework of immigration proceedings. For example, an attorney who contests charges of removability may be given time to brief the charges or the case may be set for a hearing on the charges, and the proposed rule does not limit the time immigration judges allow for briefing schedules or the scheduling of hearings related to contested charges of removability. Accordingly, representatives who contest grounds of removability will likely have additional time to address the charges, though that time will not fall under the rubric of a continuance for attorney preparation. Similarly, the normal time between a master calendar hearing and an individual merits hearing should provide an attorney ample time for preparation, as the attorney will have already presented a prima facie case for relief in order to obtain a merits hearing date in the first instance. There is no current, consistent practice among immigration judges regarding either the number or length of so-called ''attorney prep'' continuances. Accordingly, the proposed rule would also standardize motions practice in this area based on a recognition that the natural procedural progression of a case already contains a significant amount of built-in preparation time, that most typical preparatory activities—*e.g.,* writing briefs, contesting removability, filing applications or motions to terminate proceedings, and assembling evidence—occur during this time and outside of a court hearing, and that representatives may submit written pleadings and applications for relief without the need for a hearing to do so. Such standardization will benefit both practitioners and adjudicators by making procedural expectations both clear and consistent across all cases in removal proceedings. It will also ensure that hearing time is not wasted considering activities that are normally performed during the time between scheduled hearings and that representatives do not engage in dilatory tactics simply to prolong proceedings as much as possible. Although the current framework already contains substantial preparation time for either contesting removability or pursuing an application for relief, the Department nevertheless recognizes that it cannot account for every single scenario in which an attorney may allege a need for preparation time. Accordingly, in rare cases outside of the typical scenarios outlined above, the proposed rule recognizes an immigration judge's ability to grant an additional continuance for attorney preparation time of up to 14 days, which is a reasonable amount of time for a diligent and competent attorney to assess an issue beyond those otherwise contemplated in this proposed rule.

[21] The proposed rule also recognizes that attorneys may also be appointed in discrete types of civil proceedings, *e.g.* habeas proceedings. Accordingly, the rule is not limited to appointments in criminal cases and contains an exception for a conflict arising due to a subsequent appointment in any type of case, provided that the attorney timely notifies the immigration court of the conflict.

does not demonstrate good cause.[22] Sixth, if the respondent's representative fails to appear for a scheduled hearing, the proposed rule would provide that the immigration judge may grant a continuance of no more than 14 days. This provision recognizes that, while representatives are expected to attend their clients' hearings, *see id.* 1003.102(l), 1003.102(o), 1003.102(q), 1003.102(r), a respondent should not necessarily be penalized for his or her representative's failure to appear. Therefore, a continuance in these instances may be warranted, though it should be only for a limited duration of 14 days to ensure that an alien's case does not become stale due to any undue delay.

The proposed rule would also address continuances made on an immigration judge's own motion. In doing so, it would recognize that although there are multiple circumstances in which an immigration judge should continue a case on his or her own motion, those circumstances are closely circumscribed and should generally be rare. It also recognizes that the good cause standard ''plainly confines the discretion of immigration judges to grant continuances . . . [r]ather than giving 'unfettered discretion to grant or deny a continuance.' '' *Matter of L–A–B–R–,* 27 I&N Dec. at 407 (quoting *Ahmed,* 569 F.3d at 1014). Thus, the proposed rule would generally preclude an immigration judge from granting a continuance on his or her own motion except in clearly-specified circumstances.[23]

All of these enumerated reasons are obvious instances where it would be unreasonable or impossible for an immigration judge to proceed with a hearing and, thus, warrant a continuance. *See, e.g., Matter of L–A–B–R–,* 27 I&N at 407 (''There are times when the prudent use of continuances may advance the efficient enforcement of the immigration laws. . . . *When a key participant falls ill, for instance,* . . . it can be wasteful and inefficient to plow ahead immediately.'') (emphasis added); *cf. Matter of W–A–F–C–,* 26 I&N Dec. 880, 882–83 (BIA 2016) (holding that where DHS seeks to re-serve a respondent to effect a notice to appear that was defective under the regulatory requirements for serving minors under the age of 14, a continuance should be granted for that purpose).

Additionally, this list includes a catch-all provision providing authority for an immigration judge to sua sponte continue a case in situations in which unforeseen exceptional or extraordinary circumstances[24] beyond the control of the alien, the alien's representative, government counsel, or the immigration judge arise. The Department recognizes that no regulation can account for every possible scenario in which a continuance may be appropriate notwithstanding the provisions outlined in the proposed rule and that in rare cases, a continuance may be warranted for reasons wholly beyond the control of the parties and the immigration judge. Consequently, the proposed rule provides a catch-all mechanism for an immigration judge to grant a continuance in such rare circumstances.

Finally, the proposed rule discusses continuances of merits hearings, including merits hearings on applications for relief or protection and merits hearings on contested charges of removability. Under the proposed rule, continuances of merits hearings are strongly disfavored, and should only be granted in specific circumstances or upon motion by either party. *Accord* EOIR OPPM 17–01 (''Such [merits] hearings are typically scheduled far in advance, which provides ample opportunity for preparation time, and often involve interpreters or third-party witnesses whose schedules have been carefully accommodated. Moreover, slots for individual merits hearings cannot be easily filled by other cases, especially if the decision to continue the hearing is made close in time to the scheduled date. Although some continuances of individual merits hearings are unavoidable, especially in situations involving an unexpected illness or death, the continuance of an individual merits hearing necessarily has a significant adverse ripple effect on the ability to schedule other hearings across an immigration judge's docket. Thus, such a request should be reviewed very carefully, especially if it is made close in time to the hearing.'').

The proposed rule contemplates that, following the scheduling of a merits hearing, parties have ample time to prepare for the hearing and that they should be ready to proceed at that date. If a motion for a continuance were granted in such an instance, the need to reschedule would unnecessarily delay the adjudication of the respondent's case. While there are circumstances in which a continuance is warranted, the proposed rule would embody a primary desire to not continue merits hearings. To do so would be to unduly disregard EOIR's mission of adjudicating cases expeditiously and efficiently, as well as to potentially undermine consideration of an application for relief for an alien whose case is already prepared for the hearing and whose evidence may otherwise go stale during any continuance. Accordingly, the proposed rule would note that continuances of merits hearings should only be granted in compelling circumstances outlined in the proposed rule, including unforeseen exceptional or extraordinary circumstances based on a motion by either party, and should be granted for no more than 30 days. An additional continuance of that length is a reasonable amount of time to address the issue that necessitated the continuance while also ensuring that evidence does not go stale or that the parties' preparation for the merits hearing is not otherwise vitiated.

[22] The proposed rule recognizes that cases are sometimes scheduled outside of open court. In such situations, the limitation on good cause due to a scheduling conflict by a representative outlined in the proposed rule would not apply, though any continuance request in such a situation would still have to affirmatively demonstrate good cause. Moreover, the representative would need to file the continuance request within 14 days of the issuance of the scheduling notice by the immigration court.

[23] These circumstances would include those in which a continuance is required pursuant to 8 CFR 1003.47; there is evidence of serious illness of the alien, representative, or immigration judge, or serious illness or death of the spouse, child, or parent of the alien, representative, or immigration judge; the immigration judge is otherwise absent and no other immigration judge is available to preside over the hearing; there are technical difficulties with the immigration court's computer, recording system, or video teleconferencing system that prevent the case from being heard or recorded; the Department of Homeland Security or the Department of Health and Human Services fails to produce a detained alien for the hearing; an interpreter is necessary for the hearing, but is unavailable or unqualified; the record of proceedings is unavailable; the respondent did not appear at a hearing due to detention by a law enforcement entity, or due to a deficient notice and service of a new notice of hearing can correct the deficiency; the immigration judge began a hearing but was unable to complete it due to no fault of the parties; the court is closed for hearings at the time of the hearing; or unforeseen exceptional or extraordinary circumstances beyond the control of the alien, the alien's representative, government counsel, or the immigration judge.

[24] The use of ''unforeseen exceptional or extraordinary circumstances'' as a standard for rare scenarios not falling into any other category is not intended to reflect statutory or regulatory definitions of those terms used in other contexts. *See, e.g.,* INA 240(e)(1), 8 U.S.C. 1229a(e)(1); 8 CFR 1208.4(a)(5). Rather, it reflects the rare nature of such fact patterns that would warrant a continuance notwithstanding any other regulatory provision. Thus, this standard could warrant a continuance notwithstanding other provisions in truly rare or unique situations where an attorney faced a genuinely unforeseeable workload issue or a respondent faced an atypical need for additional time to obtain counsel (*e.g.,* prior counsel has engaged in unethical or unprofessional behavior preventing the respondent from obtaining new counsel).

V. Regulatory Requirements

A. Regulatory Flexibility Act

The Department has reviewed this regulation in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) and has determined that this rule will not have a significant economic impact on a substantial number of small entities. The proposed rule would not regulate ''small entities'' as that term is defined in 5 U.S.C. 601(6). Only individuals, rather than entities, are placed in immigration proceedings, and only immigration judges, not entities, adjudicate requests for continuances.

B. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

C. Congressional Review Act

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

D. Executive Order 12866 and Executive Order 13563

The Office of Information and Regulatory Affairs of the Office of Management and Budget (''OMB'') has determined that this proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866. It will neither result in an annual effect on the economy greater than $100 million nor adversely affect the economy or sectors of the economy. It does not pertain to entitlements, grants, user fees, or loan programs, nor does it raise novel legal or policy issues. It does not create inconsistencies or interfere with actions taken by other agencies. Accordingly, this rule is not a significant regulatory action subject to review by OMB pursuant to Executive Order 12866.

Executive Order 13563 directs 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 using the best available methods to quantify costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Department certifies that this regulation has been drafted in accordance with the principles of Executive Order 13563.

The proposed rule would provide additional clarity for adjudicators across many issues arising from the most types of requests for a continuance in immigration proceedings. Although the proposed regulation would provide clearer guidance for adjudicators in considering continuance requests, it does not change the nature or scope of the role of an immigration judge during immigration proceedings. Immigration judges are already trained to consider all relevant legal issues in assessing a request for a continuance, and the proposed rule does not propose any changes that would make adjudicating such requests more challenging than they currently are. If anything, the proposed rule would make adjudicating motions for a continuance easier and more efficient by providing clearer standards than the current, amorphous ''good cause'' standard. Accordingly, the Department does not expect the proposed changes to increase the adjudication time for immigration court proceedings.

The Department notes that the proposed changes may result in fewer continuances being granted; but, because such requests are inherently fact-specific, because there may be multiple reasons behind a continuance request, and because the Department does not granularly track multiple bases for a continuance, the Department cannot quantify precisely the expected decrease. Moreover, the denial of a continuance says little about the ultimate outcome of an alien's proceedings which depends on particular facts and an individual alien's eligibility for relief or protection, including relief that may be granted even after proceedings have concluded. Thus, the impact of the proposed rule on the outcomes of particular cases cannot be modeled with any degree of precision. Nevertheless, in general, the Department expects the proposed rule to result in fewer continuances which would enhance the efficiency of immigration proceedings in the aggregate, benefit aliens with valid claims who would otherwise have to wait longer to receive relief or protection, and vindicate the government and the public's interests in the prompt administration of justice. Similarly, a reduction in multiple, lengthy continuances may also provide some benefit to attorneys, particularly pro bono attorneys, who would not need to commit to representation for several years if the hearing process worked more efficiently. *See, e.g.,* Human Rights First, *The U.S. Immigration Court* at 5 (''In a February 2016 survey conducted by Human Rights First of 24 pro bono coordinators at many of the nation's major law firms, nearly 75 percent of pro bono professionals indicated that delays at the immigration court are a significant or very significant negative factor in their ability to take on a pro bono case for legal representation before the court.''). Thus, for the reasons explained above, the expected costs of this proposed rule are likely to be de minimis, whereas the benefits to all parties, though not precisely quantifiable, are significant.

E. Executive Order 13132 (Federalism)

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

G. Paperwork Reduction Act

This rule does not propose new or revisions to existing ''collection[s] of information'' as that term is defined under the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320.

List of Subjects

8 CFR Part 1003

Administrative practice and procedure, Aliens, Immigration, Legal Services, Organization and functions (Government agencies).

8 CFR Part 1240

Administrative practice and procedure, Aliens.

Accordingly, for the reasons set forth in the preamble, and by the authority vested in the Director, Executive Office for Immigration Review, by the Attorney General Order Number 4910–2020, the Department proposes to amend chapter V of title 8 of the Code of Federal Regulations as follows:

Title 8 of the Code of Federal Regulations

PART 1003—EXECUTIVE OFFICE FOR IMMIGRATION REVIEW

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

Authority: 5 U.S.C. 301; 6 U.S.C. 521; 8 U.S.C. 1101, 1103, 1154, 1155, 1158, 1182, 1226, 1229, 1229a, 1229b, 1229c, 1231, 1254a, 1255, 1324d, 1330, 1361, 1362; 28 U.S.C. 509, 510, 1746; sec. 2 Reorg. Plan No. 2 of 1950; 3 CFR, 19491953 Comp., p. 1002; section 203 of Pub. L. 105–100, 111 Stat. 2196–200; sections 1506 and 1510 of Pub. L. 106–386, 114 Stat. 1527–29, 1531–32; section 1505 of Pub. L. 106–554, 114 Stat. 2763A–326 to –328.

■ 2. Revise § 1003.29 to read as follows:

§ 1003.29 Continuances.

(a) Subject to paragraph (b), the immigration judge may grant a motion for continuance for good cause shown, provided that nothing in this section shall authorize a continuance that causes the adjudication of an asylum application by an immigration judge to exceed 180 days in the absence of exceptional circumstances, consistent with section 208(d)(5)(iii) of the Act and 8 CFR 1003.10(b).

(b) (1) *In general.* Subject to paragraphs (2) through (6), good cause is shown when a movant demonstrates a particular and justifiable need for the continuance. To determine whether good cause has been established, an immigration judge should consider the following non-exhaustive list of factors:

(i) The amount of time the movant has had to prepare for the hearing and whether the movant has exercised due diligence to ensure preparedness for that hearing;

(ii) The length and purpose of the requested continuance, including whether the reason for the requested continuance is dilatory or contrived;

(iii) Whether the motion is opposedand the basis for the opposition, though the opponent does not bear the burden of demonstrating an absence or lack of good cause;

(iv) Implications for administrative efficiency; and

(v) Any other relevant factors for consideration.

(2) *Good cause not shown.* (i) Good cause for a continuance is not shown when the continuance would not materially affect the outcome of removal proceedings or, for a continuance request based on a collateral matter, when the alien has not demonstrated by clear and convincing evidence a likelihood of obtaining relief on the collateral matter.

(ii) A request for a continuance in order to seek parole, deferred action, or the exercise of prosecutorial discretion by DHS does not demonstrate good cause.

(iii) A request for a continuance that would cause an immigration court to exceed a statutory or regulatory adjudication deadline does not demonstrate good cause unless the request meets the standard of any statutory or regulatory exception to the deadline.

(3) *Continuances of removal proceedings related to collateral immigration applications.* (i) Subject to paragraph (b)(3)(ii) of this section, a continuance request to allow an alien or a petitioner to apply for an immigrant visa or to wait for an immigrant visa for which the alien is the beneficiary to become available does not demonstrate good cause unless:

(A) (*1*) The approval of the visa application or petition provides or would provide an immediately-available visa to the alien, or

(*2*) The approval of the visa application or petition provides or would provide a visa to the alien with a priority date six months or less from the immediate action application date provided in the Visa Bulletin published by the Department of State for the month in which the continuance request is made;

(B) The alien has demonstrated prima facie eligibility for the underlying visa and, if applicable, for adjustment of status and any necessary waiver(s) based on the approval of that visa, including establishing that the alien would warrant adjustment of status and any necessary waiver(s) as a matter of discretion; and

(C) The immigration judge has jurisdiction over any application for adjustment of status, including any necessary waiver(s) in conjunction with that application, based on approval of the underlying visa.

(ii) (A) For purposes of paragraph (b)(3)(i) of this section, approval of a visa petition or application does not include interim relief, prima facie determinations, parole, deferred action, bona fide determinations or any similar dispositions short of final approval of the visa application or petition. The seeking of any of these dispositions or of any disposition short of final approval of the visa application or petition does not demonstrate good cause.

(B) Notwithstanding paragraph (b)(3)(i) of this section, an immigration judge may not grant a continuance to an alien in removal proceedings based on a visa application or petition based on a marriage entered into during any pending administrative or judicial proceedings regarding the alien's right to be admitted or remain in the United States, including during the pending removal proceedings, unless the alien establishes by clear and convincing evidence to the satisfaction of the immigration judge that the marriage was entered into in good faith and in accordance with the laws of the place where the marriage took place and the marriage was not entered into for the purpose of procuring the alien's admission as an immigrant and no fee or other consideration was given (other than a fee or other consideration to an attorney for assistance in preparation of a lawful petition) for the filing of the petition or application.

(iii) Subject to paragraph (b)(3)(iv) of this section, a continuance request to apply for a non-immigrant visa or to wait for a non-immigrant visa to become available, including any applicable waiver, in removal proceedings does not demonstrate good cause unless

(A) Receipt of the non-immigrant visa, including any applicable waiver, vitiates or would vitiate all grounds of removability with which the alien has been charged; and

(B) The alien demonstrates that final approval of the visa application or petition and receipt of the actual visa, including approval and receipt of any applicable waiver, has occurred or will occur within six months of the request for a continuance.

(iv) For purposes of paragraph (b)(3)(iii) of this section, the receipt of interim relief, prima facie determinations, parole, deferred action, bona fide determinations or any similar dispositions short of approval of the actual visa application or petition does not constitute receipt of the actual visa or evidence that the actual visa will be received within six months of the request for a continuance

(v) An immigration judge may grant a continuance in removal proceedings to await the adjudication of a non-visa application by DHS over which DHS has initial jurisdiction in the following circumstances:

(A) The alien has been found removable as charged;

(B) The alien has established prima facie eligibility for the underlying benefit;

(C) The alien has provided evidence that the application has been filed with DHS and remains pending with DHS;

(D) DHS has initial jurisdiction over the application at issue even for an alien in immigration proceedings;

(E) There are no other applications pending before the immigration judge; and

(F) The non-approval of the application would transfer jurisdiction to the immigration judge to review and adjudicate the application.

(4) *Continuances related to an alien's representation.* (i) Subject to paragraph (b)(4)(ii) of this section, an immigration judge is not required to grant a continuance to any alien in removal proceedings to secure representation if the time period described in section 239(b)(1) of the Act has elapsed and the alien has failed to secure counsel.

(ii) In the immigration judge's discretion, an immigration judge may grant one continuance to an alien in removal proceedings to secure representation if the date of the alien's initial hearing occurs less than 30 days after the date the alien was served with a Notice to Appear and the alien demonstrates that the alien has been diligent in seeking representation since that date. Such a continuance shall be for a reasonable period of time but shall not exceed 30 days.

(iii) Because representatives are presumed to take on no more cases than they can handle in accordance with professional responsibility obligations of diligence and competence, a representative's assertions about his or her workload or obligations in other cases do not constitute good cause.

(iv) An immigration judge shall grant no more than one continuance in removal proceedings to an alien or his representative for preparation time, separate from the normal preparation time between hearings. Such a continuance may be granted solely for preparation prior to pleading to the allegations and charges in a Notice to Appear. Such continuance shall be granted for no more than 14 days.

(v) A representative's scheduling conflict in another court that existed at the time the immigration judge scheduled the hearing in removal proceedings for which the representative seeks a continuance and that the representative did not disclose at the time the hearing was scheduled does not constitute good cause, unless the immigration judge scheduled the case outside of open court. An immigration judge may grant a continuance due to a representative's scheduling conflict in another court arising after the immigration hearing in removal proceedings was scheduled in open court, but only if it involves the court appointment of a representative to a case and the immigration judge was notified of the conflict in a timely manner. Such continuance shall be granted for no more than 14 days. A representative requesting a continuance of a hearing scheduled outside of open court due to a scheduling conflict in another court that existed at the time the immigration court hearing notice was issued must file a motion for a continuance with 14 days of the issuance of the immigration court hearing notice.

(vi) Upon motion by a respondent in removal proceedings, an immigration judge may grant a continuance of no more than 14 days in a case in which the respondent's representative failed to appear for a scheduled hearing.

(5) *Continuances on an immigration judge's own motion.* An immigration judge may not grant a continuance on his or her own motion, except in the following circumstances:

(i) A continuance is required pursuant to § 1003.47;

(ii) There is evidence of serious illness of the alien or serious illness or death of the spouse, child, or parent of the alien;

(iii) There is evidence of serious illness or death of the alien's representative or serious illness or death of the spouse, child, or parent of the alien's representative;

(iv) There is a serious illness of the immigration judge or serious illness or death of the spouse, child, or parent of the immigration judge;

(v) The immigration judge is absent and no other immigration judge is available to preside over the hearing;

(vi) There are technical difficulties with the immigration court's computer, recording system, or video teleconferencing system that prevent the case from being heard or recorded;

(vii) The Department of Homeland Security or the Department of Health and Human Services fails to produce a detained alien for the hearing;

(viii) An interpreter is necessary for the hearing and either an interpreter is unavailable or the interpreter present is unqualified;

(ix) The record of proceedings is unavailable;

(x) The respondent did not appear at a hearing because the respondent was detained by a law enforcement entity;

(xi) The respondent did not appear at a hearing due to a deficient notice and service of a new notice of hearing can correct the deficiency;

(xii) The immigration judge began a hearing but was unable to complete it due to no fault of the parties;

(xiii) The court is closed at the time of the hearing; or

(xiv) Unforeseen exceptional or extraordinary circumstances beyond the control of the alien, the alien's representative, government counsel, or the immigration judge require a continuance.

(6) *Continuances of merits hearings.* A continuance of a merits hearing on an alien's application for relief or protection from removal or a merits hearing on a contested charge of removability prior to or on the date of the hearing is strongly disfavored. Such continuances should only be granted in circumstances otherwise listed in paragraphs (b)(4)(v), (vi), or, upon motion by either party, paragraph (b)(5) of this section, and should be granted for no more than 30 days.

PART 1240—PROCEEDINGS TO DETERMINE REMOVABILITY OF ALIENS IN THE UNITED STATES

3. The authority for part 1240 continues to read as follows:

Authority: 8 U.S.C. 1103, 1158, 1182, 1186a, 1186b, 1225, 1226, 1227, 1228, 1229a, 1229b, 1229c, 1252 note, 1361, 1362; secs. 202 and 203, Pub. L. 105–100 (111 Stat. 2160, 2193); sec. 902, Pub. L. 105–277 (112 Stat. 2681).

4. Revise § 1240.6 to read as follows:

§ 1240.6 Postponement and adjournment of hearing.

Adjournments in removal proceedings are governed by the provisions of 8 CFR 1003.29(b).

5. Revise § 1240.45 to read as follows:

§ 1240.45 Postponement and adjournment of hearing.

Adjournments in deportation proceedings are governed by the provisions of 8 CFR 1003.29(b).

James R. McHenry III,

Director, Executive Office for Immigration Review, Department of Justice.

[FR Doc. 2020–25931 Filed 11–25–20; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF JUSTICE

Executive Office for Immigration Review

8 CFR Parts 1001 and 1003

[EOIR Docket No. 18–0503; Dir. Order No. 01–2021]

RIN 1125–AB01

Motions To Reopen and Reconsider; Effect of Departure; Stay of Removal

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Justice (''Department'') proposes to amend Executive Office for Immigration Review (''EOIR'') regulations governing the filing and adjudication of motions to reopen and reconsider and to add regulations governing requests for discretionary stays of removal.

DATES: Written or electronic comments must be submitted on or before December 28, 2020. Written comments postmarked on or before that date will be considered timely. The electronic Federal Docket Management System will accept comments prior to midnight Eastern Time at the end of that day.

ADDRESSES: You may submit comments, identified by EOIR Docket No. 18–0503, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2616, Falls Church, VA 22041. To ensure proper handling, please reference EOIR Docket No. 18–0503 on your correspondence. This mailing address may be used for paper, disk, or CD–ROM submissions.
- *Hand Delivery/Courier:* Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2616, Falls Church, VA 22041. Contact Telephone Number (703) 305–0289.

FOR FURTHER INFORMATION CONTACT: Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2616, Falls Church, VA 22041, telephone (703) 305–0289 (not a toll-free call), or email *PAO.EOIR@usdoj.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of this rule. EOIR also invites comments that relate to the economic, environmental, or federalism effects that might result from this rule. To provide the most assistance to EOIR, comments should reference a specific portion of the rule; explain the reason for any recommended change; and include data, information, or authority that support the recommended change.

All comments submitted for this rulemaking should include the agency name and EOIR Docket No. 18–0503. Please note that all comments received are considered part of the public record and made available for public inspection at *www.regulations.gov.* Such information includes personally identifiable information (such as a person's name, address, or any other data that might personally identify that individual) that the commenter voluntarily submits.

If you want to submit personally identifiable information as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONALLY IDENTIFIABLE INFORMATION'' in the first paragraph of your comment and precisely and prominently identify the information of which you seek redaction.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment and precisely and prominently identify the confidential business information of which you seek redaction. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *www.regulations.gov.* Personally identifiable information and confidential business information provided as set forth above will be placed in the agency's public docket file, but not posted online. To inspect the agency's public docket file in person, you must make an appointment with agency counsel. Please see the **FOR FURTHER INFORMATION CONTACT** paragraph above for the agency counsel's contact information specific to this rule.

The Department may withhold from public viewing information provided in comments that they determine may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

II. Background

Under the Immigration and Nationality Act (''INA'' or ''Act''), parties to proceedings before EOIR may file a motion to reopen or reconsider certain decisions of immigration judges or the Board of Immigration Appeals (''BIA'' or ''Board''). *See* INA 240(c)(6)–(7), 8 U.S.C. 1229a(c)(6)–(7); 8 CFR 1003.2, 1003.23. Each such motion must be filed with the immigration court with administrative control over the record of proceeding or with the BIA. *See* 8 CFR 1003.2, 1003.23. These motions are ''separate and distinct motions with different requirements.'' *Matter of Cerna,* 20 I&N Dec. 399, 402 (BIA 1991) (quoting *Chudshevid* v. *INS,* 641 F.2d 780, 783 (9th Cir. 1981)).

A motion to reconsider requests ''that the original decision be reexamined in light of additional legal arguments, a change of law, or an argument or aspect of the case that was overlooked.'' *Cerna,* 20 I&N Dec. at 399. A party may file only one motion to reconsider any given decision, and such motion must be filed within 30 days of a final administrative order of removal. INA 240(c)(6)(A)–(B), 8 U.S.C. 1229a(c)(6)(A)–(B); *see also* 8 CFR 1003.2(b)(2), 1003.23(b)(1). The motion must specify the errors of law or fact in the prior decision, supported by relevant authority. INA 240(c)(6)(C), 8 U.S.C. 1229a(c)(6)(C); *see also* 8 CFR 1003.2(b)(1), 1003.23(b)(2).

A motion to reopen is a party's filing to request to reopen proceedings ''so that new evidence can be presented and so that a new decision can be entered, normally after a further evidentiary hearing.'' *Cerna,* 20 I&N Dec. at 403. Subject to certain exceptions, a party may file only one motion to reopen proceedings, and such motion must generally be filed within 90 days of the date of entry of a final administrative order of removal. INA 240(c)(7)(A), (C), 8 U.S.C. 1229a(c)(7)(A), (C); *see also* 8 CFR 1003.2(c)(2), 1003.23(b)(1).[1] The motion must state new facts that will be proven at a hearing if the motion is granted and include supporting

[1] There are exceptions to the general timing and numerical limitations for certain motions to reopen (1) to apply for asylum under section 208 of the Act, 8 U.S.C. 1158, or withholding of removal under section 241(b)(3) of the Act, 8 U.S.C. 1231(b)(3), or under the Convention Against Torture based on changed country conditions; (2) to rescind *in absentia* orders entered in removal, deportation, or exclusion proceedings; (3) to apply for discretionary relief as a battered spouse, child, or parent; and (4) that are agreed to by all parties and jointly filed. *See* INA 240(c)(7)(C)(ii)–(iv), 8 U.S.C. 1229a(c)(7)(C)(ii)–(iv); 8 CFR 1003.2(c)(3), 1003.23(b)(4). Certain motions to reopen filed by the Department of Homeland Security in removal proceedings are also not subject to the timing and numerical limitations. *See* 8 CFR 1003.2(c)(2), 1003.2(c)(3)(iv), 1003.23(b)(1).

affidavits or other evidentiary material. INA 240(c)(7)(B), 8 U.S.C. 1229a(c)(7)(B); *see also* 8 CFR 1003.2(c)(1), 1003.23(b)(3).

The Department last significantly amended the immigration court and BIA regulations regarding motions to reopen and reconsider over twenty years ago. In 1996, the Department issued a final rule to establish time and number limitations on such motions pursuant to section 545(d) of the Immigration Act of 1990, Public Law 101–649, 104 Stat. 4978, 5066. *See* 61 FR 18900 (Apr. 29, 1996). In 1997, the Department issued a second regulation to implement sections 240(c)(6) and (7)[2] of the INA,[3] which Congress enacted as part of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA), Public Law 104–208, sec. 304(a), 110 Stat. 3009–546, 3009–593 (1996). *See* 62 FR 10312, 10330–33 (Mar. 6, 1997); *see also* 62 FR 444, 449 (Jan. 3, 1997) (proposed rule).

Since these changes, the Department has issued multiple Notices of Proposed Rulemaking related to motions to reopen and reconsider, *see* 81 FR 49556 (July 28, 2016); 67 FR 31157 (May 9, 2002); 63 FR 47205 (Sept. 4, 1998), and the federal courts have elaborated on the relevant regulatory provisions, *see, e.g., Dada* v. *Mukasey,* 554 U.S. 1, 12–15 (2008). Further, the Department has maintained multiple entries on its Unified Agenda that reference such motions, such as *Immigration Courts and the Board of Immigration Appeals: Motions to Reopen and Reconsider; Effect of Departure or Removal* (RIN: 1125–AA74), and *Motions To Reopen Removal, Deportation, or Exclusion Proceedings Based Upon a Claim of Ineffective Assistance of Counsel* (RIN: 1125–AA68).

A. Failure To Surrender and Fugitive Disentitlement

The Department previously proposed changes to the regulations that would have established procedures for aliens subject to a final order of removal to surrender to the Immigration and Naturalization Service (''INS'') and imposed consequences on aliens who failed to surrender as required. *See* 67 FR 31157 (May 9, 2002) (supplementary proposed rule); 63 FR 47205 (Sept. 4, 1998) (proposed rule); *see also Matter of Barocio,* 19 I&N Dec. 255, 258 (BIA 1985) (''[A]n alien who has violated a lawful order of deportation by failing to report to the Service following notification that his deportation has been scheduled does not merit the favorable exercise of discretion required for reopening of deportation proceedings.''). Under the proposed rule, an alien who was not detained when an order of removal became final had an affirmative legal obligation to surrender thereafter for removal. 67 FR at 31158. The rule would have incented compliance by denying future discretionary relief to absconding aliens who had failed to comply with their removal obligations. *Id.*

The proposed regulation provided that aliens would receive notice of the duty to surrender and consequences of failing to surrender in the Notice to Appear, as well as from the immigration judge or the BIA, upon release from government custody, and at the time of a grant of voluntary departure. *Id.* at 31163. An alien who failed to surrender as required would then have been ineligible for discretionary relief under sections 208(b), 8 U.S.C. 1158(b), 212(h), 8 U.S.C. 1182(h), 212(i), 8 U.S.C. 1182(i), 240A, 8 U.S.C. 1229b, 240B, 8 U.S.C. 1229c, 245, 8 U.S.C. 1255, 248, 8 U.S.C.1258, and 249, 8 U.S.C. 1259, of the Act for the period the alien remained in the United States and 10 years after the alien's subsequent departure. *Id.* at 31158, 31163. The regulation further provided that the immigration judge and the BIA would similarly not grant a motion to reopen in the case of an alien who had failed to surrender. *Id.* at 31158, 31161. The regulation crafted some exceptions to the prohibitions if the alien first demonstrated by clear and convincing evidence exceptional circumstances for his failure to surrender, as defined in section 240(e)(1) of the INA, 8 U.S.C. 1229a(e)(1), and that he actually surrendered as soon as possible after the circumstances passed. *Id.* at 31158.

Following the dissolution of the INS and the establishment of the Department of Homeland Security (''DHS''), neither DHS nor EOIR has finalized the supplementary proposed rule.

B. Ineffective Assistance of Counsel

Removal proceedings are civil in nature; aliens in removal proceedings have no Sixth Amendment constitutional right to counsel appointed at government expense, nor do they possess a statutory right to such counsel.[4] *Compare* U.S. Const. amend. VI, *and Gideon* v. *Wainwright,* 372 U.S. 335 (1964), *with INS* v. *Lopez-Mendoza,* 468 U.S. 1032, 1038 (1984), *and* INA 240(b)(4)(A), 8 U.S.C. 1229a(b)(4)(A). Nevertheless, for more than thirty years, the Department has allowed aliens to file a motion to reopen proceedings based on allegations of ineffective assistance of counsel. *See Matter of Lozada,* 19 I&N Dec. 637 (BIA 1988); *see also Matter of Assaad,* 23 I&N Dec. 553, 556–57 (BIA 2003). Allowing aliens to seek to reopen proceedings based upon ineffective assistance of counsel balances the public interest in ensuring fairness with the public interest in ensuring finality of decisions in removal proceedings. *See, e.g., INS* v. *Abudu,* 485 U.S. 94, 107 (1988) (''There is a strong public interest in bringing litigation to a close as promptly as is consistent with the interest in giving the adversaries a fair opportunity to develop and present their respective cases.'').

Lozada set forth standards governing motions to reopen based on claims of ineffective assistance of counsel. *See Lozada,* 19 I&N Dec. at 639; *see also Assaad,* 23 I&N Dec. at 556–57 (affirming *Lozada*'s application in removal proceedings). Under *Lozada,* an alien must meet three procedural requirements for filing such a motion: (1) Provide an affidavit stating the agreement with counsel, including what representations were and were not made; (2) give notice to counsel and an opportunity for counsel to respond; and (3) file a disciplinary complaint with the appropriate authorities or provide an explanation if no complaint has been filed. *Lozada,* 19 I&N Dec. at 639. In January 2009, Attorney General Mukasey replaced the *Lozada* framework. *See Matter of Compean, Bangaly and J–E–C–,* 24 I&N Dec. 710, 727, 732 (A.G. 2009) (''*Compean I*''). In June 2009, Attorney General Holder vacated *Compean I* and reinstated the *Lozada* framework. *See Matter of Compean, Bangaly and J–E–C–,* 25 I&N Dec. 1 (A.G. 2009). Attorney General Holder also instructed the Department to initiate rulemaking procedures to evaluate the *Lozada* framework. *See id.* at 2.

In 2016, the Department proposed to amend EOIR's regulations by adding filing and adjudication standards for

[2] At the time, current sections 240(c)(6)– and (7) of the Act (8 U.S.C. 1229a(c)(6)–(7)) were numbered 240(c)(5)– and (6) (8 U.S.C. 1229a(c)(5)–(6)). These provisions were renumbered following the REAL ID Act of 2005, which added a new section 240(c)(4) of to the Act (8 U.S.C. 1229a(c)(4)). *See* Real ID Act of 2005, Public Law 109–13, div. B, 119 Stat. 231, 304–05.

[3] At the time, current sections 240(c)(6) and (7) of the Act were numbered 240(c)(5) and (6). These provisions were renumbered following the REAL ID Act of 2005, which added a new section 240(c)(4) to the Act. *See* Real ID Act of 2005, Public Law 109–13, div. B, 119 Stat. 231, 304–05 (2005).

[4] There is a circuit split regarding whether aliens in removal proceedings have a Fifth Amendment due process right to effective assistance of counsel if they choose to employ counsel. *See Contreras* v. *Att'y Gen.,* 665 F.3d 578, 584 n.3 (3d Cir. 2012) (discussing Circuit split and citing cases); *see also Flores-Moreno* v. *Barr,* No. 19–60017, 2020 WL 4931651, at *3 n.2 (5th Cir. Aug. 24, 2020) (assuming without deciding that aliens have such a right).

motions to reopen before an immigration judge and the BIA based upon a claim of ineffective assistance of counsel. 81 FR at 49556. At the time of the proposed rule, courts had variously understood and applied the *Lozada* framework. The proposed rule sought to establish standard procedural and substantive requirements for filing such motions.

Primarily, the proposed rule would have allowed an individual to file a motion to reopen an immigration proceeding upon establishing that he ''was subject to ineffective assistance of counsel and that, with limited exceptions, he or she suffered prejudice as a result.'' *Id.* at 49557. The proposed rule would have provided standards for determining ''ineffectiveness'' and ''prejudice.'' *See id.* at 49561, 49565–67. The proposed rule would have required the following documents be included with the motion: ''(1) An affidavit or written statement executed under penalty of perjury, providing certain information; (2) a copy of any applicable representation agreement; (3) evidence that prior counsel was notified of the allegations and of the filing of the motion; and (4) evidence that a complaint was filed with the appropriate disciplinary authorities.'' *Id.* at 49557.

Regarding motions to reopen and rescind an *in absentia* order based upon a claim of ineffective assistance of counsel, the proposed rule would have codified BIA precedent in *Matter of Grijalva,* 21 I&N Dec. 472 (BIA 1996). In *Grijalva,* the BIA provided that an *in absentia* order may be rescinded upon a motion to reopen in which an alien establishes exceptional circumstances or reasonable cause based upon a claim of ineffective assistance ofcounsel. *Id.* at 473–74; *see* 81 FR at 49568–69. The alien, however, would not have to establish prejudice. *Grijalva,* 21 I&N Dec. at 473 n.2; *see* 81 FR at 49568–69.

The proposed rule also provided for the equitable tolling of filing deadlines in certain circumstances based upon a claim of ineffective assistance of counsel. *See* 81 FR at 49569. Finally, the proposed rule authorized the BIA, in its discretion, to reopen proceedings based upon counsel's failure to file a timely petition for federal appellate review. *See id.* at 49566.

EOIR received comments on the 2016 rulemaking but did not publish a final rule. Accordingly, the agency currently lacks standardized regulations for such claims, and judicial treatment continues to vary among circuits. For example, the Fifth, Sixth, Seventh, and Tenth Circuits require strict compliance with the *Lozada* factors. *See Hernandez-Ortez* v. *Holder,* 741 F.3d 644, 647 (5th Cir. 2014) (rejecting as ''without merit'' the argument ''that strict compliance with the *Lozada* requirements is not necessary''); *Pepaj* v. *Mukasey,* 509 F.3d 725, 727 (6th Cir. 2007) (''An alien who fails to comply with *Lozada*'s requirements forfeits her ineffective-assistance-of-counsel claim.'') (citing *Hamid* v. *Ashcroft,* 336 F.3d 465, 469 (6th Cir. 2003)); *Marinov* v. *Holder,* 687 F.3d 365, 369 (7th Cir. 2012) (reaffirming the *Lozada* requirements as ''a necessary condition to obtaining reopening on the basis of ineffective assistance of counsel'') (quoting *Lin Xing Jiang* v. *Holder,* 639 F.3d 751, 755 (7th Cir. 2011)); *Infanzon* v. *Ashcroft,* 386 F.3d 1359, 1363 (10th Cir. 2004) (''[A] motion based on claim of ineffective assistance of counsel *must* be supported as outlined in *Lozada.*'') (citing *Mickeviciute* v. *INS,* 327 F.3d 1159, 1161 n.2 (10th Cir. 2003)). Similarly, the First Circuit has repeatedly held that ''[t]he BIA acts within its discretion in denying motions to reopen that fail to meet the *Lozada* requirements as long as it does so in a non-arbitrary manner.'' *Taveras-Duran* v. *Holder,* 767 F.3d 120, 123 (1st Cir. 2014) (quoting *Asaba* v. *Ashcroft,* 379 F.3d 9, 11 (1st Cir. 2004)); *see also Garcia* v. *Lynch,* 821 F.3d 178, 181 n.4 (1st Cir. 2016) (noting ''consistent[ ]'' practice of upholding BIA orders denying motions to reopen when ''the *Lozada* requirements have been flouted'').

By contrast, the Second, Third, Fourth, Ninth, and Eleventh Circuits require substantial compliance. *See Piranej* v. *Mukasey,* 516 F.3d 137, 142 (2d Cir. 2008) (''[T]his Court has 'not required a slavish adherence to the [*Lozada*] requirements.' '') (quoting *Yi Long Yang* v. *Gonzales,* 478 F.3d 133, 142–43 (2d Cir. 2007)); *Rranci* v. *Att'y Gen.,* 540 F.3d 165, 173–74 (3d Cir. 2008) (warning of ''inherent dangers . . . in applying a strict, formulaic interpretation of *Lozada*'') (quoting *Xu Long Yu* v. *Ashcroft,* 259 F.3d 127, 133 (3d Cir. 2001)); *Barry* v. *Gonzales,* 445 F.3d 741, 746 (4th Cir. 2006) (''We will reach the merits of an ineffective assistance of counsel claim where the alien substantially complies with the *Lozada* requirements, such that the BIA could have ascertained that the claim was not frivolous and otherwise asserted to delay deportation.''); *Correa-Rivera* v. *Holder,* 706 F.3d 1128, 1131 (9th Cir. 2013) (''These requirements 'are not rigidly applied, especially when the record shows a clear and obvious case of ineffective assistance.' '') (quoting *Rodriguez-Lariz* v. *INS,* 282 F.3d 1218, 1227 (9th Cir. 2002)); *Flores-Panameno* v. *Att'y Gen.,* 913 F.3d 1036, 1040 (11th Cir. 2019) (requiring ''substantial, if not exact compliance'' with *Lozada*) (citing *Dakane* v. *Att'y Gen.,* 399 F.3d 1269, 1274 (11th Cir. 2005)).

Finally, the Eighth Circuit appears not to have staked out any definitive position. *See Habchy* v. *Gonzales,* 471 F.3d 858, 863 (8th Cir. 2006) (''Our circuit has not ruled on whether a strict application of those [*Lozada*] requirements could constitute an abuse of discretion in certain circumstances, and we need not do so here. At the very least, an IJ does not abuse his discretion in requiring substantial compliance with the *Lozada* requirements when it is necessary to serve the overall purposes of *Lozada*[.]''); *Avitso* v. *Barr,* 975 F.3d 719, 722 (8th Cir. 2020) (citing *Habchy* and stating both that the alien ''must . . . satisfy the procedural requirements of *Lozada*'' and that he ''did not substantially comply with these requirements'').

Further, circuit courts use various standards to evaluate prejudice. The First, Third, Fifth, Sixth, Eighth, Tenth, and Eleventh Circuits require a finding of reasonable probability that the error impacted the outcome of the proceeding. *See Zeru* v. *Gonzales,* 503 F.3d 59, 72 (1st Cir. 2007); *Fadiga* v. *Att'y Gen.,* 488 F.3d 142, 158–59 (3d Cir. 2013); *Diaz* v. *Sessions,* 894 F.3d 222, 228 (5th Cir. 2018); *Kada* v. *Barr,* 946 F.3d 960, 965 & n.1 (6th Cir. 2020); *Ortiz-Punetes* v. *Holder,* 662 F.3d 481, 485 n.2 (8th Cir. 2011) (citing *Obleshchenko* v. *Ashcroft,* 392 F.3d 970, 972 (8th Cir. 2004)); *Mena-Flores* v. *Holder,* 776 F.3d 1152, 1169 & n.25 (10th Cir. 2015) (citing *United States* v. *Aguirre-Tello,* 353 F.3d 1199, 1209 (10th Cir. 2004)); *Flores-Panameno,* 913 F.3d at 1040 (citing *Dakane,* 399 F.3d at 1274). The Third Circuit, however, has instructed that the ''reasonability probability'' standard requires ''merely a 'significant possibility.' '' *Calderon-Rosas* v. *Att'y Gen.,* 957 F.3d 378, 387 (3d Cir. 2020) (quoting *United States* v. *Payano,* 930 F.3d 186, 193 n.5 (3d Cir. 2019)).

The Seventh and Ninth Circuits maintain a more lenient standard, requiring a finding that the error may have affected the outcome of the proceeding. *See Garcia-Arce* v. *Barr,* 946 F.3d 371, 378 (7th Cir. 2019) (''The prejudice prong requires a showing that counsel's errors actually had the potential for affecting the outcome of the proceedings.'') (quoting *Sanchez* v. *Sessions,* 894 F.3d 858, 862–63 (7th Cir. 2018)); *Flores* v. *Barr,* 930 F.3d 1082, 1088–89 (9th Cir. 2019) (''[T]he question

with respect to prejudice is whether counsel's deficient performance '*may* have affected the outcome of the proceedings,' which means that the petitioner 'need only show *plausible* grounds for relief.' '') (quoting *Morales Apolinar* v. *Mukasey,* 514 F.3d 893, 898 (9th Cir. 2008)).

The Second Circuit, for its part, has stated that, in the context of an application for relief, to establish prejudice the alien must show *prima facie* eligibility and that he ''could have made a strong showing in support of his application.'' *Scarlett* v. *Barr,* 957 F.3d 316, 326 (2d Cir. 2020) (quoting *Rabiu* v. *INS,* 41 F.3d 879, 882 (2d Cir. 1994)).

Given these diverse judicial interpretations and the need for uniform direction on this subject, this rule proposes new changes to establish standardized procedures for adjudicating motions to reopen on the basis of claims of ineffective assistance of counsel in the context of broader rules regarding motions to reopen. As discussed below, this rule also addresses a number of larger issues related to all types of motions to reopen that go beyond the scope of the 2016 proposed rule, which was limited only to motions alleging ineffective assistance of counsel. Accordingly, this broader, more comprehensive rule would withdraw the narrower 2016 proposed rule.[5]

C. Departure Bar

Both the BIA and immigration court regulations contain restrictions on the filing of motions to reopen or reconsider following an alien's departure from the United States—commonly referred to as the ''departure bar.'' *See* 8 CFR 1003.2(d), 1003.23(b)(1). Specifically, the regulations prohibit an alien from filing a motion to reopen or reconsider following the alien's departure from the United States if the alien is subject to a final administrative order of removal, deportation, or exclusion. *Id.* The regulations further instruct that a departure from the United States constitutes the withdrawal of a previously filed motion to reopen or motion to reconsider. *Id.*

The departure bar regulations predate Congress's inclusion of a statutory right to file a motion to reopen and a motion to reconsider in section 240(c)(6) and (7) of the INA, 8 U.S.C. 1229a(c)(6)–(7). *See, e.g., Matter of G–Y–B-,* 6 I&N Dec. 159, 159–60 (BIA 1954) (discussing the 1952 version of the departure bar regulations). This has led some to question whether the departure bar regulations are, in effect, superseded by the statute. The BIA held over a decade ago that ''the departure bar rule remains in full effect.'' *Matter of Armendarez,* 24 I&N Dec. 646, 660 (BIA 2008). More recent federal circuit court decisions, however, have found that the departure bar now ''clearly conflicts'' with the INA, or that its application ''impermissibly restricts'' the BIA's jurisdiction. *Toor* v. *Lynch,* 789 F.3d 1055, 1057 n.1 (9th Cir. 2015) (noting decisions from the First, Second, Third, Fourth, Fifth, Sixth, Seventh, Tenth, and Eleventh Circuits).

While the Department has previously stated that it would initiate rulemaking to address the departure bar, *see* 77 FR 59567, 59568 (Sept. 28, 2012), no relevant regulation has been proposed to date. This rule would address the matter.

III. Regulatory Changes

Over the past twenty years, the Department has issued multiple Notices of Proposed Rulemaking related to motions to reopen and reconsider. *See* 81 FR at 49556; 67 FR at 31157 (supplementary proposed rule); 63 FR at 47205 (proposed rule). Further, the Department has maintained multiple entries on its Unified Agenda that reference such motions, such as *Immigration Courts and the Board of Immigration Appeals: Motions to Reopen and Reconsider; Effect of Departure or Removal* (RIN: 1125–AA74), and *Motions To Reopen Removal, Deportation, or Exclusion Proceedings Based Upon a Claim of Ineffective Assistance of Counsel* (RIN: 1125–AA68). None of these rulemakings has ever been finalized, and rather than continue to assess these related issues in a piecemeal fashion, the Department believes that a more comprehensive rulemaking would be the most efficient way to consolidate and address them. Accordingly, the Department now proposes to consolidate and address all of these issues in the proposed rulemaking.

The proposed rule would amend 8 CFR 1001.1, 1003.2, and 1003.23 and add a new section 1003.48 in subpart C. The proposed regulation would also amend the headings and table of contents of subpart C so that proposed section 1003.48 would apply to motions to reopen and related issues before both the BIA and the immigration courts. The proposed rule would also codify a clear definition of ''depart'' and ''departure'' applicable to various contexts, including those related to a grant of advance parole. The proposed changes are as follows:

A. Revision of the Departure Bar

Consistent with precedent from every circuit court to have addressed the issue, and in accordance with the Department's commitment to initiate rulemaking to address the departure bar, the Department now proposes to remove the departure bar from 8 CFR 1003.2(d) and 1003.23(b)(1). Specifically, the Department proposes to remove the prohibition on the submission of motions to reopen or reconsider by an alien subject to a final order of removal, deportation, or exclusion following the alien's removal or departure from the United States. An alien would be allowed to file a motion to reopen or reconsider whether or not the alien is physically present in the United States, though whether that motion could be granted would remain subject to applicable law, and whether an alien is physically present in the United States may determine their *prima facie* eligibility for relief.[6] *See, e.g., Sadhvani* v. *Holder,* 596 F.3d 180 (4th Cir. 2009) (holding that the Board did not abuse its discretion in denying a motion to reopen an asylum application from an alien outside of the United States because presence in the United States is required for asylum eligiblity). The Department also proposes to remove the provision that treats an alien's non-volitional departure as a withdrawal of a motion to reopen or reconsider.

In lieu of the existing departure bar, this rule proposes to add a narrow withdrawal provision stating that an alien's volitional departure from the United States, while a motion to reopen or reconsider is pending, constitutes a withdrawal of that previously filed motion to reopen or motion to reconsider. Further, the proposed rule would define ''depart'' and ''departure,'' so that this provision would apply only to volitional physical departures of an alien from the United States. *See* 8 CFR

[5] Because the Department is withdrawing the previous proposed rule, the Department does not directly address the comments received on that proposed rule; all commenters are encouraged to resubmit relevant comments for the Department's response in the context of this proposed rule.

[6] In addition, EOIR does not have the authority to order DHS to parole or admit an alien physically outside the United States into the United States following the grant of a motion to reopen or reconsider. Consequently, the granting of a motion to reopen or reconsider for an alien outside the United States would not necessarily mean that the alien would return to the United States. It may, however, undo a previous termination of an alien's status as a lawful permanent resident (LPR). *See* 8 CFR 1001.1(p) (''Such status terminates upon entry of a final administrative order of exclusion, deportation, removal, or rescission.''); *Matter of Lok,* 18 I&N Dec. 101, 106 (BIA 1981). In such a case, the alien may be eligible to enter the United States as a returning LPR, though that determination will ultimately be made by DHS in the first instance, upon the alien's physical return to the United States and application for admission.

1001.1(cc) and (dd) (proposed). This includes aliens who leave the United States after a final removal order is entered but still without having DHS enforce the order. However, the physical removal, deportation, or exclusion from the United States at the direction of DHS, or a return of the alien to a contiguous territory by DHS in accordance with section 235(b)(2)(C) of the Act, 8 U.S.C. 1225(b)(2)(C), is specifically excluded from the definition and would not constitute a departure for purposes of deeming a motion withdrawn.

The Department believes that this narrow withdrawal provision does not implicate the concerns that have led the federal circuit courts to refuse to apply the existing departure bar. First, the proposed withdrawal provision would not prevent aliens from filing motions to reopen or reconsider based on the alien's geographic location. The circuit courts have held that sections 240(c)(6) and (c)(7) of the Act, 8 U.S.C. 1229a(c)(6) and (c)(7), do not impose any geographic restrictions on the filing of motions to reopen or reconsider. *See, e.g., Santana* v *Holder,* 731 F.3d 50, 56 (1st Cir. 2013) (holding that the statute ''nowhere prescribes, or even suggests, a geographic restriction on 'an alien [who] may file' the motion''). Consistent with these holdings, this withdrawal provision would allow an alien to file a motion to reopen or reconsider from abroad, regardless of how the alien left the United States before filing the motion.

Additionally, this proposed rule merely treats an already-filed motion as withdrawn upon the alien's volitional departure from the United States, and such a motion would be denied accordingly. In this way, this proposed rule would function identically to how an alien's right to appeal is waived if the alien volitionally departs the United States prior to taking an appeal and how an alien's appeal, other than for an arriving alien, is withdrawn if the alien volitionally departs the United States while the appeal is pending. *See* 8 CFR 1003.3(e), 1003.4; *see also Aguilera-Ruiz* v. *Ashcroft,* 348 F.3d 835, 838 (9th Cir. 2003) (holding that a volitional departure—even one that is ''brief, casual, and innocent''constitutes a withdrawal of an appeal pursuant to 8 CFR 1003.4); *Madrigal* v. *Holder,* 572 F.3d 239, 244–45 & n.5 (6th Cir. 2009) (interpreting 8 CFR 1003.3(e) and 1003.4 as having an implicit volitional element to their waiver provisions); *cf.* 8 CFR 1208.8(a) (''An applicant [for asylum] who leaves the United States without first obtaining advance parole . . . shall be presumed to have abandoned his or her application.'').

Second, the proposed withdrawal provision eliminates any tension between the alien's right to file a motion to reconsider or reopen within 30 or 90 days, respectively, and DHS's requirement to remove the alien within 90 days of a final removal order. *Compare* INA 240(c)(6)–(7), 8 U.S.C. 1229a(c)(6)–(7), *with* INA 241(a)(1), 8 U.S.C. 1231(a)(1). The majority of circuit courts have held that the existing departure bar conflicts with an alien's statutory right to file a motion to reopen or reconsider because the alien's non-volitional removal by DHS would trigger the departure bar even if the removal occurred within the time periods allowed to file the motions. *See, e.g., Prestol Espinal* v. *Att'y Gen.,* 653 F.3d 213, 223 (3d Cir. 2011) (''If aliens are permitted to file motions to reconsider but are then removed by the government before the time to file has expired, the right to have that motion adjudicated is abrogated''); *Coyt* v. *Holder,* 593 F.3d 902, 907 (9th Cir. 2010) (''The only manner in which we can harmonize the provisions simultaneously affording the petitioner a ninety day right to file a motion to reopen and requiring the alien's removal within ninety days is to hold. . . . that the physical removal of a petitioner by the United States does not preclude the petitioner from pursuing a motion to reopen.''). The proposed withdrawal provision addresses this concern by limiting the provision only to an alien's volitional departure, which the Department believes evidences the alien's intention to abandon the motion or to otherwise fail to prosecute it.[7]

By definition, an alien who would be subject to the proposed volitional departure bar would already be subject to an administratively final order of removal. Therefore, the alien would know the consequences of departing the United States and, thus, executing that removal order. *See Mansour* v. *Gonzales,* 470 F.3d 1194, 1198 (6th Cir. 2006) (''It is well settled that when an alien departs the United States while under a final order of deportation, he or she executes that order pursuant to the law. . . . Once an alien departs, thereby executing the order of deportation, he loses his right to contest the lawfulness of the proceedings.'' (internal quotation omitted)); *see generally* 8 CFR 241.7, 1241.7 (providing that an alien executes an outstanding removal order or ''self-removes'' when he departs the United States). Moreover, the alien would also know that if he were to illegally re-enter the United States after executing that order, he may be ineligible to seek to reopen that original order. INA 241(a)(5), 8 U.S.C. 1231(a)(5). Thus, an alien's volitional departure notwithstanding these consequences would represent a conscious decision by the alien to forgo further presence in the United States and evince an effort to abandon or stop pursuing efforts at remaining. Such a decision to depart of the alien's own accord would be generally inconsistent with an effort to undo a removal order that, if successful, would allow an alien to remain.

Moreover, although a motion to reopen is provided for by statute, INA 240(c)(7), 8 U.S.C. 1229a(c)(7), whereas an appeal to the Board is not, a motion to reopen nevertheless functions similarly to an appeal to the Board of a removal order issued by an immigration judge. In both situations, an alien is mounting a challenge to the denial of the alien's request to remain in the United States. As discussed, an alien's departure after the filing of an appeal but before a decision has been issued by the Board usually serves as a withdrawal of the appeal, 8 CFR 1003.4,[8] and federal courts have generally affirmed the validity of this departure bar for appeals, *see, e.g., Aguilera-Ruiz,* 348 F.3d at 838.

Further, multiple courts have read an implicit volitional requirement into the application of 8 CFR 1003.4, similar to the one proposed by the Department in this rule for motions to reopen or reconsider. *See, e.g., Madrigal,* 572 F.3d at 244–45 & n.5; *Lopez-Angel* v. *Barr,* 952 F.3d 1045, 1048–49 (9th Cir. 2019) (following *Madrigal*); *see also Coyt,* 593 F.3d at 907 (agreeing with *Madrigal* and reaching a similar conclusion with respect to 8 CFR 1003.2(d)). Finally, at least one court has noted that the Department could simply engage in rulemaking to establish a volitional departure bar to motions to reopen or reconsider as a categorical discretional determination. *Marin-Rodriguez* v. *Holder,* 612 F.3d 591, 593 (7th Cir.

[7] Any departure resulting from a DHS removal would no longer constitute a departure that results in a withdrawal of the motion under the regulations.

[8] There is a regulatory exception to the withdrawal provision in 8 CFR 1003.4 for an ''arriving alien'' as defined in 8 CFR 1001.1(q) that appears to be based on a historical distinction between deportation proceedings for aliens who had entered the United States and exclusion proceedings for aliens who were stopped at a port of entry. *See* 8 CFR 1003.4; *Matter of Keyte,* 20 I&N Dec. 158, 159 (BIA 1990) (''The departure pending appeal of an alien who has been stopped at the border and ordered excluded is not necessarily incompatible with a design to prosecute the appeal to a conclusion.'').

2010) (''An agency may exercise discretion categorically, by regulation, and is not limited to making discretionary decisions one case at a time under open-ended standards.''). To that end, the proposed rule reflects the Department's discretionary determination that a motion to reopen or reconsider should be deemed withdrawn when an alien volitionally departs the United States after filing the motion but before it is decided.

While nearly every circuit has opined on the apparent tension between the existing departure bar and the statutory right to file a motion to reopen and reconsider, *see Toor,* 789 F.3d at 1060 n.3 (collecting cases), no court has decided whether the voluntary or involuntary nature of an alien's departure should determine if a previously filed motion to reopen is deemed withdrawn under 8 CFR 1003.2(d) or 1003.23(b). The Ninth Circuit has stated that the departure bar is ''invalid irrespective of how the noncitizen departed the United States,'' but its analysis was limited to the departure bar provisions that this proposed regulation would remove—that an alien may not *file* a motion to reopen following his departure from the United States. *Id.* at 1059, 1064. Under the proposed regulation, an alien may file a motion to reopen orreconsider following departure from the United States regardless of whether the departure was volitional. But under the proposed rule, a motion would be deemed withdrawn when an alien has volitionally departed the United States after filing the motion but before it is decided. Therefore, for the purposes of this rule, the terms ''depart'' and ''departure'' are defined to mean the voluntary physical departure of an alien from the United States. *Cf. Lopez-Angel,* 952 F.3d at 1050 (Lee, J., concurring) (''The ordinary meaning of the word 'departure' refers to a volitional act. . . . The context of the word 'departure' [in 8 CFR 1003.4] also suggests that it does not include forcible removals.'').

B. Definition of ''Depart'' and ''Departure''

As stated above, the proposed rule would define the terms ''depart'' and ''departure'' consistent with their ordinary meaning, which includes any voluntary physical departure from the United States. The INA does not define ''depart'' or ''departure,'' but such a definition is also consistent with existing regulations and a precedential decision of the BIA.

Regulations controlling the departure of aliens in parts 215 and 1215 of 8 CFR define the phrase ''depart from the United States'' to mean, *inter alia,* to ''depart by land, water, or air . . . [f]rom the United States for any foreign place.'' 8 CFR 215.1(h), 1215.1(h). These regulations reflect a common-sense, geography-based understanding of the meaning of departure. Although this definition applies only to the concept of departure in parts 215 and 1215, the BIA nevertheless relied on it, in part, in analyzing the status of an alien who left the United States, was denied refugee status in Canada, and then returned to the United States, concluding that the alien had ''departed'' the United States and was therefore an ''arriving alien'' not removable under section 237(a)(1)(B) of the INA, 8 U.S.C. 1227(a)(1)(B). *See Matter of R-D-,* 24 I&N Dec. 221, 223 (BIA 2007). In *Matter of Lemus,* the BIA also recognized that there was a ''plain and ordinary meaning'' of the term ''departure,'' which was defined broadly. 24 I&N Dec. 373, 376–77 (BIA 2007) (''*Lemus-Losa I*''). Further, the BIA held that leaving the United States pursuant to a grant of advance parole is a ''departure'' for purposes of section 212(a)(9)(B)(i)(II) of the INA, 8 U.S.C. 1182(a)(9)(B)(i)(II). *See id.* In 2012, prior to deciding *Arrabelly,* the BIA affirmed *Lemus-Losa I. See Matter of Lemus-Losa,* 25 I&N Dec. 734 (2012). In contrast, in *Matter of Arrabally,* 25 I&N Dec. 771 (BIA 2012), the BIA held that leaving the United States pursuant to a grant of advance parole is not a ''departure'' under section 212(a)(9)(B)(i)(II) of the Act, 8 U.S.C. 1182(a)(9)(B)(i)(II). *See Arrabally,* 25 I&N Dec. at 778–80. The BIA relied heavily on what it surmised was ''Congress' intent'' and the ''manifest purpose'' of the statutory provision. *Id.* at 776.[9] Yet the decision did not address the BIA's prior view of the concept of departure in *Matter of R-D-,* unpersuasively disregarded earlier precedential decisions on all fours, and failed to engage the regulatory text of 8 CFR 215.1(h) and 1215.1(h). Despite acknowledging that parole is never guaranteed, it found that a departure following a grant of advance parole was qualitatively different than other types of departures. In doing so, it disregarded the plain text of the statute, BIA precedent in *Matter of R-D-* and *Lemus-Losa I,* the text of 8 CFR 215.1(h) and 1215.1(h), and over twenty years of policy and practice to the contrary in lieu of a previously-unidentified ''Congressional intent.'' *Id.* at 774–77. The BIA's decision in *Arrabally* departed from a common-sense understanding of the term ''departure'' and disregarded a significant body of law and policy without a strong justification.

In order to appropriately administer the law, the Department must have a uniform definition of ''depart'' and ''departure'' to apply. The definition contained in the proposed rule is consistent with the INA, with other regulations, with historical practice, and with relevant case law, except for *Arrabally,* which represents an unsupported outlying view. Accordingly, as a adjunct of the Department's consideration of the effect of departures on certain motions, the proposed rule would overrule the BIA's decision in *Arrabally.*

C. Failure To Surrender and Fugitive Disentitlement

The proposed regulation would provide that the moving party shall include in any motion to reopen or reconsider: (1) Whether or not the subject of the order of removal, deportation, or exclusion was notified to surrender to DHS for removal, deportation, or exclusion; and (2) whether the subject, if so ordered, has complied. This rule does not propose any restrictions on the format of the surrender notification or when the notification must be given; it provides only that the immigration judge or BIA will consider all relevant information regarding any notification and the corresponding compliance or non-compliance in determining whether to grant a motion to reopen or to reconsider as a matter of discretion.

When adjudicating the motion, the judge or the BIA ''is required to weigh both favorable and unfavorable factors by evaluating all of them, assigning weight or importance to each one separately and then to all of them cumulatively.'' *Franco-Rosendo* v. *Gonzales,* 454 F.3d 965, 966–67 (9th Cir. 2006) (citing *Arrozal* v. *INS,* 159 F.3d 429, 433 (9th Cir.1998)). After being given notice of the surrender requirement, an alien's failure to surrender would generally be treated as an unfavorable factor in this determination, consistent with longstanding case law holding that an alien's failure to report for removal represents a ''deliberate flouting of the immigration laws'' and therefore counts as a ''a very serious adverse factor which warrants the denial'' of a

[9] In *Matter of Lemus-Losa,* 24 I&N Dec. 373 (BIA 2007) (''*Lemus-Losa I*''), the BIA held that leaving the United States pursuant to a grant of advance parole is a ''departure'' for purposes of section 212(a)(9)(B)(i)(II) of the INA, 8 U.S.C. 1182(a)(9)(B)(i)(II). *See Lemus-Losa I,* 24 I&N Dec. at 376–77. In 2012, prior to deciding *Arrabelly,* the BIA affirmed *Lemus-Losa I. See Matter of Lemus-Losa,* 25 I&N Dec. 734 (2012).

discretionary motion, such as a motion to reopen or reconsider. *Matter of Barocio,* 19 I&N Dec. 255 (BIA 1985); *see Franco-Rosendo,* 454 F.3d at 966–67 (citing cases in support of the proposition).

In the same vein, this proposed change adapts the fugitive disentitlement doctrine, according to which a court dismisses an appeal if the subject absconds while it is pending, from the federal court system to the immigration courts by explicitly providing that failure to surrender is an adverse factor for consideration. The fugitive disentitlemlent doctrine has existed ''for well over a century'' in the criminal law because it ''serves an important detterence function'' and protects ''the enforceability of a court's judgments.'' *Martin* v. *Mukasey,* 517 F.3d 1201, 1204–05 (10th Cir. 2008); *see also Degen* v. *United States,* 517 U.S. 820, 823–24 (1996) (explaining the doctrine). It has been extended to the immigration context, where ''the petitioners are fugitive aliens who have evaded custody and failed to comply with a removal order.'' *Giri* v. *Keisler,* 507 F.3d 833, 835 (5th Cir. 2007); *see also Martin,* 517 F.3d at 1204; *Sapoundjiev* v. *Ashcroft,* 376 F.3d 727, 728–29 (7th Cir. 2004) (''A litigant whose disappearance makes an adverse judgment difficult if not impossible to enforce cannot expect favorable action.''); *Bar-Levy* v. *Dep't. of Justice, INS,* 990 F.2d 33, 35 (2d Cir. 1993) (''Although an alien who fails to surrender to the INS despite a lawful order of deportation is not, strictly speaking, a fugitive in a criminal matter, we think that he is nonetheless a fugitive from justice. Like the fugitive in a criminal matter, the alien who is a fugitive from a deportation order should ordinarily be barred by his fugitive status from calling upon the resources of the court to determine his claims.'').

The Department believes that the proposed requirement to notify the immigration judge or the BIA whether the alien has complied with an order to surrender would appropriately balance an alien's statutory right to file a motion to reopen reconsider with the government's interests in ''encourage[ing] voluntary surrenders'' and avoiding ''the difficulty of enforcing a judgment against a fugitive.'' *Bright* v. *Holder,* 649 F.3d 397, 399 (5th Cir. 2011). It is also fully consistent with the Department's position for over thirty years that ''the incentives for an alien to voluntarily depart from the United States or to submit to a deportation order are abated by the availability of procedures which provide a seemingly endless opportunity to seek relief from deportation'' and that adjudicators should ''decline to reward [such] disdain for the law by exercising [their] discretion to reopen proceedings.'' *Barocio,* 19 I&N Dec. at 258.

In light of the revised approach set forth above, the Department does not intend at this time to pursue finalization of either of the previous proposed rules regarding the effect of failure to surrender, as published at 67 FR at 31157 and 63 FR at 47205.

D. Standards for Motions To Reopen or Reconsider Generally

The Department proposes to add general standards to further clarify the requirements for the adjudication of motions to reopen or reconsider by the immigration courts and the BIA.

Currently, the regulations require that an alien who files a motion to reopen in order to submit an application for relief must include the application, and any supporting documents, together with the motion. *See* 8 CFR 1003.2(c)(1), 1003.23(b)(3). The proposed rule would provide additional guidance regarding the impact that the nature of the relief the alien seeks may have on the adjudication of the motion to reopen or reconsider. If an alien's motion to reopen or reconsider is premised upon relief that the immigration judge or the BIA lacks authority [10] to grant, the judge or the BIA may only grant the motion if another agency has first granted the underlying relief. Neither an immigration judge nor the BIA may reopen proceedings due to a pending application for relief with another agency if the judge or the BIA would not have authority to grant the relief in the first instance,[11] though the alien may seek a stay of removal in such a circumstance with DHS pursuant to 8 CFR 241.6. In other words, there is neither a legal nor an operational basis for the BIA or an immigration judge to reopen proceedings in which neither can offer redress to the alien on an underlying application, and the inability to offer redress does not prejudice the alien because the alien can always apply to DHS for a stay of removal while DHS adjudicates the underlying application.

This proposed rule is also fully consistent with longstanding precedent, discussed below, that both requires an alien to demonstrate *prima facie* eligibility for relief in order to have a motion to reopen granted and allows a motion to reopen to be denied as a matter of discretion even when *prima facie* eligibility has been shown. In short, this change would codify *Matter of Yauri,* 25 I&N Dec. 103, 107–10 (BIA 2009), in chapter V of the regulations and make clear that neither the Board nor an immigration judge will exercise discretion to reopen proceedings in cases in which neither the Board nor an immigration judge has authority over the application the alien is ultimately pursuing.[12]

[10] Recognizing that the word ''jurisdiction'' is one of ''many, too many meanings,'' *Union Pacific Railroad Co.* v. *Brotherhood of Locomotive Engineers,* 558 U.S. 67, 81 (2009), and that its use in the context of both motions and underlying applications may be confusing, the Department believes this point is better framed in terms of authority rather than jurisdiction. There are many immigration applications which the Department lacks authority to adjudicate because such authority is committed to DHS. *See, e.g.,* 8 U.S.C. 1255(l)(1) (stating that DHS has exclusive authority to grant adjustment of status to an alien with a T visa); *Matter of Sanchez-Sosa,* 25 I&N Dec. 807, 811 (BIA 2012) (''The [DHS] has exclusive [authority] over U visa petitions and applications for adjustment of status under section 245(m) of the Act.''); *Matter of Martinez-Montalvo,* 24 I&N Dec. 778, 778–89 (BIA 2009) (stating that immigration judges have no authority to adjudicate an application filed by an arriving alien seeking adjustment of status under the Cuban Refugee Adjustment Act of November 2, 1966, with the limited exception of an alien who has been placed in removal proceedings after returning to the United States pursuant to a grant of advance parole to pursue a previously filed application); *Matter of Singh,* 21 I&N Dec. 427, 433–34 (BIA 1996) (stating that EOIR lacks authority to adjudicate legalization applications pursuant to section 245A of the INA).

[11] Many reasons militate against granting a motion to reopen based on an underlying application over which an immigration judge and the Board lack authority. Chief among those reasons is the finite nature of the agency's resources, which should be allocated to matters over which EOIR adjudicators have authority. Expending adjudicative and administrative reources on matters over which the agency has no authority results in more unnecessary and time-consuming continuances, difficulty maintaining open cases that rely on outside considerations, and the need to enter orders that simply restate another's findings and holdings. *See Matter of Yauri,* 25 I&N Dec. 103, 110–11 (BIA 2009).

[12] In *Singh* v. *Holder,* 771 F.3d 647 (9th Cir. 2014), the Ninth Circuit held that the Board possessed *sua sponte* authority to reopen a proceeding involving an application over which it lacked authority and to effectively grant a stay of removal, notwithstanding the decision in *Yauri. See Singh,* 771 F.3d at 652. *Singh,* however, did not address the Board's determination in *Yauri* that it would not exercise its discretion—even acting within its *sua sponte* authority—to reopen cases involving applications over which it lacked authority. *Compare id.* at 653 (''Because the BIA denied Singh's motion only for lack of authority, we grant the petition and remand to the BIA.''), *with Yauri,* 25 I&N Dec. at 110 (''Finally, and separately from any question of jurisdiction, with regard to untimely or number-barred motions to reopen, we conclude that *sua sponte* reopening of exclusion, deportation, or removal proceedings pending a third party's adjudication of an underlying application that is not itself within our [authority] ordinarily would not be warranted as a matter of discretion.''). *Singh* also did not address the availability of a stay of removal from DHS in circumstances in which DHS has sole authority over the application at issue. *See* 8 CFR 241.6. Consequently, the extent to which the Board has discretion to deny motions in support of

Similarly, under the proposed rule, if the alien seeks relief that the immigration judge or the BIA would have authority to grant, the immigration judge or the BIA would be able to grant the motion only if the alien first establishes *prima facie* eligibility for that relief. In other words, a lack of *prima facie* eligibility would be sufficient for an immigration judge or the BIA to deny a motion to reopen or reconsider. Such *prima facie* eligibility must include evidence that the alien has the relevant approved, current visa, if a visa is required. This proposed rule would therefore codify and explicate the same longstanding rule widely recognized in case law. *See INS* v. *Abudu,* 485 U.S. 94, 104 (1988) (''There are at least three independent grounds on which the BIA may deny a motion to reopen. First, it may hold that the movant has not established a prima facie case for the underlying substantive relief sought.'').

The proposed rule would not alter the authority of the Board and immigration judges to deny a motion to reopen as a matter of discretioneven when the alien has established a *prima facie* case for the underlying substantive relief. *See* 8 CFR 1003.2(a) (''The Board has discretion to deny a motion to reopen even if the party moving has made out a *prima facie* case for relief.''); 1003.23(b)(3) (''The Immigration Judge has discretion to deny a motion to reopen even if the moving party has established a prima facie case for relief.''); *see also INS* v. *Doherty,* 502 U.S. 314, 333 (1992) (Scalia, J., concurring in part and dissenting in part), (''[T]he Attorney General's power to grant or deny, as a discretionary matter, various forms of non-mandatory relief includes within it what might be called a 'merits-deciding' discretion to deny motions to reopen, even in cases where the alien is statutorily eligible and has complied with the relevant procedural requirements.''); *Abudu,* 485 U.S. at 104–05 (''[I]n cases in which the ultimate grant of relief is discretionary (asylum, suspension of deportation, and adjustment of status, but not withholding of deportation), the BIA may leap ahead, as it were, over the two threshold concerns . . . and simply determine that even if they were met, the movant would not be entitled to the discretionary grant of relief.''); *Mendias-Mendoza* v. *Sessions,* 877 F.3d 223, 227 (5th Cir. 2017) (quoting and applying *Abudu*); *Poniman* v. *Gonzales,* 481 F.3d 1008, 1011 (8th Cir. 2007) (same). The provisions would therefore help deter and efficiently resolve frivolous motions to reopen or reconsider, promoting the ''strong public interest'' in the completion of removal proceedings ''as promptly as is consistent with giving the adversaries a fair opportunity to develop and present their respective cases.'' *Abudu,* 485 U.S. at 107; *cf. INS* v. *Jong Ha Wang,* 450 U.S. 139, 143 n.5 (1981) (per curiam) (''If INS discretion is to mean anything, it must be that the INS has some latitude in deciding when to reopen a case. The INS should have the right to be restrictive. Granting such motions too freely will permit endless delay of deportation by aliens creative and fertile enough to continuously produce new and material facts sufficient to establish a prima facie case. It will also waste the time and efforts of immigration judges called upon to preside at hearings automatically required by the prima facie allegations.'') (quoting *Villena* v. *INS,* 622 F.2d 1352, 1362 (9th Cir. 1980) (en banc) (Wallace, J. dissenting)).

Consistent with current practice in immigration courts and the BIA,[13] the proposed regulation would also clarify that immigration judges and the BIA may not automatically grant a motion to reopen or reconsider that is jointly filed, that is unopposed, or that is deemed unopposed because a response was not timely filed.[14] As explained, the BIA is vested with broad discretion to grant or deny these motions; no authority requires the BIA to grant such a motion when it is jointly filed or unopposed, or when no timely response is made. *See Doherty,* 502 U.S. at 322–23; *see also Abudu,* 485 U.S. at 105–06; *Jong Ha Wang,* 450 U.S. at 143 n.5. The proposed rule would further specify that neither an immigration judge nor the BIA may grant a motion to reopen or reconsider for the purpose of terminating or dismissing the proceeding, unless the motion satisfies the standards for both the motion, including the *prima facie* requirement discussed above if applicable,[15] and the requested termination or dismissal. *See* 8 CFR 1239.2(c), (f); *see also Matter of S–O–G– & F–D–B–,* 27 I&N Dec. 462 (A.G. 2019) (holding that the authority to dismiss or terminate proceedings is constrained by the regulations and is not a ''free-floating power''). To facilitate this inquiry, the proposed regulation provides a definition of ''termination'' and explains that termination includes both the termination and the dismissal of proceedings, wherever those terms are used in the regulations. *Cf. id.* at 467 (''Although 'dismissal' and 'termination' have distinct meanings and different requirements under the regulations, they are similar concepts in the context of concluding removal proceedings . . . .'').

The proposed rule would also offer clarity regarding how the Board or an immigration judge should evaluate allegations and arguments made in a motion to reopen or motion to reconsider and the evidence supporting such a motion. The Board—and, by extension, immigration judges—have ''broad discretion'' to weigh the credibility of evidence offered in support of a motion to reopen. *Dieng* v. *Barr,* 947 F.3d 956, 961 (6th Cir. 2020). Although the Supreme Court has explained that a summary judgment standard is not appropriate for evaluating a motion to reopen, and that evidence in favor of the movant need not be accepted as true, the regulations provide little guidance as to when allegations should be accepted or disregarded. *Abudu,* 485 U.S. at 109 (''We have never suggested that all ambiguities in the factual averments [in a motion to reopen] must be resolved in the movant's favor, and we have never analogized such a motion to a motion for summary judgment. The appropriate analogy is a motion for a new trial in a criminal case on the basis of newly discovered evidence, as to which courts have uniformly held that the moving party bears a heavy burden.''); *Dieng,* 947 F.3d at 963 (''Comparing the BIA's adjudicatory role to that of a trial judge reviewing a motion for summary judgment is inappropriate where 'every delay works to the advantage of the deportable alien who wishes merely to remain in the United States.' '' (quoting

applications over which it has no authority remains unsettled. The proposed rule would codify the intent of *Yauri* and the procedures and standards to be used for considering requests for a stay of removal. Additionally, the Department notes that it has proposed eliminating *sua sponte* reopening authority by the Board in most instances, *Appellate Procedures and Decisional Finality in Immigration Proceedings; Administrative Closure,* 85 FR 52491 (Aug. 26, 2020), undermining *Singh*.

[13] *See* U.S. Dep't of Justice, Executive Office for Immigration Review, *Board of Immigration Appeals Practice Manual,* ch. 5.11 (Oct. 19, 2018 update) (''*BIA Practice Manual*''), *https://www.justice.gov/eoir/page/file/1103051/download;* U.S. Dep't of Justice, Executive Office for Immigration Review, *Immigration Court Practice Manual,* chs. 3.1(b) & (d)(ii), 5.12 (Aug. 2, 2018 update) (''*Immigration Court Practice Manual*''), *https://www.justice.gov/eoir/page/file/1084851/download*.

[14] As explained, the BIA is vested with broad discretion to grant or deny these motions; no authority requires the BIA to grant such a motion when it is jointly filed or unopposed, or when no timely response is made. *See Doherty,* 502 U.S. at 322–23; *see also Abudu,* 485 U.S. at 105–06 (quoting *Jong Ha Wang,* 450 U.S. at 143 n.5).

[15] For example, the *prima facie* requirement discussed above would not apply to motions to reopen filed for purposes of dismissal pursuant to 8 CFR 239.2(c) and 1239.2(c).

Doherty, 502 U.S. at 323)); *see also M.A.* v. *INS,* 899 F.2d 304, 309–10 (4th Cir. 1990) (en banc) (Wilkinson, J.) (''The term 'prima facie case' is not a buzzword that requires us to ignore the procedural posture of the case . . . . There is nothing incongruous about the Board interpreting its regulations to require that a prima facie showing in a reopening context be more demanding than the statutory standard in an original proceeding.'').

The proposed rule clarifies that factual assertions that are contradicted, unsupported, conclusory, ambiguous, or otherwise unreliable should not be accepted as true, consistent with current standards. *See, e.g., Dieng,* 947 F.3d at 963–64 (affidavits that are ''self-serving and speculative,'' statements concerning changed country conditions that are not ''based on personal knowledge,'' and letters from petitioners' family members that are ''speculative, and not corroborated with objective evidence,'' may be discredited as ''inherently unbelievable''). Consistent with *Abudu,* it would further make clear that the Board is not required to take all assertions in a motion to reopen at face value. *Contra Ghahremani* v. *Gonzales,* 498 F.3d 993, 999 (9th Cir. 2007) (''Our case law establishes, however, that the BIA was under an affirmative obligation to 'accept as true the facts stated in Ghahremani's affidavit [in support of his motion] in ruling upon his motion to reopen unless it finds those facts to be inherently unbelievable.' '') (quoting *Maroufi* v. *INS,* 772 F.2d 597, 600 (9th Cir. 1985)). The proposed rule further clarifies that an adjudicator is not required to accept the legal arguments of either party as correct. It also codifies longstanding law that assertions made in a filing by counsel, such as a motion to reopen or motion to reconsider, are not evidence and should not be treated as such. *See Matter of Ramirez-Sanchez,* 17 I&N Dec. 503, 506 (BIA 1980) (holding that counsel's ''mixed factual and legal'' assertions ''are not evidence'').

This rulemaking would also make changes to provide clearer standards for adjudicating motions to reopen and reconsider. First, the rule would relocate language concerning criminal aliens and the requirements for such aliens to include information about pending criminal prosecutions from 8 CFR 1003.2 and 1003.23 to the new regulation at 8 CFR 1003.48. Relocating this language would consolidate pertinent information into one section. In addition, the proposed rule would add a new requirement regarding disclosures of any convictions that occurred between the order of removal and the filing of the motion to reopen, to ensure that immigration judges or the Board have all relevant information about the alien's circumstances. Further, the proposed rule would require the disclosure of any reinstated order of removal pursuant to section 241(a)(5) of the Act, 8 U.S.C. 1231(a)(5). Without such a requirement, the adjudicator may inappropriately consider a motion to reopen that is otherwise prohibited by statute. All of these requirements will assist adjudicators in making proper decisions based on a current record.

The proposed rule would also prohibit the Board or an immigration judge from granting a motion to reopen or reconsider filed by an alien unless the alien has provided appropriate contact information for further notification or hearing. This proposal is similar to the requirements for a change of venue, 8 CFR 1003.20(c), and ensures that proceedings are not reopened only to be delayed because the Board or an immigration court lacks a current address for the alien. *See Degen,* 517 U.S. at 824 (explaining a court's authority to dismiss an appeal or writ of certiorari when the party seeking relief is a fugitive while the matter is pending because if ''the party cannot be found, the judgment on review may be impossible to enforce''); *cf. Sapoundjiev,* 376 F.3d at 729 (''When an alien fails to report for custody, this sets up the situation that *Antonio-Martinez* called 'heads I win, tails you'll never find me[.]' '') (quoting *Antonio-Martinez* v. *INS,* 317 F.3d 1089, 1093 (9th Cir. 2003)).

The proposed rule would add a new paragraph in 8 CFR 1003.2(c)(3) to align that regulation with both the statutory language in INA 240(c)(7)(C)(ii), 8 U.S.C. 1229a(c)(7)(C)(ii), and the provision applicable to immigration judges in 8 CFR 1003.23(b)(4)(i) relating to motions to reopen based on changed country conditions. Following INA 240(c)(7)(C)(ii), 8 U.S.C. 1229a(c)(7)(C)(ii), 8 CFR 1003.23(b)(4)(i) includes an exception to the general time and number limitations applicable to motions to reopen if the motion seeks to file a new application for asylum, statutory withholding of removal, or protection under the Convention Against Torture based on changed county conditions and supported by evidence that is material and was not available and could not have been discovered or presented at the previous proceeding. It also includes additional language related to stays of removal and the implications of finding a prior asylum application to have been frivolous. *See* 8 CFR 1003.23(b)(4)(i). No similar regulation for removal proceedings exists for the Board, however.[16]

The Department believes that immigration judges and the Board should adjudicate motions to reopen removal proceedings related to changed country conditions under the same standards. Nothing in the INA suggests that the standards should be different. Further, the Board is just as likely—if not more so—to consider stay requests in conjunction with motions to reopen in this context and to consider the implications of a prior finding of frivolousness for a motion to reopen as immigration judges are. *See, e.g., Matter of H–Y–Z-,* 28 I&N Dec. 156, 160 (BIA 2020) (''Therefore, the subsequent filing of a motion to reopen [with the Board], even one that challenges a frivolousness finding, has no effect on the statutory bar to immigration benefits. . . . This is consistent with the regulation regarding motions to reopen before the Immigration Judge. . . .''). Consequently, to harmonize the standards applied by both immigration judges and the Board to motions to reopen in this context, the Department proposes to insert the language of 8 CFR 1003.23(b)(4)(i), which tracks the statutory provisions of INA 240(c)(7)(C)(ii), 8 U.S.C. 1229a(c)(7)(C)(ii), into regulations applicable to the Board by adding a new paragraph 8 CFR 1003.2(c)(3)(v).

In addition, the proposed rule would clarify that an alien who files a motion to reopen and applies for asylum or related relief based on changed country conditions need not submit a copy of the record of proceedings or administrative file with the motion. Finally, the proposed rule would delete outdated alternate deadlines in 8 CFR 1003.23(b), 1003.2(b)(2), and 1003.2(c)(2) for filing motions to reopen or reconsider.

[16] Two provisions applicable to the Board cross-reference 8 CFR 1003.23(b)(4)(ii) and 1003.23(b)(4)(iii), but no regulation cross-references 8 CFR 1003.23(b)(4)(i). *See* 8 CFR 1003.2(c)(3) and (3)(i). Further, although 8 CFR 1003.2(c)(3)(ii) contains language broadly analogous to 8 CFR 1003.23(b)(4)(i), it appears to apply to deportation proceedings rather than removal proceedings and, accordingly, uses language different from that of the statute applicable to removal proceedings. *Compare* 8 CFR 1003.2(c)(3)(ii) (referencing ''withholding of *deportation* based on *changed circumstances* arising in the country of nationality or in the country to which *deportation* has been ordered'') (emphasis added), *with* INA 240(c)(7)(C)(ii), 8 U.S.C. 1229a(c)(7)(C)(ii) (referencing ''*changed country conditions* arising in the country of nationality or the country to which *removal* has been ordered'') (emphasis added).

E. Specific Standards for Motions To Reopen Due to Ineffective Assistance of Counsel

1. Overview of the Proposed Rule

As noted in section II.B, although courts have broadly endorsed the framework of *Lozada* in considering motions to reopen based on claims of ineffective assistance of counsel, several courts have declined to give full effect to the *Lozada* requirements where, in the court's view, compliance is not necessary. *See, e.g., Morales Apolinar* v. *Mukasey,* 514 F.3d 893, 896 (9th Cir. 2008) (''In practice, we have been flexible in our application of the *Lozada* requirements. The *Lozada* factors are not rigidly applied, especially where their purpose is fully served by other means.''). In addition, courts have adopted varying standards for establishing prejudice.

The proposed rule would therefore establish uniform procedural and substantive requirements for the filing of motions to reopen based upon a claim of ineffective assistance of counsel which will, in turn, provide a uniform standard for adjudicating such motions. The proposed rule would provide an ''objective basis from which to assess the veracity of the substantial number of ineffective assistance claims,'' would ''hold attorneys to appropriate standards of performance,'' and would ''ensure both that an adequate factual basis exists in the record for an ineffectiveness [motion] and that the [motion] is a legitimate and substantial one.'' *Tamang* v. *Holder,* 598 F.3d 1083, 1090 (9th Cir. 2010) (internal quotation marks omitted). The filing requirements described in the proposed rule would also guide an alien alleging ineffective assistance of counsel in providing evidence necessary to adjudicate the claim. As the Board noted in *Lozada,* ''[t]he high standard announced here is necessary if we are to have a basis for assessing the substantial number of claims of ineffective assistance of counsel that come before the Board. Where essential information is lacking, it is impossible to evaluate the substance of such claim.'' *Lozada,* 19 I&N Dec. at 639. In short, the proposed rule will protect aliens from incompetent or unscrupulous attorneys, protect attorneys from improper or unfounded allegations of professional misconduct, and product the integrity of EOIR's immigration proceedings as a whole.

The proposed rule would provide standards for filing and adjudicating motions to reopen or reconsider based upon a claim of ineffective assistance of counsel, generally following the BIA's instruction and current requirements under *Lozada,* 19 I&N Dec. at 639; section 240(c)(7) of the Act, 8 U.S.C.1229a(c)(7); and the applicable regulations at 8 CFR 1003.2 and 1003.23. The standard for adjudication would require such motion to demonstrate that the counsel's conduct was ineffective and prejudiced the individual. The proposed rule would allow for possible relief due to ineffective assistance of counsel, which the rule would define as attorneys or accredited representatives under 8 CFR 1292.1(a)(1) and (a)(4), or any other person who represented the alien in proceedings before the immigration court or the BIA and who the alien reasonably but erroneously believed was authorized to do so. In evaluating counsel's conduct, the proposed regulation would require that the conduct be unreasonable based on the facts of the case, viewed at the time of the conduct at issue. The proposed rule would also require the alien to demonstrate prejudice based on that conduct.

The proposed rule would not enumerate specific conduct that amounts to ineffective assistance in immigration proceedings; rather, the proposed rule would adopt a standard similar to the one rooted in *Strickland* v. *Washington,* 466 U.S. 668 (1984).[17] For an attorney's representation to constitute ineffective assistance, the representation ''must . . . [fall] below an objective standard of reasonableness,'' *id.* at 688, judged ''on the facts of the particular case, [and] viewed as of the time of counsel's conduct,'' *id.* at 690.

Under the proposed rule, a tactical decision could not amount to ineffective assistance if the decision was reasonable when it was made, even if it proved unwise in hindsight. *See id.* at 689 (''A fair assessment of attorney performance requires that every effort be made to eliminate the distorting effects of hindsight[.]''); *Mena-Flores* v. *Holder,* 776 F.3d 1152, 1169 (10th Cir. 2015) (''An attorney's objectively reasonable tactical decisions do not qualify as ineffective assistance.''); *cf. Matter of Velasquez,* 19 I&N Dec. 377, 383 (BIA 1986) (stating that attorney's ''decision to concede deportability was a reasonable tactical decision'' and thus was binding). Finally, under the proposed rule, the Department expects there would be ''a strong presumption that counsel's conduct falls within the wide range of reasonable professional assistance.'' *Strickland,* 466 U.S. at 689.

The proposed rule would require the individual to establish that he or she was prejudiced by counsel's conduct, and an immigration judge or the BIA shall consider whether a reasonable probability exists that, absent counsel's ineffective assistance, the outcome of the proceedings would have been different.[18] This reasonable probability standard well established; adopting it would provide clarity and make more uniform the way courts evaluate prejudice. *See id.* at 694 (''The [movant] must show that there is a reasonable probability that, but for counsel's unprofessional errors, the result of the proceeding would have been different. A reasonable probability is a probability sufficient to undermine confidence in the outcome.''). The proposed rule would provide that eligibility for relief or protection arising after the conclusion of proceedings will typically not affect the determination whether the individual was prejudiced during such proceedings. *Cf. Snethen* v. *State,* 308 NW2d 11, 16 (Iowa 1981) (''Counsel need not be a crystal gazer; it is not necessary to know what the law will become in the future to provide effective assistance of counsel.'').

The proposed rule would require three items to support a motion to reopen based on ineffective assistance of counsel. First, it would require an affidavit or written statement executed under penalty of perjury that details the

[17] Although immigration proceedings are civil in nature and *Strickland* applies to criminal proceedings, the use of standards imported from *Strickland* should provide greater protection to aliens since criminal defendants possess greater rights and protections than aliens in removal proceedings. The Department notes, however, that its use of *Strickland* in this context is simply a policy determination for purposes of administering the proposed regulation and should not be construed as an assertion that aliens should have the same rights afforded to criminal defendants, including the right to counsel at government expense.

[18] As with the determination of ineffective assistance of counsel, this proposed rule would not enumerate any circumstances that necessarily constitute prejudice. *See generally Assaad,* 23 I&N Dec. at 562 (rejecting the argument that counsel's failure to file an appeal is per se prejudicial). *But see Siong* v. *INS,* 376 F.3d 1030, 1037 (9th Cir. 2004) (applying a rebuttable presumption of prejudice where counsel's error deprived an individual of any appeal). Rather, each case would rest on its particulars, with the recognition that some conduct will more typically yield prejudice, but that the individual filing the motion always carries the burden to establish that prejudice does in fact exist. Additionally, the rescission of an in absentia order of removal generally requires either a showing of exceptional circumstances or a lack of notice. INA 240(b)(5)(C), 8 U.S.C. 1229a(b)(5)(C). Although prejudice would not be presumed for a motion to rescind an in absentia removal order based on ineffective assistance of counsel, the Department expects that in the ordinary case an alien who demonstrates ineffective assistance of counsel leading to the issuance of an in absentia order of removal would also likely demonstrate prejudice.

agreement between counsel and the individual. The affidavit or written statement must include the actions to be taken by counsel and the representations counsel did or did not make regarding such actions. Moreover, to ensure that the alien fully understands what he is alleging, the affidavit or written statement must also identify who drafted it, if the alien did not, and contain an acknowledgment by the alien that the affidavit or written statement had been read to the alien in a language the alien speaks and understands, and that the alien, by signing, affirms that he understands and agrees with the language of the affidavit or written statement.

A copy of any representation agreement must be included with the affidavit or written statement, or the individual should explain its absence and provide any reasonably available evidence regarding the scope of the agreement and reasons for its absence. The proposed rule would allow the BIA or an immigration judge to excuse the requirement to submit an affidavit or written statement, and accompanying evidence regarding the representation agreement, as a matter of discretion in the case of a motion filed by a *pro se* alien.

Second, the proposed rule would require evidence of the individual's notice to counsel informing him the allegations and that a motion to reopen based on such allegations will be filed. The individual must provide evidence of the date and manner in which he or she provided such notice, as well as counsel's response, if any. If there were no response, the individual must say so. The proposed rule would provide two exceptions to this requirement: When prior counsel is deceased, or when the alien exercised reasonable diligence in the attempt to locate prior counsel but was unable to do so.

Third, the proposed rule would require that the alien file a complaint with the appropriate disciplinary authorities and with EOIR disciplinary counsel. For attorneys in the United States, the alien must file a complaint with the disciplinary authority of a State, possession, territory, or Commonwealth, or of the District of Columbia, that licensed the attorney to practice law.[19] For accredited representatives as defined in 8 CFR part 1292, the individual must file a complaint with the EOIR disciplinary counsel pursuant to 8 CFR 1003.104. For persons whom the individual reasonably but erroneously believed to be an attorney or accredited representative as defined in 8 CFR part 1292, and who was retained for the purpose of representation in immigration proceedings, the individual must file a complaint with an appropriate federal, State, or local law enforcement agency that has authority to address matters involving unauthorized practice of law or immigration-related fraud. In all cases, the individual must file a complaint with EOIR disciplinary counsel. The individual must include with the motion to reopen a copy of the complaint(s) and any subsequent related correspondence, unless the counsel is deceased.[20]

In short, the proposed rule codifies the requirements of *Lozada* and reaffirms particular aspects of those requirements that have been disregarded to varying degrees by federal circuit courts. It provides a uniform standard for assessing prejudice and clear guidance that will both aid and protect respondents, practitioners, and adjudicators.[21]

2. The Current Proposed Rule's Enhancements to the Previous Proposed Rule

As previously stated, the Department withdraws its previous proposed rule regarding motions to reopen based upon ineffective assistance of counsel at 81 FR at 49556 in order to address broader issues regarding motions to reopen in a more comprehensive manner and to consolidate multiple other proposed rulemakings related to such motions. The new proposed rule nevertheless retains, either in whole or in part, many of the provisions from the previous proposed rule, including the standard for adjudication in 8 CFR 1003.48(h)(1) (proposed), the standard for evaluating counsel's ineffectiveness in 8 CFR 1003.48(h)(3) (proposed), the reasonable probability standard for prejudice in 8 CFR 1003.48(h)(4) (proposed), and the required items to support the motion in 8 CFR 1003.48(h)(5) (proposed).

The current proposed rule also enhances the previous proposed rule in several ways. First, it clarifies the regulation's applicability to proceedings before the BIA and the immigration courts by renaming subpart C. The previous proposed rule retained subpart C's name, ''Immigration Court—Rules of Procedure,'' although the rule would have applied to proceedings at the BIA and the immigration courts.

Second, the current proposed rule expands the previous proposed rule's definition of ''counsel.'' The previous proposed rule did not expressly include the conduct of attorneys retained without remuneration, but the proposed rule does. *See* 8 CFR 1003.48(h)(1)–(4) (proposed). Thus, it expands the rule's afforded protections to a broader set of individuals, though it would not extend beyond EOIR proceedings.

Third, regarding the requirement to submit the representation agreement and an affidavit or written statement detailing the agreement between counsel and the individual, the proposed rule provides that the BIA or immigration judge may, in their discretion, grant an exception if the person is not represented by counsel, explains the absence of documentation, and presents other independent evidence to support the motion. The BIA or immigration judge may not grant exceptions for the affidavit or written statement if the person has retained counsel, but, in the absence of a representation agreement, the person may explain its absence and provide reasonably available supporting evidence. Regarding the notice to counsel, the proposed rule provides specific exceptions if counsel is deceased or if the person tried to locate previous counsel with reasonable diligence but was unsuccessful.

Fourth, the earlier proposed rule would have required the individual filing the motion to reopen to notify appropriate disciplinary authorities, as listed in the regulation. This proposed

[19] If an attorney is licensed in more than one jurisdiction, a complaint need only be filed with the disciplinary authority of one jurisdiction.

[20] Although *Lozada* indicated that an alien could file a statement as to why no complaint was filed, the Department sees no reason why an alien alleging ineffective assistance of counsel would not file a complaint, unless counsel was deceased. Indeed, because the alleged ineffective assistance necessarily occurred during an EOIR proceeding, the Department can think of no logical reason why a complaint would not be filed with, at the least, the EOIR disciplinary counsel.

[21] The proposed rule would not apply to motions to reopen proceedings based on counsel's conduct before another administrative or judicial body, including before, during the course of, or after the conclusion of immigration proceedings. This includes conduct that was immigration-related or that occurred before DHS or another government agency. *Cf. Contreras* v. *Att'y Gen.,* 665 F.3d 578, 585–86 (3d Cir. 2012) (declining to find ineffective assistance of counsel in the preparation and filing of a visa petition where counsel's conduct ''did not compromise the fundamental fairness of'' subsequent removal proceedings); *Balam-Chuc* v. *Mukasey,* 547 F.3d 1044, 1051 (9th Cir. 2008) (same). One reason for this limitation is that the Board and immigration judges are generally not in a position to provide a remedy in a situation where an attorney's performance before another administrative or judicial body is alleged to be ineffective. Rather, a request for a remedy in such a situation would be more appropriately directed to that administrative or judicial body before which the alleged ineffective assistance occurred. At the same time, nothing in the proposed rule prohibits a respondent from filing a motion requesting that the Board reissue a decision in a case in which the respondent's counsel missed a deadline for filing a petition for review.

rule maintains that notification requirement in its entirety, but it adds a second notification requirement—to notify EOIR disciplinary counsel in every case in accordance with the current regulation at 8 CFR 1003.104. This ensures that all claims of ineffective assistance are reviewed for potential disciplinary action. The EOIR Disciplinary Program helps the Department ensure fairness and integrity in immigration proceedings. Through the program, EOIR regulates the professional conduct of immigration attorneys and representatives to protect the public, preserve the integrity of immigration proceedings and adjudications, and maintain high professional standards for practitioners. Consequently, it is crucial that the EOIR Disciplinary Counsel be aware of claims of ineffective assistance by practitioners so that it may take appropriate action.

By clarifying and expanding the application of these regulations, clarifying exceptions that promote consistency, uniformity, and finality in immigration proceedings, and ensuring that claims of ineffective assistance are reviewed for potential disciplinary action, this proposed rule builds upon the earlier proposed rule. Accordingly, and for the reasons discussed above, the Department withdraws its previous proposed rule at 81 FR at 49556 and proposes this rule to standardize motions to reopen immigration proceedings based upon a claim of ineffective assistance of counsel.

F. Motions To Reopen To Submit or Update an Application for Asylum or Protection

Under current regulations, an alien who files a motion to reopen in order to submit an application for relief must submit the appropriate application and the application's supporting documentation together with the motion. 8 CFR 1003.2(c)(1) (''A motion to reopen proceedings for the purpose of submitting an application for relief must be accompanied by the appropriate application for relief and all supporting documentation.''); 8 CFR 1003.23(b)(3) (same). *See also, e.g., Gen Lin* v. *Att'y Gen.,* 700 F.3d 683, 689 (3d Cir. 2012) (concluding that the failure to include a new asylum application with the motion to reopen was a sufficient basis to deny a petition for review); *Romero-Ruiz* v. *Mukasey,* 538 F.3d 1057, 1064 (9th Cir. 2008) (concluding that the BIA ''did not abuse its discretion in determining that Romero–Ruiz did not satisfy the procedural requirements'' for filing a motion to reopen because, among other things, he failed to file an accompanying application for cancellation of removal); *Waggoner* v. *Gonzales,* 488 F.3d 632, 639 (5th Cir. 2007) (holding that the BIA did not abuse its discretion in denying a motion to reopen based on changed country conditions when the alien failed to include her application for asylum and supporting documentation).

The proposed rule would further clarify that, if the immigration court or the Board grants the motion, the immigration court or the Board would further accept the application submitted with the motion to reopen. For example, an alien who submits a motion to reopen based on changed country conditions is required to submit the accompanying asylum application. 8 CFR 1003.2(c)(1), 1003.23(b)(3). Under the proposed rule, that new asylum application would be considered filed as of the date the immigration court grants the motion to reopen, and the alien would not be able to later avoid filing the application.

This change would foreclose the use of changed country conditions, which relate to a claim for asylum or withholding of removal, for the purpose of gaining reopening to pursue other claims that could not themselves have been a basis for reopening due to time- or number-bars ordinarily applicable to motions to reopen. In such circumstances, the penalty for filing a false or frivolous asylum application would continue to apply. *See* INA 208(d)(6), 8 U.S.C. 1158(d)(6); 8 CFR 1208.20. So too would civil monetary penalties for document fraud. *See* INA 274C(a), 8 U.S.C. 1324c(a).

G. Limiting the Scope of Reopened Proceedings to the Issues Upon Which Reopening Was Granted

Under current practice, a grant to reopen a case effectively reopens the case for any purpose, regardless of the motion's articulated basis. For example, a respondent may file a motion to reopen based on changed country conditions that may affect the respondent's eligibility for asylum. Under section 240(c)(7)(C)(ii) of the Act, 8 U.S.C. 1229a(c)(7)(C)(ii), changed country conditions excuse untimely filing of a motion to reopen, while changed personal circumstances do not. A respondent seeking relief based on changed personal circumstances may therefore move to reopen based on changed country conditions, and then, if the motion is granted, withdraw or fail to submit the asylum application based on changed country conditions, and, instead, pursue an alternative form of relief, such as adjustment of status, based on changed personal circumstances. Essentially, respondents commonly allege specific grounds that warrant reopening a case but then use the reopened proceedings as an opportunity to apply for other unrelated forms of relief from removal that are otherwise unavailable.

This practice undermines the Department's commitment to efficient and fair case processing because respondents who engage in such practices receive additional opportunities to raise unrelated issues or apply for relief, thereby circumventing current law and regulations providing time-based deadlines and prolonging their cases. Use of an asylum claim to reopen a case for other claims treats unfairly those aliens who have the same non-asylum claims barred by the time and number limitations but who lack an asylum claim with which to shoehorn their otherwise barred claims into reopened proceedings. To curb this practice, the Department proposes to revise the scope of reopened proceedings at 8 CFR 1003.48(d)(3). The proposed rule would limit the reopened proceeding to consider only those issues or issues upon which reopening or reconsideration was granted, as well as matters directly related, except as otherwise provided by statute, regulation, or judicial or administrative precedent. Accordingly, the respondent would be required to establish in the motion to reopen or reconsider each basis upon which the respondent intends to apply for relief.

H. Standards for Evaluating Requests for Discretionary Stays

The current regulations regarding motions to reopen and motions to reconsider provide only that an immigration judge, the BIA, or an authorized DHS officer may grant a stay of removal. *See* 8 CFR 1003.2(f), 1003.23(b)(1)(v). The current regulations lack detailed guidance pertaining to the filing and adjudication of such requests, and neither the BIA nor the Attorney General has published a decision addressing the appropriate standards for stays of removal.

The proposed regulation would provide a list of factors that the immigration judge or BIA must consider when determining whether to grant an alien's requested stay of removal as a matter of discretion: The likelihood of success on the merits; the likelihood of irreparable injury; harm that the stay may cause to other parties interested in the proceeding; and the public interest. These factors are well established in existing law and have been set out in decisions regarding the consideration of discretionary stays. *See, e.g., Nken* v.

Holder, 556 U.S. 418, 425–26 (2009); *Sofinet* v. *INS,* 188 F.3d 703, 706 (7th Cir. 1999); *Ignacio* v. *INS,* 955 F.2d 295, 299 (5th Cir. 1992). The inclusion of these provisions in the regulations will promote consistency in the adjudication of discretionary stay requests.

The proposed regulation would provide specific instructions regarding the requirements for submitting a motion for a discretionary stay in conjunction with a motion to reopen or reconsider. These provisions in the proposed regulation act as additional tools for case management, the importance of which the Attorney General emphasized in *Matter of L–A–B–R–,* 27 I&N Dec. 405, 406 (A.G. 2018) (''Efficiency is . . . a common theme in the immigration courts' procedural regulations, which promote the 'timely' and 'expeditious' resolution of removal proceedings.''). One such provision would codify in the regulations the current EOIR practice that an immigration judge and the BIA may not grant a motion for a stay of removal if the alien has not also filed an underlying motion to reopen or reconsider. *See Immigration Court Practice Manual,* ch. 8.3; *BIA Practice Manual,* ch. 6.3.

Another provision would prohibit an immigration judge or the BIA from granting a request for a discretionary stay unless the motion is accompanied by proof that the individual initially filed for a stay of removal with DHS, the agency ultimately responsible for carrying out an order of removal, deportation, or exclusion, pursuant to 8 CFR 241.6; DHS must have subsequently denied or failed to respond to the request within five business days. Requiring an individual to first file a stay request with DHS, and then subsequently be denied or receive no response in order to file with EOIR, is a commonsense procedural mechanism that ensures an alien multiple opportunities to have a stay request considered. It also promotes efficiency, as DHS, the agency seeking to remove the alien, is in the best position to evaluate a stay request in the first instance. DHS maintains the requisite personnel, expertise, and necessary information to handle such requests expeditiously because DHS is both the custodian of a removable alien and ultimately the executor of an order of removal. Further, a requirement that stays should be directed to DHS initially will encourage the filing of stay requests at the earliest possible opportunity and reduce the likelihood of dilatory gamesmanship in filing for a stay at the last moment. Consequently, stay requests are most appropriately directed to DHS in the first instance. If that request is not approved, however, an individual may still obtain a *de novo* determination from EOIR on a stay request, provided that the individual complies with other regulatory requirements.

The proposed regulation would prohibit an immigration judge or the BIA from granting a request unless the opposing party is notified and has an opportunity to respond and either affirmatively consents, joins the motion, or fails to respond to the request in three business days from the date of filing the request. Both parties in immigration proceedings are entitled to fair process, and notice to the opposing party is a tenet of fair process. Accordingly, to ensure fair consideration of all requests and consistency with how it addresses other motions, the Department proposes to require notice and an opportunity to respond before it will grant any motion for a discretionary stay. For genuinely exigent situations, nothing in this proposed rule prevents a party for moving for expedited treatment of its stay request or for the parties to file a joint request for a stay.

Ultimately, the proposed rule would emphasize that a discretionary stay is an extraordinary remedy. *See Nken,* 556 U.S. at 437 (Kennedy, J., concurring) (''A stay of removal is an extraordinary remedy that should not be granted in the ordinary case, much less awarded as of right.''). The Department believes that the implementation of discretionary stay procedures will ensure that stays are not abused or used to circumvent the statutory and regulatory structure for proceedings before EOIR. Further, these changes would ensure that EOIR's regulations are generally aligned with existing precedents.

IV. Regulatory Requirements

A. Regulatory Flexibility Act

The Department has reviewed this regulation in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) and has determined that this rule will not have a significant economic impact on a substantial number of small entities. The rule would not regulate ''small entities'' as that term is defined in 5 U.S.C. 601(6). Only individuals, and not entities, are eligible to file motions to reopen or to reconsider or to seek a stay of removal.

B. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

C. Congressional Review Act

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

D. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, distributive impacts, and equity). The Office of Information and Regulatory Affairs of the Office of Management and Budget (''OMB'') has determined that this proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866. It will neither result in an annual effect on the economy greater than $100 million nor adversely affect the economy or sectors of the economy. It does not pertain to entitlements, grants, user fees, or loan programs, nor does it raise novel legal or policy issues. It does not create inconsistencies or interfere with actions taken by other agencies. Accordingly, this rule is not a significant regulatory action subject to review by OMB pursuant to Executive Order 12866.

Executive Order 13563 directs 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 using the best available methods to quantify costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Department certifies that this regulation has been drafted in accordance with the principles of Executive Order 13563.

The proposed rule would help ensure the fairness and integrity of immigration proceedings by setting out requirements for reopening proceedings, allowing for reopening where an individual was genuinely subjected to ineffective assistance of counsel and suffered prejudice as a result. It would also establish requirements for requests for stays of removal. The Department is unaware of any monetary costs on public entities that the rule would impose. Further, the Department does not believe that, broadly speaking, the proposed rule could be said to burden the parties in EOIR proceedings, as the rule simply changes adjudicatory standards used in those proceedings.[22] At most, the Department notes that the proposed rule may result in fewer motions to reopen being granted; however, because motions to reopen are disfavored already as a matter of law, because motions to reopen are inherently fact-specific, because there may be multiple bases for denying a motion to reopen, and because the Department does not track individual bases for denying motions to reopen, it cannot quantify precisely the potential decrease.

E. Executive Order 13132 (Federalism)

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

[22] The Department acknowledges that the proposed rule would require two additional statements for motions to reopen for potential fugitive aliens, one additional statement for a motion to reopen filed by an alien subject to a reinstated removal order, and the filing of a complaint with EOIR disciplinary counsel for motions to reopen based on claims of ineffective assistance of counsel. To the extent these additional statements or actions, which largely mirror existing requirements, could be said to constitute burdens on the parties, such ''burdens'' are de minimis. Moreover, they are easily outweighed by the benefits to the Government and the improved functioning of the overall immigration system obtained through better identification of fugitive aliens, better identification of aliens statutorily ineligible to have a motion to reopen granted due to a reinstated removal order, and better identification of attorneys who have engaged in appropriate practices or provided ineffective assistance warranting discipline.

F. Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

G. Paperwork Reduction Act

This rule does not propose new or revisions to existing ''collection[s] of information'' as that term is defined under the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320.

List of Subjects

8 CFR Part 1001

Administrative practice and procedure, Immigration.

8 CFR Part 1003

Administrative practice and procedure, Aliens, Immigration.

Accordingly, for the reasons set forth in the preamble, and by the authority vested in the Director, Executive Office for Immigration Review, by the Attorney General Order Number 4910–2020, the Department proposes to amend 8 CFR parts 1001 and 1003 as follows:

Title 8 of the Code of Federal Regulations

PART 1001—DEFINITIONS

■ 1. The authority citation for part 1001 continues to read as follows:

Authority: 5 U.S.C. 301; 8 U.S.C. 1101, 1103; Pub. L. 107–296, 116 Stat. 2135; Title VII of Pub. L. 110–229.

■ 2. Section 1001.1 is amended by adding paragraphs (cc) and (dd) to read as follows:

§ 1001.1 Definitions.

* * * * *

(cc) The terms *depart* or *departure,* unless otherwise specified, refer to the physical departure of an alien from the United States to a foreign location. A departure shall not include the physical removal, deportation, or exclusion of an alien from the United States under the auspices or direction of DHS or a return of the alien to a contiguous foreign territory by DHS in accordance with section 235(b)(2)(C) of the Act, but shall include any other departure from the United States, including a departure outside of the direction of DHS by an alien subject to an order of removal, deportation, or exclusion and including a departure following the approval of an application for advance parole.

(dd) Unless otherwise specified, the terms *terminate* and *termination* refer to either termination or dismissal of proceedings under 8 CFR 1239.2(f), or termination or dismissal under any other provision of law.

PART 1003—EXECUTIVE OFFICE FOR IMMIGRATION REVIEW

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

Authority: 5 U.S.C. 301; 6 U.S.C. 521; 8 U.S.C. 1101, 1103, 1154, 1155, 1158, 1182, 1226, 1229, 1229a, 1229b, 1229c, 1231, 1254a, 1255, 1324d, 1330, 1361, 1362; 28 U.S.C. 509, 510, 1746; sec. 2 Reorg. Plan No. 2 of 1950; 3 CFR, 1949–1953 Comp., p. 1002; section 203 of Pub. L. 105–100, 111 Stat. 2196–200; sections 1506 and 1510 of Pub. L. 106–386, 114 Stat. 1527–29, 1531–32; section 1505 of Pub. L. 106–554, 114 Stat. 2763A–326 to –328.

■ 4. Section § 1003.2 is amended by:
■ a. Revising paragraphs (b)(2) and (c)(2);
■ b. Adding paragraph (c)(3)(v); and
■ c. Revising paragraphs (d) and (e).

The additions and revisions read as follows:

§ 1003.2 Reopening or reconsideration before the Board of Immigration Appeals.

* * * * *

(b) * * *

(2) A motion to reconsider a decision must be filed with the Board within 30 days after the mailing of the Board decision. A party may file only one motion to reconsider any given decision and may not seek reconsideration of a decision denying a previous motion to reconsider. In removal proceedings pursuant to section 240 of the Act, an alien may file only one motion to reconsider a decision that the alien is removable from the United States.

* * * * *

(c) * * *

(2) Except as provided in paragraph (c)(3) of this section, a party may file only one motion to reopen deportation or exclusion proceedings (whether before the Board or the immigration judge) and that motion must be filed no later than 90 days after the date on which the final administrative decision was rendered in the proceeding sought to be reopened. Except as provided in paragraph (c)(3) of this section, an alien may file only one motion to reopen removal proceedings (whether before the Board or the immigration judge) and that motion must be filed no later than 90 days after the date on which the final administrative decision was rendered in the proceeding sought to be reopened.

(3) * * *

(v) If the basis of the motion is to apply for asylum under section 208 of the Act or withholding of removal under section 241(b)(3) of the Act or withholding of removal under the Convention Against Torture, and is

based on changed country conditions arising in the country of nationality or the country to which removal has been ordered, if such evidence is material and was not available and could not have been discovered or presented at the previous proceeding. The filing of a motion to reopen under this section shall not automatically stay the removal of the alien. However, the alien may request a stay and, if granted by the Board, the alien shall not be removed pending disposition of the motion by the Board. If the original asylum application was denied based upon a finding that it was frivolous, then the alien is ineligible to file either a motion to reopen or reconsider, or for a stay of removal.

(d) *Departure.* Any departure by an alien from the United States while a motion to reopen or motion to reconsider is pending shall constitute a withdrawal of the motion, and the motion shall be denied.

(e) *Judicial proceedings.* Motions to reopen or reconsider shall state whether the validity of the exclusion, deportation, or removal order has been or is the subject of any judicial proceeding and, if so, the nature and date thereof, the court in which such proceeding took place or is pending, and its result or status.

* * * * *

■ 5. Section § 1003.23 is amended by revising the introductory text of paragraph (b)(1); and paragraph (b)(1)(I) to read as follows

§ 1003.23 Reopening or reconsideration before the immigration court.

* * * * *

(b) * * * (1) *In general.* An immigration judge may upon his or her own motion at any time, or upon motion of the Service or the alien, reopen or reconsider any case in which he or she has made a decision, unless jurisdiction is vested with the Board of Immigration Appeals. Subject to the exceptions in this paragraph and paragraph (b)(4), a party may file only one motion to reconsider and one motion to reopen proceedings. A motion to reconsider must be filed within 30 days of the date of entry of a final administrative order of removal, deportation, or exclusion. A motion to reopen must be filed within 90 days of the date of entry of a final administrative order of removal, deportation, or exclusion. Any departure from the United States while a motion to reopen or reconsider is pending shall constitute a withdrawal of such motion, and the motion shall be denied. The time and numerical limitations set forth in this paragraph do not apply to motions by DHS in removal proceedings pursuant to section 240 of the Act. Nor shall such limitations apply to motions by DHS in exclusion or deportation proceedings, when the basis of the motion is fraud in the original proceeding or a crime that would support termination of asylum in accordance with § 1208.22(e) of this chapter.

(i) *Form and contents of the motion.* The motion shall be in writing and signed by the affected party or the attorney or representative of record, if any. The motion and any submission made in conjunction with it must be in English or accompanied by a certified English translation. Motions to reopen or reconsider shall state whether the validity of the exclusion, deportation, or removal order has been or is the subject of any judicial proceeding and, if so, the nature and date thereof, the court in which such proceeding took place or is pending, and its result or status.

* * * * *

Subpart C—Rules of Procedure

■ 6. Revise the heading of subpart C to read as set forth above:

■ 7. Add § 1003.48 to subpart C to read as follows:

§ 1003.48 Motions to reopen or reconsider; stays.

(a) *In general.* The provisions of this section apply to all motions to reopen or reconsider filed with either an immigration court or the Board on or after [the effective date of this section]. The failure of a motion to reopen or reconsider to comply with any provision of this section or any other applicable requirement may result in the denial of that motion.

(b) *Allegations of fact.* (1) Section 1003.1(d)(3)(i) does not apply to the Board's consideration of the factual allegations in any affidavit or written statement offered to support a motion to reopen or reconsider, except to the extent that the facts had previously been determined by an immigration judge.

(i) Allegations of fact contained in a motion to reopen or motion to reconsider are not evidence and shall not be treated as evidence. Allegations of fact contained in a motion to reopen or motion to reconsider that is filed on behalf of the moving party by counsel or an accredited representative shall not be relied on as evidence by either the Board or an immigration judge. Such allegations made by counsel or an accredited representative shall not be accepted as true for purposes of adjudicating the motion.

(ii) Alleged conclusions of law contained in a motion to reopen or motion to reconsider are not evidence and shall not be treated as evidence nor relied on as evidence by either the Board or an immigration judge. Neither the Board nor an immigration judge shall accept alleged conclusions of law contained in a motion to reopen or motion reconsider as true, but shall conduct its own legal analysis in adjudicating the motion.

(iii) There is no presumption that factual allegations offered in support of a motion to reopen or motion to reconsider are true.

(2) Neither the Board nor an immigration judge shall accept factual allegations as true in support of a motion to reopen or motion to reconsider if:

(i) Those allegations are contradicted by other evidence of record;

(ii) Those allegations are contradicted by evidence described in § 1208.12(a);

(iii) Those allegations are conclusory, uncorroborated, or unsupported by other evidence in the record or are otherwise based principally on hearsay;

(iv) Those allegations are made solely by the respondent regarding individuals who are not presently within the United States; or

(v) Those allegations are otherwise inherently unbelievable or unreliable.

(c) *Fugitive aliens.* In any case in which an exclusion, deportation, or removal order is in effect, any motion to reopen or reconsider such order shall include a statement by or on behalf of the moving party declaring whether the subject of the order has been notified to surrender to DHS for exclusion, deportation, or removal and, if so ordered, whether the subject has complied with the notification to surrender. The alien's failure to comply with a notification to surrender may result in the denial of the alien's motion.

(d) *Criminal aliens and aliens subject to a reinstated removal order.* Any motion to reopen or reconsider filed on behalf of an alien who has an exclusion, deportation, or removal order in effect shall include a statement by or on behalf of the alien declaring whether the alien is also the subject of any conviction after the date of the final order or any pending criminal proceeding under the Act, and, if so, the current status of that conviction or proceeding. Any motion to reopen or reconsider filed on behalf of an alien who has an exclusion, deportation, or removal order in effect shall include a statement by or on behalf of the alien declaring whether that removal order has been reinstated pursuant to section 241(a)(5) of the Act.

(e) *Underlying eligibility.* (1) Neither an immigration judge nor the Board

shall grant a motion to reopen or reconsider based on an application for relief from removal over which the immigration judge or Board lacks authority unless that application for relief has been granted by another agency, the granted application provides complete relief from removal, the motion is not otherwise barred by applicable law, and the motion otherwise warrants being granted under applicable law.

(i) For purposes of this paragraph (e)(1), a grant of an application for relief does not include interim relief, *prima facie* determinations, parole, deferred action, bona fide determinations or any similar dispositions short of final approval of the application for relief.

(ii) Nothing in this section shall preclude an alien from applying for an administrative stay of removal from DHS pursuant to 8 CFR 241.6 while an application over which the immigration judge or the Board lacks authority is pending with DHS.

(2) Neither an immigration judge nor the Board shall grant a motion to reopen or reconsider based on an application for relief or protection over which the immigration judge or Board does have authority, but for which the alien has not established *prima facie* eligibility for that relief or protection. For purposes of this section, for an application for relief that requires an immediately-available immigrant visa, an alien must establish, in addition to any other eligibility requirements, (i) that he has an approved, relevant immigrant visa and (ii) that the immigrant visa is in a category not subject to a numerical limitation or has a priority date earlier than the relevant ''Date for Filing Applications'' listed in the U.S. Department of State Visa Bulletin for the month in which the motion is filed.

(3) Except as otherwise provided by statute or regulation, or a binding judicial or administrative precedent, further proceedings in a case that is reopened or reconsidered pursuant to a respondent's motion described in paragraph (e)(1) or (e)(2) of this section shall be limited to the issues upon which reopening or reconsideration was sought and granted, and issues directly related.

(4) Nothing in this paragraph (e) shall preclude an immigration judge or the Board from granting a motion to reopen or reconsider that is jointly filed if the motion otherwise warrants being granted.

(f) *Joint or unopposed motions.* A motion to reopen or reconsider to which a response is not timely filed may be deemed unopposed, provided that neither an unopposed motion nor a joint motion may be automatically granted without any further consideration. An immigration judge or the Board retains discretion to deny a joint motion or an unopposed motion if warranted.

(g) *Termination.* A motion to reopen or reconsider and to terminate proceedings may be granted only if it satisfies the requirements both for reopening or reconsideration and for termination.

(h) *Motions. based on changed country conditions.* When filing a motion to reopen to apply for asylum, withholding of removal under the Act, or protection under the Convention Against Torture, based on changed country conditions arising in the country of nationality or the country to which removal has been ordered, the alien filing the motion does not need to file a copy of his or her record of proceedings or administrative file (A-file) with the motion.

(i) *Ineffective assistance of counsel.*—(1) *Standard for adjudication.* The Board or an immigration judge shall adjudicate a motion to reopen based upon a claim of ineffective assistance of counsel in accordance with applicable law. The alien filing the motion must demonstrate that counsel's conduct was ineffective and prejudiced the individual. Unless otherwise expressly provided in this paragraph, the Board or an immigration judge shall not waive or excuse any requirement for a motion to reopen based upon a claim of ineffective assistance of counsel.

(2) *Counsel.* The term ''counsel,'' as used in this section, only applies to the conduct of:

(i) An attorney or an accredited representative as defined in part 1292; or

(ii) A person whom the individual filing the motion reasonably but erroneously believed to be an attorney or an accredited representative and who was retained with or without remuneration, to represent him or her in the proceedings before the BIA or an immigration judge and who did represent him or her in those proceedings.

(3) *Standard for evaluating counsel's ineffectiveness.* A counsel's conduct constitutes ineffective assistance of counsel if the conduct was objectively unreasonable, based on the facts of the particular case, viewed at the time of the conduct.

(4) *Standard for evaluating prejudice.* In evaluating whether an individual has established that he or she was prejudiced by counsel's conduct, the BIA or the immigration judge shall determine whether there is a reasonable probability that, but for counsel's ineffective assistance, the result of the proceeding would have been different. Eligibility for relief or protection occurring after the conclusion of proceedings will ordinarily have no bearing on the determination of whether the individual was prejudiced during the course of proceedings.

(5) *Form, contents, and procedure for filing a motion to reopen based upon a claim of ineffective assistance of counsel.* A motion to reopen based upon a claim of ineffective assistance of counsel shall include the following items to support the claim of ineffective assistance of counsel and that the alien suffered prejudice as a result:

(i) *Affidavit or written statement executed under penalty of perjury.* (A) The alien filing the motion must, in every case, submit an affidavit by the alien or a written statement executed by the alien under the penalty of perjury as provided in 28 U.S.C. 1746, setting forth in detail the agreement that was entered into with counsel with respect to the actions to be taken by counsel and what representations counsel did or did not make to the individual in this regard. The affidavit or written statement must also identify who drafted it, if the alien did not, and contain an acknowledgment by the alien that the affidavit or written statement had been read to the alien in a language the alien speaks and understands and that the alien, by signing, affirms that he or she understands and agrees with the language of the affidavit or written statement.

(B) In addition, the individual filing the motion must submit a copy of any applicable representation agreement in support of the affidavit or written statement. If no representation agreement is provided, the individual must explain its absence in the affidavit or written statement and provide any reasonably available evidence on the scope of the agreement and the reason for its absence.

(C) The Board or an immigration judge shall not waive the requirement to submit an affidavit or written statement executed under penalty of perjury under paragraph (i)(5)(i)(A) or the representation agreement or the explanation of the absence of the agreement and evidence of the scope of the agreement under paragraph (i)(5)(i)(B), except, in an exercise of discretion committed solely to the agency, the requirement may be excused in the case of an alien who filed the motion *pro se* and without any assistance from counsel and whose motion is accompanied by other independent evidence indicating the

nature, scope, and alleged deficiency of counsel's representation.

(ii) *Notice to counsel.* The alien filing the motion must provide evidence that he or she informed counsel whose representation is claimed to have been ineffective of the allegations leveled against that counsel and that a motion to reopen alleging ineffective assistance of counsel will be filed on that basis. The individual must provide evidence of the date and manner in which he or she provided notice to prior counsel and include a copy of the correspondence sent to the prior counsel and the response from the prior counsel, if any, or state that no such response was received. The requirement that the individual provide a copy of any response from prior counsel continues until such time as a decision is rendered on the motion to reopen. The Board or an immigration judge may excuse failure to provide the required notice only if the alien establishes that the prior counsel is deceased or that the alien has tried with reasonable diligence to locate the prior counsel but has been unable to do so.

(iii) *Complaint filed with the appropriate disciplinary authorities and with EOIR.* (A) The alien filing the motion must file a complaint with the appropriate disciplinary authorities with respect to any violation of counsel's ethical or legal responsibilities, and provide a copy of that complaint and any correspondence from such authorities. In all cases the alien must also file a complaint with EOIR disciplinary counsel in accordance with § 1003.104. The fact that counsel has already been disciplined, suspended from the practice of law, or disbarred does not, on its own, excuse the individual from filing the required disciplinary complaint with the appropriate disciplinary authorities and with EOIR. The appropriate disciplinary authorities are as follows:

(*1*) With respect to attorneys in the United States: The disciplinary authority of a State, possession, territory, or Commonwealth of the United States, or of the District of Columbia that has licensed the attorney to practice law. If an attorney is licensed in more than one jurisdiction, a complaint need only be filed with one jurisdiction.

(*2*) With respect to accredited representatives: The EOIR disciplinary counsel pursuant to § 1003.104(a).

(*3*) With respect to a person described in 8 CFR 1003.48(i)(2)(ii): The appropriate federal, State, or local law enforcement agency with authority over matters relating to the unauthorized practice of law or immigration-related fraud.

(B) The Board or an immigration judge shall not waive the requirement to file a complaint with the appropriate disciplinary authorities and with EOIR unless the counsel is deceased.

(6) *Prejudice.* The alien filing the motion shall establish that he or she was prejudiced by counsel's conduct. The standard for prejudice is set forth in paragraph (i)(4) of this section. The Board or an immigration judge shall not waive the requirement to establish prejudice. Allegations of fact establishing the background and nature of prejudice by counsel's conduct shall be contained in the affidavit or written statement submitted under penalty of perjury.

(j) *Address.* Neither an immigration judge nor the Board shall grant a motion to reopen or reconsider filed by an alien unless the alien has provided the information in § 1003.20(c) where the alien may be reached for further notification or hearing.

(k) *Discretionary stay of removal.* (1) A discretionary stay of removal is an extraordinary remedy and is not a matter of right. Neither the Board nor an immigration judge shall grant a discretionary stay of removal except as provided in this section.

(i) An alien may submit a motion for a discretionary stay of removal at any time after an alien becomes subject to a final order of removal, provided that such a motion may be filed only while a motion to reopen or reconsider is pending before an immigration judge or the Board or in conjunction with the filing of a motion to reopen or reconsider before an immigration judge or the Board.

(ii) Neither the Board nor an immigration judge shall grant a motion for a discretionary stay of removal without the filing of an underlying motion to reopen or reconsider.

(iii) Neither the Board nor an immigration judge shall grant a motion for a discretionary stay of removal unless the underlying motion to reopen or reconsider is *prima facie* grantable.

(iv) Neither the Board nor an immigration judge shall grant a motion for a discretionary stay of removal unless the alien exercised reasonable diligence in seeking a stay and filing a motion to reopen or reconsider after the circumstances underlying the motion arose

(v) Neither the Board nor an immigration judge shall grant a motion for a discretionary stay of removal unless the alien has first applied for a stay of removal with DHS under 8 CFR 241.6 and either (A) that application has been denied or (B) the alien has not received a decision on the application within five business days after it was filed.

(vi)(A) Neither the Board nor an immigration judge shall grant a motion for a discretionary stay of removal unless the opposing party:

(*1*) Has been notified and joins or affirmatively consents to the motion or

(*2*) Has been given three business days from the date of filing to respond to the motion.

(B) Notwithstanding the provisions of § 1003.32, service of a motion for a discretionary stay of removal on an opposing party shall be simultaneous to the filing of the motion and shall be accomplished by the same method by which the motion is filed with an immigration court or the Board. A certificate of service shall accompany the filing of the motion certifying that service was effectuated on the opposing party in an identical manner to the filing of the motion. Neither the Board nor an immigration judge shall excuse this service requirement, and any motion for a discretionary stay of removal failing to conform to this service requirement shall be summarily denied.

(2) An alien requesting a discretionary stay of removal before the immigration court or the Board must submit a motion in writing stating the complete case history and all relevant facts. The motion must include a copy of the stay application filed with DHS under 8 CFR 241.6 and the decision on that application, if any. The motion must also include a copy of the order of removal that the alien seeks to have stayed, if available, or a description of the ruling and reasoning, as articulated by the immigration judge or the BIA. If facts are in dispute, the alien must provide appropriate evidence.

(3)(i) Subject to the other provisions of this section, the Board or an immigration judge, in the exercise of discretion, may grant a stay of removal if consideration of all of the following factors supports granting the stay:

(A) Whether the alien stay applicant has made a strong showing that he or she is likely to succeed on the merits of the underlying motion to reopen or reconsiderincluding the applicability of any time or numbers bars;

(B) Whether the alien stay applicant will be irreparably injured absent a stay;

(C) Whether issuance of the stay will substantially injure the other parties interested in the proceeding; and

(D) Where the public interest lies.

(ii) For purposes of paragraph (k)(3)(i) of this section, neither an immigration judge nor the Board shall presume that

the balance of factors weighs in favor of granting a discretionary stay.

James R. McHenry III,

Director, Executive Office for Immigration Review, Department of Justice.

[FR Doc. 2020–25912 Filed 11–25–20; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 30

[Docket No. PRM–30–66; NRC–2017–0159; NRC–2017–0031]

Naturally-Occurring and Accelerator-Produced Radioactive Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will consider in its rulemaking process issues raised in a petition for rulemaking submitted by Matthew McKinley on behalf of the Organization of Agreement States (OAS, the petitioner. The petitioner requests that the NRC amend its decommissioning financial assurance regulations for sealed and unsealed byproduct material not listed in a table that sets out radionuclide possession values for calculating these financial assurance requirements. The NRC will also examine ways to make the table's values and other NRC decommissioning funding requirements more risk-informed.

DATES: The docket for the petition for rulemaking, PRM–30–66, is closed on November 27, 2020.

ADDRESSES: Please refer to Docket ID NRC–2017–0031 when contacting the NRC about the availability of information related to the future rulemaking. Please refer to Docket ID NRC–2017–0159 when contacting the NRC about the availability of information for this petition closure. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Public comments and supporting materials related to this petition can be found at *https://www.regulations.gov* by searching on the petition Docket ID NRC–2017–0159. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the reader's convenience, instructions about obtaining materials referenced in this document are provided in Section VI, ''Availability of Documents.''
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *PDR.Resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Torre Taylor, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–7900, email: *Torre.Taylor@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Summary of the Petition

The NRC received a petition for rulemaking dated April 14, 2017, filed by Matthew McKinley on behalf of the Organization of Agreement States. On August 23, 2017, the NRC published a notification of docketing and request for comment on the petition (82 FR 39971).

The petitioner requests that the NRC amend its existing regulations in appendix B, ''Quantities of Licensed Material Requiring Labeling,'' in part 30 of title 10 of the *Code of Federal Regulations,* ''Rules of General Applicability to Domestic Licensing of Byproduct Material,'' to add appropriate unlisted radionuclides and their corresponding values. Section 30.35, ''Financial Assurance and Recordkeeping for Decommissioning,'' uses multiples of the applicable quantities of material listed in appendix B to determine the need for decommissioning financial assurance for sealed and unsealed radioactive materials. Licensees using radionuclides not specifically listed in this appendix must use generic default values that the petitioner believes result in overly burdensome requirements.

Without this rulemaking, the petitioner asserts, ''regulators are forced to evaluate new products against these [default appendix B] criteria and apply overly burdensome financial assurance obligations or to evaluate case-by-case special exemptions . . . . Rather than issuing exemptions on a case by case basis, the more appropriate way to address the inconsistency in Appendix B['s treatment of listed and unlisted radionuclides] is to amend it to add appropriate nuclides and their corresponding activities, as determined by a rulemaking working group.''

The petitioner also notes that the NRC did not update appendix B when the Energy Policy Act of 2005 amended the Atomic Energy Act of 1954 to give the NRC regulatory authority over discrete sources of naturally-occurring and accelerator-produced radioactive material (NARM). A significant number of medical radionuclides are accelerator-produced. Although the NRC did update schedule B of part 30, which lists possession values of byproduct material exempt from the requirements for a license, to add some NARM, it did not do the same for appendix B, the petitioner points out, even though appendix B is ''the driver'' for decommissioning financial assurance.

The petition is available in ADAMS under Accession No. ML17173A063.

II. Background

To determine the amount of decommissioning financial assurance required to possess a given radionuclide with a half-life greater than 120 days, a licensee must multiply the appendix B value for that radionuclide by the applicable number in §§ 30.35 or 70.25. Sections 30.35(a) and 70.25(a) require a license-specific decommissioning funding plan (DFP) to possess a quantity of radionuclides greater than provided in the corresponding tables set forth in §§ 30.35(d) and 70.25(d). These tables require specific amounts of funding for specified ranges in the quantity of the radionuclide possessed. Both tables' funding amounts and quantity ranges are identical, but § 30.35 applies to byproduct material and § 70.25 applies to special nuclear material. Although the petition addressed only byproduct material licensed under part 30, appendix B has an identical use for special nuclear material licensed under part 70.

Section 30.35 sets a series of thresholds for decommissioning funding for possession and use of byproduct material. If the license authorizes

possession of an unsealed radionuclide in a quantity more than 1,000 times its appendix B value, the licensee must provide $225,000 in financial assurance for decommissioning. If authorized to possess more than 10,000 times the appendix B value of that radionuclide, the licensee must provide $1,125,000. To possess more than 100,000 times the appendix B value, the licensee must provide a DFP for an amount based on the license's possession limit for the radionuclide. For radionuclides in the form of plated foils or sealed sources, a licensee must provide $113,000 in financial assurance for decommissioning to possess more than 10 billion times the appendix B value for the radionuclide, and a DFP to possess more than a trillion times the appendix B value.

Appendix B also includes possession values for radionuclides not specifically listed. Known as the ''default'' possession values, these are equal to the lowest values listed in Appendix B for specific alpha-emitting and non-alpha-emitting radionuclides, respectively, and restrict the quantity a licensee may possess without having to meet the applicable financial assurance requirements. For unlisted radionuclides that are in unsealed form and do not emit alpha radiation, the default possession value is 0.1 microcuries (μCi, one millionth of a curie), and for unsealed unlisted alpha-emitters, the default value is 0.01 μCi. Thus, using the table in § 30.35(d), a licensee would need to provide financial assurance for decommissioning funding of $225,000 to possess more than 0.1 millicurie (mCi, one thousandth of a curie) of an unsealed non-alpha-emitting radionuclide not listed in appendix B. To possess more than 1 mCi of such a radionuclide, the licensee would need to have financial assurance for decommissioning of $1,125,000. A DFP is required to possess more than 10 mCi. For unsealed alpha-emitting radionuclides not listed in appendix B, the corresponding threshold quantities are 0.01 mCi for $225,000 in financial assurance, 0.1 mCi for $1,125,000, and 1 mCi for a DFP.

These default values for unlisted radionuclides did not originate with a decommissioning funding purpose in mind. The default values, like the other values now in appendix B, were originally established to conform possession thresholds for the labeling of radioactive materials with the thresholds requiring a license, so that a label would only be required to possess an isotope in a quantity that required a license. The labeling values, issued in 1970 in appendix C to part 20 (35 FR 6425; April 22, 1970), were redesignated in 1993 for decommissioning funding purposes as appendix B to part 30 (58 FR 67659; December 22, 1993).

Appendix B values were not based on an explicit consideration of risk, which involves an evaluation of the probability as well as the consequence of a postulated event. Appendix B values were based on a deterministic approach to regulation, which was widely used to develop early radiation protection requirements (60 FR 42622; August 16, 1995). Under this deterministic approach, the function of a safety limit is to ensure that the consequences of a postulated credible event would be acceptably small. Although the determination that an event is credible involves some consideration of probability, safety limits set deterministically are, by definition, not considered risk-informed, because the probability of the event is not required to be fully considered. Despite their derivation from values established deterministically for labeling purposes, however, the NRC's experience with appendix B's possession values over more than 30 years has shown that they are generally adequate to determine the level of funding assurance required for decommissioning.

The DFP requirements in § 30.35(e) were also established with a different purpose in mind. Originally set forth in the 1988 decommissioning rule (53 FR 24018, 24035, 24043; June 27, 1988), DFPs were intended for major facilities possessing large quantities of radioactive material, not for facilities possessing the quantities of radionuclides typically used by medical licensees. Licensees of these major facilities are required to submit a DFP with a cost estimate specific to their facilities. Although medical and industrial licensees possessing smaller quantities of radioactive material may also develop facility-specific decommissioning cost estimates, it is not necessary to ensure adequate decommissioning funding, and not cost effective for many such licensees. When the rule was issued, it was estimated that very few such licensees possessing such smaller quantities would need DFPs.

These DFPs are subject to detailed requirements for their original content and ongoing maintenance. Under § 30.35(e), DFPs must contain, among other things, a detailed cost estimate for an independent contractor to decommission the site for release for unrestricted use, and a certification that financial assurance in the amount of the cost estimate has been provided. The licensee must resubmit the DFP every 3 years with adjustments as necessary to account for changes in costs and the extent of contamination. Even if a licensee possesses only one radionuclide in a quantity requiring a DFP, that DFP must also cover all other radionuclides at the site, whether or not the aggregated total quantity of these other radionuclides would have required a DFP.

The NRC staff has determined that DFPs are not likely to be necessary for licensees that possess small quantities of certain unlisted radionuclides, particularly if it is returned in its container to the manufacturer/distributor (M&D) after use. This has been the case for germanium-68 (Ge-68) generators of the medical radionuclide gallium-68 (Ga-68).

In an August 2015 report on the effect of the DFP requirement on Ge-68 generators, the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) concluded that ''current Part 30 regulations are preventing and/or deterring the use of promising . . . Ga-68 diagnostic imaging agents for patients due to the decommissioning funding plan burden for its parent Ge-68'' (ADAMS Accession No. ML15231A047).

After analysis, the NRC staff agreed that the DFP requirement could impede or limit patient access to the radiopharmaceuticals developed from these generators and that a DFP is not necessary to ensure the safe decommissioning of facilities that use them. Pending rulemaking, the NRC staff developed guidance on the issuance of exemptions from the DFP requirement for licensees that have entered into written agreements binding them to return the generators to an M&D and binding the affected M&D to accept them.

Beyond the impact on Ge-68 generator licensees, a decision to forego rulemaking would also be likely to elicit requests for exemptions from existing decommissioning funding requirements by users of other unlisted radionuclides. As noted in Section IV. below, commenters have identified several radionuclides with actual or potential medical applications that are or could be negatively affected because these radionuclides are not currently listed in appendix B.

III. Discussion

The petitioner advances three main reasons for amending appendix B to part 30. First, although Congress gave the NRC regulatory authority over discrete sources of NARM in 2005, the NRC has not updated appendix B to add

possession values for any NARM, which accounts for an increasing number of medical uses.

Second, the petitioner argues that the default possession values for radionuclides not listed in appendix B force regulators either to ''apply overly burdensome financial assurance obligations'' or ''evaluate case by case special exemptions.''

The petitioner's third reason for rulemaking cites the time and cost impacts of needing to request and process exemptions from these requirements on a case-by-case basis. Because of the need for exemptions, ''[t]he OAS believes that patient health and safety is being compromised due to licensing delays of important diagnostic and therapeutic products that utilize radionuclides not listed in the 10 CFR 30 appendix B table. . . . Further, development of new products could be discouraged due to these obstacles, diminishing the possibility of new innovative and beneficial options in both medical and industrial applications.''

IV. Public Comments on the Petition

Overview of Public Comments

The original comment period on PRM–30–66 closed on November 6, 2017. To allow a larger number of stakeholders to comment, the NRC published a **Federal Register** notification extending the comment period to December 6, 2017. The NRC received 20 comment submissions containing 137 discrete comments. Comments came from industry, government and non-government organizations, and members of the public. The name of the commenter, the commenter's affiliation (if any), and the ADAMS accession number for each comment submission are provided in the following table, listed alphabetically by affiliation.

Commenter	Affiliation	ADAMS accession No.
Bill Diamantopoulos	Advanced Accelerator Applications	ML17307A292
David Walter	Alabama Office of Radiation Control	ML17276A099
Melissa Martin	American Association of Physicists in Medicine	ML17321A166
James Brink	American College of Radiology	ML17321A167
Michael Baxter	American Pharmacists Association	ML17307A461
Anonymous	Anonymous	ML17345A861
Angela Minden	Arkansas Department of Health Radiation Control Section	ML17311A614
Glenn Sullivan	Cardinal Health	ML17311A618
Conference of Radiation Control Program Directors' Committee on Nuclear Medicine.	Conference of Radiation Control Program Directors	ML17345A862
Michael Guastella	Council for Radionuclides and Radiopharmaceuticals	ML17311A616
Kimberly Steves	Kansas Department of Health and Environment	ML17325B724
Glenn Sturchio	Mayo Clinic	ML17338A830
B. J. Smith	Mississippi Department of Health	ML17279B157
Catherine Ribaudo	National Institutes of Health	ML17311A612
Diane D'Arrigo, Hugh MacMillan, and Terry Lodge.	Nuclear Information and Resource Service, Food & Water Watch, and the Toledo Coalition for Safe Energy.	ML17341A057
Hendrik Engelbrecht and Richard Van Sant.	PharmaLogic Holdings Corp. and subsidiaries	ML17345A859
Susan Langhorst	Private Citizen	ML17311A619
Caitlin Kubler and Bennett Greenspan	Society of Nuclear Medicine and Molecular Imaging	ML17321A165
Roger Macklin	Tennessee Department of Environment and Conservation	ML17296A183
Lt. Col. Scott Nemmers	U.S. Air Force, Master Materials License Management Staff	ML17312B336

In its **Federal Register** document announcing the docketing of the petition, the NRC posed four questions related to the petition's scope. The NRC analyzed the comments received in response, sorted them into 47 categories of common concerns, and traced each category to one of the questions in the notification (See ''Categorization of Comments on NRC Questions about PRM–30–66'' (ADAMS Accession No. ML18292A481.)) Below are summaries of the principal categories of comments received in response to each of the questions. The NRC evaluated each comment in deciding whether to consider or deny the issues raised by the petitioner. The NRC will also consider the comments further during the development of the regulatory basis document for this rulemaking and any methodology for setting more risk-informed appendix B values. These documents will be made available for public comment.

Summaries of Responses to the NRC's Questions

Question 1: What products or technologies, other than the Ge-68 generators cited in the petition, are being or could be negatively affected because the radioactive materials required for these products or technologies are not currently listed on the table in appendix B?

Most of the commenters who responded to this question stated that LUTATHERA® (lutetium-177 oxodotreotide), a radiopharmaceutical used to treat gastro-entero-pancreatic neuro-endocrine tumors, could be negatively affected because a contaminant in this radiopharmaceutical, a metastable isomer of lutetium-177 (Lu-177m), is not listed in appendix B to part 30.

Commenters also identified several other radionuclides whose use could be unnecessarily restricted because they are not listed in appendix B. Actinium-227, thorium-228, and titanium-44 are being considered for potential radionuclide generators, commenters stated. Silicon-32 has potential therapeutic applications, and sodium-22 and aluminum-26 have potential diagnostic applications. One commenter noted that rhenium-184m should be listed because it is an activation product from certain cyclotron target windows used to produce other radionuclides. Other commenters identified cobalt-57 because the use of products based on or associated with it could be negatively affected.

Question 2: Please provide specific examples of how the current NRC regulatory framework for decommissioning financial assurance has put an undue hardship on potential

license applicants. Explain how this hardship has discouraged the development of beneficial new products, or otherwise imposed unnecessarily burdensome requirements on licensees or members of the public (e.g., users of medical diagnostic or therapeutic technologies) that depend on NARM.

Commenters provided several examples of undue hardship. Commenters said that the DFP requirement is a hardship for medical licensees with multiple locations of use, since a DFP is required for each site using an unlisted radionuclide. Commenters also noted that the need to seek case-by-case exemptions from appendix B's default requirements is an administrative burden, and that the regulatory delays in obtaining exemptions from the financial assurance hardships negatively affect patient care.

Three commenters also said that the NRC should address inequities in applying § 30.35 in different States. One commenter said that the increased financial assurance burden for those possessing accelerator-produced radionuclides ''cascades to the Agreement States, which look to NRC for guidance, and absent that guidance they either move forward on their own or temporarily stop processing [license] amendment requests [for exemptions].''

Question 3: Given the NRC's current regulatory authority over the radiological safety and security of NARM, what factors should the NRC take into account in establishing possession limits for any of these materials that should be listed in appendix B?

Thirteen commenters provided a total of 38 recommendations on factors the NRC should consider in setting any new possession limits. Several of these recommendations shared common themes. One was that the NRC should provide special regulatory consideration for radiopharmaceuticals. Four commenters said, for example, that the NRC should consider the unique purpose of radiopharmaceuticals, the importance of patient access to these pharmaceuticals, and the fact that they undergo extensive evaluation by the U.S. Food and Drug Administration before they are allowed to be manufactured and regulated for their radiological properties.

A related theme was that generators using unlisted radionuclides to produce these radiopharmaceuticals also deserve special consideration. Five commenters said these generators should either be considered as sealed sources or as a separate category qualifying for more risk-informed regulatory treatment.

Another theme was that for appendix B to part 30, the NRC should consider possession values already established in other NRC tables. Five commenters said, for example, that the NRC should align the values in appendix B to part 30 with those for the same radionuclides in appendix C to part 20 on labeling.

Two commenters recommended similar sets of considerations with respect to which other factors should be accounted for in setting new appendix B possession values. These included the physical and chemical form and half-life of the radionuclide and its progeny, and the disposal pathway for these radionuclides at the time of facility decommissioning.

Two commenters stated that in determining the amount of financial assurance required for a DFP, only the area of use of the subject radionuclide should be considered. These commenters noted that medical licensees use different radionuclides in different areas of their facilities, and that some of these radionuclides, such as technetium-99 and iodine-125, do not require any financial assurance for decommissioning.

Four other commenters shared a concern that establishing new possession limits in appendix B to part 30 could result in unsafe waste disposal practices. Three commenters submitting a single set of comments argued that possession values high enough to make decommissioning financial assurance requirements more commensurate with the radiological hazards of medical uses could also effectively exempt some industrial and commercial licensees, including those engaged in oil and gas fracking, from a requirement to dispose of their wastes in licensed facilities. These commenters also said that the NRC must prepare a ''programmatic'' (*i.e.,* generic) environmental impact statement for any rulemaking to amend appendix B.

Two commenters raised issues about the number of radionuclides with half-lives greater than 120 days—the minimum, as noted at § 30.35, for decommissioning funding requirements—that should be added to appendix B. One commenter said that the appendix should list all radionuclides with such half-lives, ''since it is hard to predict where the next medically useful radionuclide will come from in the future.'' The other commenter noted that appendix B to part 30 contains only 45 radionuclides (the staff counted 49) with half-lives greater than 120 days, while appendix C to part 20 lists 150.

One commenter on Question 3 suggested that, because the factors that need to be considered in setting new appendix B possession limits may change with time, the NRC should review part 30 decommissioning funding requirements every 3 to 5 years.

Question 4: Does this petition raise other issues not addressed by the questions above about labeling or decommissioning financial assurance for radioactive materials? Must these issues be addressed by a rulemaking, or are there other regulatory solutions that NRC should consider?

On the question of whether the NRC should consider solutions other than rulemaking, 15 of the 20 comment submissions explicitly supported the need for rulemaking, and one requested that § 30.35 requirements not apply to certain radiopharmaceuticals approved by the U.S. Food and Drug Administration—a change that can only be effected by rule. No commenters opposed rulemaking, although three commenters that submitted a single set of comments were concerned that setting new possession limits for medical radionuclides could effectively exempt from needed regulation industrial wastes containing those radionuclides. Of those commenters that explicitly supported rulemaking, seven also said it would be preferable to issuing exemptions, and two said that a rulemaking would improve or minimize negative impacts on research, medical licensees, and the availability of new radiopharmaceuticals to patients.

On the question of whether the petition raised any issues not addressed by the other three NRC questions, responding commenters raised 16 additional issues. The majority of these are related to Question 3 on factors to be considered in setting new appendix B possession limits. Six commenters, for example, called on the NRC to address the inconsistencies in possession values between appendix B to part 30 and appendix C to part 20. Two of these commenters recommended replacing appendix B values with appendix C values, and one recommended that the NRC withdraw appendix B and reference appendix C instead.

Two other commenters recommended that the NRC describe the methodology for deriving possession values in a footnote to appendix B to part 30. Providing a formula instead of the current default values for unlisted radionuclides, one commenter said, ''will alleviate the need for subsequent amendments to appendix B and minimize [the] negative impact (or potential impact) on medical licensees and patient care.''

Four commenters raised a new issue unrelated to the issues associated with

setting possession limits. These commenters noted that the title of appendix B to part 30, ''Quantities of Licensed Material Requiring Labeling,'' does not express the actual purpose of the appendix.

V. Reasons for Consideration

The NRC has reviewed the petition in accordance with § 2.803(h). For several reasons, the NRC concludes that the issues raised by the petitioner and commenters should be considered in the rulemaking process. First, the Energy Policy Act of 2005 gave the NRC regulatory authority over discrete sources of NARM, and the NRC needs to incorporate appropriate NARM into its regulatory framework for decommissioning funding. This would also provide a clearer, more predictable basis for Agreement State regulation of decommissioning funding for these radionuclides. Second, rulemaking would also reduce, if not eliminate, the need to process exemption requests from licensees seeking a more risk-informed alternative to the generic default values that result in decommissioning funding requirements that are not commensurate with likely costs.

Moreover, a rulemaking would also advance the NRC's commitment to more risk-informed regulation by better aligning NRC funding requirements with the risks of decommissioning the affected licensee facilities.

In addition, the NRC expects that rulemaking would be more cost-effective than maintaining applicable existing regulations. The short-term savings to the NRC from denying this petition for rulemaking would likely be outweighed by the higher aggregate cost to license applicants, Agreement States, and the NRC for case-by-case exemption reviews over the long term. The higher cost of NRC inaction would accrue not only for Ge-68 generators and the Lu-177 radiopharmaceuticals cited by most commenters on Question 1, but foreseeably for other new technologies. In addition to making costly exemption reviews unnecessary, a rulemaking would also provide a more stable, risk-informed basis for decommissioning funding requirements by using radionuclide-specific possession values that better reflect the amount of financial assurance required.

Further, more predictable and risk-informed decommissioning funding requirements could remove an unnecessary barrier to making Ge-68 generator-supported Ga-68 imaging, Lu-177 radiotherapy, and other emerging medical and industrial technologies that depend on unlisted radionuclides available to the public.

An additional reason to undertake rulemaking on appendix B is to align its title with its decommissioning funding purpose.

Lastly, adding unlisted radionuclides in a single comprehensive rulemaking would minimize the need for additional rulemakings in the future when new applications are developed for radionuclides remaining unlisted in appendix B.

VI. Availability of Documents

The documents identified in the following table, listed by their order of reference in this proposed rule, are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No. or **Federal Register** citation
Petition letter of Organization of Agreement States Board Chairman Mathew McKinley, April 14, 2017	ML17173A063
Federal Register notification of docketing of petition for rulemaking PRM–30–66 and request for public comment, August 23, 2017.	82 FR 39971
Federal Register notification extending comment period, November 6, 2017	82 FR 51363
Federal Register notification, Final rule, Part 20—Standards for Protection Against Radiation, Appendix C, April 16, 1970	35 FR 6425
Federal Register notification, Final decommissioning rule, June 27, 1988	53 FR 24018
Federal Register notification, Final rule, removal of expired material, December 22, 1993	58 FR 67659
''Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement,'' August 16, 1995	60 FR 42622
''Categorization of Comments on NRC Questions about PRM–30–66''	ML18292A481
''Advisory Committee on the Medical Use of Isotopes Germanium-68 (Ge-68) Decommissioning Funding Plan (DFP) Final Report,'' August 12, 2015.	ML15231A047
NRC Strategic Plan, Fiscal Years 2018–2022	ML18032A561

VII. Conclusion

For the reasons cited in this document, the NRC will consider in the rulemaking process the issues raised in PRM–30–66 and will seek public input on any proposed changes to its requirements in appendix B to part 30, 10 CFR 30.35, and 10 CFR 70.25. The rulemaking is titled ''Decommissioning Financial Assurance Requirements for Sealed and Unsealed Radioactive Materials.'' Publication of this document in the **Federal Register** closes Docket ID NRC–2017–0159 for PRM–30–66.

The public can monitor further action on the rulemaking that will address this petition by searching Docket ID NRC–2017–0031 on the Federal rulemaking website, *https://www.regulations.gov.* The site allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Search for and open the docket folder (NRC–2017–0031); (2) click the ''Email Alert'' link; and (3) enter an email address and select the frequency for email receipts (daily, weekly, or monthly). The NRC also tracks the status of all NRC rules and PRMs on its website at *https://www.nrc.gov/about-nrc/regulatory/rulemaking/rules-petitions.html.*

Dated at Rockville, Maryland, this 4th day of November, 2020.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2020–24872 Filed 11–25–20; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1035; Project Identifier MCAI–2020–01017–T]

RIN 2120–AA64

Airworthiness Directives; Yaborã Indústria Aeronáutica S.A. (Type Certificate Previously Held by Embraer S.A.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Yaborã Indústria Aeronáutica S.A. Model EMB–135, EMB–145, –145ER, –145MR, –145LR, –145XR, –145MP, and –145EP airplanes. This proposed AD was prompted by reports that calculations provided by the automatic takeoff thrust control system (ATTCS) are incorrect under certain conditions. This proposed AD would require updating the software of the installed full authority digital engine control (FADEC) systems, as specified in an Agência Nacional de Aviação Civil (ANAC) AD, which will be incorporated by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 11, 2021.

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

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

For ANAC material incorporated by reference (IBR) in this AD, contact National Civil Aviation Agency (ANAC), Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, BRAZIL, Tel: 55 (12) 3203–6600; Email: *pac@anac.gov.br;* internet *www.anac.gov.br/en/.* You may find this IBR material on the ANAC website at *https://sistemas.anac.gov.br/certificacao/DA/DAE.asp.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1035.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1035; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218; email *kathleen.arrigotti@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to participate in this rulemaking by submitting written comments, data, or views about this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–1035; Project Identifier MCAI–2020–01017–T'' at the beginning of your comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this NPRM because of those comments.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person identified in the **FOR FURTHER INFORMATION CONTACT** section. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The ANAC, which is the aviation authority for Brazil, has issued ANAC AD 2020–07–02, effective July 21, 2020 (''ANAC AD 2020–07–02'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Yaborã Indústria Aeronáutica S.A. Model EMB–135, EMB–145, –145ER, –145MR, –145LR, –145XR, –145MP, and –145EP airplanes. Model EMB–145EU, EMB–145LU, and EMB–145MK airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

This proposed AD was prompted by reports that calculations provided by the ATTCS do not take into consideration the required engine air bleed during operations with a single engine and anti-ice system on. The FAA is proposing this AD to address the risk of over-prediction of the operational margins, without the necessary alert being provided to the flightcrew in some situations. This condition, if not corrected, could lead to a performance reduction during takeoff, in which case

the aircraft may not be able to take off safely. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

ANAC AD 2020–07–02 describes procedures for updating the software of the installed FADECs to version B9.4 or B9.4.1. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA 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 require accomplishing the actions specified in ANAC AD 2020–07–02 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 initially worked with Airbus and the European Union Aviation Safety Agency (EASA) to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, ANAC AD 2020–07–02 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with ANAC AD 2020–07–02 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information specified in ANAC AD 2020–07–02 that is required for compliance with ANAC AD 2020–07–02 will be available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1035 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD affects 494 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
5 work-hours × $85 per hour = $425	$0	$425	$209,950

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Yaborã Indústria Aeronáutica S.A. (Type Certificate Previously Held by Embraer S.A.): Docket No. FAA–2020–1035; Project Identifier MCAI–2020–01017–T.

(a) Comments Due Date

The FAA must receive comments by January 11, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Yaborã Indústria Aeronáutica S.A. Model EMB–135BJ, –135ER, –135KE, –135KL, and –135LR airplanes, EMB–145, –45ER, –145MR, –145LR, –145XR, –145MP, and –145EP, certificated in any category, as identified in Agência Nacional de Aviação Civil (ANAC) AD 2020–07–02, effective July 21, 2020 (''ANAC AD 2020–07–02'').

(d) Subject

Air Transport Association (ATA) of America Code 73, Engine fuel and control.

(e) Reason

This AD was prompted by reports that calculations provided by the automatic takeoff thrust control system (ATTCS) are incorrect under certain conditions. The FAA is issuing this AD to address the risk of over-prediction of the operational margins,

without the necessary alert being provided to the flightcrew in some situations. This condition, if not corrected, could lead to a performance reduction during takeoff, in which case the airplane may not be able to take off safely.

(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, ANAC AD 2020–07–02.

(j) Exceptions to ANAC AD 2020–07–02

(1) Where ANAC AD 2020–07–02 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Alternative method of compliance (AMOC)'' section of ANAC AD 2020–07–02 does not apply to this AD.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (l)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or ANAC; or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

(l) Related Information

(1) For information about ANAC AD 2020–07–02, contact National Civil Aviation Agency (ANAC), Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, BRAZIL, Tel: 55 (12) 3203–6600; Email: *pac@anac.gov.br;* internet *www.anac.gov.br/en/.* You may find this IBR material on the ANAC website at *https://sistemas.anac.gov.br/certificacao/DA/DAE.asp.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1035.

(2) For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218; email *kathleen.arrigotti@faa.gov.*

Issued on November 19, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–26045 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1034; Project Identifier MCAI–2020–00951–T]

RIN 2120–AA64

Airworthiness Directives; Bombardier Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bombardier Inc., Model CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. This proposed AD was prompted by a determination that certain airplanes have outdated magnetic variation (MagVar) tables inside navigation systems. This proposed AD would require revising the existing airplane flight manual (AFM) to update the Flight Management System (FMS) and Inertial Reference System (IRS) limitations. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 11, 2021.

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

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

For service information identified in this NPRM, 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: *https://www.bombardier.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1034; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Steven Dzierzynski, Aerospace Engineer, Avionics and Electrical Systems Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7367; fax: 516–794–5531; email: *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–1034; Project Identifier MCAI–2020–00951–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any

personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Steven Dzierzynski, Aerospace Engineer, Avionics and Electrical Systems Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7367; fax: 516–794–5531; email: *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2020–24, dated July 10, 2020 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier Inc., Model CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. You may examine the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1034.

This proposed AD was prompted by a determination that certain airplanes have outdated MagVar tables inside navigation systems. The FAA is proposing this AD to address outdated MagVar tables inside navigation systems, which can affect the performance of the navigation systems and result in the presentation of misleading magnetic heading references on the Primary Flight Displays (PFDs) and Multi-Function Displays (MFDs), positioning the airplane outside of the terrain and obstacle protection provided by instrument flight procedures and flight route designs (*e.g.,* outdated MagVar tables can lead to significantly inaccurate heading, course, and bearing calculations). See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

Bombardier has issued the following service information, which provides procedures for updating, among other systems, the FMS and IRS of the applicable AFM. These documents are distinct since they apply to different airplane configurations.

- Section 02–09, Navigation Systems Limitations, of Chapter 2—LIMITATIONS, of the Bombardier Challenger CL–604 AFM, PSP 604–1, Revision 116, dated December 18, 2019.
- Section 02–09, Navigation Systems Limitations, of Chapter 2—LIMITATIONS, Bombardier Challenger CL–605 AFM, PSP 605–1, Revision 54, dated December 18, 2019.

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.

FAA's Determination

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

Proposed Requirements of This NPRM

This proposed AD would require revising the existing AFM to update the FMS and IRS limitations of the applicable AFM.

Costs of Compliance

The FAA estimates that this proposed AD affects 39 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$3,315

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Bombardier, Inc.: Docket No. FAA–2020–1034; Project Identifier MCAI–2020–00951–T.

(a) Comments Due Date

The FAA must receive comments by January 11, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model CL–600–2B16 (601–3A, 601–3R, and 604 Variants), serial numbers 5301 through 5665 inclusive, and 5701 through 5988 inclusive, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Reason

This AD was prompted by a determination that certain airplanes have outdated magnetic variation (MagVar) tables inside navigation systems. The FAA is issuing this AD to address outdated MagVar tables inside navigation systems, which can affect the performance of the navigation systems and result in the presentation of misleading magnetic heading references on the Primary Flight Displays (PFDs) and Multi-Function Displays (MFDs), positioning the airplane outside of the terrain and obstacle protection provided by instrument flight procedures and flight route designs (*e.g.,* outdated MagVar tables can lead to significantly inaccurate heading, course, and bearing calculations).

(f) Compliance

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

(g) Airplane Flight Manual (AFM) Revision

Within 60 days after the effective date of this AD: Revise the existing AFM to incorporate the information specified in Section 02–09, Navigation Systems Limitations, of Chapter 2—LIMITATIONS, of the applicable Bombardier Challenger AFM specified in figure 1 to paragraph (g) of this AD.

Figure 1 to paragraph (g) – *AFM Revisions*

Bombardier Airplane Model/Serial Number	AFM Title	AFM Revision
CL-600-2B16 (Variant 604) 5301 through 5665 inclusive	Bombardier Challenger CL-604 AFM, PSP 604-1	Revision 116, dated December 18, 2019
CL-600-2B16 (Variant 604) 5701 through 5988 inclusive	Bombardier Challenger CL-605 AFM, PSP 605-1	Revision 54, dated December 18, 2019

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(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 responsible Flight Standards 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, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2020–24, dated July 10, 2020, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1034.

(2) For more information about this AD, contact Steven Dzierzynski, Aerospace Engineer, Avionics and Electrical Systems Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7367; fax: 516–794–5531; email: *9-avs-nyaco-cos@faa.gov.*

(3) 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: *https://www.bombardier.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on November 19, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–26044 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1021; Project Identifier AD–2020–00847–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all The Boeing Company Model 727 series airplanes. This proposed AD was prompted by a determination that excessive sealant coating on internal wing Structural Significant Items (SSIs) may not reveal cracks during inspections required by AD 98–11–03 R1. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate inspections that will give no less than the required damage tolerance rating (DTR) for certain SSIs of the wing. This proposed AD would also require repetitive inspections for cracking of the affected SSIs and repair if necessary. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 11, 2021.

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

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

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1021; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Mohit Garg, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5264; fax: 562–627–5210; email: *mohit.garg@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–1021; Project Identifier AD–2020–00847–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Mohit Garg, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712 4137; phone: 562–627–5264; fax: 562–627–5210; email: *mohit.garg@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The FAA has determined that excessive sealant coating on internal wing SSIs may prevent the detection of cracks during inspections required by AD 98–11–03 R1, Amendment 39–10983 (64 FR 989, January 7, 1999) (AD 98–11–03 R1) for The Boeing Company Model 727 airplanes. AD 98–11–03 R1 refers to Boeing Document No. D6–48040–1, Volumes 1 and 2, ''Supplemental Structural Inspection Document'' (SSID), Revision H, dated June 1994, as the appropriate source of service information for the required inspections. Boeing SSID document No. D6–48040–1, Revision H, dated June 1994, assumes that wing structural components such as fastener caps, splice plates, splice fittings stringers, collars, chords, webs, and wing skins are accessible for nondestructive testing (NDT), general visual (GVI) and detailed (DET) internal inspections. An investigation determined excessive sealant might have been applied during production on The Boeing Company Model 727 airplanes and might prevent the detection of cracks during SSI inspections. This condition, if not addressed, could result in propagation of structural cracks that could lead to the inability of a wing SSI to sustain limit load and result in loss of control of the airplane.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume I, Temporary Revision 08–1001, dated February 2020; and Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume II, Temporary Revision 11–1001, dated February 2020. In combination, this service information describes repetitive inspections for cracking of internal wing

SSIs. 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.

FAA's Determination

The FAA is proposing this AD because the agency 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 require revising the existing maintenance or inspection program, as applicable, to incorporate inspections that will give no less than the required DTR for certain SSIs of the wing. This proposed AD would also require repetitive inspections for cracking of the affected SSIs and repair if necessary.

This proposed AD does not supersede AD 98–11–03 R1. Rather, the FAA has determined that a stand-alone AD would be more appropriate to address the changes.

Accomplishing the revision required by paragraph (g)(1) of this proposed AD and the accomplishing the initial inspections required by paragraph (g)(2) of this proposed AD, which are identified in Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume I, Temporary Revision 08–1001, dated February 2020; and Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume II, Temporary Revision 11–1001, dated February 2020, would terminate the corresponding SSI inspections specified in Boeing Document No. D6–48040–1, Volumes 1 and 2, ''Supplemental Structural Inspection Document'' (SSID), Revision H, dated June 1994, as required by AD 98–11–03 R1. All other SSI inspections specified in the SSID document, dated June 1994, that do not specifically correspond to SSID inspections referenced in the SSID documents, dated February 2020, remain fully applicable and must be complied with accordingly.

Costs of Compliance

The FAA estimates that this proposed AD affects 40 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. In the past, the FAA has estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the FAA estimates the average total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	48 work-hours × $85 per hour = $4,080 per inspection cycle.	$0	$4,080 per inspection cycle.	$163,200 per inspection cycle.

* Table does not include estimated costs for revising the existing maintenance or inspection program.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2020–1021; Project Identifier AD–2020–00847–T.

(a) Comments Due Date

The FAA must receive comments by January 11, 2021.

(b) Affected Airworthiness Directives (ADs)

This AD affects AD 98–11–03 R1, Amendment 39–10983 (64 FR 989, January 7, 1999) (AD 98–11–03 R1).

(c) Applicability

This AD applies to all The Boeing Company 727, 727C, 727–100, 727–100C, 727–200, and 727–200F series airplanes, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a determination that excessive sealant coating on internal wing Structural Significant Items (SSIs) may not reveal cracks during inspections required by AD 98–11–03 R1. The FAA is issuing this AD to address excessive sealant coating on internal wing SSIs that may prevent the detection of cracks during inspections. This condition, if not addressed, could result in propagation of structural cracks that could lead to the inability of a wing SSI to sustain limit load and result in loss of control of the airplane.

(f) Compliance

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

(g) Maintenance or Inspection Program Revision, Repetitive Inspections, and Repair

(1) Prior to reaching the applicable time specified in paragraph (g)(2)(i) or (ii) of this AD, incorporate a revision into the existing maintenance or inspection program, as applicable, that provides no less than the required damage tolerance rating (DTR) for each SSI of the wing listed Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume I, Temporary Revision 08–1001, dated February 2020; and Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume II, Temporary Revision 11–1001, dated February 2020.

(2) At the applicable time specified in paragraph (g)(2)(i) or (ii) of this AD, perform initial inspections to detect cracks in the SSIs identified in Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume I, Temporary Revision 08–1001, dated February 2020; and Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume II, Temporary Revision 11–1001, dated February 2020.

(i) For Model 727–100C and 727–200F series airplanes: Inspect prior to the accumulation of 46,000 total flight cycles, or within 12 months after the effective date of this AD, whichever occurs later.

(ii) For all airplanes except for those airplanes identified in paragraph (g)(2)(i) of this AD: Inspect prior to the accumulation of 55,000 total flight cycles, or within 3,000 flight cycles measured from the date 12 months after the effective date of this AD, whichever occurs later.

(3) At the intervals specified in in Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume I, Temporary Revision 08–1001, dated February 2020; and Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume II, Temporary Revision 11–1001, dated February 2020, as applicable, repeat the inspections required by paragraph (g)(2) of this AD.

(4) If any cracked structure is found during any inspections required by paragraph (g) of this AD, repair before further flight using an FAA-approved method or using a method approved in accordance with the procedures specified in paragraph (j) of this AD. Within 12 months after repair, incorporate a revision into the maintenance or inspection program, as applicable, to include a damage-tolerance-based alternative inspection program for the repaired structure. Thereafter, inspect the affected structure in accordance with the alternative program. The inspection method and compliance times (*i.e.,* threshold and repetitive intervals) of the alternative program must be approved in accordance with the procedures specified in paragraph (j) of this AD.

(h) No Alternative Actions or Intervals

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

(i) Terminating Action for Certain Inspections Required by AD 98–11–03 R1

Accomplishing the revision required by paragraph (g)(1) of this AD and the initial inspections identified in Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume I, Temporary Revision 08–1001, dated February 2020; and Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume II, Temporary Revision 11–1001, dated February 2020, as required by paragraph (g)(2) of this AD, terminate the corresponding SSI inspections specified in Boeing Document No. D6–48040–1, Volumes 1 and 2, ''Supplemental Structural Inspection Document'' (SSID), Revision H, dated June 1994, as required by AD 98–11–03 R1.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles 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 (k)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

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

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

(4) AMOCs approved previously for AD 98–11–03 R1 are approved as AMOCs for the corresponding provisions of this AD for the SSIs identified in Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume I, Temporary Revision 08–1001, dated February 2020; and Boeing 727 Supplemental Structural Inspection Document D6–48040–1, Volume II, Temporary Revision 11–1001, dated February 2020.

(k) Related Information

(1) For more information about this AD, contact Mohit Garg, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5264; fax: 562–627–5210; email: *mohit.garg@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on November 5, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–25614 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2020–N–2111]

Ag Chem Resources, LLC; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Ag Chem Resources, LLC, proposing that the food additive regulations be amended to provide for the safe use of tannic acid as a flavoring agent in animal feed.

DATES: The food additive petition was filed on October 5, 2020.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the

heading of this document into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Chelsea Cerrito, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240–402–6729, *Chelsea.Cerrito@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), we are giving notice that we have filed a food additive petition (FAP 2313), submitted by Ag Chem Resources, LLC, 10120 Dutch Iris Drive, Bakersfield, California 93311. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of tannic acid as a flavoring agent in animal feed.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(r) because it is of a type that does not individually or cumulatively have a significant effect on the human environment. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: November 18, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26049 Filed 11–25–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 127, 154, and 156

[Docket No. USCG–2020–0315]

RIN 1625–AC61

Electronic Submission of Facility Operations and Emergency Manuals

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The purpose of this proposed rule is to enable electronic submission of Operations Manuals and Emergency Manuals and electronic communication between the operators of regulated facilities and the Coast Guard, reducing the time and cost associated with mailing and processing printed manuals. Current regulations stipulate that these facilities send the Coast Guard two copies of their Operations Manual, their Emergency Manual, if applicable, and any amendments to the manuals. This proposed rule would allow facility operators to submit one electronic or printed copy of the manuals and amendments to the manuals. This proposed rule would also require these facilities to maintain either an electronic or a printed copy of each required manual in the marine transfer area of the facility during transfer operations.

DATES: Comments and related material must be received by the Coast Guard on or before January 26, 2021.

ADDRESSES: You may submit comments identified by docket number USCG–2020–0315 using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

Collection of information. Submit comments on the collection of information discussed in section VI.D of this preamble both to the Coast Guard's online docket and to the Office of Information and Regulatory Affairs (OIRA) in the White House Office of Management and Budget (OMB) using their website. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Comments sent to OMB on collection of information must reach OMB on or before the comment due date listed on their website.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Lieutenant Omar La Torre Reyes, Coast Guard; telephone 202–372–1132, email *omar.latorrereyes@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Public Participation and Request for Comments

The Coast Guard views 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 *https://www.regulations.gov.* If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions. Documents mentioned in this proposed rule, and all public comments, will be available in our online docket at *https://www.regulations.gov,* and can be viewed by following that website's instructions. Additionally, if you visit the online docket and sign up for email alerts, you will be notified when comments are posted or if a final rule is published.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more information about privacy and submissions in response to this document, see the Department of Homeland Security's (DHS) eRulemaking System of Records notice (Volume 85 of the **Federal Register** (FR) at 14226, March 11, 2020).

We do not plan to hold a public meeting, but we will consider doing so if we determine from public comments that a meeting would be helpful. We would issue a separate **Federal Register** notice to announce the date, time, and location of such a meeting.

II. Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
FWPCA Federal Water Pollution Control Act
CG–FAC U.S. Coast Guard Office of Port and Facility Compliance
IT Information technology
LHG Liquefied Hazardous Gas
LNG Liquefied Natural Gas
MISLE Marine Information for Safety and Law Enforcement
MTR Facilities that transfer oil or hazardous material in bulk
NEPA National Environmental Policy Act
NPRM Notice of proposed rulemaking
OMB Office of Management and Budget
PIC Person in charge of transfer
SBA Small Business Administration
§ Section
SME Subject matter expert
U.S.C. United States Code

III. Basis and Purpose

Section 70011 of Title 46 of the United States Code (U.S.C.) authorizes the Secretary of Homeland Security to establish procedures and measures for handling of dangerous substances, including oil and hazardous material, to prevent damage to any structure on or in the navigable waters of the United States. Additionally, the Federal Water Pollution Control Act (FWPCA), as amended and codified in 33 U.S.C. 1321(j)(5), authorizes the President to establish procedures to prevent discharges of oil and hazardous substances from vessels, onshore facilities, and offshore facilities. The FWPCA functions in 33 U.S.C. 1321(j)(5) have been delegated from the President to the Secretary of DHS by Executive Order 12777 Sec. 2(d)(2), as amended by Executive Order 13286. The authorities in 33 U.S.C. 1321(j)(5) and 46 U.S.C. 70011 (formerly 33 U.S.C. 1225) have been delegated to the Coast Guard under section II, paragraphs 70 and 73, of DHS Delegation No. 0170.1.

The Coast Guard requires all operators of facilities that transfer oil and hazardous materials in bulk, to or from certain vessels, to develop and maintain an Operations Manual in order to help prevent discharges of oil and hazardous substances into the marine environment. Operators of facilities that transfer liquefied natural gas (LNG), or liquefied hazardous gas (LHG) in bulk, to or from a vessel, must also develop and maintain an Operations Manual and an Emergency Manual. Copies of each manual must be submitted to the Coast Guard for review.

IV. Background

Title 33 of the Code of Federal Regulations (CFR) part 127 requires facilities that transfer LNG and LHG in bulk, to or from a vessel, to maintain both an Operations Manual and an Emergency Manual. Similarly, part 154 requires facilities that transfer oil or hazardous materials in bulk, to or from a vessel with a capacity of 39.75 cubic meters (250 barrels) or more, to maintain an Operations Manual.

An Operations Manual for either LNG and LHG or oil and hazardous materials transfer facilities describes how the facility meets applicable operating rules and equipment requirements, and describes the responsibilities of personnel in charge of conducting transfer operations. An Emergency Manual for LNG and LHG facilities describes emergency shutdown procedures, fire equipment and systems, contact information, emergency shelter information, first aid procedures, emergency procedures for mooring and unmooring a vessel, and how the facility would respond to releases of cargo.

According to §§ 127.019 and 154.300, these manuals must be submitted to the Captain of the Port (COTP) for examination before a facility may operate. Under both provisions, the facility operator must submit two copies of each required manual to the COTP for examination. The COTP evaluates whether the operations and safety procedures outlined in the manuals meet the requirements of 33 CFR part 127 (for LNG and LHG) or part 154 (for oil and hazardous material).

If these manuals meet the minimum requirements of the regulations, then they are considered ''adequate.'' The COTP accepts the manuals, keeps one copy and returns the other, after marking it ''examined.'' The facility operator keeps the examined copy and is required to conduct all operations in accordance with its operations or emergency procedures, in accordance with §§ 127.309, 127.1309, or 156.102(t)(2).

If the manuals fail to meet the minimum requirements of the regulations, then they are considered ''inadequate.'' The COTP rejects the manuals, and returns the relevant section, or the entire manual, if necessary, with an explanation of why the procedures in it failed to meet the relevant regulatory requirements. The operator makes the required corrections and then sends two corrected copies back to the COTP for re-examination.

Although the regulations do not explicitly state that the copies must be printed, the requirement for two copies and the return of a marked copy have suggested the use of printed documents. The two-copy requirement was issued in 1988 for LNG and LHG facilities (53 FR 3370, Feb. 5, 1988) and in 1996 for oil and hazardous materials facilities (61 FR 41458, Aug. 8, 1996), when electronic mail and electronic storage were not common practice. In practice, operators submit the manuals in printed form.

This proposed rule would remove the two-copy requirement and allow facility operators to submit one printed or electronic copy of each required manual to the COTP for examination. It would also allow facilities to maintain either a printed or an electronic copy of the most recently examined manual(s) in the marine transfer area of the facility.

V. Discussion of Proposed Rule

This notice of proposed rulemaking (NPRM) proposes to change the following sections in title 33 of the CFR: 127.019, 127.309, 127.1309, 154.300, 154.320, 154.325, and 156.120. A section-by-section explanation of the proposed changes follows. Section V.A discusses the proposed changes to 33 CFR part 127 that would apply to facilities that transfer LNG and LHG, in bulk, to or from a vessel. Section V.B contains the proposed changes to 33 CFR part 154 that would apply to facilities that transfer oil and hazardous materials, in bulk, to or from a vessel. Section V.C describes the change in 33 CFR part 156 which would also allow the oil and hazardous material transfer facilities to maintain either an electronic or printed copy of the Facility Operations Manual. Finally, in Section V.D, this proposed rule discusses technical revisions to replace the word ''shall'' with the plain language terms ''must'' and ''will.''

A. Part 127–Waterfront Facilities Handling Liquefied Natural Gas and Liquefied Hazardous Gas

Section 127.019 Operations Manual and Emergency Manual: Procedures for examination.

This section currently requires owners and operators of facilities that transfer LNG and LHG, in bulk, to or from a vessel to submit two copies of an Operations Manual and an Emergency Manual to the COTP for examination. The revised § 127.019 would allow the owners and operators to submit one copy of each manual in printed or electronic format to the COTP for examination.

Additionally, to codify current practices, we propose that manuals submitted after the effective date of the final rule include a date, revision date, or other identifying information generated by the facility. All manuals currently have some unique identifying information in them. This provision

would allow them to continue to use their own identifying information or to use a revision date. The date, revision date, or other identifying information would allow the facility operator and the Coast Guard to determine quickly if the most recent version of the manual is being used. Other identifying information generated by the facility may include document control numbers under an existing internal management system, which make it easier to verify that the most recent version of the manual is being used by the facility.

In this section, this proposed rulemaking would modify the manner in which the COTP notifies the facility operator that the Operations Manual and Emergency Manual have been examined. Currently, if the manual meets the requirements of this part, the COTP physically marks the manual ''Examined by the Coast Guard'' and returns one copy by mail to the facility operator. In conjunction with requiring only one copy and allowing electronic submission of the manual, we propose allowing the COTP to respond to the facilities electronically to reduce paperwork-processing costs. Under this proposed rule, the COTP would provide notice to the facility that the manual has been examined, and would no longer return a marked copy of the manual to the facility.

The COTP would determine the best method to return the notice to the facility operator by considering the facility's available contact information and the method in which the manuals were submitted. We expect the COTP's notice to take the form of a printed or electronically submitted letter to the facility operator initially, but could eventually include an electronic certification with the information. The COTP's notice would also include the manual's date, revision date, or other identifying information generated by the facility so that the Coast Guard and facility operators can verify which manual is the most recently examined.

In proposed § 127.019(e), we would also amend the way the COTP notifies a facility when the manual does not meet the requirements of part 127. Currently, the COTP is required to return a printed copy of the manual with an explanation of why it does not meet the requirements of part 127. This proposed rule would allow the COTP to notify a facility with an explanation of why it does not meet the requirements of this part, without returning a printed copy of the manual. This proposed change would enable electronic communication between the Coast Guard and a facility while reducing associated printing and mailing costs for the Coast Guard. The COTP would retain the discretion to send the letters and manuals via mail to the facility when appropriate.[1]

Finally, within § 127.019, this proposed rule would remove the word ''existing'' where it appears in the context of ''existing facility'' in paragraphs (a) and (b). ''Existing'', as applied to a waterfront facility, is defined in § 127.005 ''Definitions'', but the definition is limited to facilities that were constructed before June 2, 1988 for LNG facilities and before January 30, 1996 for LHG facilities. The specific dates used within the definition of ''existing'' were never intended to apply to the use of ''existing'' in this section. To avoid confusion, we propose removing ''existing'' from this section. The requirements in paragraph (a) would continue to apply to all active facilities, and the requirements of paragraph (b) would continue to apply to all new or inactive facilities.

Section 127.309 Operations Manual and Emergency Manual: Use.

Paragraph (a) of this section currently requires the operator of an LNG facility to ensure the facility's Operations Manual and Emergency Manual have both been examined by the Coast Guard before LNG transfer operations are conducted. The proposed revisions to § 127.309(a) would require the operator to ensure that the person in charge of transfer (PIC) has printed or electronic copies of the most recently examined Operations Manuals and Emergency Manuals readily available in the marine transfer area.

The proposed changes to this paragraph enable the PIC to maintain electronic or printed copies in the marine transfer area. The proposed Operations Manual submission requirements in § 127.019 would contain the procedures and requirements for obtaining examination by the Coast Guard, including the requirement for manuals submitted after the effective date of a final rule to have a date, revision date, or other identifying information generated by the facility.

In § 127.309, the phrase ''readily available in the marine transfer area'' means that a printed or electronic copy of the manual is available for viewing within the operating station of the PIC. The PIC would not be expected to keep the manual in their possession while conducting routine rounds during a transfer operation.

At this time, facilities typically have a printed copy of the examined Operations Manuals and Emergency Manuals in the marine transfer area. While PICs must know the contents of the manuals under § 127.301(a)(4), the Coast Guard recognizes that it is difficult for a PIC to instantly recall every step of every procedure outlined in these manuals. Because both § 127.309(b) and (c) require each transfer and emergency operation to be conducted in accordance with the examined Operations Manuals and Emergency Manuals, respectively, it is currently common practice for PICs to have a copy of the Operations Manual and Emergency Manual in the marine transfer area during transfer operations to reference when needed. Therefore, adding a requirement that a printed or electronic copy of the most recently examined Operations Manuals and Emergency Manuals must be readily available to the PIC in the marine transfer area would not add a significant burden to facility operators.

Section 127.1309 Operations Manual and Emergency Manual: Use.

Similarly, § 127.1309(a) currently requires the operator of an LHG waterfront facility to ensure that the facility has an examined copy of the Operations Manual and Emergency Manual prior to any transfer. The proposed changes to § 127.1309(a) would require, instead, that the facility operators ensure the facility's PIC has a printed or electronic copy of the most recently examined Operations Manual and Emergency Manual readily available in the marine transfer area. This proposed change to § 127.1309(a) would help ensure that PICs have access to the manuals, if needed, because the facility would no longer have a COTP-marked printed copy in the facility. For the purpose of this section, the phrase ''readily available in the marine transfer area'' means a printed or electronic copy of the manual is available for viewing within the operating station of the PIC, but the PIC would not be expected to keep the manual in their possession.

Under § 127.1302(a)(5), LHG facilities, like LNG facilities, typically maintain a copy of the examined Operations Manual and Emergency Manual in the marine transfer area because the PIC is required to know the contents of the manuals. Additionally, under § 127.1309(b) and (c), each transfer operation must be conducted in accordance with the examined Operations Manual. In the event of an emergency, all response efforts must be executed in accordance with the

[1] We use the term ''mail'' throughout this NPRM to refer to the delivery method used by the Captain of the Port or the facility to send and receive printed copies of letters and manuals. These methods include, but are not limited to, the United States Postal Service, FedEx, UPS, and courier.

examined Emergency Manual. Because of these knowledge and procedural requirements, it is currently common practice for PICs to have a copy of the Operations Manual and Emergency Manual in the marine transfer area during transfer operations to reference in uncommon situations outlined in the manuals. Therefore, adding the requirement explicitly stating that a printed or electronic copy of the most recently examined Operations Manual and Emergency Manual must be readily available to the PIC in the marine transfer area should not add a significant burden to facility operators.

B. Part 154—Facilities Transferring Oil or Hazardous Materials in Bulk

Section 154.300 Operations Manual; General. This section currently requires operators of facilities that transfer oil or hazardous materials in bulk to or from a vessel with a capacity of 39.75 cubic meters (250 barrels) or more to submit two copies of their Operations Manual to the COTP.

We propose to add text to paragraph (a) to clarify that the facility operator must submit the manuals to the COTP of the zone in which the facility operates. The current text in paragraph (a) requires facilities to submit their Operations Manual, but does not explicitly state to whom. The proposed clarification would align the text with current requirements and practice.

The revised § 154.300 would allow facility operators to submit one printed or electronic copy of the manual to the COTP with a date, a revision date, or other identifying information generated by the facility. This is to allow the facility and the COTP to determine quickly if the most recent version of the manual is being used during inspections of the facility. Other identifying information generated by the facility may include document control numbers under an internal management system, which would make it easier to verify that the most recent version of the manual is being used by the facility. As the inclusion of such information is current practice, we are only codifying current practice.

We also propose to modify the manner in which the COTP notifies the facility that the Operations Manual has been examined. Currently, after examination and determination that the manual meets the requirements of this part, the COTP marks the manual ''Examined by the Coast Guard'' and returns one copy to the facility operator. Under this proposed rule, the COTP would notify the facility that the manual has been examined and would no longer return a copy of the manual to the facility. We expect this notice to take the form of a printed or emailed letter, initially, with the revision date or other identifying information generated by the facility on the letter, but could eventually include an electronic certification with the information.

Proposed revisions to paragraph (f) of § 154.300 would allow either a printed or electronic copy of the most recently examined Operations Manual to be readily available for each facility's PIC while conducting a transfer operation. This would effectively allow the facility to store the manual in print or electronic format. Additionally, this proposed rule would allow the facility to have printed or electronic copies of the manual in any translations required under § 154.300(a)(3).

In § 154.300(d), the proposed rule would add ''products transferred'' to the list of items the COTP considers when determining whether the manual meets the requirements of part 154 and part 156. Currently, paragraph (d) indicates that the COTP will consider the size, complexity, and capability of the facility. Information about the products transferred, meaning the type of oil and hazardous material, is already required to be included in the Operation Manuals under § 154.310(a)(5), and knowledge of the products being transferred is important to reviewing the adequacy of the Operations Manual. The facility develops their capabilities based in part on the characteristics of the oil or hazardous material they want to transfer. Adding ''products transferred'' to the list of considerations will increase transparency regarding the manual examination process.

Section 154.320 Operations Manual: Amendment.

This section addresses amendments to Operations Manuals. Paragraph (a) of this section states that the COTP may require the facility operator to amend their Operations Manual if the manual does not meet the requirements of this part. This NPRM proposes to change the statement from ''requirements of this part'' to ''requirements of this subchapter'' because there are other regulations in the subchapter that apply to the Operations Manual. The applicable subchapter would be subchapter O, titled ''Pollution,'' which includes 33 CFR parts 151 through 159.

Section 154.320(a)(1) allows facility operators to submit to the Coast Guard any information, views, arguments, and proposed amendments in response to the inadequacies identified by the COTP. In alignment with other changes proposed by this NPRM, we propose adding language to this section allowing facility operators to send their information, views, arguments, and proposed amendments to the COTP in print or electronically.

In § 154.320(b)(1), this proposed rule would allow facilities to submit amendments to the manuals either in print or electronically. Proposed paragraph (e) would describe how amendments can be submitted and the procedures to follow in the event the entire manual is submitted for amendments. Currently, amendments are submitted as page replacements or as an entire manual, at the option of the submitter, depending on the extent of the changes to the manual. This proposed rule would allow the choice of page or whole-manual replacement, but would require the inclusion of the date, revision date, or other identifying information generated by the facility.

If a facility submits the entire manual with the proposed amendments, this proposed rule would require that the changes since the last examined manual be highlighted, or otherwise annotated, by the facility. It may be easier for a facility to submit the entire manual with the amendments highlighted or annotated, rather than isolating individual pages that were amended. Examples of ways facility operators could highlight or annotate the amendments include use of an electronic or ink highlighting tool, comment or text boxes noting where the changes are, or noting the changes in correspondence or a document. Ultimately, the method that the facility operator uses can be anything that identifies all the changes, and is not limited to the methods mentioned in this preamble. The purpose of highlighting or annotating the amendments is to assist the COTP in understanding what changes are being made and to reduce the resources required to examine amendments. After the COTP examines the amendments, the facility must maintain the Operations Manual with the most recently examined changes, but there would be no requirement to keep the changes highlighted or annotated after they are examined.

Currently, § 154.320 paragraphs (b)(2) and (c) state that the COTP will approve or disapprove amendments to manuals, and provide reasons if disapproved. We propose to align this text with other sections in this part providing that the COTP examines the amendments to manuals for compliance with the subpart, and then notifies the facility that the amendments have been examined by the Coast Guard. If the amendments do not meet the requirements for Operations Manuals in subchapter O, the COTP would notify

the facility operator of the inadequacies and explain why the amendments do not meet the requirements of that subchapter.

Section 154.325 Operations Manual: Procedures for examination.

This section currently requires facility operators to submit two copies of an Operational Manual to the COTP for examination and outlines the procedures for Coast Guard examination of Operations Manuals for new facilities and facilities that are removed from caretaker status. The proposed § 154.325 would allow facility operators to submit the manual in print or electronic format to the COTP.

This NPRM proposes to remove paragraph (a) of § 154.325, which would remove the requirement that the facility operator must submit two copies of the Operations Manual. In alignment with other proposed changes in part 154, the facility operator of a new facility would be able to submit one electronic or printed copy of the Operations Manual to the COTP.

In re-designated paragraphs (a) and (b) of this section, the proposed rule would clarify that the operator of a new facility or facility removed from caretaker status must submit the manual to the COTP for examination prior to the first transfer operation, rather than prior to any transfer operation. This proposed rule would replace the current text ''any transfer operation'' with ''the first transfer operation'' to make the regulatory text more precise. This change clarifies that the facility must submit the Operations Manual prior to a new facility's first transfer or the first transfer after a facility is removed from caretaker status.

We would amend the process in § 154.325 so that the COTP would notify the facility when the manual has been examined. Because we are proposing to allow electronic submission, the COTP would no longer send back a marked printed copy of the manual stating it has been examined by the Coast Guard. The COTP's notice would restate the manual's date, revision date, or other identifying information provided by the facility. Where the manual does not meet the requirements of subchapter O, the COTP would notify the facility with an explanation of why the manual does not meet the requirements of that subchapter. In proposed § 154.325(d) (currently paragraph (e)), this proposed rulemaking would change for accuracy the text ''requirements of this chapter'' to ''requirements of this subchapter''. The applicable subchapter would be subchapter O, which includes 33 CFR parts 151 through 159.

C. Part 156—Oil and Hazardous Material Transfer Operations

Section 156.120 Requirements for transfer.

Part 156 contains regulations related to oil and hazardous material transfer operations. Paragraph (t)(2) of § 156.120 currently requires each PIC to have access to a copy of the facility Operations Manual. Proposed § 156.120(t)(2) would require the PIC to have either a printed or electronic copy of the most recently examined facility Operations Manual readily available in the marine transfer area. For the purpose of this section, ''readily available'' means that a printed or electronic copy of the manual is available for viewing within the operating station of the PIC. The PIC would not be expected to keep the manual in their possession while conducting routine rounds during the transfer operation.

D. Technical Revisions Within Part 127 and Part 154

Throughout the sections amended by this proposed rule, we propose to replace all uses of the word ''shall'' with ''must'' when specifying the actions facility operators are required to perform. This would align the regulations with plain language guidelines. Additionally, where the COTP is required to respond or to notify a facility, we propose changing ''the COTP shall'' to ''the COTP will'' to state clearly what the COTP will do in certain cases. This change would help clarify what the facility operators can expect from the COTP and align the regulations with plain language guidelines. These proposed technical revisions would not change requirements for facility operators or the Coast Guard.

VI. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. A summary of the analysis based on these statutes and Executive orders follows.

A. Regulatory Planning and 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 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.''

Although this proposed rule is not a significant regulatory action, it provides a cost savings and, therefore, DHS considers it an Executive Order 13771 deregulatory action. See the OMB Memorandum, ''Guidance Implementing Executive Order 13771, titled 'Reducing Regulation and Controlling Regulatory Costs''' (April 5, 2017).

A Regulatory Analysis (RA) follows. The first section covers the alternatives considered, the second covers the affected population, the third covers the cost savings components, and the fourth discusses the summary of the cost savings and costs.

This proposed rulemaking would result in a cost savings to industry and to the Coast Guard because it would allow operators of facilities that transfer LNG and LHG or facilities that transfer oil or hazardous material in bulk (MTR) to submit Operations Manuals and Emergency Manuals and amendments to the Coast Guard in electronic or in print format. LNG and LHG facilities are required to submit Operations Manuals and Emergency Manuals and amendments, while MTR facilities are required to submit only Operations Manuals and amendments.

Under current regulations, facility operators are required to send two printed copies of each manual and amendments to the COTP. The proposed rulemaking would permit these documents to be submitted electronically. Facility operators exercising this option would no longer need to assemble and mail printed versions, resulting in cost savings. The proposed rulemaking would also permit facility owners mailing their documentation in print format to submit only one copy of their documents, resulting in another cost savings.

Additionally, current regulation requires those facility operators whose documents were not approved by the COTP to resubmit any revisions. These are currently sent to the COTP in print format. The proposed rulemaking would permit facility operators to send in their documents in electronic or print formats. Facility operators exercising this option would no longer need to

assemble and mail printed versions, resulting in cost savings.

Finally, the proposed rulemaking would permit facilities to keep documentation in either electronic or print format at their facility's marine transfer area. Currently this documentation is kept in print format at these locations. According to Coast Guard subject matter experts (SME) from the Office of Port and Facility Compliance (CG–FAC), the typical facility has, on average, two marine transfer areas.[2] LNG and LHG facilities are required to keep one copy of an Operations Manual and one copy of an Emergency Manual (and to keep each manual up-to-date with amendments) at each of its marine transfer areas. MTR facility operators are required to keep only one Operations Manual (and amendments) at marine transfer areas. Those facility operators that exercise the option to use electronic documents instead of print would experience a cost savings resulting from no longer having to assemble these printed documents (two copies, one for each marine transfer area), as well as not having to physically place this documentation at the two marine transfer areas.[3]

The proposed rulemaking would also result in a cost savings to the Coast Guard. Currently, when the COTP examines an Operations or Emergency Manual and finds it meets the regulatory requirements or is ''adequate'', they must return a stamped copy to the facility. Under the proposed rulemaking, the COTP would not return a copy of the adequate manual via mail. The COTP would have the option to send either a printed or electronic letter back to facility stating that the manual has been examined by the Coast Guard.[4] As a result, the Coast Guard would experience a cost savings from not having to handle and mail back to the facility a stamped, printed version of the manual.

On the other hand, if the COTP finds ''inadequacies'' in the submitted manual, meaning the manual does not meet the regulatory requirements, the COTP must mail back a copy of the manual, or a notification, with annotations or comments on how to correct the manual.[5] Based on the requirements in the proposed rulemaking, the COTP would only be required to send electronically or by mail a letter explaining why the manual does not meet the requirements of the part, reducing costs for the Coast Guard.

In table 1, we show a summary of the impacts of the NPRM.

TABLE 1—SUMMARY OF THE IMPACTS OF THE NPRM[6]

Category	Summary
Applicability	• Updates 33 CFR parts 127 and 154 to permit regulated facilities to submit Operations Manuals and Emergency Manuals and amendments in electronic or printed format. • Updates 33 CFR parts 127 and 154 to permit regulated facilities that submit printed Operations Manuals and Emergency Manuals and amendments to submit only one copy in that format. • Updates 33 CFR parts 127 and 154 to permit the Coast Guard to send notices of adequacy or inadequacy to facilities electronically. • Updates 33 CFR parts 127 and 154 to permit regulated facilities to store electronic or printed versions of their Operations Manuals and Emergency Manuals and amendments, at the marine transfer areas of their facilities.
Affected Population (Annually)	60 facilities that transfer LNG and LHG and 703 MTR facilities (total of 763 facilities) *
Costs Savings to Industry ($2019, 7% discount rate)	10-year cost savings: $255,007. Annualized: $36,307.
Costs Savings to the Coast Guard ($2019, 7% discount rate).	10-year cost savings: $52,160. Annualized: $7,426.
Total Cost Savings ($2019, 7% discount rate)	10-year cost savings: $307,167. Annualized: $43,734.

* Of the 60 LNG/LHG facilities, 54 are forecast to submit their documentation in electronic format and 6 in paper. Of the 703 MTR facilities, 527 are expected to submit their documents in electronic format and 176 in paper. For a detailed discussion of these estimates and calculations, refer to the ''affected population'' section of this Regulatory Analysis.

Note: Numbers may not sum due to rounding.

Alternatives Considered

We considered three alternatives. The first is a continuation of current regulation (no change). The second is a modification to the current regulations that would require all regulated facilities to submit their required Operations Manuals and Emergency Manuals and amendments electronically. The third is giving regulated facilities flexibility on submitting documentation in either electronic or printed format. We discuss each in more detail in the following sections.

Alternative 1 —No Change.

This alternative would require regulated facility operators to continue to submit two printed copies of the Operations Manuals and Emergency Manuals, and the COTP to continue to examine these manuals and to return them by mail. This alternative would also require facility operators to maintain the manuals in a printed format near the marine transfer areas of their facilities. This alternative would not result in any cost savings and would not meet the Coast Guard's goal of reducing regulatory burdens under Executive Order 13771. Therefore, we rejected Alternative 1.

Alternative 2—All Electronic Format Manuals.

This alternative would amend regulations to require regulated facility operators to submit only electronic copies of the Operations Manuals and

[2] Based on an SME assessment from CG–FAC. All Coast Guard SME input assessments mentioned in this NRPM, unless stated otherwise, are from CG–FAC.

[3] These areas are not the same as the administrative offices of the facilities; hence, labor time needs to be expended to place Manuals there after they are assembled.

[4] The Coast Guard envisions sending back an electronic format of the manual with an electronically stamped watermark, notification, or similar method.

[5] The word ''inadequacies'' is used on numerous occasions in the text of the current regulation. Sections where the word is explicitly cited include § 154.320(a)(1) and § 154.320(c)(2).

[6] All dollar figures are closest whole dollar.

Emergency Manuals, and the COTP to examine these manuals (and amendments) and return them only via email or other electronic means. Facility operators would not be permitted the option of submitting printed documents. Facilities would be permitted to keep Operations Manuals and Emergency Manuals in printed or electronic format at their marine transfer areas.

Facility operators may experience greater cost savings than what was proposed by Alternative 1 or the chosen alternative because they would be required to submit their documentation electronically and to maintain electronic copies of all their manuals in the marine transfer areas. Savings from this alternative would result from the facilities not having to assemble and mail printed documentation to the COTP. Savings would also result from facilities no longer needing to assemble printed documentation for the marine transfer areas and having to place it there physically. For alternative 1, as there is no possibility of such electronic submissions, there would be no such savings. Alternative 2 would result in greater savings with respect to these as it would require all in-scope facilities to submit all their documents electronically while the chosen will not result in all documents being submitted electronically as some operators are expected to send in their documentation in paper format.

However, Alternative 2 also has the highest potential cost associated with its implementation. The reason for this is that a number of facilities may not currently have the required information technology (IT) infrastructure to permit the use of electronic documentation at their marine transfer areas. For those facilities without the pre-existing IT infrastructure, building the infrastructure could prove expensive compared to the cost savings from reducing the amount of printed Operations Manuals and Emergency Manuals. Factors affecting the building of such IT infrastructure (not all inclusively) include:

- The size of the facility;
- How many marine transfer areas there are (each area must have an Operations Manual, and LNG and LHG facilities must also have an Emergency Manual);
- The number and type of products transferred at the facility;
- The types of transfer operations occurring at the facility; and
- Any pre-existing infrastructure that can already facilitate accessing and using electronic documentation (such as ''Wi-Fi,'' or hardwired broadband connections).

Based on these factors, for some facilities the total costs required to access electronic documents could exceed the cost savings experienced from switching to electronic documentation In addition, these IT costs could disproportionately affect facilities that are relatively small in terms of revenue. Therefore, we rejected Alternative 2.

Alternative 3—Option to Use Either Printed or Electronic Manuals.

This alternative is the selected alternative for this rulemaking. This alternative explicitly states that facility operators can submit the required Operations Manuals, Emergency Manuals, and amendments either in print or electronically. In addition, if submitting the required documents in print, only one copy would be required. In this alternative, facilities facing higher IT improvement costs could continue to use printed manuals and submissions. Hence, this alternative will lead to the highest net benefits of the three alternatives.

For these reasons, Alternative 3 is the preferred alternative. We provide a discussion of this alternative below.

Affected Population

We identified 121 LNG and LHG facilities that could be potentially impacted by this regulation, based on a search of the U.S. Coast Guard's Marine Information for Safety and Law Enforcement (MISLE) database.[7] We also identified 2,497 MTR facilities that could be potentially impacted. A discussion follows describing how the impacted population itself is reached.

LNG and LHG facilities transfer liquefied natural gas and liquefied hazardous gas from vessels to the shore or from the shore to the vessel. MTR facilities transfer oil or hazardous material in bulk from vessels to the shore or from the shore to the vessel. Operations Manuals provide information relating to these LNG, LHG, and MTR facilities, such as physical characteristics (including plans and maps) and descriptions of transfer systems; mooring areas; and diagrams of piping, electrical systems, control rooms, and security systems, among other items.[8] Emergency Manuals cover topics such as emergency shutdown procedures, descriptions of fire equipment and other emergency equipment as well as their operating procedures, first-aid procedures and stations, and emergency response procedures, among other items.[9] These manuals vary in terms of their size, anywhere from 0.5-inch, three-ring binders containing 50 pages, to 3-inch, three-ring binders.[10] We have estimated these 3-inch, three-ring binders to be 514 pages in length.[11] The 0.5-inch manuals are the most common size, accounting for the majority of manuals.[12] Therefore, in our cost savings estimate, we assume that all manuals are 0.5-inch, three-ring binders of 50 pages.

Amendments to both Operations Manuals and Emergency Manuals are intended to keep those manuals up to date.[13] Their length depends on the information that needs to be updated. If the information is significant, these amendments may be as long as the original document submitted to the COTP. If the change is relatively minor, the amendments may only be a few pages. If the amendments are only a few pages, they are submitted to the COTP

[7] The search of MISLE was conducted on November 18, 2019.

[8] A full list of details of what Operations Manuals need to cover for MTR facilities can be found under 33 CFR 154.310 and for LNG and LHG facilities under 33 CFR 127.305 and 127.1305.

[9] The full list items that Emergency Manuals need to cover for LNG facilities can be found under 33 CFR 127.307 and for LHG 127.1307.

[10] Coast Guard SMEs.

[11] The estimate of 514 was based on the maximum size capacity of 5 3-inch three ring binders found on 5 office supply stores on the internet. The 5 were: Office Depot (*https://www.officedepot.com/a/products/502062/Wilson-Jones-Binder-3-Rings-36percent/* & *https://www.amazon.com/WLJ36849NB-Wilson-3-Ring-Holder-Binders/dp/B003QX85TG/ref=sr_1_2?keywords=WLJ36849NB&qid=1573426316&s=office-products&sr=1-2,* accessed November 5, 2019, 480 pages), Staples (*https://www.staples.com/Simply-3-Inch-Round-3-Ring-Binder-Black-26857/product_1319200,* accessed November 5, 2019, 460 pages), Walmart (*https://www.walmart.com/ip/Universal-Economy-Round-Ring-View-Binder-3-Capacity-Black-UNV20991/21454956* and *https://www.amazon.com/UNV20991-Universal-Round-Economy-Binder/dp/B005V3T3P4/ref=sr_1_1?keywords=universal+economy+3+ring+3+inch+binder&qid=1573424798&s=office-products&sr=1-1,* accessed November 5, 2019, 480 pages), Target (*https://www.target.com/p/avery-3-34-one-touch-slant-rings-600-sheet-capacity-heavy-duty-view-binder-white/-/A-14432722* & *https://www.amazon.com/Avery-Heavy-Duty-One-Touch-670-Sheet-79693/dp/B000VXF23G/ref=sr_1_2?keywords=Avery+3%22+One+Touch+Slant+Rings+600+Sheet+Capacity+Heavy-Duty+View+Binder&qid=1573425256&sr=8-2,* accessed November 5, 2019, 600 pages), and Amazon (*https://www.amazon.com/Wilson-Jones-Binder-Basic-W362-49W/dp/B0001N9WM8/ref=sr_1_5?keywords=3+ring+3+inch+binder&qid=1573433167&sr=8-5,* accessed on November 5, 2019, 550 pages). The mean of these 5 comes to 514 pages.

[12] Coast Guard SMEs.

[13] A complete list of items that must be kept current can be found, for LHG facilities, for operations manuals in 33 CFR 127.1305. For LNG facilities, the complete list can be found, for operations manuals, in 33 CFR 127.305, and for emergency manuals in 33 CFR 127.307. For MTR facilities, 33 CFR 154.300(b) and 33 CFR 154.300(b)(1) states that ''the facility operator shall maintain the operations manual so that it is current''.

as individual pages. The COTP then examines those pages and, after determining their adequacy, inserts them into the previously existing edition of the Operations Manual or Emergency Manual.[14] Coast Guard SMEs estimate that 80 percent of amendments to Operations Manuals and Emergency Manuals consist of 5-page inserts while 20 percent consist of documents that are as long as full-length Operations or Emergency Manuals. In our cost savings estimate for this RA, we assumed that all amendments would be 5 pages.

The Coast Guard examined MISLE data between 2009 and 2019 (inclusively) to determine that an average of 60 Emergency Manuals and Operations Manuals and amendments are filed by LNG and LHG facilities per year.[15] Of those 60 Manuals and amendments, there were an average of 18 Manuals and 42 amendments. The number of these Manuals and amendments differ from the numbers in appendices A and B in the latest Collection of Information (COI).[16] The numbers in appendix A and B were 8 Manuals and 14 amendments, for a total of 22.[17] The explanation for the difference in numbers (60 versus 22) is attributable to two reasons. One is that the total LNG and LHG populations were different between the COI and the MISLE pull this RA is based on. The COI mentioned a combined LNG and LHG population of 108 while the MISLE indicated 121. This difference was because the MISLE data was pulled on different dates. This RA's MISLE pull was performed on November 18, 2019 while the MISLE pull the COI was based on was sometime previous to the date of its publication, August 30, 2019. The second and related reason for the numerical difference is that the Manual and amendment numbers themselves were pulled on different dates. The COI data was pulled before the publication of the COI, on August 30, 2019, while the RA was based pulled from MISLE on November 18, 2019. Hence, the latter would be expected to be larger.

Coast Guard SMEs estimate that 90 percent of LNG and LHG facilities would submit their documentation to the Coast Guard electronically. Thus, the affected annual population of LNG and LHG facilities is estimated to be, 54 per year with respect to facilities that will be submitting their documentation in electronic form, The population that will be submitting their documents in paper form (this is also referred to as ''traditional'' form this document) is estimated to be six, the remaining 10% of the LNG and LHG facilities. Hence, the total impacted population of LNG and LHG facilities is 60.

The average number of Operations Manuals and amendments filed by MTR facilities was 703 for the same period (2009–2019).[18] MTR facilities are only required to file Operations Manuals and amendments, not Emergency Manuals and amendments. Of those 703 Manuals and amendments, there were an average of 261 Manuals and 442 amendments. Since Coast Guard SMEs in CG–FAC estimate that 75 percent of MTR facilities would submit their documentation in an electronic format, the estimated regulated population of MTRs is 527 with respect to electronic submission. Twenty-five percent of MTR facilities are estimated to submit their documentation in paper traditional form, accounting for another 176 firms.[19] As a result, the total MTR affected population is 703.

The number of annually impacted facilities broken out by LNG and LHG and MTR facility, as well as the number of different types of manuals and amendments for each facility type, is summarized in the following table.

TABLE 2—AFFECTED POPULATION AND NUMBER OF MANUALS AND AMENDMENTS FILED ANNUALLY

Facility type	Total operations and emergency manuals filed	Total operations and emergency manual amendments filed	Total documents filed	Total operations and emergency manuals filed electronically	Total operations and emergency manual amendments filed electronically	Total manuals filed electronically	Total operations and emergency manuals filed in traditional form	Total operations and emergency manual amendments filed in traditional form	Total manual amendments filed in traditional form
LNG/LHG	18	42	60	16	38	54	2	4	6
MTR	261	442	703	195.75	331.5	527	65	111	176

Note: all ''total'' numbers rounded to closest whole number.

Cost Savings Components

Tables 3 and 4 summarize the proposed rulemaking's cost savings for the private sector and for the Coast Guard. Table 3 provides the private sector's cost savings by private sector population group (LNG, LHG, and MTR) as well as by the four different cost savings categories estimated. Table 4 summarizes Coast Guard's cost savings.

TABLE 3—ANNUAL COST SAVINGS OF PROPOSED RULEMAKING TO PRIVATE SECTOR BY POPULATION AND COST SAVINGS ELEMENT

Population	Cost savings element	Annual net cost savings ($2019) [1]
LNG and LHG	Savings from not having to produce printed manuals (and amendments) to mail to the COTP [2].	$498
	Savings from not having to produce printed manuals (and amendments) for placement at facility marine transfer areas [3].	234

[14] The original pages that the newly submitted ones replace are disposed of.

[15] This number is rounded to the nearest whole number, as are all population numbers mentioned below.

[16] Collection of Information under Review by Office of Management and Budget, Control Number: 1625–0049. This was published in the **Federal Register** Vol. 84, No. 169, on August 30, 2019.

[17] In the COI there were 6 manuals and 12 amendments for LHG facilities and 2 manuals and 2 amendments for LNG facilities (for a total of 8 manuals and 14 amendments and a total of 22 of both).

[18] The search of MISLE was conducted on November 18, 2019.

[19] This number is rounded up to closest whole number.

TABLE 3—ANNUAL COST SAVINGS OF PROPOSED RULEMAKING TO PRIVATE SECTOR BY POPULATION AND COST SAVINGS ELEMENT—Continued

Population	Cost savings element	Annual net cost savings ($2019) [1]
	Savings from not having to mail manuals (and amendments) to the COTP	994
	Savings from not having to place printed manuals (and amendments) at facility marine transfer areas.	1,605
Total Annual LNG and LHG Cost Savings.		[4] *3,331*
MTR	Savings from not having to produce printed manuals (and amendments) to mail to the COTP [5].	9,895
	Savings from not having to produce printed manuals (and amendments) for placements at facility marine transfer areas [6].	2,023
	Savings from not having to mail manuals (and amendments) to the COTP	13,536
	Savings from not having to place printed manuals (and amendments) at facility marine transfer areas.	7,522
Total Annual MTR Cost Savings		[7] *32,976*
Total		[8] *36,307*

[1] Rounded to closest whole dollar.
[2] Includes cost of binder, paper, printing and labor required to assemble.
[3] Includes cost of binder, paper, printing and labor required to assemble. It is also assumed that each facility, as per Coast Guard SME assessment, has an average of 2 marine transfer areas.
[4] Total figure may not be exact due to fact preceeding numbers have been rounded.
[5] Includes cost of binder, paper, printing and labor required to assemble.
[6] Includes cost of binder, paper, printing and labor required to assemble. It is also assumed that each facility, as per Coast Guard SME assessment, has an average of 2 marine transfer areas.
[7] Total figure may not be exact due to fact preceeding numbers have been rounded.
[8] Total figure may not be exact due to fact preceeding numbers have been rounded.

TABLE 4—COST SAVINGS IMPLICATIONS OF PROPOSED RULEMAKING TO COAST GUARD

Population	Cost savings element	Annual net cost savings ($2019) [20]
The Coast Guard	Cost Savings from not having to mail printed manuals (and amendments) back to facilities	$7,426

Cost Savings Methodology, Calculations, and Estimates

We broke out the cost savings analysis for this rulemaking into three sections. The first examines the cost savings for the private sector. The second discusses cost savings for the Coast Guard. The third provides an aggregated summary of the cost savings as well as the estimates on a discounted basis.

Private Sector Cost Savings

We broke out cost savings for the private sector into two categories. The first involves the cost savings associated with facility operators having the option to submit Operations Manuals and Emergency Manuals (and amendments) in electronic format. The second involves the option to place electronic editions of their Operations Manuals and Emergency Manuals (and amendments) at their marine transfer areas. The cost savings associated with each of these is discussed in separate sections below.

Cost Savings From the Reduced Numbers of Operations and Emergency Manuals (and Amendments) Sent to the Coast Guard

LNG and LHG facility operators are currently required to submit two copies of their Operations Manuals and Emergency Manuals and amendments to the COTP, as required.[21] Generally, they are not sent at the same time.[22] MTR facility operators are currently required to submit two copies of their Operations Manuals and amendments.[23] Although current regulations do not explicitly state that the copies submitted must be printed, the wording and context suggest the use of printed documents, and current industry practice is to submit printed documents.[24]

The cost components that make up the 0.5-inch binders consist of the actual cost of the empty 0.5-inch, 3 ring binder, the cost of 50 pages of paper, the cost of printing those 50 pages, and the labor required to put the manual together. The cost of all these elements, with the notable exception of labor, are the same whether the manual is for an LNG and LHG facility or an MTR facility. We estimate that the cost of the empty 0.5-inch binders, in 2019-dollar terms, is $3.66, based on the mean found for 0.5-inch binders from 5

[20] Rounded to closest whole dollar.

[21] 33 CFR 127.019(a) and (b).

[22] Due to fact that they are usually written by different personnel and do not need to be received simultaneously, they are generally not sent together.

[23] 33 CFR 154.300(a).

[24] The current regulation regarding the two-copy requirement was issued in 1988 for LNG and LHG facilities (53 FR 3370, Feb. 5, 1988), and in 1996 for MTR facilities (61 FR 41458, Aug. 8, 1996). At that time, it was not possible to electronically send a document as large and complicated as a complete Operations or Emergency Manual as an attachment via email or other electronic means. Operations Manuals and Emergency Manuals can range in size from 0.5-inch 3 ring binders to 3-inch 3 ring binders.

different websites selling this item.[25] We estimate the cost of 50 sheets of copier paper to be 62.5 cents, based on the mean we found for boxes of 500 pages from 5 different supply stores.[26] We found the cost to print in black and white, 50 pages, to be $2.23.[27] Combined, these costs come to $6.51 (rounded to closest whole cent).

As the labor costs between LNG and LHG and MTR facilities are different, the labor component of assembling these manuals differ. According to Coast Guard SMEs as well as COI 1625–0049, ''Waterfront Facilities Handling Liquefied Natural Gas and Liquefied Hazardous Gas'', clerical workers perform this function. In the Bureau of Labor Statistics (BLS) website, under North American Industry Classification System (NAICS) industry 483000 (Water Transportation), there was no specific labor category for clerical workers. The closest we were able to find was ''Office Clerks, General'' (Occupational Code 43–9061).[28] The mean hourly wage for this category of labor was found to be $19.92.[29] As wages account for only a portion of total employee costs (employee benefits account for the other part), the wages need to be adjusted to take into account benefits. Using the BLS U.S. Department of Labor New Release for March 19, 2020 (USDL–0451) benefits for employees in the ''Production, Transportation and Material Moving'' sector of the economy, private sector, were found to be account for $10.62 per hour, or 52% of wages.[30] [31] Thus the fully burdened wage rate is estimated at $30.28 per hour for LNG and LHG facilities.[32]

According to Coast Guard SMEs as well as the latest COI 1625–0093, ''Facilities Transferring Oil and Hazardous Material in Bulk—Letter of Intent and Operations Manual'', MTR facilities use general and operations managers to assemble Operations Manuals. On the BLS website, under NAICS industry 483000 (Water Transportation) general and operations managers (Occupational Code 11–1021) were found to have an hourly mean wage of $65.81.[33] As stated previously, according to the BLS, employees in the ''Production, Transportation and Material Moving'' sector of the economy, private sector, were found to have benefits associated with 52% of wages in that industry.[34] Hence, the fully burdened labor rate for general and operations managers is $100.03 per hour.[35]

With respect to the assembly of a 0.5-inch, 50-page manual, we performed the task ourselves and found that it took an average of 5.12 minutes (or 0.09 hours).[36] As a result, the labor cost of assembly for an LNG and LHG facility came to $2.73. [37] For an MTR facility, the cost came to $9.00.[38] Thus, for an LNG and LHG facility, we estimate the total cost of assembling a 0.5-inch binder for an Operations Manual or Emergency Manual to be $9.25.[39] It should be emphasized that these are the costs associated with producing one copy of an Operations Manual or of an Emergency Manual (they are estimated to cost the same to assemble). For an Operations Manual for an MTR facility, we estimate total cost to assemble to be $15.52.[40] All binder assembly costs are shown in Table 5.

TABLE 5—COST TO ASSEMBLE 0.5-INCH 3 RING BINDERS FOR LNG AND LHG AND MTR FACILITIES

0.5-Inch 3 ring binder assembly costs					
	Binder	Paper	Printing	Labor	Total
LNG and LHG	$3.66	$0.63	$2.23	$2.73	$9.25
MTR	3.66	0.63	2.23	9.00	15.52

[25] The five different websites were: Office Depot (*https://www.officedepot.com/a/products/765530/Aurora-EarthView-Round-Ring-Organization-Binder/*) (*$5.99*), Staples (*https://www.staples.com/Simply-5-inch-Light-Use-Round-3-Ring-Binder-Red-26852/product_1337664*) (*$3.29*), Walmart (*https://www.walmart.com/ip/Pen-Gear-0-5-inch-Durable-Binder-Clearview-Cover-White/945565181*) (*$2.47*), Target (*https://www.target.com/p/avery-120-sheet-0-5-34-durable-view-ring-binder-black/-/A-16978071*) (*$2.59*), and Amazon (*https://www.amazon.com/Avery-Economy-Binder-0-5-Inch-Round/dp/B0006SWEEG/ref=sr_1_6?qid=1583117388&refinements=p_n_feature_keywords_two_browse-bin%3A7103303011&s=office-products&sr=1-6*) (*$4.60*). All websites cited were accessed on Nov. 10, 2019. The mean of all these websites is $3.66.

[26] The websites were: Office Depot (*https://www.officedepot.com/a/products/841195/Office-Depot-Copy-And-Print-Paper/*) ($8.29), Staples (*https://www.staples.com/500+ream+paper/directory_500%20ream%20paper?sby=1*) ($5.79), Walmart (*https://www.walmart.com/ip/Pen-Gear-Copy-Paper-8-5x11-92-Bright-20-lb-1-ream-500-Sheets/487634010*) ($5.79), Amazon (*https://www.amazon.com/Hammermill-Recycled-Printer-Letter-086790R/dp/B009ZMP31K/ref=sr_1_6?keywords=500+ream+paper&qid=1573437715&sr=8-6*) ($9.20), and Target (*https://www.target.com/p/avery-120-sheet-0-5-34-durable-view-ring-binder-black/-/A-16978071*) ($3.99). The mean average of these five is $6.25. Dividing $6.25 by 500 pages this totals .625 cents a page. That amount multiplied by 50 pages gives us a cost of 62.5 cents.

[27] The cost found in ''Ink-onomics: Can you Save Money by Spending More on Your Printer'', PCWorld, May 2, 2012 (*https://www.pcworld.com/article/254899/ink_onomics_can_you_save_money_by_spending_more_on_your_printer_.html*) was found to be 3.9 cents per page for printers costing over $200. This May 2012 dollar figure was converted to $2019 using a GDP deflator (*https://www.bea.gov/iTable/iTableHtml.cfm?reqid=19&step=3&isuri=1&1910=x&0=-99&1921=survey&1903=4&1904=2009&1905=2018&1906=a&1911=0*). This deflator was the BEA, NIPA, Table 1.1.4 Price Indexes for Gross Domestic Product, Annual Series, last revised on April 29, 2020. This can be accessed by, in the previously mentioned link, clicking the modify button on the right, choosing ''annual'' series, and then ''refresh table''. The GDP deflator for 2012 was 100 and for 2019 112.348. Hence, 3.9 cents was multiplied by 12.348% to yield a figure of 4.45 cents (rounded to closest whole penny. Multiplying this figure by 50 (for the number of pages) yields, in turn, $2.23 for 50 pages (rounded to closest whole penny).

[28] ''May 2019 National Industry-Sepcific Occupational Employment and Wage Estimates, NAICS 483000-Water Transportation, (*www.bls.gov/oes/current/naics3_483000.htm*), downloaded September 6, 2020.

[29] Ibid.

[30] *www.bls.gov/news.release/archives/ecec_03192020.pdf,* referenced September 6, 2020.

[31] Table 5, page 10, BLS U.S. Department of Labor New Release for March 19, 2020 (USDL–0451), (*www.bls.gov/news.release/archives/ecec_03192020.pdf,* referenced September 6, 2020. According to this document, for the ''production, transportation and material moving'' industry, benefits were $10.62 per hour while wages were $20.41 (for a ratio of benfits to wages of 52%).

[32] $19.92 + ($19.92 × 52%) = $30.28.

[33] ''May 2019 National Industry-Sepcific Occupational Employment and Wage Estimates, NAICS 483000-Water Transportation, (*www.bls.gov/oes/current/naics3_483000.htm*), downloaded September 6, 2020.

[34] Table 5, page 10, BLS U.S. Department of Labor New Release for March 19, 2020 (USDL–0451), (*www.bls.gov/news.release/archives/ecec_03192020.pdf*), referenced September 6, 2020.

[35] $65.81 + ($65.81 × 52%) = $100.03.

[36] This time estimate is based on the average amount of time the Coast Guard consumed to print 50 pages and to assemble them in a 0.5-inch 3 ring binder.

[37] 0.09 hrs × $30.28 = $2.73.

[38] 0.09 hrs × $100.03 = $9.00.

[39] $3.66 (cost of binder) + $0.63 (cost of blank paper) + $2.23 (printing cost) + $2.73 (labor cost of assembly) = $9.258.

[40] $3.66 (cost of binder) + $0.63 (cost of blank paper) + $2.23 (printing cost) + $9.00 (labor cost of assembly) = $15.52.

As amendments to both Operations Manuals and Emergency Manuals are usually 5 pages, the cost of paper is estimated to total $0.06.[41] The cost of printing is estimated to total $0.22.[42] The total cost of amendments, other than labor and shipping, is $0.28 per amendment. These costs are the same regardless whether the amendment is for an LNG and LHG facility or an MTR facility.

The costs of labor for assembling amendments is different, due to the difference in labor costs between LNG and LHG facilities and MTR facilities. As stated previously, we found the labor cost for LNG and LHG facilities to be $65.81 per hour for LNG and LHG facilities, and $100.03 for MTR facilities. We found that the printing of these 5 pages and their collection from a printer took 1.25 minutes (0.02 hours). Hence, we estimate the labor costs for LNG and LHG facilities at $1.32 and for MTR facilities $2.00.[43] [44] The total costs of creating a 5-page amendment for an LNG and LHG facility is $1.56 per document and $2.42 for MTR facilities.[45] [46] These costs are provided in detail in Table 6.

TABLE 6—COST TO ASSEMBLE 5-PAGE AMENDMENTS FOR LNG AND LHG AND MTR FACILITIES

Five-page amendment assembly costs				
Cost element	Paper	Printing	Labor	Total
LNG and LHG	$0.06	$0.22	$1.32	$1.60
MTR	0.06	0.22	2.00	2.28

In addition to the cost of assembling each manual and amendment, we also considered shipping and handling costs. As there are situations where only one copy of a document needs to be mailed and other situations where two are needed, shipping and handling costs must be calculated for both scenarios.[47]

Because it is a legal requirement for these facilities to send their documents to the COTP, we assume that the manuals and amendments would be sent with a mail service that permits tracking. We also assumed that facilities would use a cost-effective ground shipping method.[48] As of August 7, 2017, there were 41 COTP zones.[49] All of these sites are clustered around shipping points in order to ensure that COTPs can perform their functions. Hence, no facility should be very far, geographically, from a shipping point.

We assume that the manuals and amendments are sent via a shippingservice such as United Parcel Service (UPS) or FedEx. As of November 2019, the U.S. Postal Service did not publish retail guides containing information as detailed and comparable to the UPS and FedEx Guides, that were readily available to the public. Hence it was not possible to estimate mailing costs for the U.S. Postal Service that would be as detailed and comparable to those estimated for UPS and FedEx. We assume shipping distances to correspond to zone 2 distances, in the UPS and FedEx pricing guides, as this is the closest shipping distance price point.[50] Regulations require that two copies be submitted to the COTP. Therefore, we calculate the shipping cost for two 0.5-inch binders.[51] The total weight for two 0.5-inch binders with 50 pages was an estimated 2.8 pounds, or 5.6 pounds total. Based on a 6-pound package, as of November 2019, the average for these shipping services is $10.11.[52]

Current regulations also require that, when the COTP determines that the Operations Manual or Emergency Manual is inadequate, the facility must send back one revised version of the manual, in paper format. Under the proposed regulation, only one copy of the document needs to be needs to be mailed back to the COTP. This can be in either paper or electronic format. Hence, the shipping costs must also be calculated for mailing a single 0.5-inch Operations Manual or Emergency Manual. We estimate that a single 0.5-inch manual weighs 2.8 pounds. For mailing purposes, UPS and FedEx would charge a cost associated with a 3-pound item. The average of these mailing services is $9.56.

[41] The mean cost of a 500-page ream of paper based on 5 prices at different retailers was found to be $6.25. Dividing $6.25 by 500 yields a per-sheet price of 1.25 cents per page. Multiplying 1.25 by 5 yields 6.25 cents, which is rounded down to 6 cents.

[42] As stated previously, based on the article ''Ink-onomics: Can you Save Money by Spending More on your Printer?'', PCWorld, May 2, 2012, the price of printing was estimated at 4.45 per page. 4.45 × 5 pages = 22.25 cents, which we round to the nearest whole cent.

[43] $65.81 × 0.02 = $1.316.

[44] $100.03 × 0.02 = $2.0006.

[45] $0.06 (cost of paper) + $0.22 (cost to print pages) + $1.32 (labor cost to assemble) = $1.60.

[46] $0.06 (cost of paper) + $0.22 (cost to print pages) + $2.00 (labor cost to assemble) = $2.28.

[47] For example, currently, when documents are initially sent to the Coast Guard two copies of each are currently required to be sent but when documents are required to be sent to the Coast Guard to correct inadequacies found by the Coast Guard, only one copy of a document needs to be sent.

[48] The exact amount of time depends on the relevant applicable section of the regulations. 33 CFR 127.019(b) and 145.325(c) give facilities a time period of 30 days to file, 145.320(a)(1) and 145.320(b)(1) 45 days and 145.325(b) 60 days.

[49] U.S. Coast Guard Homeport, *https://homeport.uscg.mil/#*.

[50] As of November 2019, the UPS pricing guide ''2019 UPS Rate and Service Guide, Retail Rates, updated November 4, 2019'' (*https://www.ups.com/assets/resources/media/en_US/retail_rates.pdf*) was available on-line as of November 8, 2019; The latest available FedEx price guide was ''Federal Express Service Guide, January 7, 2019, updated November 1, 2019'' (*https://www.fedex.com/content/dam/fedex/us-united-states/services/Service_Guide_2019.pdf*).

[51] The weight of an empty 0.5-inch binder was estimated at 13 ounces. This was based on the mean weight of same 5 binders used to determine the mean cost of 0.5-inch binders. For the web pages for those binders, where weight data was available, the mean was estimated. The web pages were: *https://www.officedepot.com/a/products/765530/Aurora-EarthView-Round-Ring-Organization-Binder/; https://www.staples.com/Simply-5-inch-Light-Use-Round-3-Ring-Binder-Red-26852/product_1337664; https://www.walmart.com/ip/Pen-Gear-0-5-inch-Durable-Binder-Clearview-Cover-White/945565181; https://www.target.com/p/avery-120-sheet-0-5-34-durable-view-ring-binder-black/-/A-16978071; https://www.amazon.com/Avery-Economy-Binder-0-5-Inch-Round/dp/B0006SWEEG/ref=sr_1_6?qid=1583117388&refinements=p_n_feature_keywords_two_browse-bin%3A71033030011&s=office-products&sr=1-6.* The weight of the 50 pages was estimated at 32 ounces. This was based on the 5 web pages that were used to determine the average price of paper. The weight of a 500 page ream of paper, on each of these websites, was 320 ounces (50/500*320 = 32 ounces). Those 5 websites were: *https://www.officedepot.com/a/products/841195/Office-Depot-Copy-And-Print-Paper/; https://www.staples.com/500+ream+paper/directory_500%20ream%20paper?sby=1; https://www.walmart.com/ip/Pen-Gear-Copy-Paper-8-5x11-92-Bright-20-lb-1-ream-500-Sheets/487634010; https://www.target.com/p/500ct-letter-printer-paper-white-up-up-153/-/A-75001545; https://www.amazon.com/Hammermill-Recycled-Printer-Letter-086790R/dp/B009ZMP31K/ref=sr_1_6?keywords=500+ream+paper&qid=1573437715&sr=8-6.* 32 oz + 13 = 45 oz = 2.8 pounds.

[52] ''2019 UPS Rate and Service Guide, Retail Rates, Updated November 4, 2019'', p. 68; ''Federal Express Service Guide. January 7, 2019, updated November 1, 2019'', p. 68 and 106.

With respect to shipping costs associated with amendments, we make many of the same assumptions that we do for shipping and handling 0.5-inch manuals. For example, we assume that UPS or FedEx ground shipping is the selected service. As either one or two 5-page amendments weigh less than 1 pound, the shipping cost is the same whether one or two are mailed together. That cost is $9.90 for UPS and $7.85 for FedEx (for a mean of $8.88).[53] Table 7 shows shipping costs for manuals and amendments.

TABLE 7—SHIPPING COSTS FOR MANUALS AND AMENDMENTS

Shipping Costs for Manuals and Amendments	
1 Manual	$9.56
2 Manuals	10.11
Amendments	8.88

Additionally, facilities must handle these manuals as part of the shipping process. As stated previously, labor costs differ between LNG and LHG facilities and MTR facilities. For LNG and LHG facilities, the loaded labor rate is $65.81 per hour, and for MTR facilities $100.03. We estimate the time required to assemble manuals to be 5 minutes (0.08 hours),[54] rounded to the closest whole minute, for assembling either one manual or two. [55] As a result, we estimate labor time for assembling manuals to mail to the COTP to cost $5.27 [56] for LNG and LHG facilities and $8.00 for MTR facilities.[57]

Labor handling costs for amendments are also slightly different due to the labor cost differences between LNG and LHG and MTR facilities. We estimate that handling a package that contains either one or two 5-page amendments, rounded to the nearest whole minute, takes 4 minutes (0.07), regardless of facility type. As a result, we estimate labor-handling costs for packages that held one or two amendments to be $4.61 [58] for LNG and LHG facilities and $7.00 for MTR facilities. [59]

The handling costs for all types of documents by both LNG and LHG facilities and MTR facilities are summarized in Table 8 below.

TABLE 8—HANDLING COSTS BY FACILITY AND DOCUMENT TYPE

Handling (Labor Costs)	
Operations Manuals and Emergency Manuals (One or Two 0.5-inch Binder) for LNG and LHG Facilities	$5.27
Amendments (One or Two 5 page Amendment) for LNG and LHG Facilities	4.61
Operations Manuals (One or Two 0.5-inch Binder) for MTR Facilities	8.00
Amendments (One or Two 5 page Amendment) for MTR Facilities	7.00

Table 9 shows the mailing costs summarized in Table 7 added to the labor handling costs in Table 8.

TABLE 9—SHIPPING AND HANDLING COSTS BY FACILITY AND DOCUMENT TYPE

Shipping and Handling (Labor) Costs by Facility and Document Type	
Operations Manuals and Emergency Manuals (one 0.5-inch binder) for LNG and LHG facilities	[60] $14.83
Operations Manuals and Emergency Manuals (two 0.5-inch binders) for LNG and LHG facilities	[61] 15.38
Amendments (one or two 5-page amendments) for LNG and LHG facilities	[62] 13.49
Operations Manuals (one 0.5-inch binder) for MTR facilities	[63] 17.56
Operations Manuals (two 0.5-inch binders) for MTR facilities	[64] 18.11
Amendments (one or two 5-page amendments) for MTR facilities	[65] 15.88

The final component of the cost savings estimate to industry is the quantity of manuals and amendments that facilities are sending to the COTP. LNG and LHG facilities are currently required to submit two copies of their Operations Manuals and Emergency Manuals and amendments to the COTP, and MTR facilities are currently required to send two copies of their Operations Manuals (and amendments).[66] The proposed rulemaking would permit facilities to submit their documents in either print or electronic format. Facility operators submitting electronically would save the cost of assembling and shipping two copies of their documents.

The proposed rulemaking also permits those facility operators submitting printed documents to submit one copy instead of two. Hence, those facilities would save the costs associated with producing and mailing one copy of their manuals. Coast Guard SMEs estimate that 90 percent of LNG and LHG facilities will submit their manuals and amendments electronically, and 75 percent of MTR facilities will submit their manuals and amendments electronically. The reason

[53] ''2019 UPS Rate and Service Guide, Retail Rates, Updated November 4, 2019'', p.68; ''Federal Express Service Guide. January 7, 2019, updated November 1, 2019'', p. 106.

[54] This includes time to obtain a box, box up a manual(s), complete required mailing paperwork, and to place it into the office ''out'' mailbox.

[55] Based on time samples we ran, we estimated that 4.8 minutes were needed to remove the paper from the copier, put it in an envelope, fill out the documentation and place it in the office pick up tray for one manual. To package and complete two manuals, we estimated that 5.1 minutes would be required. Rounding both to 5 minutes, this totals and estimated 0.08 hours.

[56] $65.81 × 0.08 = $5.2648.

[57] $100.03 × 0.08 = $8.0024.

[58] 0.07 × $65.81 = $4.6067, rounded to $4.61.

[59] 0.07 × $100.03 = $7.0021.

[60] $9.56 + $5.27 = $14.83.

[61] $10.11 + $5.27 = $15.38.

[62] $8.88 + $4.61 = $13.49.

[63] $9.56 + $8.00 = $17.56.

[64] $10.11 + $8.00 = $18.11.

[65] $8.88 + $7.00 = $15.88.

[66] It should be stressed that two copies need to be sent in initially but if copies of manuals or amendments need to be sent in again because they were found inadequate by the Coast Guard, only one copy needs to be sent. This issue is discussed in more detail later in this NPRM.

for this difference is that LNG and LHG facilities are much more likely owned by large multi-national conglomerates than MTR facilities.[67] LNG and LHG facilities are, therefore, more likely to more fully utilize IT systems and more likely to submit their documents electronically.

During the review process of the initially submitted documents, the COTP rejects a portion of the manuals and amendments submitted due to inadequacies in meeting the regulatory requirements put forth in 33 CFR parts 127 for LNG and LHG facilities or part 154 for MTR facilities. Coast Guard SMEs estimate that 30 percent of the total number of all manuals (not amendments) sent by facilities are inadequate and need to be returned for corrections. For amendments, Coast Guard SMEs estimate that the rejection rate is only 15 percent. The reason for the lower rejection rate is that amendments are based on previously approved documents and are shorter, having a lower chance of containing errors. Under the current regulatory regime, facilities send back only one copy. Hence, facility operators choosing to submit their documentation electronically save the costs associated with mailing back that single copy. For facility operators mailing in their modified documents in print form, there are no cost savings.

In summary, the cost savings for the private sector come from:

- LNG and LHG facilities printing and mailing fewer printed Operations Manuals and Emergency Manuals (0.5-inch binders) and amendments (5 pages) to the Coast Guard.
- LNG and LHG facilities printing and mailing fewer printed Operations Manuals and Emergency Manuals (0.5-inch binders) and amendments (5 pages) that have to be resubmitted to the Coast Guard.
- LNG and LHG facilities storing fewer printed Operations Manuals and Emergency Manuals (0.5-inch binders) and amendments (5 pages) at marine transfer areas.
- MTR facilities printing and mailing fewer printed Operations Manuals (0.5-inch binders) and amendments (5 pages) to the Coast Guard (assembly and mailing).
- MTR facilities printing and mailing fewer printed Operations Manuals (0.5-inch binders) and amendments that have to be resubmitted to the Coast Guard (assembly and mailing).
- MTR facilities storing fewer printed Operations Manuals (0.5-inch binders) and amendments (5 pages) at marine transfer areas.

We calculated the cost savings with several simple equations. Generally, it is the annual population of facilities multiplied by the number of manuals or amendments per facility multiplied by the facility probability of transitioning to electronic multiplied by the production and shipping costs. The costs savings from the proposed changes are the same each year. Tables 10 through 16 show the annual cost savings to facilities by activity. Table 10 is the cost savings to LNG and LHG facilities from producing fewer Operations Manuals and Emergency Manuals that are mailed to the Coast Guard. We expect 90 percent of LNG and LHG facilities to convert their Operations Manuals and Emergency Manuals to an electronic format.

The remaining 10 percent of LNG and LHG facilities, which we classified as earlier as traditional, still experience some cost savings since they would only be required to assemble one copy of their manuals to initially mail to the COTP (instead of the current two). As these 10 percent of LNG and LHG facilities will continue to send the same number of ''corrected'' paper manuals (as under the current regulatory regime) back to the COTP, they will not experience cost savings with respect to these. The cost elements to produce manuals and amendments were previously shown in tables 5 and 6.

The cost savings realized by LNG and LHG facilities are summarized in table 10. A brief summary of the components of that table follows.

The term ''Population of Documents Forecast to be Filed'' is an annual average of the number of Manuals and Amendments that have been filed over the past 10 years. This was based on MISLE data. A more thorough discussion of these numbers can be found in the ''affected population'' section of the NPRM. ''The Expected Rate of Electronic Documents Production'' is the percentage of documents expected to be submitted in electronic format instead of paper. As stated previously, the terms were based on Coast SME input. The 27 percent was derived from the fact that SMEs estimate that 90 percent of manuals will be submitted in electronic format and 30 percent of all Manuals submitted to the Coast Guard are found inadequate for one reason or another.[68] The 14 percent was derived from the 90 percent figure combined with the SME estimate that 15 percent of all amendments submitted are found to not be adequate.

The ''Reduction in Paper Documents Needed'' column reflects the documents no longer needed as a result of the actions in the first column (compared to current regulatory regime). For example, in the first row, when LNG and LHG facilities submit their manuals in electronic form, as opposed to paper, they will not need to submit two copies of electronic manuals. As a result, these facilities will experience a cost savings that is equal to the cost of assembling the documents. In the second row, the facilities that continue to submit paper Manuals (instead of electronic) will experience a cost savings from having to submit one document instead of two.[69]

For inadequate documents that are submitted electronically to the COTP, the cost of one paper document is saved as they a required to send only one paper copy.[70]

TABLE 10—ANNUAL LNG AND LHG PRODUCTION COST SAVINGS[71]

LNG and LHG production cost savings from:	Population of documents forecast to be filed	Expected rate of electronic documents production (percent)	Reduction in documents needed	Production costs (each)	Total production cost savings
Manuals submitted Electronically	18	90	2	$9.25	$299.70
Manuals Submitted in the Traditional Paper Form	18	10	1	9.25	16.65
Amendments Submitted Electronically	42	90	2	1.60	120.96

[67] LNG and LHG facilities cost in the billions to build while MTR, typically, cost much less.

[68] 90% × 30% = 27%.

[69] The current regulation requires the submission of two documents while the proposed regulation only requires those facilities submitting paper documentation to submit one copy of each document instead of 2.

[70] Facilities still continuing to submit paper documents to address documents that were not initially accepted by the Coast Guard will experience no cost savings as the current regulation currently requires them to submit one copy.

TABLE 10—ANNUAL LNG AND LHG PRODUCTION COST SAVINGS [71]—Continued

LNG and LHG production cost savings from:	Population of documents forecast to be filed	Expected rate of electronic documents production (percent)	Reduction in documents needed	Production costs (each)	Total production cost savings
Amendments Submitted in the Traditional Paper Form	42	10	1	1.60	6.72
Inadequate Manuals (submitted electronically)	18	27	1	9.25	44.96
Inadequate Amendments (submitted electronically)	42	14	1	1.60	9.41

Table 11 presents the cost savings to MTR facilities from producing fewer Operations Manuals. Of MTR facilities, Coast Guard SMEs estimate that 75 percent would convert their Operations Manuals to an electronic format. The remaining 25 percent of MTR facilities would still experience some cost savings since they would only be required to produce and mail in one copy of their manuals (instead of the current two).

With respect to inadequate documents that have been returned to facilities by the COTP, only those facilities that will be sending their documents electronically will experience a cost savings. They will no longer need to a paper version of the corrected document. The traditional facilities that do not make use of electronic submissions will not experience a cost savings as they will have to continue sending in a single copy of their corrected paper Operations Manual or Amendment.

In table 11 it can be seen that the number of Operations Manuals that are forecast to be required annually in the future are 261 and the number of Amendments 442. This was based on MISLE data. A more thorough discussion of these numbers can be found in the ''affected population'' section of the NPRM. ''The Expected Rate of Electronic Documents Production'' is the Percentage of documents expected to be submitted in electronic format as opposed to paper. As stated previously the terms were based on Coast Guard SME input. For the manuals this was 75 percent and for the amendments 25 percent.

The 23 percent was derived based on the fact that SMEs estimated that of 30 percent of the manuals submitted electronically would require correction.[72] The 11 percent was derived from the 75 percent figure combined with the SME estimate that 15 percent of all amendments submitted are found to be inadequate.[73]

The ''Reduction in Paper Documents Needed'' column reflects, analogous to Table 10, the decrease in each type of documents required in paper form. For inadequate documents that are submitted electronically to the COTP, the cost of one paper document is saved as they a required to send only one paper copy.[74]

TABLE 11—ANNUAL MTR PRODUCTION COST SAVINGS

MTR production cost savings from:	Population of documents forecast to be filed	Expected rate of electronic documents production (percent)	Reduction in documents needed	Production costs (each)	Total production cost savings
Manuals Submitted Electronically	261	75	2	$15.52	$6,076.08
Manuals Submitted in the Traditional Paper Form	261	25	1	15.52	1,012.68
Amendments Submitted Electronically	442	75	2	2.28	1,511.64
Amendments Submitted in the Traditional Paper Form	442	25	1	2.28	251.94
Inadequate Manuals (submitted electronically)	261	23	1	15.52	931.67
Inadequate Amendments (submitted electronically)	442	11	1	2.28	110.85

In addition to the cost savings associated with the need to manufacture and assemble less documentation, there will also be a cost savings associated with having to mail fewer documents to the COTP. Tables 12 and 13 capture these savings by facility and document type.

The ''Population'' column represents the forecast total number of each type of document expected to be submitted to the Coast Guard. The ''Expected Rate of Electronic Documents'' are the percentage of each type of document that is expected to be submitted in electronic format. The shipping costs are the costs associated with mailing and handling each type of document. The shipping and handling costs are in table 9 and the discussion regarding their calculation immediately precedes that table.

[71] All figures rounded to nearest whole cent.

[72] 30% × 75% = 23% (rounded to closest whole percentage).

[73] 15% × 75% = 11% (rounded to closest whole percentage).

[74] Facilties still continuting to submit paper documents to address documents that were not initially accepted by the USCG will experience no cost savings as the current regulation currently requires them to submit one copy.

TABLE 12—ANNUAL LNG AND LHG SHIPPING COST SAVINGS

LNG and LHG shipping cost savings from:	Population of documents forecast to be filed	Expected rate of electronic documents	Shipping costs (each)	Total annual shipping cost savings
Manuals Submitted Electronically	18	0.9	$15.38	$249.16
Manuals Submitted in the Traditional Paper Form	18	0.1	14.83	26.69
Amendments Submitted Electronically	42	0.9	13.49	509.92
Amendments Submitted in the Traditional Paper Form	42	0.1	13.49	56.66
Inadequate Manuals (submitted electronically)	18	0.27	14.83	72.07
Inadequate Amendments (submitted electronically)	42	0.14	13.49	79.32

TABLE 13—ANNUAL MTR SHIPPING COST SAVINGS

MTR shipping cost savings from:	Population of documents per year	Expected rate of electronic documents production	Shipping costs (each)	Total annual shipping cost savings
Manuals Submitted Electronically	261	0.75	$18.11	$3,545,03
Manuals Submitted in the Traditional Paper Form	261	0.25	17.56	1,145.79
Amendments Submitted Electronically	442	0.75	15.88	5,264.22
Amendments Submitted in the Traditional Paper Form	442	0.25	15.88	1,754.74
Inadequate Manuals (submitted electronically)	261	0.23	17.56	1,054.13
Inadequate Amendments (submitted electronically)	442	0.11	15.88	772.09

Next, in tables 14 and 15, we show the cost savings to facilities from assembling fewer Operations Manuals and Emergency Manuals that are stored at marine transfer areas.[75] Marine transfer areas are those parts of a facility where the products the facility transfers, from vessel to shore or shore to vessel, are transferred. According to Coast Guard SMEs, a facility typically has two marine transfer areas. These cost savings are only for facilities that would save their documentation at these areas in electronic format.[76] Each facility is currently required to keep a copy of their manuals at each marine transfer areas. Facilities currently keep their records at these locations in printed format. The reasons for this are similar to the reasons for mailing printed editions of the Operations Manuals and Emergency Manuals to the Coast Guard: The regulations that established this requirement were originally published before it was commonly accepted practice (or even possible) to access electronic records in a portable fashion.

According to Coast Guard SMEs, LNG and LHG facilities have a 50-percent likelihood of storing their manuals and amendments in electronic format at marine transfer areas, and MTR facilities have a 20-percent likelihood of storing them electronically.

The reason that these percentages are low is that for the adoption of electronic documents at these areas, a facility must be equipped to provide the ability to access electronic documentation at marine transfer areas already.[77] The cost of purchasing the new IT equipment for these purposes greatly offsets the cost savings from using electronic documentation, so facilities must already have the necessary IT infrastructure in place to experience the cost savings. As LNG and LHG facilities are typically much more capital intensive and state-of-the-art in terms of IT infrastructure than MTR facilities, they are more likely to use electronic documentation.

As stated previously, the costs to assemble Manuals and amendments, for LNG and LHG facilities, was $9.25 and $1.60 (each).[78] As also stated previously, the in-scope population was estimated at 18 for Manuals and 42 amendments for LNG and LHG facilities.[79] Combining these numbers with the fact that there are an average of two marine transfer areas per facility, we end up with the annual production cost savings figures shown in table 14.

TABLE 14—ANNUAL LNG AND LHG PRODUCTION COST SAVINGS

Marine transfer area cost savings:	Population of documents per year	Electronic document use at marine transfer areas (percent)	Marine transfer areas per facility	Production costs (each)	Annual production costs savings
Manuals	18	50	2	$9.25	$166.50
Amendments	42	50	2	1.60	67.50

[75] LNG and LHG facilities must have Operations Manuals and Emergency Manuals at these locations, and MTR facilities have Operations Manuals only.

[76] This electronic documentation would be accessed via a device such as an electronic tablet.

[77] For example via Wi-Fi or hardwire connection.

[78] See Tables 5 and 6 and the discussions accompanying them.

[79] See discussion under the ''affected population'' section of this NPRM.

As stated previously, the costs to assemble Manuals and amendments, for MTR facilities, was $15.52 and $2.28 (each).[80] As also stated previously, the in-scope population was estimated at 261 for Manuals and 442 amendments for MTR facilities.[81] Combining these numbers with the fact that there are an average of two marine transfer areas per facility, we end up with the annual production cost savings figures shown in table 15.

TABLE 15—ANNUAL MTR PRODUCTION COST SAVINGS

Marine transfer area cost savings:	Population of documents per year	Electronic document use at marine transfer areas (percent)	Marine transfer area per facility	Production costs (each)	Annual production costs savings
Manuals	261	20	2	$15.52	$1,620.29
Amendments	442	20	2	2.28	403.10

Finally, in Tables 16 and 17, we show the labor cost savings to facilities that choose to retain electronic documents instead of printed documents at marine transfer areas. According to Coast Guard SMEs, normally a PIC (or someone with similar background) would perform this duty in an hour, due to the size of the facilities. The closest occupation found to this in the BLS occupational code series was ''First Line Supervisors of Production and Operating Workers'' (Occupational Code 51–1011), under NAICS 325000 (Chemical Manufacturing).[82] We found the mean wage to be $35.43.[83] We estimated the loaded rate to be $53.50.[84] [85]

Using the estimated loaded labor rate of $53.50 per hour, multiplied by the in-scope populations discussed previously under the ''affected population'' portion of this economic analysis (18 manuals for LNG and LHG facilities and 261 for MTR facilities as well as 42 amendments for LNG and LHG facilities and 442 for MTR) and the estimated rate of electronic document use at marine transfer areas discussed previously (50 percent at LNG and LHG facilities and 20 percent at MTR), we derive the annual labor cost savings in tables 16 and 17.

TABLE 16—ANNUAL LNG AND LHG LABOR COST SAVINGS WITH RESPECT TO ELECTRONIC AND OPERATIONS MANUALS (AND AMENDMENTS) THAT WOULD NOT HAVE TO BE PLACED AT MARINE TRANSFER AREAS

Labor of storing manuals and amendments	Population of documents per year	Electronic document use at marine transfer areas (percent)	Labor costs	Total annual labor cost savings
Manuals	18	50	$53.50	$481.50
Amendments	42	50	53.50	1,123.50

TABLE 17—ANNUAL MTR LABOR COST SAVINGS WITH RESPECT TO OPERATIONS MANUALS (AND AMENDMENTS) THAT WOULD NOT HAVE TO BE PLACED AT MARINE TRANSFER AREAS

Labor of storing manuals and amendments	Population of documents per year	Electronic document use at marine transfer areas (percent)	Labor costs	Total annual labor cost savings
Manuals	261	20	$53.50	$2,792.70
Amendments	442	20	53.50	4,729.40

[80] See Tables 5 and 6 and the discussions accompanying them.

[81] See discussion under the ''affected population'' section of this NPRM.

[82] There is no comparable BLS occupational code under the BLS's NAICS 483000 (Water Transportation) code 51–1011.

[83] May 2019 National-Industry Specific Occupational Employment and Wage Estimates, NAICS 325000 Chemical Manufacturing, *https://www.bls.gov/oes/2019/may/naics3_325000.htm#51-0000, downloaded September 30, 2020.*

[84] The loaded rate was estimated by accessing latest available BLS News Release on Employer Costs for Employee Compensation June 2020 (News Release dated September 17, 2020, USDL–20–1736, *https://www.bls.gov/news.release/ecec.htm,* accessed September 30, 2020). Normally the Coast Guard, to determine benefits, uses all workers in private industry, transportation, and material moving as the basis. Due to the fact that the labor category identified above was First Line Supervisors of Production and Operating Workers, it was thought more appropriate to use the line associated with ''production, transportation and material moving, Production'' in table 2 instead. LNG, LHG, and MTR facilities would be expected to have benefits packages closer to this line item category than that associated with line item ''private industry, transportation and material moving, transportation and moving'' as they are closer, in terms of workforce, to a production type environment than a transportation. To calculate the benefits ratio, total compensation in this line item ($28.70) was divided by ''wages and salaries'' ($19.00). This provided a benefits ratio of 1.51.

[85] $35.43 × 1.51 = $53.50.

Tables 18 and 19 show the total annual cost savings for LNG and LHG and MTR facilities in both nominal and discounted terms. These savings estimates were found by summing the previous tables for the total number of facilities by respective facility type.

TABLE 18—ANNUAL COST SAVINGS FOR LNG AND LHG FACILITIES ON A NOMINAL BASIS AND DISCOUNTED AT 7%

LNG and LHG cost savings	Nominal terms	7% Discounted rate
Year 1	$3,330.92	$3,113.01
Year 2	3,330.92	2,909.35
Year 3	3,330.92	2,719.02
Year 4	3,330.92	2,541.14
Year 5	3,330.92	2,374.90
Year 6	3,330.92	2,219.53
Year 7	3,330.92	2,074.33
Year 8	3,330.92	1,938.62
Year 9	3,330.92	1,811.80
Year 10	3,330.92	1,693.27
Total	33,309.18	23,394.97
Annualized	.....	3,330.92

TABLE 19—ANNUAL COST SAVINGS FOR MTR FACILITIES ON A NOMINAL BASIS AND DISCOUNTED AT 7%

MTR cost savings	Nominal terms	7% discounted rate
Year 1	$32,976.35	$30,819.02
Year 2	32,976.35	28,802.82
Year 3	32,976.35	26,918.52
Year 4	32,976.35	25,157.50
Year 5	32,976.35	23,511.68
Year 6	32,976.35	21,973.53
Year 7	32,976.35	20,536.01
Year 8	32,976.35	19,192.53
Year 9	32,976.35	17,936.95
Year 10	32,976.35	16,763.50
Total	329,763.46	231,612.06
Annualized	.....	32,976.35

Table 20 shows the total private sector cost savings.

TABLE 20—TOTAL PRIVATE SECTOR COST SAVINGS ON A NOMINAL BASIS AND DISCOUNTED AT 7%

Total private sector cost savings	Nominal terms	7% discounted rate
Year 1	$36,307.26	$33,932.02
Year 2	36,307.26	31,712.17
Year 3	36,307.26	29,637.54
Year 4	36,307.26	27,698.64
Year 5	36,307.26	25,886.58
Year 6	36,307.26	24,193.06
Year 7	36,307.26	22,610.34
Year 8	36,307.26	21,131.16
Year 9	36,307.26	19,748.75
Year 10	36,307.26	18,456.77
Total	363,072.64	255,007.03
Annualized	.....	36,307.26

1. Coast Guard Cost Savings

Under current regulations, the COTP examines the Operations Manuals and Emergency Manuals and amendments that are submitted by LNG and LHG facilities, and the Operations Manuals and amendments submitted by MTR facilities. After examining LNG and LHG documentation, the COTP finds the document either adequate or inadequate. If the document is found adequate, the current regulation requires

that ''the Captain of the Port returns-one copy to the [facility] owner or operator marked 'Examined by the Coast Guard' ''.[86] The same applies to MTR documentation. If the document is found to be adequate, the current regulation requires that ''the COTP . . . return one copy of the manual marked 'Examined by the Coast Guard' ''.[87] All these copies are currently submitted and returned in printed format.

Cost Savings From the Option for the COTP to Return Electronic Documents to Facility Operators if Those Documents Were Electronically Submitted

This proposed rulemaking would permit the COTP the option of returning these documents to the facilities in either electronic or printed format, depending on the format in which the document was received. If a document was received from a facility in printed format, then it would not be returned to the facility in electronic format. As previously stated, Coast Guard SMEs estimate that 90 percent of LNG and LHG documents would be received in electronic format, and 75 percent for MTR. Thus, this is same the percentage that the COTP would return to the facilities in electronic format.

The cost savings the Coast Guard would experience from returning electronic responses would be the shipping and handling costs saved by not having to mail back the printed editions of the Operations Manuals and Emergency Manuals and amendments. The Coast Guard, like the private sector, would likely use a mailing service such as UPS or FedEx Ground shipping. Since the same packages would be returned to the facilities, the Coast Guard's mailing costs would likely be the same as the private sector's. For a 0.5-inch manual, this is estimated to total $9.56, and for a 5-page amendment, this is estimated to total $8.88.

Because labor costs differ between the Coast Guard and the private sector, labor-handling costs do also. The type of Coast Guard personnel expected to package documents to return to facilities would be either E–4s or E–5s. According to the latest available Commandant Instruction, the fully loaded hourly rate for an E–4 is $45.00 and for an E–5 $54.00.[88] We assume that it takes the same amount of time to pack and prepare a 0.5-inch and a 5-page amendment for shipping as it takes the private sector: 5 minutes, rounded to the closest whole minute, for a 0.5-inch manual and 4 minutes for a 5-page amendment.[89] [90] We estimate labor costs at $3.60 for an E–4 and $4.32 for an E–5 to mail a 0.5-inch manual.[91] [92] We estimate that it costs $3.15 for an E–4 and $3.78 for an E–5 to mail a 5-page amendment.[93] [94] We take an average of the E–4 and E–5 rates, thus deriving an estimated labor cost of $3.96 per 0.5-inch amendment and $3.47 per 5-page amendment.[95] Thus, the total cost to mail a 0.5-inch manual and $12.35 to mail a 5-page amendment is $13.52. These costs are summarized in table 21.

TABLE 21—COAST GUARD SHIPPING AND HANDLING COSTS

Shipping and Handling Costs			
	Mailing costs	Handling (labor costs)	Total
Manuals	$9.56	$3.96	$13.52
Amendments	8.88	3.47	12.35

In addition to the documents that have been found adequate, there is the issue of those documents that are deemed inadequate by the COTP. The current regulations require the COTP to notify the facility in writing.[96] [97] This notification usually comes in the form of a marked-up copy of the document, showing what needs to be corrected. This proposed rule would provide the COTP the option to respond electronically or in print to either electronic or printed copies from the facility operators.

In summary, the cost savings for the Coast Guard would be produced from the reduced number of printed Operations Manuals and Emergency Manuals and amendments returned to LNG, LHG, and MTR facilities. These savings can be broken out into the labor costs and the shipping costs. Table 22 shows the annual cost saving calculations for the Coast Guard.

TABLE 22—COAST GUARD ANNUAL COST SAVINGS FROM SHIPPING AND HANDLING FOREGONE

Cost savings to the coast guard	Population of documents per year *	Expected rate of electronic documents production (percent)	Shipping and handling costs	Annual cost savings
LNG Manuals	18	90	$13.52	$219.02
LNG Amendments	42	90	12.35	466.83
MTR Manuals	261	75	13.52	2,646.54
MTR Amendments	442	75	12.35	4,094.03

* See tables 11 and 12.

[86] 33 CFR 127.019(c).

[87] 33 CFR 154.300(e).

[88] Commandant Instruction 7310.1U, dated 27 February 2020, page 2 under the ''Hourly Standard Rates for Personnel'' section. *https://media.defense.gov/2020/Mar/04/2002258826/-1/-1/0/CI_7310_1U.PDF*

[89] 5/60 = 0.08 hours.

[90] 4/60 = 0.07 hours.

[91] .08 × $45= $3.60.

[92] .08 × $54 = $4.32.

[93] .07 × $45 = $3.15.

[94] .07 × $54 = $3.78.

[95] Both of these figures are rounded to the nearest whole cent.

[96] 33 CFR 154.320(a)(1) states: ''The COTP will notify the facility operator [of an MTR facility] in writing of any inadequacies''.

[97] 33 CFR 127.019(d) states: ''If the COTP finds that the Operations Manual or the Emergency Manual does not meet this part, the Captain of the Port will return the manual with an explanation of why it does not meet this part [to the LNG and LHG facility].''

The summary of these calculations for 10 years is in Table 23.

TABLE 23—COAST GUARD COSTS SAVINGS ON A NOMINAL BASIS AND DISCOUNTED AT 7%

Coast guard cost savings	Nominal terms	7% Discounted rate
Year 1	$7,426.42	$6,940.58
Year 2	7,426.42	6,486.52
Year 3	7,426.42	6,062.17
Year 4	7,426.42	5,665.58
Year 5	7,426.42	5,294.93
Year 6	7,426.42	4,948.54
Year 7	7,426.42	4,624.80
Year 8	7,426.42	4,322.24
Year 9	7,426.42	4,039.48
Year 10	7,426.42	3,775.21
Total	74,264.19	52,160.06
Annualized	.....	7,426.42

2. Summary of Cost Savings

We show the total aggregate cost savings for both the private sector and government, in nominal and discounted terms, in table 24.

TABLE 24—TOTAL COSTS SAVINGS (PRIVATE SECTOR PLUS GOVERNMENT) ON A NOMINAL BASIS AND DISCOUNTED AT 7%

Total private sector + coast guard cost savings	Nominal terms	7% Discounted rate
Year 1	$43,733.68	$40,872.60
Year 2	43,733.68	38,198.69
Year 3	43,733.68	35,699.71
Year 4	43,733.68	33,364.22
Year 5	43,733.68	31,181.51
Year 6	43,733.68	29,141.60
Year 7	43,733.68	27,235.14
Year 8	43,733.68	25,453.40
Year 9	43,733.68	23,788.23
Year 10	43,733.68	22,231.99
Total	437,336.83	307,167.09
Annualized	.....	43,733.68

Using a perpetual period of analysis, we estimate the total annualized cost savings to both industry and the Coast Guard of the proposed rulemaking to be $29,406 in 2016 dollars, using a 7-percent discount rate and discounted back to 2016.[98] The anticipated year of the rule's implementation is 2021.

B. Small Entities

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612) (RFA) and Executive Order 13272 (Consideration of Small Entities in Agency Rulemaking) requires a review of proposed and final rules to assess their impacts on small entities. An agency must prepare an initial regulatory flexibility analysis unless it determines and certifies that a rule, if promulgated, would not have a significant impact on a substantial number of small entities.

Under the RFA, we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. 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 proposes to allow MTR facilities, and LNG and LHG facilities to submit their Operations Manuals, Emergency Manuals, and amendments in electronic format. These facilities will experience a cost savings. Therefore, we estimate that this proposed rule would provide cost savings to 703 MTR facilities, and 60 LNG and LHG facilities.

This proposed rulemaking would reduce the time and cost burden for regulated LNG, LHG, and MTR facilities to submit Operations Manuals and Emergency Manuals and amendments for the purposes of 33 CFR parts 127, 154 and 156. The proposed rulemaking would enable these facilities to submit the required documentation electronically. This would enable facilities to save time associated with mailing and processing printed manuals. In addition, it would permit facilities to place electronic copies of their manuals and amendments at their marine transfer areas. This would result in a savings to facilities that choose this route because they would not have to

[98] Rounded to the nearest whole dollar. We assume that the regulation will be implemented in 2021, hence deflate the 2016 dollar terms to that year.

print manuals and amendments and place them physically at those locations.

Section 70011 of Title 46 of the U.S.C. authorizes the Secretary of Homeland Security to establish procedures and measures for handling dangerous substances, including oil and hazardous material, to prevent damage to any structure on or in the navigable waters of the United States. Additionally, the FWPCA, as amended and codified in 33 U.S.C. 1321(j)(5), authorizes the President to establish procedures to prevent discharges of oil and hazardous substances from vessels, onshore facilitates, and offshore facilities. The FWPCA functions in 33 U.S.C. 1321(j)(5) have been delegated from the President to the Secretary of DHS by Executive Order 12777 Sec. 2(d)(2), as amended by Executive Order 13286. The authorities in 33 U.S.C. 1321(j)(5) and 46 U.S.C. 70011 have been delegated to the Coast Guard under section II, paragraphs 70 and 73, of DHS Delegation No. 0170.1. This serves as the legal basis of the proposed rulemaking. We have searched for relevant Federal rules that may duplicate, overlap and conflict with the proposed rule but have found none.

We examined the LNG and LHG and MTR facility populations separately, to provide a detailed analysis. With respect to the LNG and LHG population, as stated previously, we estimate that 54 facilities a year would be impacted by the proposed regulation, or 45 percent of the 121 total number of LNG and LHG facilities.[99] [100] A search of the MISLE database revealed a total of 85 unique owners for these 121 LNG and LHG facilities.[101] Of these unique owners, 15 were found to be small businesses, as defined by the SBA ''Table of Small Size Standards''.[102] We were unable to find employee or revenue information for 16 entities. Entities for which data was not available were assumed to be small entities. Assuming that the proportion of owners is directly related to the number of impacted owners, 45 percent of the 85 unique owners yielded a total of 38 unique owners who would be affected by the proposed rule.[103] We estimate total nominal cost savings per year for LNG and LHG facilities to be $3,331 per year, as shown in Table 18.[104] This totals $86.66 per owner per year.[105] There were no small LNG and LHG facilities, for which gross sales data existed, for which costs savings exceeded 1 percent of gross revenue.

With respect to the MTR population, as stated previously, we estimate that 527 facilities would be impacted per year.[106] As we found the total number of MTR facilities to be 2,497, the proportion of impacted facilities is 21 percent.[107] A search of the MISLE database found 1,390 unique owners of all MTR facilities.[108] We used Cochran's Formula to reduce 1,390 to a representative sample.[109] Applying this formula, while assuming a 95-percent confidence interval, yields a sample size of 302. We used this sample size on which to base our small business analysis.[110] Of the 302 facilities, 223 were estimated to be small. Of the 223 facilities, 139 were small (in terms of either gross sales or number of employees) according to the definition provided by the SBA. With respect to the remaining 84 facilities, no sales or employee data was available, so we assumed that these facilities were also small.

The estimated number of total impacted unique MTR owners is 292.[111] We estimate the total cost savings, as shown in table 19, to be $32,976 per year for all MTR facilities per year.[112] Hence, we estimate that the projected cost savings per impacted facility would be $112.93 per year.[113] Assuming that the proportion of small facilities among the 292 total impacted facilities reflects the ratio of small in the sample derived by the application of Cochran's formula (74 percent), 216 small facilities are estimated to exist.[114] [115] For the 139 small MTR facilities for which gross sales data existed, there were no facilities for which costs savings exceeded 1 percent of gross revenue. Based on the information provided above, 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. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment to the docket at the address listed in the **ADDRESSES** section of this preamble. In your comment, explain why you think it qualifies and how and to what degree this proposed rule would economically affect it.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule. 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.

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).

[99] The discussion under the ''affected population'' section of this NPRM should be referenced.

[100] 54/121 = 45%.

[101] The search of the MISLE database was conducted mid-December 2020.

[102] As of the latest available SBA ''Table of Size Standards'' at the time this analysis was performed. That table was effective as of Aug. 19, 2019 and is available at *https://www.sba.gov/document/support-table-size-standards.*

[103] Rounded to nearest whole number. 85 × 45% = 38.25 (rounded to 38).

[104] Rounded to closest whole dollar.

[105] $3,331/38 = $86.66 per impacted owner per year.

[106] The discussion under the ''affected population'' section of this regulatory analysis should be referenced.

[107] Rounded to closest whole percentage point (527/2,497 = 21.1%). This assumes that this ratio, based on historical MISLE data over the past 10 years, remains constant over the future.

[108] The search of the MISLE database was conducted in Mid-Dec. 2020.

[109] Cochran's formula is defined as: n= (Z^2xpxq)/e^2 where n is the sample size number that matches a particular precision (*i.e.* margin of error) and confidence level. Z is the z-value (1.96 in our case, a number that matches 2 standard deviations), p is the estimated proportion of the population which has the attribute in question (0.5 in our case, as we are looking numbers around a center), q = 1–p and e is the estimated margin of error (0.05, as we are assuming a 95-percent confidence level). The use of this equation yields a corresponding sample size of 385. However, as the population is relatively small (in terms of statistical analysis) 1,390, we need to use a slight modification of this formula. That modification is as follows: n = (n0)/(1+ (n0–1)/N). n0 is the sample size from our first calculation (385) and N is the sample size (1,390). Thus, we obtain: 385/(1 + (385–1)/1390)) = 302.

[110] We picked the 302, from the 1,390, by assigning the 1,390 a randomly selected number between 0 and 1 using the random number generator in Excel and then picking the first 302 facilities, from highest to lowest, based on the number the random number generator created for each.

[111] 1,390 × 21% = 291.9.

[112] Figure rounded to closest whole dollar.

[113] $32,976/292 = $112.93.

[114] 223/302 = 73.8%.

[115] 292 × 74% = 216.08.

D. Collection of Information

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires the U.S. Coast Guard to consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid OMB control number.

This action contains the proposed amendments to the existing information collection requirements previously approved OMB collections of information. The Coast Guard will submit these proposed information collection amendments to OMB for its review.

Hence, the COI amendments under this proposed rule falls under the same collection of information already required for waterfront facilities handling LNG and LHG described in OMB Control Number 1625–0049, and facilities transferring Oil or Hazardous Materials in Bulk described in OMB Control Number 1625–0093. This proposed rule does not change the content of responses, nor the estimated burden of each response, but because it changes the estimated burden of many of the responses required in those COIs, it proposes to decrease the total annual burden for both of these collections of information.

As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. The title and description of the information collections, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

Title: Waterfront Facilities Handling Liquefied Natural Gas (LNG) and Liquefied Hazardous Gas (LHG).

OMB Control Number: 1625–0049.

Summary of the Collection of Information: LNG and LHGs present a risk to the public when transferred at waterfront facilities. Title 33 CFR part 127 prescribes safety standards for the design, construction, equipment, operations, maintenance, personnel training, and fire protection at waterfront facilities handling LNG or LHG. The facility operators must submit Operational Manuals and Emergency Manuals and amendments to the Coast Guard.

Need for Information: The information in an Operations Manual is used by the Coast Guard to ensure the facility follows proper and safe procedures for handling LNG and LHG and to ensure facility personnel are trained and follow proper and safe procedures for transfer operations. The Emergency Manual is used by the Coast Guard to ensure the facility follows proper procedures in the event of an emergency during transfer operations. These procedures include actions in the event of a release, fire, or other event that requires an emergency shutdown, first aid, or emergency mooring or unmooring of a vessel. Operations Manuals and Emergency Manuals are updated periodically by amendments to ensure they are kept current to reflect changes in procedures, equipment, personnel, and telephone number listings.

Use of Information: The Coast Guard uses this information to monitor compliance with the rule.

Description of the Respondents: Waterfront Facilities Handling LNG and LHG.

Number of Respondents: This proposed rule would not have any impact on the number of respondents. Based on the Coast Guard's MISLE database, there are currently 121 LNG and LHG facilities operating in the United States and its territories.[116] The proposed rule would reduce the number of hours spent assembling manuals and amendments, submitting them to the COTP, updating numerous copies of each manual that is amended, and ensuring that the most recent version of the manual with all amendments is available to the PIC.

Frequency of Response: The number of responses per year for this proposed rule would vary by participating facilities. The Coast Guard anticipates that each new participant will submit an Operations Manual and Emergency Manual once when the new facility becomes operational. The operator will submit updates, in the form of amendments, to the manual whenever there is a significant change.

The number of responses has increased since the most recently approved COI and this proposed rulemaking. The proposed rulemaking will lead to an increase in the number of annual responses.

The proposed rulemaking does not increase the number of annual responses. The number of responses since the last COI, however, do increase because the population size since that time has increased. The most recently approved COI estimates 3,356 annual responses for all LNG and LHG facilities.[117] Under the current proposed rulemaking, the annual responses are estimated to be 3,502.[118] This difference is due to a change in the populations as opposed to other impacts of the proposed rulemaking.

Burden of Response: The burden of response would decrease due to the fact that facility operators would no longer need to print the manuals that will be submitted to the Coast Guard, mail them to the COTP, and place them at the marine transfer areas of the facilities (for those manuals and amendments that will be kept at marine transfer areas in electronic format).

In the latest available COI, using the new LNG and LHG population of 121 instead of 108, along with the per-response burden hours in that COI, the total burden hours for both LNG and LHG facilities, per year, is 6,768. The hours per response for the development of an Operations or Emergency Manual is 150 hours, and the hours per response for Operations Manual or Emergency Manual amendments is 2 hours.[119] The proposed rulemaking is estimated to reduce the burden hours for Operations Manuals and Emergency Manuals and amendments for facility operators submitting their documents to the COTP and storing their documentation at their marine transfer areas in electronic format. This total time saved time is estimated at 60 hours per year. Thus, the Coast Guard estimates that 60 burden hours would be eliminated per year.

Estimate of Total Annual Burden: The proposed rule would decrease the total

[116] In the most current COI, the number of LNG and LNG facilities was 108. The current figure of 121 reflects an increase in this population; it is not due to a change in the proposed rulemaking. The relevant COI is 1625–0049. This can be found in Regulations.Gov (specifically under *https://www.regulations.gov/docket?D=USCG-2019-0353*).

[117] Annual responses are defined as not only the number of Operations Manuals and Emergency Manuals and amendments but also other documentation such as letters of intent and declarations of intent. The full list of documents that constitute responses can be found in the COI (1625–0049).

[118] Ibid.

[119] The relevant COI is 1625–0049. The 150- and 2-hour figures can be seen in *Regulations.Gov* (specifically under *https://www.regulations.gov/docket?D=USCG-2019-0353*), in the supporting document ''1625–0049_SS_r0_2019_calcs-sheet_App-A-to-C'', pages 2–3. In that document, it can be seen that the total hours per response, for both LNG and LHG facilities, is 150 hours for development of Operations Manuals and Emergency Manual Amendments and 2 hours for Operations Manual and Emergency Manual amendments.

burden by 60 hours, from 6,768 hours to 6,708.

Title: Facilities Transferring Oil or Hazardous Materials in Bulk.

OMB Control Number: 1625–0093.

Summary of the Collection of Information: The Operations Manual regulations in 33 CFR 154.300 through 154.325 establish procedures for facilities that transfer oil or hazardous materials, in bulk, to or from a vessel with a capacity of 39.75 cubic meters (250 barrels) or more. The facility operator must submit Operations Manuals and associated amendments to the Coast Guard.

Need for Information: The Coast Guard uses the information in an Operations Manual to ensure that facility personnel follow proper and safe procedures for transferring oil or hazardous materials and to ensure facility personnel follow proper and safe procedures for dealing with any spills that occur during a transfer. Operations Manuals are updated periodically by amendments to ensure they are kept current to reflect changes in procedures, equipment, personnel, and telephone number listings.

Use of Information: The Coast Guard uses this information to monitor compliance with the rule.

Description of the Respondents: Facilities transferring oil or hazardous materials in bulk.

Number of Respondents: This proposed rule would not have any impact on the number of respondents. Based on the Coast Guard's MISLE database, there are currently 2,497 oil and hazardous material facilities operating in the United States and its territories. The electronic submission opportunity in this proposed rule would reduce the number of hours spent printing the manuals and amendments, mailing them to the Coast Guard, updating numerous copies of each manual following amendment, and ensuring the most recent printed version of the manual, with all amendments, is available to the person in charge of transfer operations.

Frequency of Response: The number of responses per year for this proposed rule would vary by participating facilities. The Coast Guard anticipates that each new participant will submit an Operations Manual once when the new facility becomes operational. The operator will submit updates to the Manual whenever there is a significant change. Based on historical information, the Coast Guard expects facilities to submit 261 new Operations Manuals and 442 Operations Manual amendments per year. The number of Letters of Intent Submission are 261, equivalent to the number of Operations Manuals. The current COI assumes that the number of letters of intent equals the number of Operations Manual submissions. These figures are derived from the MISLE database. Hence, the total number of responses are 964 per year.

Burden of Response: The proposed rulemaking gives regulated facilities the option of submitting Operations Manuals and associated amendments to the Coast Guard, at their discretion, in either print or electronic format. For those facilities submitting documentation in electronic format, the burden of response would decrease due to eliminating the need to print and mail these manuals. For facility operators placing electronic copies of their documents at their marine transfer areas, costs associated with printing copies and labor time related to placing them there will be saved.

According to the latest COI, 115 hours are required to prepare an Operations Manual; 16 hours are required to prepare an Operations Manual amendment; and 2 hours are required to submit a Letter of Intent.[120] Assuming that there are 261 Operations Manual submissions, 442 Operations Manual amendments submissions, and 261 Letters of Intent, the total annual burden hours associated with the assumptions in that COI are 37,609.[121]

The proposed rulemaking would reduce the burden hours for facilities because it will permit them to submit their documentation in electronic format and permit them to store their documents at their marine transfer areas in electronic format. The estimated burden hours reduced as a result is 528 hours per year.

Estimate of Total Annual Burden: The proposed rule would decrease the total burden hours by 528, from 37,609 hours to 37,081 per year.

As required by 44 U.S.C. 3507(d), we will submit a copy of this proposed rule to OMB for its review of the collection of information.

We ask for public comment on the proposed revisions to the existing collection of information to help us determine, among other things—

- How useful the information is;
- Whether the information can help us perform our functions better;
- How we can improve the quality, usefulness, and clarity of the information;
- Whether the information is readily available elsewhere;
- How accurate our estimate is of the burden of collection;
- How valid our methods are for determining the burden of collection; and
- How we can minimize the burden of collection.

If you submit comments on the collection of information, submit them to both the OMB and to the docket where indicated under **ADDRESSES**.

You need not respond to a collection of information unless it displays a currently valid control number from OMB. Before the Coast Guard could enforce the collection of information requirements in this proposed rule, OMB would need to approve the Coast Guard's request to collect this information.

E. Federalism

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

This proposed rule amends the Operations Manual and Emergency Manual submission procedures and COTP approval process for facilities that transfer LNG, LHG, oil, or hazardous material to or from a vessel in bulk. These proposed changes involve procedural requirements for the Coast Guard's own approval process, safety risk analysis, and appeal process for a facility that transfers LNG, LHG, oil, or hazardous material in bulk. The changes proposed in this NPRM do not conflict with State interests. For individual States, or their political subdivisions, any requirements for facilities to submit their Operations or Emergency Manuals to them for review or approval would be unaffected by this proposed rule.

Pursuant to 46 U.S.C. 70011(b)(1), Congress has expressly authorized the Coast Guard to establish ''procedures, measures and standards for the handling, loading, unloading, storage, stowage and movement on a structure of explosives or other dangerous articles and substances, including oil or hazardous material.'' The Coast Guard affirmatively preempts any State rules related to these procedures, measures, and standards (*See United States* v. *Locke,* 529 U.S. 89, 109–110 (2000)).

[120] OMB Control Number: 1625–0093.

[121] The current COI states that the Letters of Intent submissions equal the number of Operation Manual submissions.

Therefore, because the States may not regulate within these categories, this proposed rule is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

The Coast Guard recognizes the key role that State and local governments may have in making regulatory determinations. Additionally, for rules with federalism implications and preemptive effect, Executive Order 13132 specifically directs agencies to consult with State and local governments during the rulemaking process. If you believe this proposed rule would have implications for federalism under Executive Order 13132, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

F. Unfunded Mandates

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 million (adjusted for inflation) or more in any one year. Although this proposed rule would not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

G. Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights).

H. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, (Civil Justice Reform), to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this proposed rule under Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks). This proposed rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

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.

K. Energy Effects

We have analyzed this proposed rule under Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use). We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

L. Technical Standards

The National Technology Transfer and Advancement Act, codified as a note to 15 U.S.C. 272, directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01, Rev. 1, associated implementing instructions and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have 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. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

This proposed rule would be categorically excluded under paragraphs A3 (part d) and L54 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. Paragraph A3 (part d) pertains to the promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures that interpret or amend an existing regulation without changing its environmental effect, and paragraph L54 pertains to regulations which are editorial or procedural. This proposed rule involves allowing facilities that transfer oil, hazardous materials, LNG, or LHG in bulk to submit and maintain the facility Operations Manuals and Emergency Manuals electronically or in print, and would amend the COTP examination procedures for those documents, thus enabling electronic communication between the facility operators and the Coast Guard, which would reduce the time and cost associated with mailing printed manuals. This action is consistent with the Coast Guard's port and waterway security and marine safety missions. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects

33 CFR Part 127

Fire prevention, Harbors, Hazardous substances, Natural gas, Reporting and recordkeeping requirements, Security measures.

33 CFR Part 154

Alaska, Fire prevention, Hazardous substances, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 156

Hazardous substances, Oil pollution, Reporting and recordkeeping requirements, Water pollution control.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR parts 127, 154, and 156 as follows:

PART 127—WATERFRONT FACILITIES HANDLING LIQUEFIED NATURAL GAS AND LIQUEFIED HAZARDOUS GAS

■ 1. The authority citation for part 127 is revised to read as follows:

Authority: 46 U.S.C. 70034; 46 U.S.C. Chapter 701; Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 127.019 as follows:
■ a. Revise paragraphs (a) and (b);
■ b. Redesignate paragraphs (c) and (d) as paragraphs (d) and (e);

■ c. Add new paragraph (c); and
■ d. Revise newly redesignated paragraphs (d) and (e).

The additions and revisions read as follows:

§ 127.019 Operations Manual and Emergency Manual: Procedures for examination.

(a) The owner or operator of an active facility must submit an Operations Manual and Emergency Manual in printed or electronic format to the COTP of the zone in which the facility is located.

(b) At least 30 days before transferring LHG or LNG, the owner or operator of a new or an inactive facility must submit an Operations Manual and Emergency Manual in printed or electronic format to the Captain of the Port of the zone in which the facility is located, unless the manuals have been examined and there have been no changes since that examination.

(c) Operations Manuals and Emergency Manuals submitted after [INSERT DATE 30 DAYS AFTER PUBLICATION OF FINAL RULE] must include a date, revision date or other identifying information generated by the facility.

(d) If the COTP finds that the Operations Manual meets § 127.305 or § 127.1305 and that the Emergency Manual meets § 127.307 or § 127.1307, the COTP will provide notice to the facility stating each manual has been examined by the Coast Guard. This notice will include the revision date of the manual or other identifying information generated by the facility.

(e) If the COTP finds that the Operations Manual or the Emergency Manual does not meet this part, the COTP will notify the facility with an explanation of why it does not meet this part.

■ 3. In § 127.309, revise the introductory text and paragraph (a) to read as follows:

§ 127.309 Operations Manual and Emergency Manual: Use.

The operator must ensure that—

(a) LNG transfer operations are not conducted unless the person in charge of transfer for the waterfront facility handling LNG has in the marine transfer area a readily available printed or electronic copy of the most recently examined Operations Manual and Emergency Manual;

* * * * *

■ 4. In § 127.1309, revise the introductory text and paragraph (a) to read as follows:

§ 127.1309 Operations Manual and Emergency Manual: Use.

The operator must ensure that—

(a) LHG transfer operations are not conducted unless the person in charge of transfer for the waterfront facility handling LHG has a printed or electronic copy of the most recently examined Operations Manual and Emergency Manual readily available in the marine transfer area;

* * * * *

PART 154—FACILITIES TRANSFERRING OIL OR HAZARDOUS MATERIAL IN BULK

■ 5. The authority citation for part 154 is revised to read as follows:

Authority: 33 U.S.C. 1321(j)(1)(C), (j)(5), (j)(6), and (m)(2); 46 U.S.C. 70011, 70034; sec. 2, E.O. 12777, 56 FR 54757; Department of Homeland Security Delegation No. 0170.1. Subpart F is also issued under 33 U.S.C. 2735. Vapor control recovery provisions of Subpart P are also issued under 42 U.S.C. 7511b(f)(2).

■ 6. Amend § 154.300 as follows:
■ a. Revise the introductory text of paragraph (a) and add paragraph (a)(4);
■ b. In paragraphs (b) and (c), remove the word ''shall'' and add, in its place, the word ''must''; and
■ c. Revise paragraphs (d), (e), and (f).

The additions and revisions read as follows:

§ 154.300 Operations manual: General.

(a) The facility operator of each facility to which this part applies must submit to the COTP of the zone(s) in which the facility operates, with the letter of intent, an Operations Manual in printed or electronic format that:

* * * * *

(4) After [INSERT DATE 30 DAYS AFTER PUBLICATION OF FINAL RULE], includes a date, revision date, or other identifying information generated by the facility.

* * * * *

(d) In determining whether the manual meets the requirements of this part and part 156 of this chapter, the COTP will consider the products transferred and the size, complexity, and capability of the facility.

(e) If the manual meets the requirements of this part and part 156 of this chapter, the COTP will provide notice to the facility stating the manual has been examined by the Coast Guard as described in § 154.325. The notice will include the date, revision date of the manual, or other identifying information generated by the facility.

(f) The facility operator must ensure printed or electronic copies of the most recently examined Operations Manual, including any translations required by paragraph (a)(3) of this section, are readily available for each facility person in charge while conducting a transfer operation.

* * * * *

■ 7. Amend § 154.320 as follows:
■ a. Revise paragraphs (a), (b)(1) and (2), (c) introductory text, and (c)(1) and (2);
■ b. Remove paragraphs (c)(3) and (4); and
■ c. Add paragraph (e).

The additions and revisions read as follows:

§ 154.320 Operations manual: Amendment.

(a) Using the following procedures, the COTP may require the facility operator to amend the operations manual if the COTP finds that the operations manual does not meet the requirements in this subchapter:

(1) The COTP will notify the facility operator in writing of any inadequacies in the Operations Manual. The facility operator may submit information, views, and arguments regarding the inadequacies identified, and proposals for amending the Manual, in print or electronically, within 45 days from the date of the COTP notice. After considering all relevant material presented, the COTP will notify the facility operator of any amendment required or adopted, or the COTP will rescind the notice. The amendment becomes effective 60 days after the facility operator receives the notice, unless the facility operator petitions the Commandant to review the COTP's notice, in which case its effective date is delayed pending a decision by the Commandant. Petitions to the Commandant must be submitted in writing via the COTP who issued the requirement to amend the Operations Manual.

(2) If the COTP finds that there is a condition requiring immediate action to prevent the discharge or risk of discharge of oil or hazardous material that makes the procedure in paragraph (a)(1) of this section impractical or contrary to the public interest, the COTP may issue an amendment effective on the date the facility operator receives notice of it. In such a case, the COTP will include a brief statement of the reasons for the findings in the notice. The owner or operator may petition the Commandant to review the amendment, but the petition does not delay the amendment.

(b) * * *

(1) Submitting any proposed amendment and reasons for the amendment to the COTP in printed or electronic format not less than 30 days before the requested effective date of the proposed amendment; or

(2) If an immediate amendment is needed, requesting the COTP to examine the amendment immediately.

(c) The COTP will respond to proposed amendments submitted under paragraph (b) of this section by:

(1) Notifying the facility operator that the amendments have been examined by the Coast Guard; or

(2) Notifying the facility operator of any inadequacies in the operations manual or proposed amendments, with an explanation of why the manual or amendments do not meet the requirements of this subchapter.

* * * * *

(e) Amendments may be submitted as page replacements or as an entire manual. When an entire manual is submitted, the facility operator must highlight or otherwise annotate the changes that were made since the last version examined by the Coast Guard. A revision date or other identifying information generated by the facility must be included on the page replacements or amended manual.

■ 8. Amend § 154.325 as follows:

■ a. Remove paragraph (a);

■ b. Redesignate paragraphs (b) through (g) as paragraphs (a) through (f); and

■ c. Revise newly redesignated paragraphs (a) through (d).

The revisions read as follows:

§ 154.325 Operations manual: Procedures for examination.

(a) Not less than 60 days prior to the first transfer operation, the operator of a new facility must submit, with the letter of intent, an Operations Manual in printed or electronic format to the COTP of the zone(s) in which the facility is located.

(b) After a facility is removed from caretaker status, not less than 30 days prior to the first transfer operation, the operator of that facility must submit an Operations Manual in printed or electronic format to the COTP of the zone in which the facility is located, unless the manual has been previously examined and no changes have been made since the examination.

(c) If the COTP finds that the Operations Manual meets the requirements of this part and part 156 of this chapter, the COTP will provide notice to the facility stating the manual has been examined by the Coast Guard. The notice will include the date, revision date of the manual, or other identifying information generated by the facility.

(d) If the COTP finds that the Operations Manual does not meet the requirements of this part or part 156 of this subchapter, the COTP will notify the facility with an explanation of why the manual does not meet the requirements of this subchapter.

* * * * *

PART 156—OIL AND HAZARDOUS MATERIAL TRANSFER OPERATIONS

■ 9. The authority citation for part 156 is revised to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 3703, 3703a, 3715, 70011, 70034; E.O. 11735, 3 CFR 1971–1975 Comp., p. 793; Department of Homeland Security Delegation No. 0170.1.

■ 10. Revise § 156.120(t)(2) to read as follows:

§ 156.120 Requirements for transfer.

* * * * *

(t) * * *

(2) Has readily available in the marine transfer area a printed or electronic copy of the most recently examined facility operations manual or vessel transfer procedures, as appropriate; and

* * * * *

Dated: November 9, 2020.

R.V. Timme,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Prevention Policy.

[FR Doc. 2020–25192 Filed 11–25–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0556]

RIN 1625–AA11

Regulated Navigation Area; Sparkman Channel, Tampa, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to remove an existing regulated navigation area in Sparkman Channel, located in Tampa, FL. The regulated navigation area is no longer needed to protect vessels navigating in the area. This proposed action would remove the existing regulations related to restricting vessel draft in the channel due to an underwater pipeline that is no longer a navigational concern. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before December 28, 2020.

ADDRESSES: You may submit comments identified by docket number USCG–2020–0556 using the Federal eRulemaking Portal at *https://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 Lieutenant Clark Sanford, Sector St Petersburg, Coast Guard; telephone (813) 228–2191 x8105, email *Clark.W.Sanford@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, Purpose, and Legal Basis

On January 25, 1991, the Coast Guard established a regulated navigation area in Sparkman Channel. The regulated navigation area is described in 33 CFR 165.752. The regulated navigation area was created to restrict navigation in the area to vessels with a draft of less than 34.5 feet. A recent survey places the sewer line at or below the permitted depth of 42 feet. The navigation hazard is properly marked on the water surface as well as on navigation charts. With the advancement in technologies and mechanical innovations coupled with the expertise of the pilots that guide vessels in and around Port Tampa Bay, the current restricted navigation area along Sparkman Channel has become outdated.

The purpose of this rulemaking is to remove unnecessary navigation regulations in Tampa, Florida that are no longer needed to ensure the safety of vessels and the navigable waters within Sparkman Channel. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

III. Discussion of Proposed Rule

The Coast Guard is proposing to remove the existing regulated navigation area established in 33 CFR 165.752. This regulation placed restrictions on vessel navigation in Sparkman Channel in Tampa, Florida based on vessel drafts. 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.

A. Regulatory Planning and 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, of 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 (OMB) has not designated this proposed rule a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. Because this proposed rule is not a significant regulatory action, it is exempt from the requirements of Executive Order 13771. See the OMB Memorandum titled ''Guidance Implementing Executive Order 13771, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (April 5, 2017).

The Coast Guard proposes to revise its regulations by removing the existing regulated navigation area established in 33 CFR 165.752. This regulation placed restrictions on vessel navigation in Sparkman Channel in Tampa, Florida based on vessel drafts.

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 Sparkman Channel may be small entities, for the reasons stated in section IV.A above, this proposed rule would 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 call or email 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 call or email 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, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have 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 proposed rule involves removing existing regulations established in 33 CFR 165.752. Normally such actions are categorically excluded from further review under paragraph L60(b) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Memorandum for Record supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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 *https://www.regulations.gov.* If your material

cannot be submitted using *https://www.regulations.gov,* call or email 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 *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *https://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 Record keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing 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; 33 CFR 1.01–1, 6.04–1, and 160.5; Department of Homeland Security Delegation No. 01070.1.

§ 165.752 [Removed]

■ 2. Remove § 165.752.

Dated: October 29, 2020.

Eric C. Jones,

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

[FR Doc. 2020–25654 Filed 11–25–20; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL PERMITTING IMPROVEMENT STEERING COUNCIL

40 CFR Chapter IX

[FPISC Case 2020–001; Docket No. 2020–0018; Sequence No. 1]

RIN 3121–AA01

Adding Mining as a Sector of Projects Eligible for Coverage Under Title 41 of the Fixing America's Surface Transportation Act

AGENCY: Federal Permitting Improvement Steering Council.

ACTION: Proposed rule.

SUMMARY: The Federal Permitting Improvement Steering Council (Permitting Council) proposes to add mining as a sector with infrastructure projects eligible for coverage under Title 41 of the Fixing America's Surface Transportation Act (FAST–41). Current FAST–41 sectors include renewable and conventional energy production, electricity transmission, surface transportation, aviation, ports and waterways, water resource projects, broadband, pipelines, and manufacturing. The addition of mining as a FAST–41 sector would allow a qualified mining infrastructure project to become a FAST–41 covered project. FAST–41 coverage does not predetermine the outcome of any Federal decision making process, but is intended to improve the timeliness, predictability, and transparency of the Federal environmental review and authorization processes for covered infrastructure projects.

DATES: Please send your comments on this proposal to the Permitting Council Office of the Executive Director on or before December 28, 2020.

ADDRESSES: You may send comments, identified by FPISC Case 2020–001, or RIN 3121–AA01, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for sending comments.
- *Mail:* Federal Permitting Improvement Steering Council, Office of the Executive Director, 1800 G St. NW, Suite 2400, Washington, DC 20006, Attention: RIN 3121–AA01.

Instructions: Please submit comments only and cite FPISC Case 2020–001 in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov* approximately two-to-three business days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: John G. Cossa, General Counsel, Federal Permitting Improvement Steering Council, 1800 G St. NW, Suite 2400, Washington, DC 20006, *john.cossa@fpisc.gov,* or by telephone at 202–255–6936. Persons who use a telecommunications device for the deaf may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact this individual during normal business hours or to leave a message at other times. FIRS is available 24 hours a day, seven days a week. You will receive a reply to a message during normal business hours.

SUPPLEMENTARY INFORMATION: Title 41 of the Fixing America's Surface Transportation Act (FAST–41), 42 U.S.C. 4370m *et seq.,* established the Federal Permitting Improvement Steering Council (Permitting Council), which comprises the Permitting Council Executive Director; 13 Federal agency council members (including the designees of the Secretaries of Agriculture, Army, Commerce, Interior, Energy, Transportation, Defense, Homeland Security, and Housing and Urban Development, the Administrator of the Environmental Protection Agency, and the Chairmen of the Federal Energy Regulatory Commission, Nuclear Regulatory Commission, and the Advisory Council on Historic Preservation); and additional council members, the Chairman of the Council on Environmental Quality (CEQ) and the Director of the Office of Management and Budget (OMB). 42 U.S.C. 4170m–1(a) & (b). The Permitting Council and the procedural provisions of FAST–41 can improve the timeliness, predictability, and transparency of the Federal environmental review and authorization processes for ''covered'' infrastructure projects. *See* 42 U.S.C. 4370m–2, 4370m–4. The FAST–41 statute provides that infrastructure projects in the following 10 sectors are eligible for FAST–41 coverage: (1) Renewable energy production; (2) conventional energy production; (3) electricity transmission; (4) surface transportation; (5) aviation; (6) ports and waterways; (7) water resource projects; (8) broadband; (9) pipelines; and (10) manufacturing. 42 U.S.C. 4370m(6)(A). FAST–41 authorizes the Permitting Council to designate additional sectors by majority vote of the Permitting Council members.

To qualify for FAST–41 coverage, an infrastructure project in a FAST–41 sector must be located in the United States and require environmental review and authorization by a Federal agency. *Id.* A project also must: (i) Be subject to review under the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.;* (ii) be likely to require a total investment of $200 million or more; and (iii) not qualify for abbreviated authorization or environmental review processes under any applicable law. 42 U.S.C. 4370m(6)(A)(i). Alternatively, a project in a FAST–41 sector could qualify for FAST–41 coverage if: (i) It is subject to

NEPA; and (ii) in the opinion of the Permitting Council, the size and complexity of the project make it likely to benefit from the enhanced oversight and coordination provided by FAST–41, including projects likely to require environmental review and authorization from multiple agencies or projects for which the preparation of an environmental impact statement (EIS) is required. 42 U.S.C. 4370m(6)(A)(ii). Projects that are subject to the Department of Transportation's procedures for Efficient Environmental Reviews for Project Decisionmaking pursuant to 23 U.S.C. 139, and projects subject to the Department of the Army's Project Acceleration Procedures pursuant to 33 U.S.C. 2348, cannot become FAST–41 covered projects. 42 U.S.C. 4370m(6)(B); *see also* 49 U.S.C. 24201 (Requiring Department of Transportation to apply its Efficient Environmental Reviews for Project Decisionmaking procedures to certain railroad projects, thereby precluding those projects from FAST–41 coverage). The Permitting Council applies the FAST–41 covered project eligibility requirements consistent with OMB M–17–14, *Guidance to Federal Agencies Regarding the Environmental Review and Authorization Process for Infrastructure Projects* (FAST–41 Guidance), issued jointly by CEQ and OMB on January 17, 2017 pursuant to 42 U.S.C. 4370m–1(c)(1)(D).[1]

The Permitting Council proposes to add mining to the list of FAST–41 sectors identified in 42 U.S.C. 4370m(6)(A). This addition would enable sponsors of qualified mining projects to seek the same FAST–41 coverage currently available to qualified projects in the statutorily identified FAST–41 sectors. After considering the comments received in response to this proposed rule, the Permitting Council will vote on the proposal to include mining as a FAST–41 sector. If a majority of the councilmembers vote in favor of including mining, the Permitting Council will promulgate a final rule at 40 CFR part 1900 that adds mining as a FAST–41 sector. The Permitting Council seeks public comment on this proposal and will address all substantive comments that it receives in response to this proposal in the **Federal Register** notice for any final rule.

Designating mining as a FAST–41 sector is not a determination that any particular mining project will qualify as a FAST–41 covered project and does not predetermine the outcome of the Federal decision making process with respect to any covered project. FAST–41 is a voluntary program governed by the eligibility criteria in 42 U.S.C. 4370m(6) and the procedural requirements of 42 U.S.C. 4370m–2 and 4370m–4. To become a FAST–41 covered project, a mining project sponsor, like project sponsors in the other FAST–41 sectors, must first demonstrate that its project meets the criteria for coverage pursuant to 42 U.S.C. 4370m(6) by submitting a notice of the initiation of a proposed covered project (also known as a FAST–41 Initiation Notice or ''FIN'') to the Permitting Council Executive Director and the appropriate facilitating or lead agency. 42 U.S.C. 4370m–2(a)(1). Within 14 days of receiving the FIN, the Permitting Council Executive Director must create an entry for the project on the Permitting Dashboard,[2] which means that the project is a FAST–41 covered project, unless the Executive Director or the facilitating or lead agency determines that the project does not meet the statutory covered project criteria. 42 U.S.C. 4370m–2(b)(2)(A)(ii).

Substantively, FAST–41 provides for timely Federal agency review, enhanced interagency coordination, predictability, and accountability in the Federal decision making process for covered projects, and certain legal protections. Participation in the FAST–41 program can provide covered project sponsors with increased certainty of timely Federal action in accordance with publicly available project-specific permitting timetables. 42 U.S.C. 4370m–2; see Permitting Dashboard at *https://www.permits.performance.gov/*. FAST–41 provides for early coordination of agencies' schedules and synchronization of environmental reviews and related authorizations without altering the substance or scope of those Federal agency efforts. 42 U.S.C. 4370m(4) (Coordination of required reviews). It provides mechanisms for resolving interagency disputes and disputes involving the project sponsor. 42 U.S.C. 4370m–2(c)(2)(C) (Dispute resolution). FAST–41 further ensures agency accountability and transparency by providing clear processes and notice requirements for altering project permitting milestones and timetables. 42 U.S.C. 4370m–2(c)(2)(D) (Modification after approval). The statute also provides certain legal protections, such as a two-year limitations period for claims related to agency authorizations for covered projects, and specific criteria for granting injunctive relief. 42 U.S.C. 4370m–6 (Litigation, judicial review, and savings provision).

FAST–41 does not mandate or predetermine any substantive result in the permitting process. The provisions of FAST–41 do not supersede or alter any internal procedure or decision making authority of any Federal agency or official. *See* 42 U.S.C. 4370m–6(d)(2); *id.* 4370m–6(d)(i) (FAST–41 does not supersede, amend, or modify any Federal statute or affect the responsibility of any Federal agency officer to comply with or enforce any statute); *id.* 4370m–6(e)(i) (''Nothing in this section preempts, limits, or interferes with . . . any practice of seeking, considering, or responding to public comment''); *id.* 4370m–6(e)(ii) (''Nothing in [FAST–41] preempts, limits, or interferes with . . . any power, jurisdiction, responsibility, or authority that a Federal, State, or local governmental agency, metropolitan planning organization, Indian tribe, or project sponsor has with respect to carrying out a project or any other provisions of law applicable to any project, plan, or program.''); *see also id.* 4370m–11 (NEPA is not amended by FAST–41). Accordingly, designating mining as a FAST–41 sector will not grant any permit, authorization, or approval for a covered project. *See* 42 U.S.C. 4370m–6(d)(2) (''Nothing in [FAST–41] . . . creates a presumption that a covered project will be approved or favorably reviewed by any agency'').

The Permitting Council has twice voted on proposals to include mining as a FAST–41 sector. On May 14, 2019, the Permitting Council voted in favor of a proposal to add as a FAST–41 sector mining projects that involve construction of infrastructure for extraction of locatable minerals, leasable minerals, and saleable minerals located on Federal lands. On January 15, 2020, the Permitting Council voted in favor of a refined proposal to add as a FAST–41 sector only ''non-energy mining'' because, in the Permitting Council's view, it was unnecessary to extend duplicative FAST–41 coverage to mining projects that were eligible for coverage under the statutory FAST–41 sectors, such as the conventional energy sector. The January 2020 vote also expanded the scope of the proposed sector to cover non-energy mining on non-Federal as well as Federal lands, and to include mining for critical minerals. The Permitting Council has determined that it would be appropriate to solicit and consider public comments on this topic before adding mining as a FAST–41 sector.

[1] Available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/m-17-14.pdf*.

[2] Available at *https://www.permits.performance.gov/*.

Specifically, the Permitting Council proposes to designate all mining as a FAST–41 sector. This proposed designation includes mining on and off federally managed lands, mining of federally managed and non-Federally managed minerals, and mining of any mineral, ore, or raw material extracted from the ground, regardless of whether such mineral, ore, or raw material is used for energy production, manufacturing, or any other purpose. Oil and gas exploration and production are not included in the proposed FAST–41 mining sector.

The FAST–41 statute does not provide or imply that a project must fall within only one FAST–41 sector. Indeed, a number of projects currently covered under FAST–41 are eligible for coverage under a number of FAST–41 sectors. For example, a project involving a natural gas pipeline and a coastal liquefied natural gas export facility could be covered under the statutory ''conventional energy production,'' ''pipelines,'' or ''ports and waterways'' sectors. A natural gas pipeline project could be covered under either the ''conventional energy production'' or ''pipelines'' sectors. Likewise, a uranium mining project could be covered under either the ''conventional energy production'' or the proposed ''mining'' sector described herein. As with the other FAST–41 sectors, the Permitting Council will decide at the time of coverage which sector is most appropriate for the specific project proposed. *See* FAST–41 Guidance at 19–21.

The purpose of this proposed rule, like the Permitting Council's previous vote on the proposal to add ''non-energy mining,'' is to ensure that any qualified mining sector projects that are not part of a statutory FAST–41 sector have the option to become FAST–41 covered projects. Accordingly, the Permitting Council proposes to add ''mining'' as a FAST–41 sector. The Permitting Council also proposes to define ''mining'' for the purpose of 42 U.S.C. 4370m(6)(A) as the process of extracting ore, minerals, or raw materials from the ground. As a result, projects (i) ''that involve the construction of infrastructure,'' (ii) to extract ore, minerals, or raw materials from the ground, and (iii) that meet the other ''covered project'' criteria of 42 U.S.C. 4370m(6) will be eligible for FAST–41 coverage.

The Permitting Council continues to believe that, like the other FAST–41 sectors, mining, including non-energy mining, is an important infrastructure sector. Mining projects also can involve the construction of significant infrastructure, involve substantial investment, and, in certain circumstances, necessitate extensive Federal review and authorization. Accordingly, like qualified projects from the statutory FAST–41 sectors, mining projects that satisfy the other requirements of 42 U.S.C. 4370m(6) could benefit from the enhanced interagency coordination and permitting timeline predictability provided by FAST–41 coverage. Extending FAST–41 coverage to qualified mining projects is consistent with Executive Order (E.O.) 13807, Establishing Discipline and Accountability in the Environmental Review and Permitting Process for Infrastructure Projects, 82 FR 40463 (Aug. 14, 2017) and E.O. 13817, A Federal Strategy to Ensure Secure and Reliable Supplies of Critical Minerals, 82 FR 60,835 (Dec. 20, 2017).

I. Economic Analysis

Adding mining as a sector with infrastructure projects eligible for coverage under FAST–41could result in improved timeliness, predictability, and transparency associated with the projects that ultimately become FAST–41 covered projects, and for the Federal agencies participating in the FAST–41 process for those covered projects. *See* Permitting Council, FAST–41 Annual Report to Congress for FY 2019, and related documents, *available at https://www.permits.performance.gov/fpisc-content/fast-41-annual-report-congress-fy-2019.* However, quantifying any potential economic benefits that might result from adding mining as a FAST–41 sector is speculative. Simply providing the option of FAST–41 coverage to qualified mining projects does not indicate how many, if any, mining project FINs will be submitted to the Permitting Council for coverage or how many projects ultimately will be covered. Nor does it guarantee that any economic benefits would result from such coverage, particularly given that the permitting and environmental review requirements and permitting timetables for each covered project are unique.

Although the Permitting Council cannot predict how many mining projects may become covered projects, the number will be small. The eligibility criterion for FAST–41 coverage is selective; only the largest projects that are the most prepared for Federal review may become covered projects. *See* 42 U.S.C. 4370m(6) (definition of ''covered project'' including $200 million project value threshold or alternative permitting complexity requirement); 4370m–2(c)(1)(A) & (B)(ii), 4370m–2(c)(2)(A) (sponsors must provide agencies with information sufficient to create a comprehensive and complete project permitting timetable within 60 days of initial project coverage); FAST–41 Guidance, Sec. 3 (project description must be sufficient at the outset to facilitate appropriate level of analysis under NEPA and interagency coordination on all required permits/authorizations). Since FAST–41's enactment in 2015, a total of 52 projects have been covered. Of these projects, only 20 were covered as the result of successfully submitted FINs that met the FAST–41 coverage criteria. The remaining 34 projects were statutorily covered as pending projects immediately after the enactment of FAST–41 pursuant to 43 U.S.C. 4370m–1(c)(1)(A)(i) and 4370m–2(b)(2)(A)(i). The 20 successfully submitted FINs include one conventional energy production project, one electricity transmission project, two pipeline projects, one ports and waterways project, 13 renewable energy production projects, and two water resource projects.

Adding mining as a FAST–41 sector likely will result in only a small number of new covered projects through 2022. Since the enactment of FAST–41 in 2015, the Permitting Council has received fewer than five FINs for projects that involve mining that may potentially have been eligible for coverage under the statutory FAST–41 sectors (*e.g.,* conventional energy). But all of these FINs either were rejected for failing to meet other FAST–41 eligibility criteria or were withdrawn by the project sponsor for other reasons. The Permitting Council anticipates receiving very few—likely 10 or fewer—additional project FINs through 2022 as a result of adding mining as a FAST–41 sector, particularly given that the FAST–41 program is currently scheduled to sunset in 2022 (42 U.S.C. 4370m–12). Moreover, based on historical experience, only a portion of the newly submitted FINs likely will become covered projects. It is therefore unlikely that adding mining to the 10 statutory FAST–41 sectors will result in the coverage of a substantial number of new projects.

Designating mining as a FAST–41 sector could result in reduced costs for any mining project sponsor that obtains FAST–41 coverage for its project and for the Federal agencies with review and permitting responsibilities for the covered project by virtue of potentially improved timeliness, predictability, and transparency, associated increased Federal agency coordination, and reduced duplication of Federal and project sponsor effort. However, these benefits are difficult to quantify,

particularly given that the Federal permitting and environmental review requirements and the permitting timetable for each project are unique and vary widely from project to project. Because the Permitting Council does not know in advance how many projects will be covered as FAST–41 mining projects, what the permitting or environmental review requirements might be for any potential future covered mining project, or what opportunities might exist to coordinate any Federal agency reviews that might be necessary for any such covered mining project, it is impossible to predict with any specificity what, if any, economic benefit might broadly accrue as a result of designating mining as a FAST–41 sector.

The proposal to add mining as a FAST–41 sector will not directly increase or decrease the costs to agencies of complying with the substantive provisions of FAST–41, although there will be costs to the Permitting Council associated with any additional project that might become a covered project.

FAST–41 does not impose any regulatory requirements on covered project sponsors; FAST–41 implementation obligations fall primarily on the government. However, because FAST–41 is a voluntary program, sponsors of mining projects potentially eligible for FAST–41 coverage would incur some costs associated with seeking FAST–41 coverage. These costs associated with a request to be a covered project likely will be small. Seeking FAST–41 coverage involves formulating and submitting a project FIN, which is expected to take only a few hours. *See* 42 U.S.C. 4370m–2(a)(i)(C). Because the Permitting Council anticipates receiving few additional project FINs as a result of adding mining as a FAST–41 sector, and the burden associated with preparing a FIN is minimal, the additional economic cost associated with adding mining as a FAST–41 sector, if any, would be negligible, and likely would be counterbalanced by the benefits of FAST–41 coverage.

II. Procedural Matters

A. Regulatory Planning and Review (E.O. 12866) and Improving Regulation and Regulatory Review (E.O. 13563)

This action is a significant regulatory action that was submitted to OMB for review.

B. Reducing Regulation and Controlling Regulatory Costs (E.O. 13771)

This proposed rule is expected to be an E.O. 13771 deregulatory action. A discussion of the potential economic benefits of this proposed rule can be found in the rule's economic analysis.

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

Congress enacted the RFA to ensure that government regulations do not unnecessarily or disproportionately burden small entities. Small entities include small businesses, small governmental jurisdictions, and small not-for-profit enterprises. The RFA generally requires that Federal agencies prepare a regulatory flexibility analysis for regulatory proposals that are subject to the notice and comment rulemaking requirements of 5 U.S.C. 503 if the proposal would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. *See* 5 U.S.C. 601–612. Pursuant to 5 U.S.C. 605(b), the Permitting Council certifies that the proposal to provide the option of FAST–41 coverage for qualified mining projects that are not already eligible for FAST–41 coverage under any of the statutory FAST–41 sectors will not have a significant economic impact on a substantial number of small entities.

As explained in the Economic Analysis section of this proposal, the Permitting Council anticipates that the addition of mining as a FAST–41 sector will result in the submission of 10 or fewer mining project FINs, at least some of which, based on the Permitting Council's past experience with project FINs that involve mining, likely will not become FAST–41 covered projects. Though the Permitting Council does not conduct an analysis of the business structures of FAST–41 project sponsors to determine whether they are small entities, it is possible that at least some of the 10 or fewer project sponsors that submit FINs for mining projects could be small entities. The Permitting Council reviewed the Small Business Administration size standards for small businesses across the mining industry, and, depending on the nature of the minerals mined, the threshold for small North American Industry Classification System (NAICS) Sector-21 mining entities ranges from below 250 employees (for anthracite, or uranium-radium-vanadium ore mining) to below 1,500 employees (for underground bituminous coal mining and gold mining). The small entity threshold for other forms of hardrock and ''other'' mining projects falls within this range. However, because 10 or fewer entities likely will be affected, the Permitting Council does not anticipate that adding mining as a FAST–41 sector will affect a substantial number of small entities.

Nor will adding mining as a FAST–41 sector significantly or disproportionately impose costs on any small entity that is affected by the rule. The requirements for submitting a project FIN are simple and not burdensome. The FAST–41 statute only requires the project sponsor to formulate and send to the Permitting Council and the lead or facilitating agency a project FIN that contains: (1) A statement of the purpose and objectives of the project; (2) a description of the general project location; (3) any available geospatial information about project and environmental, cultural, and historic resource locations; (4) a statement regarding the technical and financial ability of the project sponsor to construct the proposed project; (5) a statement of any Federal financing, environmental reviews, and authorizations anticipated to be required to complete the proposed project; and (6) an assessment that the proposed project meets the definition of a covered project pursuant to 42 U.S.C. 4370m(6)(A) with supporting rationale. 42 U.S.C. 4370m–2(a)(1)(A) & (C). Any project sponsor credibly seeking Federal authorization and environmental review for a project that requires $200 million or more in investment will have the information required to submit a successful project FIN readily available, and preparing and submitting a project FIN should require only a few hours of effort. FAST–41 contains no pre-FIN requirements (although project sponsors are free to consult the Permitting Council with any questions about the FAST–41 program and FIN preparation or submission), and there are no regulations implementing FAST–41 that impose any additional requirements on the project sponsor. The lead or facilitating agency (and in some instances, the Executive Director) will review the FIN in accordance with sections 4.4–4.12 of the FAST–41 Guidance to determine whether the project is a FAST–41 covered project. *See* Fast-41 Guidance at 30–34. If the project is a covered project, FAST–41 imposes no requirements or obligations on the project sponsor that are additional to those imposed by the substantive Federal authorization or environmental review statutes that otherwise apply to the project. As explained in the Economic Analysis

section of this proposal, any potential economic benefits that might accrue to a covered project sponsor by virtue of the project's FAST–41 covered status are speculative and project-specific. Accordingly, adding mining as FAST–41 sector will not significantly affect a substantial number of small entities, and the RFA does not apply.

C. Congressional Review Act

The proposed rule is not a ''major rule'' as defined under 5 U.S.C. 804(2) because it will not cause a major increase in costs or prices for consumers, individual industries, Federal, state, or local government agencies, or geographic regions. The proposal will not have an annual effect on the economy of $100 million or more.

D. Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1501 et seq.

The proposed rule does not impose an unfunded mandate on state, local, or tribal governments, or on the private sector of more than $100 million per year. The rule does not have a significant or unique effect on state, local, or tribal governments or the private sector. Therefore, a statement containing the information required by the UMRA is not required. The proposed rule also is not subject to the requirements of UMRA section 203 because it contains no regulatory requirements that might significantly or uniquely affect small governments. The proposed rule contains no requirements that apply to small governments, nor does it impose obligations upon them.

E. Federalism (E.O. 13132)

This action does not have federalism implications under E.O. 13132. The proposed rule will not have a substantial direct effect on the states, on the relationship between the Federal government and the states, or on the distribution of power and responsibilities among the levels of government. The proposal affects only the eligibility of mining project proponents to participate in the voluntary FAST–41 program; it will not affect the obligations or rights of states or local governments or state or local governmental entities.

F. Civil Justice Reform (E.O. 12988)

This proposal complies with section 3(a) of E.O. 12988, which requires agencies to review all rules to eliminate errors and ambiguity and to write all regulations to minimize litigation. This rule also meets the criteria of section 3(b)(2), which requires agencies to write all regulations in clear language with clear legal standards.

III. Paperwork Reduction Act

The proposed rule does not involve an agency request for information, nor does it require an information response subject to Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The proposal would not alter any of the other FAST–41 eligibility criteria or implementation of FAST–41, and does not change the information collected from project sponsors seeking FAST–41 coverage. The proposal could result in a small increase in the number of project sponsors submitting FINs to the Permitting Council.

IV. National Environmental Policy Act

NEPA requires agencies to consider the reasonably foreseeable environmental consequences of major Federal actions significantly affecting the quality of the human environment. The proposed rule does not make any project-level decisions and does not authorize any activity or commit resources to a project that may affect the environment. Furthermore, under FAST–41 all eligible covered projects are subject to NEPA review (42 U.S.C. 4370m(6)(A)).

FAST–41 focuses on facilitating interagency coordination and agency accountability for meeting self-imposed environmental review and permitting timetables and providing certain legal protections for covered projects. The statute expressly does not supersede NEPA or affect any internal procedure or decision-making authority of any agency. *See* 42 U.S.C. 4370m–6(d)(2); 42 U.S.C. 4370m–6(d)(i) (FAST–41 does not supersede, amend, or modify any Federal statute or affect the responsibility of any Federal agency officer to comply with or enforce any statute); 42 U.S.C. 4370m–6(e)(i) (''Nothing in this section preempts, limits, or interferes with . . . any practice of seeking, considering, or responding to public comment''); 42 U.S.C. 4370m–6(e)(2) (''Nothing in [FAST–41] preempts, limits, or interferes with . . . any power, jurisdiction, responsibility, or authority that a Federal, State, or local governmental agency, metropolitan planning organization, Indian tribe, or project sponsor has with respect to carrying out a project or any other provisions of law applicable to any project, plan, or program.''); 42 U.S.C. 4370m–11 (providing that FAST–41 does not amend NEPA). Because FAST–41 coverage does not alter or affect the discretion of any agency to approve or deny any permit or authorization for any project, extending potential FAST–41 eligibility to otherwise qualified mining projects does not make any mining project more or less likely to be permitted, authorized, or constructed, or any environmental effect that may be associated with such a project to occur. *See* 42 U.S.C. 4370m–6(d)(2) (''Nothing in [FAST–41] . . . creates a presumption that a covered project will be approved or favorably reviewed by any agency'').

V. Effects on the Energy Supply (E.O. 13211)

This proposed rule is not a significant energy action for the purposes of E.O. 13211 because it will not have any discernible effect on the energy supply. As noted above, qualified energy-related mining projects such as coal and uranium are eligible for coverage under FAST–41's ''conventional energy production'' sector. The only additive effect of the proposal would be to make mining projects that are unrelated to energy production (and not covered under other statutory FAST–41 sectors) eligible for coverage under FAST–41.

Adding mining as a FAST–41 sector will not extend FAST–41 coverage to any specific project—energy related or otherwise—nor will it permit or authorize any mining project. Qualified applicants must first seek and obtain FAST–41 coverage. Participation in the FAST–41 program does not alter any agency's existing discretion to approve or deny project permits or authorizations, and does not make ultimate project authorization more or less likely. Accordingly, the proposal to add mining as a FAST–41 sector will not affect the supply, distribution, or use of energy, and is not a ''significant energy action'' for the purpose of E.O. 13211.

List of Subjects in 40 CFR Part 1900

Critical infrastructure, Infrastructure, Mines, Mineral resources, Permitting, Reporting and recordkeeping requirements, Underground mining.

Nicholas Falvo,

Attorney Advisor, Federal Permitting Improvement Steering Council.

For the reasons stated in the preamble, under the authority of 42 U.S.C. 4370m *et seq.,* FPISC proposes to add chapter IX to title 40 of the Code of Federal regulations as set forth below:

CHAPTER IX—FEDERAL PERMITTING IMRPOVEMENT STEERING COUNCIL

■ 1. Add chapter IX to read as follows:

PART 1900—FEDERAL PERMITTING IMPROVEMENT

Sec.
1900.1 Definitions.
1900.2 FAST–41 Sectors.

Authority: 42 U.S.C. 4370m *et seq.*

1900.1 Definitions.

For the purposes of this part, the following terms shall have the meaning indicated:

FAST–41 means Title 41 of the Fixing America's Surface Transportation Act, 42 U.S.C. 4370m *et seq*.

Federal Permitting Improvement Steering Council or *Permitting Council* means the Federal agency established pursuant to 42 U.S.C. 4370m-1(a).

Mining means the process of extracting ore, minerals, or raw materials from the ground. *Mining* does not include the process of extracting oil or natural gas from the ground.

1900.2 FAST–41 Sectors.

Pursuant to 42 U.S.C. 4370m(6)(A), the Federal Permitting Improvement Steering Council has added the following sectors to the statutorily defined list of FAST–41 sectors:

(a) Mining.

[FR Doc. 2020–25235 Filed 11–25–20; 8:45 am]

BILLING CODE 6820–PL–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A

Request for Information (RFI) on Redundant, Overlapping, or Inconsistent Regulations

AGENCY: Immediate Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The Immediate Office of the Secretary (IOS) is issuing this Request for Information (RFI) to assist the Department in identifying redundant, overlapping, or inconsistent regulations.

DATES: To be considered, responses and comments must be received electronically, at the email address provided below, no later than 11:59 p.m., Eastern on December 21, 2020, and will be reviewed on a rolling basis during this period.

ADDRESSES: Responses must be submitted electronically, and should be addressed to *DuplicativeRegulations@hhs.gov*.

SUPPLEMENTARY INFORMATION: The Chief of Staff for the Department has issued a policy statement entitled ''Avoiding Duplicative Regulation.'' In the policy statement, the Chief of Staff noted that redundant, overlapping, or inconsistent regulations undermine agency and regulatory goals by injecting uncertainty, creating potentially conflicting regulatory regimes, and increasing transaction costs with no discernible benefit to the public. The policy statement also placed new requirements on HHS agencies to avoid duplicative regulation. This Request for Information seeks input from the public on how HHS may improve its regulations, to include regulations issued by any HHS office or agency. HHS plans to use comments from the public to improve existing regulations, and eliminate unnecessary or duplicative regulations through future exercise of rulemaking authority. Specifically, responders may address one or more of the topics below:

1. Any HHS regulations that are redundant with other HHS regulations, and how HHS could best eliminate such redundancies.

2. Any HHS regulations that are inconsistent with other HHS regulations, and how HHS could best resolve any inconsistencies.

3. Any HHS regulations that overlap with federal regulation issued by another HHS office or agency in a manner that creates confusion or uncertainty, and how HHS could best address potential problems caused by such overlapping HHS regulations.

4. Challenges faced by you, your company or others when trying to comply with redundant, overlapping, or inconsistent HHS regulations and the impact or result of facing such challenges.

Collection of Information Requirements: This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. However, this document does contain a general solicitation of comments in the form of a request for information. In accordance with implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Brian Harrison,

Chief of Staff, Department of Health and Human Services.

[FR Doc. 2020–26022 Filed 11–24–20; 8:45 am]

BILLING CODE 4150–03–P

Notices

Federal Register
Vol. 85, No. 229
Friday, November 27, 2020

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc No. AMS–FGIS–20–0065]

United States Standards for Beans

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Reopening of comment period.

SUMMARY: Notice is hereby given that the comment period for a notice for comment published in the **Federal Register** on September 29, 2020 is reopened. The publication invited comments on the revision to the method of interpretation for determining ''sample grade criteria,'' as it pertains to the class ''Blackeye beans,'' in the U.S. Standards for Beans under the United States Agricultural Marketing Act (AMA).

DATES: The comment period for the proposed rule published on September 29, 2020 at 85 FR 60957 is reopened. Comments are due by January 11, 2021.

ADDRESSES: We invite you to submit written comments via the internet at *http://www.regulations.gov.* All comments should refer to the date and page number of this issue of the **Federal Register**. All comments submitted in response to the notice, including the identity of individuals or entities submitting comments, will be made available to the public on the internet via *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Loren Almond, USDA AMS; Telephone: (816) 891–0422; Email: *Loren.L.Almond@usda.gov.*

SUPPLEMENTARY INFORMATION: On September 29, 2020, AMS published a notice seeking comment on a proposal to amend the Bean Inspection Handbook. The proposal would revise the ''sample grade criteria,'' as it pertains to the class ''Blackeye beans.'' The proposed revision would remove clean-cut weevil-bored beans as a sample grade factor and change the sample grade tolerances for insect webbing or filth to a percent of 0.10 or more. The original 30-day comment period provided in the proposed rule closed on October 29, 2020. A stakeholder submitted a comment requesting an extension of the comment period. The Agricultural Marketing Service is reopening the public comment period for an additional 30 days to ensure that interested persons have sufficient time to review and comment on the notice for comment. The comment period is reopened for 30 days from the date of publication of this notice.

(Authority: 7 U.S.C. 1621–1627)

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–26207 Filed 11–25–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc No. AMS–FGIS–20–0067]

United States Standards for Split Peas

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Reopening of comment period.

SUMMARY: Notice is hereby given that the comment period for a notice for comment published in the **Federal Register** on September 29, 2020 is reopened. The publication invited comments on the revision to the method of interpretation for determining ''whole peas'' under the authority of the Agricultural Marketing Act (AMA).

DATES: The comment period for the proposed rule published September 29, 2020 at 85 FR 60955 is reopened. Comments are due by December 28, 2020.

ADDRESSES: We invite you to submit written comments via the internet at *http://www.regulations.gov.* All comments should refer to the date and page number of this issue of the **Federal Register**. All comments submitted in response to the notice, including the identity of individuals or entities submitting comments, will be made available to the public on the internet via *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Loren Almond, USDA AMS; Telephone: (816) 891–0422; Email: *Loren.L.Almond@usda.gov.*

SUPPLEMENTARY INFORMATION: A notice seeking comment on a proposal to amend the Pea and Lentil Inspection Handbook to revise the definition of whole peas, by increasing the percent needed to consider a split pea to be a whole pea from 55 percent or more to 60 percent or more, under the authority of the AMA (7 U.S.C. 1621–1627), was published in the **Federal Register** on September 29, 2020 (85 FR 60955). The original 30-day comment period provided in the proposed rule closed on October 29, 2020. A stakeholder submitted a comment requesting an extension of the comment period. The Agricultural Marketing Service is reopening the public comment period for an additional 30 days to ensure that interested persons have sufficient time to review and comment on the notice for comment. The comment period is reopened for 30 days from the date of publication of this notice.

Authority: 7 U.S.C. 1621–1627.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–25808 Filed 11–25–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 23, 2020.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of

appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 28, 2020 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: National Veterinary Service Laboratories; Bovine Spongiform Encephalopathy Surveillance Program.

OMB Control Number: 0579–0409.

Summary of Collection: The Animal Health Protection Act (AHPA) of 2002 (7 U.S.C. 8301–8317) is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary, to prevent the spread of any livestock or poultry pest or disease. APHIS' National Veterinary Services Laboratories (NVSL) safeguard U.S. animal health and contribute to public health by ensuring that timely and accurate laboratory support is provided by their nationwide animal health diagnostic system. USDA complies with the standard set by the World Organization for Animal Health for bovine spongiform encephalopathy surveillance.

Need and Use of the Information: APHIS will collect information using forms VS 17–146 and VS 17–146a, BSE Surveillance Submission Form/Continuation Sheet and VS 17–131, BSE Surveillance Data Collection Form. APHIS will use the information collected to safeguard the U.S. animal health population against BSE. Without the information APHIS would be unable to monitor and prevent the incursion of BSE into the United States.

Description of Respondents: Business or other for-profit; State, Local or Tribal Government.

Number of Respondents: 1,099.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 2,565.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2020–26195 Filed 11–25–20; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0108]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Importation of Poultry Meat and Other Poultry Products From Sinaloa and Sonora, Mexico; Poultry and Pork Transiting the United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations for the importation of poultry meat and other poultry products from Sinaloa and Sonora and for pork and poultry products transiting the United States.

DATES: We will consider all comments that we receive on or before January 26, 2021.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-*0108.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0108, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0108* or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the importation of poultry meat and other poultry products from Sinaloa and Sonora, Mexico, and poultry and pork transiting the United States, contact Dr. Nathaniel J. Koval, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737; (301) 851–3434. For more information on the information collection process, contact Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Poultry Meat and Other Poultry Products From Sinaloa and Sonora, Mexico; Poultry and Pork Transiting the United States.

OMB Control Number: 0579–0144.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Animal Health Protection Act (7 U.S.C. 8301 *et seq.*) is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict the import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the U.S. Department of Agriculture's Animal and Plant Health Inspection Services' (APHIS') ability to allow U.S. animal producers to compete in the world market of animal and animal product trade. APHIS is the agency charged with carrying out disease prevention by regulating the importation of animals and animal products into the United States. The regulations under which APHIS conducts these disease prevention activities are contained in 9 CFR parts 91 through 99. These regulations govern the importation of animals and animal products.

The regulations in § 94.6 provide the requirements for, among other things, the importation of poultry carcasses, parts, products, and eggs (other than hatching eggs) from regions where Newcastle disease (ND) is considered to exist. However, § 94.15 allows poultry carcasses, parts, products, and eggs (other than hatching eggs) that are not eligible for entry into the United States

to transit the United States via land ports, for immediate export, from certain Mexican States.[1] APHIS believes that allowing such in-transit movements presents a negligible risk of introducing ND into the United States while simultaneously avoiding unnecessary restrictions on trade.

APHIS also currently has regulations in place that restrict the importation of poultry meat and other poultry products from Mexico due to the presence of ND in that country. However, under the regulations in § 94.30, APHIS allows the importation of poultry meat and poultry products from the Mexican States of Sinaloa and Sonora, if imported according to APHIS' requirements, because APHIS has determined that poultry meat and products from these two Mexican States pose a negligible risk of introducing ND into the United States.

To ensure the above commodities are safe for importation, APHIS requires that certain information collection activities take place such as foreign meat inspection certificates, serially numbered seals, applications for import permits, emergency action notification, and pre-arrival notifications.

This collection includes activities associated with the regulations currently in § 94.15 for the transit of pork and pork products from certain Mexican States through the United States, under seal, to export to another country. These regulations were adopted because APHIS considered Mexico, except for certain States, to be affected with classical swine fever (CSF). However, in January 16, 2018, APHIS published a notice (83 FR 2131–2132, APHIS–2016–0038) announcing the addition of Mexico to the list of regions that are considered to be free of CSF, thus eliminating the basis for this regulatory requirement.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.99 hours per response.

Respondents: Federal animal health authorities in Mexico and U.S. importers and exporters of poultry meat, other poultry products, pork, and pork products from Mexico.

Estimated annual number of respondents: 79.

Estimated annual number of responses per respondent: 41.

Estimated annual number of responses: 3,214.

Estimated total annual burden on respondents: 3,212 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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.

Done in Washington, DC, this 23rd day of November 2020.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020–26208 Filed 11–25–20; 8:45 am]

BILLING CODE 3410–34–P

[1] The Mexican States of Campeche, Quintana Roo, and Yucatan can import certain poultry and poultry products into the United States under the restrictions set forth in § 94.33 because they: (1) Supplement their meat supply by importing fresh (chilled or frozen) poultry meat from regions where ND is considered to exist; (2) share a common land border with regions where ND is considered to exist; or (3) import live poultry from regions where ND is considered to exist under conditions less restrictive than would be acceptable for importation into the United States.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0088]

International Sanitary and Phytosanitary Standard-Setting Activities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with legislation implementing the results of the Uruguay Round of negotiations under the General Agreement on Tariffs and Trade, we are informing the public of the international standard-setting activities of the World Organization for Animal Health, the Secretariat of the International Plant Protection Convention, and the North American Plant Protection Organization, and we are soliciting public comment on the standard-setting activities.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0088.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0088, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0088* or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For general information on the topics covered in this notice, contact Ms. Jessica Mahalingappa, Associate Deputy Administrator for International Services, APHIS, Room 1132, USDA South Building, 14th Street and Independence Avenue SW, Washington, DC 20250; (202) 799–7121.

For specific information regarding standard-setting activities of the World Organization for Animal Health, contact Dr. Paul Gary Egrie, Office of International Affairs, Veterinary Services, APHIS, 4700 River Road Unit 33, Riverdale, MD 20737; (301) 851–3304.

For specific information regarding the standard-setting activities of the International Plant Protection Convention, contact Dr. Marina Zlotina, PPQ's IPPC Technical Director, International Phytosanitary Standards, PPQ, APHIS, 4700 River Road Unit 130, Riverdale, MD 20737; (301) 851–2200.

For specific information on the North American Plant Protection Organization, contact Ms. Patricia Abad, PPQ's NAPPO Technical Director, International Phytosanitary Standards, PPQ, APHIS, 4700 River Road Unit 130, Riverdale, MD 20737; (301) 851–2264.

SUPPLEMENTARY INFORMATION:

Background

The World Trade Organization (WTO) was established as the common international institutional framework for governing trade relations among its members in matters related to the Uruguay Round Agreements. The WTO is the successor organization to the General Agreement on Tariffs and Trade. U.S. membership in the WTO was approved by Congress when it enacted the Uruguay Round Agreements Act (Pub. L. 103–465), which was signed into law on December 8, 1994. The WTO Agreements, which established the WTO, entered into force with respect to the United States on January 1, 1995. The Uruguay Round Agreements Act amended Title IV of the Trade Agreements Act of 1979 (19 U.S.C. 2531 *et seq.*). Section 491 of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2578), requires the President to designate an agency to be responsible for informing the public of the sanitary and phytosanitary (SPS) standard-setting activities of each international standard-setting organization. The designated agency must inform the public by publishing an annual notice in the **Federal Register** that provides the following information: (1) The SPS standards under consideration or planned for consideration by the international standard-setting organization; and (2) for each SPS standard specified, a description of the consideration or planned consideration of that standard, a statement of whether the United States is participating or plans to participate in the consideration of that standard, the agenda for U.S. participation, if any, and the agency responsible for representing the United States with respect to that standard.

''International standard'' is defined in 19 U.S.C. 2578b as any standard, guideline, or recommendation: (1) Adopted by the Codex Alimentarius Commission (Codex) regarding food safety; (2) developed under the auspices of the World Organization for Animal Health (OIE, formerly known as the Office International des Epizooties) regarding animal health; (3) developed under the auspices of the Secretariat of the International Plant Protection Convention (IPPC or the Convention) and the North American Plant Protection Organization (NAPPO) regarding plant health; or (4) established by or developed under any other international organization agreed to by the member countries of the United States-Mexico-Canada Agreement (USMCA) or the member countries of the WTO.

The President, pursuant to Proclamation No. 6780 of March 23, 1995 (60 FR 15845), designated the Secretary of Agriculture as the official responsible for informing the public of the SPS standard-setting activities of Codex, OIE, IPPC, and NAPPO. The United States Codex Office (USCO), in the United States Department of Agriculture's (USDA's) Trade and Foreign Affairs mission area, informs the public of standard-setting activities of Codex, and USDA's Animal and Plant Health Inspection Service (APHIS) informs the public of OIE, IPPC, and NAPPO standard-setting activities.

USCO publishes an annual notice in the **Federal Register** to inform the public of SPS standard-setting activities for Codex (85 FR 34161). Codex was established in 1963 by two United Nations organizations, the Food and Agriculture Organization and the World Health Organization. It is the principle international organization for establishing food standards that protect consumer health and promote fair practices in food trade.

APHIS is responsible for publishing an annual notice of OIE, IPPC, and NAPPO activities related to international standards for plant and animal health and representing the United States with respect to these standards. Following are descriptions of the OIE, IPPC, and NAPPO organizations and the standard-setting agenda for each of these organizations. We have described the agenda that each of these organizations will address at their annual general sessions, including standards that may be presented for adoption or consideration, as well as other initiatives that may be underway at the OIE, IPPC, and NAPPO.

The agendas for these meetings are subject to change, and the draft standards identified in this notice may not be sufficiently developed and ready for adoption as indicated. Also, while it is the intent of the United States to support adoption of international standards and to participate actively and fully in their development, it should be recognized that the U.S. position on a specific draft standard will depend on the acceptability of the final draft. Given the dynamic and interactive nature of the standard-setting process, we encourage any persons who are interested in the most current details about a specific draft standard or the U.S. position on a particular standard-setting issue, or in providing comments on a specific standard that may be under development, to contact APHIS. Contact information is provided at the beginning of this notice under **FOR FURTHER INFORMATION CONTACT**.

OIE Standard-Setting Activities

The OIE was established in Paris, France, in 1924 with the signing of an international agreement by 28 countries. It is currently composed of 182 Members, each of which is represented by a delegate who, in most cases, is the chief veterinary officer of that country or territory. The WTO has recognized the OIE as the international forum for setting animal health standards, reporting global animal disease events, and presenting guidelines and recommendations on sanitary measures relating to animal health.

The OIE facilitates intergovernmental cooperation to prevent the spread of contagious diseases in animals by sharing scientific research among its Members. The major functions of the OIE are to collect and disseminate information on the distribution and occurrence of animal diseases and to ensure that science-based standards govern international trade in animals and animal products. The OIE aims to achieve these through the development and revision of international standards for diagnostic tests, vaccines, and the safe international trade of animals and animal products.

The OIE provides annual reports on the global distribution of animal diseases, recognizes the free status of Members for certain diseases, categorizes animal diseases with respect to their international significance, publishes bulletins on global disease status, and provides animal disease control guidelines to Members. Various OIE commissions and working groups undertake the development and preparation of draft standards, which are then circulated to Members for consultation (review and comment). Draft standards are revised accordingly and are presented to the OIE World Assembly of Delegates (all the Members) for review and adoption during the General Session, which meets annually every May. Adoption, as a general rule, is based on consensus of the OIE membership.

The most recent OIE General Session was scheduled to occur from May 24 to 29, 2020, in Paris, France. The Associate Administrator for APHIS serves as the official U.S. Delegate to the OIE. Information about OIE draft Terrestrial and Aquatic Animal Health Code chapters may be found on the internet at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_international_standard_setting_activities_oie* or by

contacting Dr. Paul Gary Egrie (see **FOR FURTHER INFORMATION CONTACT** above).

The COVID–19 situation worldwide did not allow the OIE to have its General Session in 2020, and consequently no Code chapters were presented for adoption. The corresponding chapters will be proposed for adoption during the General Session tentatively scheduled for May 2021.

- Chapter 1.1., *Notification of diseases, infections and infestations, and provision of epidemiological information.*
- Chapter 1.4.3., *Animal Health Surveillance.*
- Chapter 1.6., *Procedures for self-declaration and for official recognition by the OIE.*
- Chapter 3.2., *Evaluation of Veterinary Services.*
- Chapter 3.4., *Veterinary legislation.*
- Chapter 4.Y., *Draft new chapter on official control programs for listed and emerging diseases.*
- Chapter 7.Z., *Draft new chapter on animal welfare and laying hen production systems.*
- Chapter 8.Y., *Infection with animal trypanosomes of African origin.*
- Chapter 8.15., *Infection with Rift Valley fever virus.*
- Chapter 9.4, Article 9.4.5., *Infestation with Aethina tumida (small hive beetle).*
- Chapter 10.4., *Infection with avian influenza viruses.*
- Chapter 15.2., *Infection with classical swine fever virus.*
- Articles 14.7.3., 14.7.7., 14.7.24. and 14.7.34., *Infection with peste des petits ruminants virus.*

IPPC Standard-Setting Activities

The IPPC is a multilateral convention adopted in 1952 to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control. The WTO recognizes the IPPC as the standard setting body for plant health. Under the IPPC, the understanding of plant protection encompasses the protection of both cultivated and non-cultivated plants from direct or indirect injury by plant pests. The IPPC addresses the following activities: Developing, adopting, and implementing international standards for phytosanitary (plant health) measures (ISPMs); harmonizing phytosanitary activities through adopted standards; facilitating the exchange of official and scientific information among contracting parties; and providing technical assistance to developing countries that are contracting parties to the Convention.

The IPPC is deposited within the Food and Agriculture Organization of the United Nations and is an international agreement of 184 contracting parties. National plant protection organizations (NPPOs), in cooperation with regional plant protection organizations, the Commission on Phytosanitary Measures (CPM), and the Secretariat of the IPPC, implement the Convention. The IPPC continues to be administered at the national level by plant quarantine officials, whose primary objective is to safeguard plant resources from injurious pests. In the United States, the NPPO is APHIS' Plant Protection and Quarantine (PPQ) program.

Because of the COVID–19 pandemic, the 15th Session of the CPM was tentatively postponed to 2021.

Standards recommended for adoption in 2020 will be tabled for adoption in 2021, and are listed below. The United States develops its position on each of these draft standards prior to the CPM session based on APHIS' analyses and other relevant information from other U.S. Government agencies and interested stakeholders:

- Draft Revision of ISPM 8: *Determination of pest status in an area.*
- Draft ISPM: *Requirements for the use of modified atmosphere treatments as phytosanitary measures.*
- Draft ISPM 5: *Glossary of phytosanitary terms* (2018 revisions).

In lieu of the Commission meeting, the CPM Bureau has been advancing the IPPC work program, including standards setting, as actively as possible via virtual means. The IPPC Standards Committee and Implementation and Capacity Development Committee also continued working during the pandemic by virtually approving draft standards for consultation, selecting experts to expert drafting groups, and addressing pending standard setting and other plant health initiatives. The IPPC electronic certification system (ePhyto) solution also progressed in 2020. For example, 27 countries in the European Union joined ePhyto through its own system of electronic certification named TRACES; Argentina and Chile moved to fully electronic operation for all their plant trade; the United Nations International Computing Centre and the ePhyto Steering Committee are developing and providing training on ePhyto; and preparations are underway to deploy features allowing industry systems to receive ePhytos.

New IPPC Standard-Setting Initiatives, Including Those Under Development

A number of expert working group (EWG) meetings and technical consultations took place from October 2019 through September 2020 on the topics listed below. These IPPC projects are currently under development and intended for future adoption and publication. APHIS participated actively and fully in each of these working groups. APHIS developed its position on each of the topics prior to the working group meeting. The APHIS position was based on relevant scientific information and technical analyses, including information from other U.S. Government agencies and from interested stakeholders:

- EWG for the focused revision of ISPM 12: *Phytosanitary certificates* in relation to re-export.
- Working group for the revision of the plant pest surveillance guide.
- Reviewing and commenting on the Implementation Guide to ISPM 8 currently under development.
- Reviewing and commenting on the draft outline of the future Implementation Guide on e-Commerce.
- Technical Panel on Diagnostic Protocols.
- Technical Panel on Phytosanitary Treatments.
- Technical Panel for the Glossary.

For more detailed information on the above, contact Dr. Marina Zlotina (see **FOR FURTHER INFORMATION CONTACT** above).

PPQ actively works to achieve broad participation by States, industry, and other stakeholders in the development and use of international and regional plant health standards, including through the use of APHIS Stakeholder Registry notices [1] and the APHIS public website. Plant health stakeholders are strongly encouraged to comment on draft standards, documents, and specifications during the consultation periods. In 2020, 16 draft standards (including phytosanitary treatments), 3 draft specifications, 1 draft outline, and 1 draft CPM recommendation were open for consultation. APHIS posts links to draft standards on its website as they become available and provides information on the due dates for comments.[2] Additional information on IPPC standards (including the IPPC work program (list of topics [3]), calls for new standards, experts to serve on technical panels and other working

[1] To sign up for the Stakeholder Registry, go to: *https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new.*

[2] For more information on the IPPC draft ISPM consultation: *https://;www.aphis.usda.gov/aphis/ourfocus/planthealth/international/sa_phytostandards/ct_draft_standards.*

[3] IPPC list of topics: *https://www.ippc.int/en/core-activities/standards-setting/list-topics-ippc-standards/.*

groups, proposed phytosanitary treatments, standard-setting process, and adopted standards) is available on the IPPC website.[4] For the most current information on official U.S. participation in IPPC activities, including U.S. positions on standards being considered, contact Dr. Marina Zlotina (see **FOR FURTHER INFORMATION CONTACT** above). Those wishing to provide comments on any of the areas of work being undertaken by the IPPC may do so at any time by responding to this notice (see **ADDRESSES** above) or by providing comments through Dr. Zlotina.

NAPPO Standard-Setting Activities

NAPPO, a regional plant protection organization created in 1976 under the IPPC, coordinates the efforts among the United States, Canada, and Mexico to protect their plant resources from the entry, establishment, and spread of harmful plant pests, while facilitating safe intra- and inter-regional trade. As the NPPO of the United States, APHIS' PPQ is the organization officially identified to participate in NAPPO. Through NAPPO, APHIS works closely with its regional counterparts and industries to develop harmonized regional standards and approaches for managing pest threats. This critical work facilitates the safe movement of plants and plant products into and within the region. NAPPO conducts its work through priority-driven projects approved by the NAPPO Executive Committee via an annual work program, and conducted by expert groups, including subject matter experts from each member country and regional industry representatives. Project results and updates are provided during the NAPPO annual meeting as well as NAPPO governance meetings. Projects can include the development of positions, policies, technical documents, or the development or revision of regional standards for phytosanitary measures (RSPMs). Projects can also include implementation of standards or other capacity development activities such as workshops.

The 43rd NAPPO annual meeting was held October 28 to November 1, 2019, in Montreal, Canada. The meeting featured several strategic topics related to NAPPO's work program (*e.g.* seeds, forest pests, lab accreditation, plants for planting, biological control, and risk-based sampling), as well as discussions on sea containers, invasive species, the International Year of Plant Health (IYPH), the United States-Mexico-Canada Agreement (USMCA), and a live ePhyto exchange demonstration between the United States and Jamaica. The meeting also featured a 1-day symposium on comparing the decision-making procedures used by the three countries (Canada, Mexico, and the United States) when an exotic plant pest is confirmed in a NAPPO member country. The NAPPO Executive Committee meetings took place on October 28, 2019, and July 16, 2020 (virtual meeting). The Deputy Administrator for PPQ is the U.S. member of the NAPPO Executive Committee.

Despite the COVID–19 pandemic, NAPPO's Secretariat and its member countries, including regulatory, plant health, and industry officials, continue to actively progress on projects and initiatives under the NAPPO work program, taking advantage of teleconferencing and other virtual meeting tools. NAPPO governance committees, including NAPPO's Executive Committee and the Advisory and Management Committee, as well as expert groups, continue to communicate and meet virtually on a regular basis to actively progress on NAPPO strategic and work program initiatives. NAPPO's Advisory and Management Committee continued working during the pandemic by virtually approving draft standards for consultation; selecting and onboarding experts to newly launched NAPPO expert groups on seeds and diagnostics, consignments in transit, and wooden and bamboo commodities; and addressing other pending work program initiatives. The NAPPO expert groups, including member countries' subject matter experts, in collaboration with NAPPO's Secretariat, significantly progressed or finalized the following regional standards, documents, products, and projects during the period of October 2019 to the end of September 2020:

- Reviewed, discussed, and agreed to archive RSPM 17: *Guidelines for the establishment, maintenance and verification of fruit fly free areas in North America.* Experts from all three member countries agreed that more comprehensive international standards have been adopted at the IPPC that effectively build-on and supersede RSPM 17.
- Completed and published proceedings from the NAPPO-organized March 2019, Hemispheric Workshop on ISPM 38: *International movement of seeds.* Proceedings are now available on the NAPPO website.[5]
- Completed the revision or development of the following regional standards and documents and launched them for country consultation (public comment period) during the summer of 2020: RSPM 9: *Authorization of laboratories for performing phytosanitary testing,* RSPM 5: *NAPPO glossary of phytosanitary terms,* and NAPPO Science and Technology (S&T) Document on the risks associated with the introduction of exotic lymantriid species of potential concern to the NAPPO region. As next steps, comments received from the consultation will be reviewed by expert group members to adjust the documents for eventual Executive Committee approval.
- Issued via NAPPO's Phytosanitary Alert System: 23 Official Pest Reports for Fiscal Year 2020 (from October 2019 to September 2020).

In addition, NAPPO conducted a call for new project proposals for its 2020 Work Program during 2019. U.S. stakeholders were invited to submit topics and comment on their priorities through APHIS. In late October 2019, the NAPPO call for new project proposals (taking stakeholders' comments into account) resulted in three new prioritized projects by the NAPPO's Executive Committee, which have been added to the 2020 annual work program. The new, prioritized projects focus on the following topics: The harmonization of diagnostic protocols for seed pests focused on Tomato brown rugose virus (ToBRFV); consignments in transit; and the import of wooden and bamboo commodities.

New NAPPO Standard-Setting Initiatives, Including Those in Development

The 2020 work program[6] includes the following topics being worked on by NAPPO expert groups and NAPPO's Advisory and Management Committee. APHIS is actively and fully participating in the 2020 NAPPO work program. The APHIS position on each topic is guided and informed by the best technical and scientific information available, as well as on relevant input from stakeholders. For each of the following, where applicable, the United States will consider its position on any draft standard after it reviews a prepared draft. Information regarding the following NAPPO projects, assignments, activities, and updates on meeting times and locations may be obtained from the

[4] IPPC website: *https://www.ippc.int/.*

[5] Proceedings of the NAPPO Organized Hemispheric Workshop on ISPM 38: *International movement of seeds: https://nappo.org/application/files/7115/8687/1174/Final__Proceedings_ISPM_38_Implementation_Workshop.pdf.*

[6] NAPPO work program: *https://mail.nappo.org/application/files/5415/8624/3760/FINAL_2020_NAPPO_Work_Program_-e.pdf.*

NAPPO website or by contacting Ms. Patricia Abad (see **FOR FURTHER INFORMATION CONTACT** above).

1. Seed Diagnostics: A pilot for the harmonization of diagnostic protocols for seed pests focused on ToBRFV.

2. Development of harmonized regional guidance for North America based on ISPM 25: *Consignments in transit* and the IPPC Transit Manual.

3. Revision of RSPM 38: *Importation of certain wooden and bamboo commodities into a NAPPO member country.*

4. Revision of RSPM 22: *Guidelines for construction and operation of a containment facility for insects and mites used as biological control agents.*

5. Forest Products: Develop a NAPPO Science and Technology (S&T) document to provide scientific background on live contaminant pests associated with wood commodities and wood packaging; and provide guidance regarding actions appropriate for addressing related phytosanitary risks.

6. Support the IYPH: Exchange ideas, develop appropriate materials, and support IYPH events in the NAPPO region.

7. Revision of RSPM 9: *Authorization of laboratories for performing phytosanitary testing.*

8. Revision of RSPM 35: *Guidelines for the movement of stone and pome fruit trees and grapevines into a NAPPO member country.*

9. Lymantriids: Complete a NAPPO Science and Technology (S&T) document on the risks associated with the introduction of exotic lymantriid species of potential concern to the NAPPO region.

10. Revision of RSPM 5: *NAPPO glossary of phytosanitary terms.*

11. Risk-Based Sampling: Complete and publish a Risk-Based Sampling Manual.

12. Asian Gypsy Moth: Validate specific risk periods for regulated Asian gypsy moth in countries of origin.

13. Foundation and Procedure documents: Continue to update and finalize various NAPPO foundation or procedure documents.

14. Phytosanitary Alert System: Continue to manage the NAPPO pest reporting system.

15. Electronic phytosanitary certification (ePhyto): Provide assistance and technical support to the IPPC ePhyto Steering Group.

16. Stakeholder Engagement: Plan, coordinate and execute activities for the next NAPPO Annual Meeting, and publish the quarterly newsletter. Because of the COVID–19 pandemic, the 2020 NAPPO annual meeting has been postponed to 2021. The 2021 NAPPO annual meeting is expected to take place in the United States (and hosted by APHIS) in accordance with the NAPPO country rotation.

17. Regional Collaboration: Collaboration, focused on information exchange, with the Inter-American Coordinating Group in Plant Protection, via Technical Working Groups on ePhyto, citrus greening (Huanglongbing), fruit flies, and *Tuta absoluta.*

The PPQ Assistant Deputy Administrator, as the official U.S. delegate to NAPPO, intends to participate in the adoption of these regional plant health standards and projects, including the work described above, once they are completed and ready for such consideration.

The information in this notice contains all the information available to us on NAPPO standards or projects under development or consideration. For updates on meeting times and for information on the expert groups that may become available following publication of this notice, visit the NAPPO website or contact Ms. Patricia Abad (see **FOR FURTHER INFORMATION CONTACT** above). PPQ actively works to achieve broad participation by States, industry, and other stakeholders in the development and use of international and regional plant health standards, including through the use of APHIS Stakeholder Registry notices and the APHIS public website. Plant health stakeholders are strongly encouraged to comment on draft standards, documents, and specifications during consultation periods. In 2020, two revised NAPPO standards and one Science & Technology document were open for consultation. APHIS posts links to draft standards on the internet as they become available and provides information on the due dates for comments.[7] Additional information on NAPPO standards (including the NAPPO Work Program, standard setting process, and adopted standards) is available on the NAPPO website.[8] Information on official U.S. participation in NAPPO activities, including U.S. positions on standards being considered, may also be obtained from Ms. Abad. Those wishing to provide comments on any of the topics being addressed in the NAPPO work program may do so at any time by responding to this notice (see **ADDRESSES** above) or by transmitting comments through Ms. Abad.

Done in Washington, DC, this 23rd day of November 2020.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020–26210 Filed 11–25–20; 8:45 am]

BILLING CODE 3410–34–P

[7] For more information on the NAPPO draft RSPM consultation: *https://www.aphis.usda.gov/aphis/ourfocus/planthealth/international/sa_phytostandards/ct_draft_standards.*

[8] NAPPO website: *http://nappo.org/.*

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Illinois 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 and the Federal Advisory Committee Act that the Illinois Advisory Committee (Committee) will hold a meeting via teleconference on Tuesday, December 8, 2020 at 12:00 p.m. Central Time, the purpose of the meeting is for the Committee to approval the report on Fair Housing in Illinois.

DATES: The meeting will be held on Tuesday, December 8, 2020 at 12:00 p.m. Central Time. Public Call Information: Dial: 800–367–2403; Conference ID: 2202630.

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Official, at *dbarreras@usccr.gov* or 202–499–4066.

SUPPLEMENTARY INFORMATION: Members of the public may listen to the discussion. This meeting is available to the public through the call-in information listed above. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement to the Committee as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. 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 also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Carolyn Allen at *callen@usccr.gov.in* the Regional Program Unit Office/Advisory Committee Management Unit. Persons who desire additional information may contact the Regional Program Unit at 202–499–4066.

Records generated from this meeting may be inspected and reproduced at the Chicago office, as they become available, both before and after the meeting. Records of the meeting will be available via *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlZAAQ* under the Commission on Civil Rights, Illinois Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Chicago Office at the above email or phone number.

Agenda:

I. Welcome and Roll Call
II. Discussion: to approve the Committee's report on Fair Housing in Illinois
III. Next Steps
IV. Public Comment
V. Adjournment

Dated: November 23, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–26202 Filed 11–25–20; 8:45 am]

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DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2107]

Approval of Subzone Status; Lake Charles LNG Export Company, LLC; Lake Charles, Louisiana

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Act provides for ''. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of subzones for specific uses;

Whereas, the Lake Charles Harbor and Terminal District, grantee of Foreign-Trade Zone 87, has made application to the Board for the establishment of a subzone at the facility of Lake Charles LNG Export Company, LLC, located in Lake Charles, Louisiana (FTZ Docket B–50–2020, docketed August 5, 2020);

Whereas, notice inviting public comment has been given in the **Federal Register** (85 FR 48503, August 11, 2020) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's memorandum, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, therefore, the Board hereby approves subzone status at the facility of Lake Charles LNG Export Company, LLC, located in Lake Charles, Louisiana (Subzone 87H), as described in the application and **Federal Register** notice, subject to the FTZ Act and the Board's regulations, including Section 400.13.

Dated: November 19, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2020–26180 Filed 11–25–20; 8:45 am]

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DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–49–2020]

Foreign-Trade Zone (FTZ) 183—Austin, Texas Authorization of Production Activity; Flextronics America, LLC (Automated Data Processing Machines), Austin, Texas

On July 24, 2020, Flextronics America, LLC submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 183C, in Austin, 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 (85 FR 47165, August 4, 2020). On November 23, 2020, 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: November 23, 2020.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2020–26232 Filed 11–25–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–971]

Multilayered Wood Flooring From the People's Republic of China: Final Results and Partial Rescission of Countervailing Duty Administrative Review; 2017

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

SUMMARY: The Department of Commerce (Commerce) continues to determine that Baroque Timber Industries (Baroque Timber) and its cross-owned affiliates (Riverside Plywood Corporation and Suzhou Times Flooring Co., Ltd.), and Jiangsu Guyu International Trading Co., Ltd. (Jiangsu Guyu) and its cross-owned affiliates (Jiangsu Shengyu Flooring Co., Ltd., Siyang County Shunyang Wood Co., Ltd., and Shanghai Woyuan Industrial Co., Ltd.), producers and/or exporters of multilayered wood flooring (wood flooring) from the People's Republic of China (China), received countervailable subsidies during the period of review (POR) January 1, 2017 through December 31, 2017.

DATES: Applicable November 27, 2020.

FOR FURTHER INFORMATION CONTACT: Bob Palmer or Suzanne Lam, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9068 or (202) 482–0783, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* of the administrative review in the **Federal Register** on February 6, 2020.[1] We invited interested parties to comment on the *Preliminary Results.*

[1] *See Multilayered Wood Flooring from the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, and Intent to Rescind Review, in Part; 2017,* 85 FR 6908 (February 6, 2020) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

On March 13, 2020, we received case briefs from the following interested parties: Baroque Timber, Jiangsu Guyu, Fine Furniture (Shanghai) Limited and Double F Limited (collectively, Fine Furniture), the Government of the People's Republic of China (GOC), and the American Manufacturers of Multilayered Wood Flooring. On March 24, 2020, we received rebuttal case briefs from Baroque Timber, Jiangsu Guyu, the GOC and the American Manufacturers of Multilayered Wood Flooring. For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[2]

On April 24, 2020, Commerce exercised its discretion to toll all deadlines in administrative reviews by 50 days.[3] On June 5, 2020, we extended the deadline for these final results to September 23, 2020.[4] On July 21, 2020, Commerce tolled all deadlines in administrative reviews by an additional 60 days.[5] Accordingly, the revised deadline for the final results of this review is now November 23, 2020.

Scope of the Order

The product covered by the *Order*[6] is multilayered wood flooring from the PRC. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the parties' briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed is attached to this notice at Appendix I. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of the case and rebuttal briefs and the evidence on the record, we made certain changes from the *Preliminary Results.* Specifically, Commerce changed the plywood benchmark calculation for both respondents and adjusted the import duty rates to exclude import duties for HS categories not used in the plywood benchmark calculation. These changes are explained in the Issues and Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (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.[7] The Issues and Decision Memorandum contains a full description of the methodology underlying Commerce's conclusions, including any determination that relied upon the use of adverse facts available pursuant to sections 776(a) and (b) of the Act.

Partial Rescission of Administrative Review

As noted in the *Preliminary Results,* Commerce timely received no-shipment certifications from Anhui Boya Bamboo Ltd., Anhui Yaolong Bamboo and Wood Products Co. Ltd., Armstrong Wood products (Kunshan) Co. Ltd., Changzhou Hawd Flooring Co. Ltd., Dalian Shengyu Science and Technology Development Co. Ltd., Hunchun Forest Wolf Wooden Industry Co. Ltd., Jiashan On-Line Lumber Co. Ltd., Kingman Floors Co. Ltd., Yingyi-Nature (Kunshan) Wood Industry Co. Ltd., and Zhejiang Shiyou Timber Co. Ltd. We inquired with U.S. Customs and Border Protection (CBP) whether these companies had shipped merchandise to the United States during the POR, and CBP provided no evidence to contradict the claims of no shipments made by these companies. Accordingly, in the *Preliminary Results,* Commerce stated its intention to rescind the review with respect to these companies in the final results. As the facts have remained the same since the *Preliminary Results,* we are rescinding the administrative review of these companies, pursuant to 19 CFR 351.213(d)(3).

Final Results of Administrative Review

In accordance with 19 CFR 351.221(b)(5), we calculated a final countervailable subsidy rate for each of the mandatory respondents, Baroque Timber and Jiangsu Guyu. For the companies subject to this review which were not selected for individual examination, we followed Commerce's practice, which is to base the subsidy rates on an average of the subsidy rates calculated for those companies selected for individual examination, excluding *de minimis* rates or rates based entirely on adverse facts available. In this case, for the non-selected companies, we calculated a rate by weight-averaging the calculated subsidy rates of Baroque Timber and Jiangsu Guyu using their publicly-ranged sales data for exports of subject merchandise to the United States during the POR. We find the countervailable subsidy rates for the producers/exporters under review to be as follows:

Producer/exporter	Subsidy rate (percent)
Baroque Timber Industries (Zhongshan) Co., Ltd. and its Cross-Owned Affiliates[8]	14.09
Jiangsu Guyu International Trading Co., Ltd. and its Cross-Owned Affiliates[9]	122.92
Non-Selected Companies Under Review[10]	20.75

Assessment Rates

Pursuant to 19 CFR 351.212(b)(2), Commerce will determine, and CBP shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review, for the above-listed companies at the applicable *ad valorem* assessment rates listed. We

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2017 Countervailing Duty Administrative Review of Multilayered Wood Flooring from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[4] *See* Memorandum, ''Administrative Review of the Countervailing Duty Order on Multilayered Wood Flooring from the People's Republic of China: Extension of Deadline for Final Results,'' dated June 5, 2020. As the actual (tolled) deadline was Saturday, July 25, 2020, we extended the final results deadline 60 days from this date.

[5] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated April 24, 2020.

[6] *See Multilayered Wood Flooring from the People's Republic of China: Countervailing Duty Order,* 76 FR 76693 (December 8, 2011) (*Order*); *see also Multilayered Wood Flooring from the People's Republic of China: Amended Antidumping and Countervailing Duty Orders,* 77 FR 5484 (February 3, 2012) (*Amended Order*); and *Multilayered Wood Flooring from the People's Republic of China: Final Clarification of the Scope of the Antidumping and Countervailing Duty Orders,* 82 FR 27799 (June 19, 2017).

[7] *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.

[8] Cross-owned affiliates are Riverside Plywood Corp. and Suzhou Times Flooring Co., Ltd.

[9] Cross-owned affiliates are Jiangsu Shengyu Flooring Co., Ltd.; Siyang County Shunyang Wood Co., Ltd.; and Shanghai Woyuan Industrial Co., Ltd.

[10] *See* Appendix II.

intend to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

For the companies for which this review is rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the POR in accordance with 19 CFR 351.212(c)(l)(i).

Cash Deposit Instructions

Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respective companies listed above 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 administrative review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, effective upon publication of these final results, shall remain in effect until further notice.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to 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 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.

We are issuing and publishing these final results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 20, 2020.

Joseph A. Laroski Jr.,

Deputy Assistant Secretary for Policy and Negotiations.

Appendix I—List of Topics Discussed in the Final Decision Memorandum

Appendix II—Non-Selected Companies Under Review

1. A&W (Shanghai) Woods Co., Ltd.
2. Anhui Longhua Bamboo Product Co., Ltd.
3. Anhui Suzhou Dongda Wood Co., Ltd.
4. Baishan Huafeng Wooden Product Co., Ltd.
5. Baiying Furniture Manufacturer Co., Ltd.
6. Benxi Flooring Factory (General Partnership)
7. Benxi Wood Company
8. Changbai Mountain Development And Protection Zone Hongtu Wood Industrial Co., Ltd.
9. Cheng Hang Wood Co., Ltd.
10. Chinafloors Timber (China) Co., Ltd.
11. Dalian Dajen Wood Co., Ltd.
12. Dalian Deerfu Wooden Product Co., Ltd.
13. Dalian Huade Wood Product Co., Ltd.
14. Dalian Huilong Wooden Products Co., Ltd.
15. Dalian Jaenmaken Wood Industry Co., Ltd.
16. Dalian Jiahong Wood Industry Co., Ltd.
17. Dalian Jinda Wood Products Corporation
18. Dalian Jiuyuan Wood Industry Co., Ltd.
19. Dalian Kemian Wood Industry Co., Ltd.
20. Dalian Meisen Woodworking
21. Dalian Penghong Floor Products Co., Ltd.
22. Dalian Qianqiu Wooden Product Co., Ltd.
23. Dalian Shumaike Floor Manufacturing Co., Ltd.
24. Dalian T-Boom Wood Products Co., Ltd.
25. Dalian Xinjinghua Wood Co., Ltd.
26. Dongtai Fuan Universal Dynamics, LLC
27. Dongtai Zhangshi Wood Industry Co. Ltd.
28. Dun Hua Sen Tai Wood Co., Ltd.
29. Dunhua City Dexin Wood Industry Co., Ltd.
30. Dunhua City Hongyuan Wood Industry Co., Ltd.
31. Dunhua City Jisen Wood Industry Co., Ltd.
32. Dunhua City Wanrong Wood Industry Co., Ltd.
33. Dunhua Shengda Wood Industry Co., Ltd.
34. Fine Furniture (Shanghai) Limited
35. Fu Lik Timber (HK) Co., Ltd.
36. Fujian Wuyishan Werner Green Industry Co., Ltd.
37. Furnco International Shanghai Company
38. Fusong Jinlong Wooden Group Co., Ltd.
39. Fusong Jinqiu Wooden Product Co., Ltd.
40. Fusong Qianqiu Wooden Product Co., Ltd.
41. Gaotang Weilong Industry and Trade
42. Gold Seagull Shanghai Flooring
43. GTP International Ltd.
44. Guangdong Fu Lin Timber Technology Limited
45. Guangdong Yihua Timber Industry Co., Ltd.
46. Guangzhou Homebon Timber Manufacturing Co., Ltd.
47. Guangzhou Panyu Kangda Board Co., Ltd.
48. Guangzhou Panyu Southern Star Co., Ltd.
49. HaiLin LinJing Wooden Products, Ltd.
50. HaiLin XinCheng Wooden Products, Ltd.
51. Hangzhou Dazhuang Floor Co., Ltd. (DBA Dasso Industrial Group Co., Ltd.)
52. Hangzhou Hanje Tee Company Limited
53. Hangzhou Huahi Wood Industry Co., Ltd.
54. Hangzhou Zhengtian Industrial Co., Ltd.
55. Henan Xingwangjia Technology Co., Ltd.
56. Hong Kong Chuanshi International
57. Hong Kong Easoon Wood Technology Co., Ltd.
58. Huaxin Jiasheng Wood Co., Ltd.
59. Huber Engineering Wood Corp.
60. Houzhou Chenchang Wood Co., Ltd.
61. Hunchun Xingja Wooden Flooring Inc.
62. Huzhou City Nanxun Guangda Wood Co., Ltd.
63. Huzhou Daruo Import and Export
64. Huzhou Fulinmen Imp. & Exp. Co., Ltd.
65. Huzhou Fuma Wood Co., Ltd.
66. Huzhou Jesonwood Co., Ltd.
67. Huzhou Laike Import and Export Co
68. Huzhou Muyun Wood Co., Ltd.
69. Huzhou Sunergy World Trade Co., Ltd.
70. Innomaster Home (Zhongshan) Co., Ltd.
71. Jesonwood Forest Products ZJ
72. Jiafeng Wood (Suzhou) Co., Ltd.
73. Jiangsu Kentier Wood Co., Ltd.
74. Jiangsu Keri Wood Co., Ltd.
75. Jiangsu Mingle Flooring Co., Ltd.
76. Jiangsu Senmao Bamboo and Wood Industry Co., Ltd.
77. Jiangsu Simba Flooring Co., Ltd.
78. Jiangsu Yuhui International Trade Co., Ltd.
79. Jiashan Fengyun Timber Co., Ltd.
80. Jiashan HuiJiaLe Decoration Material Co., Ltd.
81. Jiaxing Hengtong Wood Co., Ltd.
82. Jilin Forest Industry Jinqiao Flooring Group Co., Ltd.
83. Jilin Xinyuan Wooden Industry Co., Ltd.
84. Karly Wood Product Limited
85. Kember Flooring, Inc.
86. Kemian Wood Industry (Kunshan) Co., Ltd.
87. Kornbest Enterprises Limited
88. Kunming Alston (AST) Wood Products Co., Ltd.
89. Les Planchers Mercier, Inc.
90. Liaoning Daheng Timber Group
91. Linyi Anying Wood Co., Ltd.
92. Linyi Bonn Flooring Manufacturing Co., Ltd.
93. Linyi Youyou Wood Co., Ltd.
94. Logwin Air and Ocean Hong Kong
95. Max Choice Wood Industry

96. Metropolitan Hardwood Floors, Inc.
97. Mudanjiang Bosen Wood Industry Co., Ltd.
98. Nakahiro Jyou Sei Furniture (Dalian) Co., Ltd.
99. Nanjing Minglin Wooden Industry Co., Ltd.
100. Ningbo Tianyi Bamboo and Wood Products Co., Ltd.
101. Pinge Timber Manufacturing (Zhejiang) Co., Ltd.
102. Power Dekor Group Co., Ltd.
103. Power Dekor North America Inc.
104. PT. Tanjung Kreasi Parquet Industry
105. Qingdao Barry Flooring Co., Ltd.
106. Qingdao Wisdom International
107. Samling Elegant Living Trading (Labuan) Ltd.
108. Samling Riverside Co., Ltd.
109. Scholar Home (Shanghai) New Material Co. Ltd.
110. Shandong Kaiyuan Wood Industry Co., Ltd.
111. Shandong Longteng Wood Co., Ltd.
112. Shandong Puli Trading Co., Ltd.
113. Shanghai Anxin (Weiguang) Timber Co., Ltd.
114. Shanghai Demeija Timber Co., Ltd.
115. Shanghai Eswell Timber Co., Ltd.
116. Shanghai Lairunde Wood Co., Ltd.
117. Shanghai Lizhong Wood Products Co., Ltd. (aka The Lizhong Wood Industry Limited Company of Shanghai)
118. Shanghai New Sihe Wood Co., Ltd.
119. Shanghai Shenlin Corporation
120. Shanghaifloor Timber (Shanghai) Co., Ltd.
121. Shenyang Haobainian Wooden Co., Ltd.
122. Shenyang Sende Wood Co., Ltd.
123. Shenzhenshi Huanwei Woods Co., Ltd.
124. Sino-Maple (Jiangsu) Co., Ltd.
125. Suifenhe Chengfeng Trading Co., Ltd.
126. Sunyoung Wooden Products
127. Suzhou Anxin Weiguang Timber Co., Ltd.
128. Suzhou Dongda Wood Co., Ltd.
129. Tak Wah Building Material (Suzhou) Co.
130. Tech Wood International Ltd.
131. The Greenville Flooring Co., Ltd.
132. Tongxiang Jisheng Import and Export Co., Ltd.
133. Topocean Consolidation Service
134. Vicwood Industry (Suzhou) Co. Ltd.
135. Xiamen Yung De Ornament Co., Ltd.
136. Xuzhou Antop International Trade Co., Ltd.
137. Xuzhou Shenghe Wood Co., Ltd.
138. Yekalon Industry, Inc.
139. Yihua Lifestyle Technology Co., Ltd.
140. Yixing Lion-King Timber Industry
141. Zhejiang Anji Xinfeng Bamboo and Wood Industry Co., Ltd.
142. Zhejiang Biyork Wood Co., Ltd.
143. Zhejiang Dadongwu Auto Elect Motor
144. Zhejiang Dadongwu Green Home Wood Co., Ltd.
145. Zhejiang Desheng Wood Industry Co., Ltd.
146. Zhejiang Fudeli Timber Industry Co., Ltd.
147. Zhejiang Fuerjia Wooden Co., Ltd.
148. Zhejiang Fuma Warm Technology Co., Ltd.
149. Zhejiang Haoyun Wooden Co., Ltd.
150. Zhejiang Jesonwood Co., Ltd.
151. Zhejiang Jiaye Flooring
152. Zhejiang Jiechen Wood Industry Co., Ltd.
153. Zhejiang Longsen Lumbering Co., Ltd.
154. Zhejiang Shuimojiangnan New Material Technology Co., Ltd.
155. Zhejiang Simite Wooden Co., Ltd.
156. Zhejiang Tianzhen Bamboo & Wood Development Co., Ltd.
157. Zhejiang Yongyu Bamboo Joint-Stock Co., Ltd.

[FR Doc. 2020–26230 Filed 11–25–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–854]

Certain Steel Nails From Taiwan: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018–2019

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

SUMMARY: The Department of Commerce (Commerce) determines that certain steel nails from Taiwan were sold in the United States at less than normal value during the period of review (POR), July 1, 2018 through June 30, 2019.

DATES: Applicable November 27, 2020.

FOR FURTHER INFORMATION CONTACT: Irene Gorelik, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6905.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* on April 6, 2020.[1] On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days.[2] On July 21, 2020, Commerce tolled all deadlines in administrative reviews by an additional 60 days.[3] The deadline for the final results of this review is now November 23, 2020.

Scope of the Order[4]

The merchandise covered by this order is certain steel nails. The certain steel nails subject to the order are currently classifiable under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this order also may be classified under HTSUS subheadings 7907.00.60.00, 8206.00.00.00 or other HTSUS subheadings. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[5]

Analysis of Comments Received

In the Issues and Decision Memorandum, we addressed all issues raised in parties' case and rebuttal briefs. In the Appendix to this notice, we provide a list of the issues raised by parties. The Issues and Decision Memorandum is a public document and is on-file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov*. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html*. The signed and the electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our review of the record and comments received from interested parties, we made no changes to our *Preliminary Results,* with the exception of the cash deposit and assessment instructions regarding suspended subject merchandise entries exported by

[1] *See Certain Steel Nails from Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2018–2019,* 85 FR 19138 (April 6, 2020) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[3] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[4] *See Certain Steel Nails from the Republic of Korea, Malaysia, the Sultanate of Oman, Taiwan, and the Socialist Republic of Vietnam: Antidumping Duty Orders,* 80 FR 39994 (July 13, 2015) (*Order*).

[5] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review: Certain Steel Nails from Taiwan; 2018–2019'' dated concurrently with, and hereby adopted by, this notice.

Quick Advance, Inc., and produced by Ko's Nail, Inc., as discussed in the Issues and Decision Memorandum.

Final Determination of No Shipments

In the *Preliminary Results,* Commerce determined that Astrotech Steels Private Limited, Jinhai Hardware Co., Ltd., Region International Co., Ltd., Region Industries, and Region System Sdn Bhd. had no shipments during the POR.[6] As we have not received any information to contradict this determination, consistent with our practice, we will instruct U.S. Customs and Border Protection (CBP) to liquidate any existing entries of subject merchandise produced by these five companies, but exported by other parties, at the rate for the intermediate reseller, if available, or at the all-others rate.

Final Determination of No Reviewable Sales

In the *Preliminary Results,* Commerce determined that Create Trading Co., Ltd. (Create Trading) had no reviewable sales during the POR.[7] As we have not received any information to contradict this determination, we continue to find that Create Trading had no reviewable sales of subject merchandise during the POR. As discussed further in the ''Assessment Rates'' section below, we will instruct CBP to liquidate any existing entries of merchandise produced by Create Trading's unaffiliated producers and exported by Create Trading at the rate applicable to the unaffiliated producers, *i.e.,* the all-others rate.[8]

Rate for Non-Selected Companies

As we stated in the *Preliminary Results,* in accordance with the U.S. Court of Appeals for the Federal Circuit's decision in *Albemarle,*[9] we are applying a rate based on the simple average of the individual rates applied to Bonuts Hardware Logistics Co., LLC (Bonuts) and Pro-Team Coil Nail Enterprise, Inc. (PT) in this administrative review (*i.e.,* 78.17 percent) to the companies not selected for individual examination. Commerce has addressed arguments from various interested parties regarding our preliminary determination and, for the final results, the determination remains unchanged, as discussed in the Issues and Decision Memorandum.

Final Results of the Administrative Review

We have determined the following dumping margins for the firms listed below for the period July 1, 2018 through June 30, 2019:

Exporter/producer	Dumping margin (percent)
Bonuts Hardware Logistics Co., LLC	78.17
PT Enterprise, Inc./Pro-Team Coil Nail Enterprise, Inc	78.17
Review-Specific Average Rate Applicable to Companies Under Review Not Selected for Individual Examination (percent)	
See Appendix II for the 75 companies under review subject to the review-specific average rate[10]	78.17

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.212(b)(1), Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. For these final results, we will instruct CBP to apply an *ad valorem* assessment rate of 78.17 percent to all entries of subject merchandise during the POR which were produced and/or exported by mandatory respondents, Bonuts and PT, and the companies which were not selected for individual examination.

As indicated above, for each company which we determined had ''no shipments'' of the subject merchandise during the POR, we will instruct CBP to liquidate all POR entries associated with these companies at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction, consistent with Commerce's reseller policy.[11]

We determined that Create Trading was not the first party in the transaction chain to have knowledge that the merchandise was destined for the United States, and thus Create Trading is not considered the exporter of subject merchandise during the POR for purposes of this review. In our May 6, 2003, ''automatic assessment'' clarification, we explained that, where respondents in an administrative review demonstrate that they had no knowledge of sales through resellers to the United States, we would instruct CBP to liquidate such entries at the all-others rate applicable to the proceeding. Here, Commerce finds that Create Trading had no shipments of subject merchandise to the United States during the POR for which it was the first party with knowledge of U.S. destination. Because ''as entered'' liquidation instructions do not alleviate the concerns which the May 2003 clarification was intended to address, we find it appropriate in this case to instruct CBP to liquidate any existing entries of merchandise produced by Create Trading's unaffiliated producers and exported by Create Trading.

Finally, based on the *Final Determination* of the underlying investigation and *Order,*[12] no suspension of liquidation is required for entries of subject merchandise exported by Quick Advance, Inc. and produced by Ko's Nail, Inc. because the estimated weighted-average final dumping margin calculated for this transaction channel was zero. Commerce calculated its dumping margin during the investigation based on sales of Quick Advance, Inc. that were produced by Ko's Nail, Inc. Therefore, Quick Advance Inc.'s exclusion from antidumping duty liability and any cash deposit requirement pertains only to the channel(s) of sales that were examined by Commerce in the investigation. Therefore, for any subject merchandise exported by Quick Advance, Inc. that was produced by Ko's Nail, Inc. during the POR, we will instruct CBP to liquidate those POR entries, pertaining to the above-noted channel of sales, without regard to antidumping duties. However, for any entries of subject merchandise exported by Quick Advance Inc., and produced by companies other than Ko's Nail Inc., or produced by Ko's Nail Inc., and exported by companies other than

[6] *See Preliminary Results,* 85 FR at 19139.

[7] *Id.*

[8] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954, 23954 (May 6, 2003) (*Assessment of Antidumping Duties*); *see also Certain Pasta from Turkey: Notice of Preliminary Results of Antidumping Duty Administrative Review,* 76 FR 23974, 23977 (April 29, 2011), unchanged in *Pasta from Turkey: Notice of Final Results of the 14th Antidumping Duty Administrative Review,* 76 FR 68399 (November 4, 2011).

[9] *See Preliminary Results,* 85 FR at 19139 (citing *Albemarle Corp.* v. *United States,* 821 F. 3d 1345 (Fed. Cir. 2016) (*Albemarle*)).

[10] As stated in the Issues and Decision Memorandum and in this notice, this rate does not apply to entries of subject merchandise exported by Quick Advance Inc. *and* produced by Ko's Nail Inc. This exporter-producer channel of sales is excluded from the *Order. See Order,* 80 FR at 39996.

[11] *See, e.g., Magnesium Metal from the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 26922, 26923 (May 13, 2010), unchanged in *Magnesium Metal from the Russian Federation: Final Results of Antidumping Duty Administrative Review,* 75 FR 56989 (September 17, 2010). For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[12] *See Certain Steel Nails From Taiwan: Final Determination of Sales at Less Than Fair Value,* 80 FR 28959, 28961 (May 20, 2015) (*Final Determination*); *see also Order,* 80 FR at 39996.

Quick Advance Inc., the assessment rate will be 78.17 percent.

We intend to issue liquidation instructions to CBP 15 days after the date of publication of this notice.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for the respondents noted above will be the rate established in the final results of this administrative review; (2) for merchandise exported by manufacturers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 2.16 percent, the all-others rate in the less-than-fair-value investigation.[13]

As noted above, no cash deposits are required for entries exported by Quick Advance, Inc. and produced by Ko's Nail, Inc. However, for any entries of subject merchandise exported by Quick Advance, Inc. and produced by companies other than Ko'sNail, Inc. *or* produced by Ko's Nail, Inc. and exported by companies other than Quick Advance, Inc., the cash deposit requirements in the above paragraph will apply. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a final reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: November 20, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Issues
  Comment 1: Commerce's Calculation of the Review-Specific Rate for Non-Examined Companies
  Comment 2: Quick Advance Inc. and Ko's Nail Inc. Exclusion From the Order
V. Recommendation

Appendix II—List of Companies Under Review Not Selected for Individual Examination

1. All Precision Co., Ltd.
2. Aplus Pneumatic Corp.
3. Basso Industry Corporation
4. Challenge Industrial Co., Ltd.
5. Cheng Ch International Co. Ltd.
6. Chia Pao Metal Co. Ltd.
7. China Staple Enterprise Corporation
8. Chite Enterprises Co., Ltd.
9. Crown Run Industrial Corp.
10. Da Yong Enterprise Co., Ltd.
11. Daejin Steel Company Ltd.
12. De Fasteners Inc.
13. Dragon Iron Factory Co., Ltd.
14. Easylink Industrial Co., Ltd.
15. ECI Taiwan Co., Ltd.
16. Encore Green Co., Ltd.
17. Faithful Engineering Products Co. Ltd.
18. Fastenal Asia Pacific Ltd.
19. Four Winds Corporation
20. Gaun Ting Technology Co., Ltd.
21. General Merchandise Consolidators
22. Ginfa World Co. Ltd.
23. Gloex Inc.
24. Home Value Co., Ltd.
25. Hor Liang Industrial Corp.
26. Hoyi Plus Co., Ltd.
27. Integral Building Products Inc.
28. Interactive Corp.
29. J C Grand Corporation
30. Jade Shuttle Enterprise Co., Ltd.
31. Jau Yeou Industry Co., Ltd.
32. Jen Ju Enterprise Co., Ltd.
33. Jet Crown International Co., Ltd.
34. Jiajue Industrial Co. Ltd.
35. Jinsco International Corp.
36. Ko's Nail Inc.[14]
37. Korea Wire Co., Ltd.
38. Liang Chyuan Industrial Co., Ltd.
39. Linkwell Industry Co., Ltd.
40. Locksure Inc.
41. Long Ngyuen Trading & Service Co.
42. Lu Kang Hand Tools Industrial Co., Ltd. (Prommer)
43. Master United Corp.
44. Maytrans International Corp.
45. Ming Cheng Hardware Co., Ltd.
46. Nailermate Enterprise Corporation
47. Nailtech Co., Ltd.
48. Newrex Screw Corporation
49. NS International Ltd.
50. Panther T&H Industry Co.
51. Patek Tool Co., Ltd.
52. Point Edge Corp.
53. President Industrial Inc.
54. Quick Advance Inc.[15]
55. Romp Coil Nail Industries Inc.
56. Shinn Chuen Corp.
57. Six-2 Fastener Imports Inc.
58. Taiwan Shan Yin Int'l Co. Ltd.
59. Taiwan Wakisangyo Co. Ltd.
60. Techart Mechanical Corporation
61. Test-Rite Int'l Co., Ltd.
62. Theps Co., Ltd.
63. Trans-Top Enterprise Co., Ltd.
64. Trim International Inc.
65. U-Can-Do Hardware Corp.
66. UJL Industries Co., Ltd.
67. Unicatch Industrial Co. Ltd.
68. VIM International Enterprise Co., Ltd.
69. Wattson Fastener Group Inc.
70. Wictory Co. Ltd.
71. Yeh Fong Hsin
72. Yehdyi Enterprise Co., Ltd.
73. Yu Chi Hardware Co., Ltd.
74. Zhishan Xing Enterprise Co., Ltd.
75. Zon Mon Co. Ltd.

[FR Doc. 2020–26231 Filed 11–25–20; 8:45 am]

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[13] The all-others rate from the underlying investigation was revised in *Certain Steel Nails from Taiwan: Notice of Court Decision Not in Harmony with Final Determination in Less than Fair Value Investigation and Notice of Amended Final Determination,* 82 FR 55090, 55091 (November 20, 2017).

[14] Where Quick Advance Inc. is the exporter *and* Ko's Nail Inc. is the producer, suspension of liquidation is not required.

[15] Where Quick Advance Inc. is the exporter *and* Ko's Nail Inc. is the producer, suspension of liquidation is not required.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Federal Consistency Appeal by Jordan Cove Energy Project, L.P. and Pacific Connector Gas Pipeline, LP

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice—closure of administrative appeal decision record.

SUMMARY: This announcement provides notice that the decision record has closed for an administrative appeal filed by Jordan Cove Energy Project, L.P. and Pacific Connector Gas Pipeline, LP (collectively, ''Appellants'') under the Coastal Zone Management Act. Appellants have requested that the NOAA Administrator, pursuant to authority delegated by the Secretary of Commerce to decide Coastal Zone Management Act of 1972 (CZMA) federal consistency appeals, override an objection by the Oregon Department of Land Conservation and Development to a consistency certification for a proposed project to construct and operate a liquefied natural gas export terminal and a 229-mile natural gas pipeline and compressor station off the Pacific Coast.

DATES: The decision record for Appellants' Federal consistency appeal of Oregon Department of Land Conservation and Development's objection closed on November 27, 2020.

ADDRESSES: NOAA has provided access to publicly available materials and related documents comprising the appeal record on the following website: *https://www.regulations.gov/docket?D=NOAA-HQ-2020-0058.*

FOR FURTHER INFORMATION CONTACT: For questions about this Notice, contact Rachel Morris, Attorney-Advisor, NOAA Office of the General Counsel, Oceans and Coasts Section, and Patrick Carroll, Attorney-Advisor, NOAA Office of the General Counsel, Oceans and Coasts Section, at *jordancove.appeal@noaa.gov* or (301) 713–7387.

SUPPLEMENTARY INFORMATION: On March 20, 2020, the NOAA Administrator, pursuant to authority delegated by the Secretary of Commerce to decide Coastal Zone Management Act of 1972 (CZMA) federal consistency appeals, received a ''Notice of Appeal'' filed by Jordan Cove Energy Project, L.P. and Pacific Connector Gas Pipeline, LP (collectively, ''Appellants'') under the CZMA, 16 U.S.C. 1451 *et seq.,* and implementing regulations found at 15 CFR part 930, subpart H. The Notice of Appeal is taken from an objection by the Oregon Department of Land Conservation and Development to Appellants' consistency certification for a proposed project to construct and operate a liquefied natural gas export terminal and a 229-mile natural gas pipeline and compressor station off the Pacific Coast. This matter constitutes an appeal of an ''energy project'' within the meaning of the CZMA regulations. *See* 15 CFR 930.123(c).

Under the CZMA, the NOAA Administrator may override Oregon Department of Land Conservation and Development's objection on grounds that the project is consistent with the objectives or purposes of the CZMA, or is necessary in the interest of national security. To make the determination that the proposed activity is ''consistent with the objectives or purposes of the CZMA,'' the Department of Commerce must find that: (1) The proposed activity furthers the national interest as articulated in sections 302 or 303 of the CZMA, in a significant or substantial manner; (2) the national interest furthered by the proposed activity outweighs the activity's adverse coastal effects, when those effects are considered separately or cumulatively; and (3) no reasonable alternative is available that would permit the proposed activity to be conducted in a manner consistent with the enforceable policies of the applicable coastal management program. 15 CFR 930.121. To make the determination that the proposed activity is ''necessary in the interest of national security,'' the Department of Commerce must find that a national defense or other national security interest would be significantly impaired if the proposed activity is not permitted to go forward as proposed. 15 CFR 930.122.

The NOAA Administrator must close the decision record in a federal consistency appeal 160 days after the Notice of Appeal is published in the **Federal Register**. 15 CFR 930.130(a)(1). However, the CZMA authorizes the NOAA Administrator to stay the closing of the decision record for up to 60 days when the NOAA Administrator determines it is necessary to receive, on an expedited basis, any supplemental information specifically requested by the NOAA Administrator to complete a consistency review or any clarifying information submitted by a party to the proceeding related to information in the consolidated record compiled by the lead Federal permitting agency. 15 CFR 930.130(a)(2), (3).

In order to solicit supplemental and clarifying information, the NOAA Administrator stayed the closure of the decision record for a total of 60 days. 85 FR 60766 (September 28, 2020). Consistent with the above schedule, the decision record for Appellants' Federal consistency appeal of Oregon's objection closed on November 27, 2020. No further information or briefs will be considered in deciding this appeal.

NOAA has provided access to publicly available materials and related documents comprising the appeal record on the following website: *https://www.regulations.gov/docket?D=NOAA-HQ-2020-0058.*

Adam Dilts,

Chief, Oceans and Coasts Section, NOAA Office of the General Counsel.

[FR Doc. 2020–25721 Filed 11–25–20; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XY074]

Endangered and Threatened Species; Initiation of a 5-Year Review for the Arctic, Okhotsk, Baltic, and Ladoga Subspecies of the Ringed Seal

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

ACTION: Notice of initiation of 5-year review; request for information.

SUMMARY: NMFS announces its intent to conduct a 5-year review of the threatened Arctic (*Pusa hispida hispida*), Okhotsk (*Pusa hispida ochotensis*), Baltic (*Pusa hispida botnica*), and endangered Ladoga (*Pusa hispida ladogensis*) subspecies of the ringed seal. NMFS is required by the Endangered Species Act (ESA) to conduct 5-year reviews to ensure that listing classifications of species are accurate. The 5-year review must be based on the best scientific and commercial data available at the time of the review. We request submission of any such information on these ringed seal subspecies, particularly information on their status, threats, and recovery, that has become available since their listing on December 28, 2012 (77 FR 76706).

DATES: To allow us adequate time to conduct this review, we must receive your information no later than January 26, 2021. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: Submit your information, identified by docket number NOAA–

NMFS–2020–0014, by either of the following methods:

• *Federal e-Rulemaking Portal.* Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0014,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written information to Jon Kurland, Assistant Regional Administrator for Protected Resources, Alaska Region NMFS, Attn: Records Office. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: NMFS may not consider comments if they are sent by any other method, to any other address or individual, or received after the comment period ends. All comments received are a part of the public record and NMFS will post the comments for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender is publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Tammy Olson, NMFS Alaska Region, 907–271–2373, *tammy.olson@noaa.gov.*

SUPPLEMENTARY INFORMATION: Section 4(c)(2)(A) of the ESA requires that we conduct a review of listed species at least once every 5 years. The regulations in 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing species currently under active review. On the basis of such reviews, under section 4(c)(2)(B) we determine whether a listed species should be delisted, or reclassified from endangered to threatened or from threatened to endangered (16 U.S.C. 1533(c)(2)(B)). As described by the regulations in 50 CFR 424.11(e), the Secretary shall delist a species if the Secretary finds that, after conducting a status review based on the best scientific and commercial data available: (1) The species is extinct; (2) the species does not meet the definition of an endangered species or a threatened species; or (3) the listed entity does not meet the statutory definition of a species. Any change in Federal classification would require a separate rulemaking process.

Another subspecies of ringed seal, the Saimaa seal (*Phoca hispida saimensis*), was listed as an endangered species in 1993 (58 FR 26920; May 6, 1993). NMFS completed a 5-year review for the Saimaa seal on January 11, 2018, so that subspecies is not being included in this 5-year review.

Background information on the ringed seal subspecies listed above is available on the NMFS website at: *http://www.fisheries.noaa.gov/species/ringed-seal.*

Determining if a Species Is Threatened or Endangered

Section 4(a)(1) of the ESA requires that we determine whether a species is endangered or threatened based on one or more of the five following factors: (1) The present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) the inadequacy of existing regulatory mechanisms; or (5) other natural or manmade factors affecting its continued existence. Section 4(b) also requires that our determination be made on the basis of the best scientific and commercial data available after conducting a review of the status of the species and after taking into account those efforts, if any, being made by any State or foreign nation to protect such species.

Public Solicitation of New Relevant Information

To ensure that the 5-year review is complete and based on the best scientific and commercial data available, we are soliciting new information from the public, governmental agencies, Tribes, the scientific community, industry, environmental entities, and any other interested parties concerning the status of Arctic, Okhotsk, Baltic, and Ladoga ringed seals. Categories of requested information include: (1) Species biology including, but not limited to, population trends, distribution, abundance, demographics, and genetics; (2) habitat conditions including, but not limited to, amount, distribution, and important features for conservation; (3) status and trends of threats; (4) conservation measures that have been implemented that benefit the species, including monitoring data demonstrating effectiveness of such measures; (5) need for additional conservation measures; and (6) other new information, data, or corrections including, but not limited to, taxonomic or nomenclatural changes and improved analytical methods for evaluating extinction risk.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: November 23, 2020.

Angela Somma,

Chief, Endangered Species Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2020–26212 Filed 11–25–20; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 201120–0310]

RIN 0648–XH060

Endangered and Threatened Wildlife; 90-Day Finding on a Petition to Delist the Arctic Subspecies of Ringed Seal Under the Endangered Species Act

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

ACTION: Notice; 90-Day petition finding.

SUMMARY: We (NMFS) announce a negative 90-day finding on a petition to delist the Arctic subspecies of ringed seal (*Pusa hispida hispida*) under the Endangered Species Act (ESA). We find that the petition and information readily available in our files does not present new information or analyses that had not been previously considered and therefore does not present substantial scientific or commercial information indicating that the petitioned action may be warranted. Nevertheless, we note that we are separately initiating a five-year review of the status of the Arctic ringed seal pursuant to section 4(c)(2) of the ESA, including whether the best scientific and commercial data available indicate delisting is warranted.

ADDRESSES: Copies of the petition and related materials are available from the NMFS website at *https://www.fisheries.noaa.gov/national/endangered-species-conservation/negative-90-day-findings* or upon request from the Assistant Regional Administrator for Protected Resources, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668.

FOR FURTHER INFORMATION CONTACT: Tamara Olson, NMFS Alaska Region, (907) 271–2373; Jon Kurland, NMFS Alaska Region, (907) 586–7638; or Heather Austin, NMFS Office of Protected Resources, (301) 427–8422.

SUPPLEMENTARY INFORMATION:

Background

On March 26, 2019, we received a petition from the State of Alaska, Arctic Slope Regional Corporation, Iñupiat

Community of the Arctic Slope, and the North Slope Borough to delist the Arctic subspecies of ringed seal under the ESA. On April 30, 2019, we received a letter in support of this petition from the Alaska Oil and Gas Association and the American Petroleum Institute. The petition asserts that new information became available after the species was listed as threatened under the ESA (77 FR 76706; December 28, 2012) and a reanalysis of the information considered in our listing determination for this species demonstrates that our listing decision was in error. The Arctic subspecies of ringed seal is currently listed as threatened under the ESA. Copies of this petition are available from us (see **ADDRESSES**, above).

The Arctic ringed seal is listed with the scientific name *Phoca (= Pusa) hispida hispida.* In this 90-day finding, we use the genus name *Pusa* to reflect currently accepted use (*e.g.,* Committee on Taxonomy, 2018; Integrated Taxonomic Information System (online database), available at *http://www.itis.gov*).

ESA Statutory, Regulatory, and Policy Provisions and Evaluation Framework

Section 4(b)(3)(A) of the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires, to the maximum extent practicable, that within 90 days of receipt of a petition to list a species as threatened or endangered, or to delist a species, the Secretary of Commerce make a finding on whether that petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted, and to promptly publish such finding in the **Federal Register** (16 U.S.C. 1533(b)(3)(A)). If we find that substantial scientific or commercial information in a petition indicates the petitioned action may be warranted (a ''positive 90-day finding''), we are required to promptly commence a review of the status of the species concerned during which we will conduct a comprehensive review of the best available scientific and commercial information. In such cases, we conclude the review with a finding as to whether, in fact, the petitioned action is warranted within 12 months of receipt of the petition. Because the finding at the 12-month stage is based on a more thorough review of the available information, as compared to the narrow scope of review at the 90-day stage, a ''may be warranted'' finding at the 90-day stage does not prejudge the outcome of the status review.

Under the ESA, a listing determination may address a species, which is defined to also include subspecies and, for any vertebrate species, any distinct population segment (DPS) that interbreeds when mature (16 U.S.C. 1532(16)). A joint NMFS–U.S. Fish and Wildlife Service (USFWS) (jointly, ''the Services'') policy clarifies the agencies' interpretation of the phrase ''distinct population segment'' for the purposes of listing, delisting, and reclassifying a species under the ESA (61 FR 4722; February 7, 1996). A species, subspecies, or DPS is ''endangered'' if it is in danger of extinction throughout all or a significant portion of its range, and ''threatened'' if it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range (ESA sections 3(6) and 3(20), respectively, 16 U.S.C. 1532(6) and (20)). Pursuant to the ESA and our implementing regulations, we determine whether species are threatened or endangered based on any one or a combination of the following five section 4(a)(1) factors: The present or threatened destruction, modification, or curtailment of habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease or predation; the inadequacy of existing regulatory mechanisms to address identified threats; or any other natural or manmade factors affecting the species' existence (16 U.S.C. 1533(a)(1), 50 CFR 424.11(c)).

ESA-implementing regulations issued jointly by the Services (50 CFR 424.14(h)(1)(i)) define ''substantial scientific or commercial information'' in the context of reviewing a petition to list, delist, or reclassify a species as credible scientific or commercial information in support of the petition's claims such that a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted. Conclusions drawn in the petition without the support of credible scientific or commercial information will not be considered ''substantial information.'' In reaching the initial (90-day) finding on the petition, we will consider the information described in sections 50 CFR 424.14(c), (d), and (g) (if applicable).

Our determination as to whether the petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted will depend in part on the degree to which the petition includes the following types of information: (1) Information on current population status and trends and estimates of current population sizes and distributions, both in captivity and the wild, if available; (2) identification of the factors under section 4(a)(1) of the ESA that may affect the species and where these factors are acting upon the species; (3) whether and to what extent any or all of the factors alone or in combination identified in section 4(a)(1) of the ESA may cause the species to be an endangered species or threatened species (*i.e.,* the species is currently in danger of extinction or is likely to become so within the foreseeable future), and, if so, how high in magnitude and how imminent the threats to the species and its habitat are; (4) information on adequacy of regulatory protections and effectiveness of conservation activities by States as well as other parties, that have been initiated or that are ongoing, that may protect the species or its habitat; and (5) a complete, balanced representation of the relevant facts, including information that may contradict claims in the petition. *See* 50 CFR 424.14(d).

If the petitioner provides supplemental information before the initial finding is made and states that it is part of the petition, the new information, along with the previously submitted information, is treated as a new petition that supersedes the original petition, and the statutory timeframes will begin when such supplemental information is received. *See* 50 CFR 424.14(g).

We may also consider information readily available at the time the determination is made. We are not required to consider any supporting materials cited by the petitioner if the petitioner does not provide electronic or hard copies, to the extent permitted by U.S. copyright law, or appropriate excerpts or quotations from those materials (*e.g.,* publications, maps, reports, letters from authorities). *See* 50 CFR 424.14(h)(1)(ii).

The ''substantial scientific or commercial information'' standard must be applied in light of any prior reviews or findings we have made on the listing status of the species that is the subject of the petition. Where we have already conducted a finding on, or review of, the listing status of that species (whether in response to a petition or on our own initiative), we will evaluate any petition received thereafter seeking to list, delist, or reclassify that species to determine whether a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted despite the previous review or finding. Where the prior review resulted in a final agency action—such as a final listing determination, 90-day not-substantial finding, or 12-month not-warranted finding—a petitioned

action will generally not be considered to present substantial scientific or commercial information indicating that the action may be warranted unless the petition provides new information or analysis not previously considered. *See* 50 CFR 424.14(h)(1)(iii).

At the 90-day finding stage, we do not conduct additional research, and we do not solicit information from parties outside the agency to help us in evaluating the petition. We will accept the petitioners' sources and characterizations of the information presented if they appear to be based on accepted scientific principles, unless we have specific information in our files that indicates the petition's information is incorrect, unreliable, obsolete, or otherwise irrelevant to the requested action. Information that is susceptible to more than one interpretation or that is contradicted by other available information will not be dismissed at the 90-day finding stage, so long as it is reliable and a reasonable person conducting an impartial scientific review would conclude it supports the petitioners' assertions. In other words, conclusive information indicating the species may meet the ESA's requirements for delisting is not required to make a positive 90-day finding. We will not conclude that a lack of specific information alone negates a positive 90-day finding, if a reasonable person conducting an impartial scientific review would conclude that the unknown information itself suggests the petitioned action may be warranted.

To make a 90-day finding on a petition to delist a species, we evaluate whether the petition presents substantial scientific or commercial information indicating the subject species may not be threatened or endangered, as defined by the ESA. First, we evaluate whether the information presented in the petition, in light of other information readily available in our files, indicates that the petitioned entity constitutes a ''species'' eligible for delisting under the ESA. Next, we evaluate whether the information indicates that the species does not face an extinction risk such that delisting may be warranted; this may be indicated in information expressly discussing the species' status and trends, or in information describing impacts and threats to the species. We evaluate any information on specific demographic factors pertinent to evaluating extinction risk for the species (*e.g.,* population abundance and trends, productivity, spatial structure, age structure, sex ratio, diversity, current and historical range, habitat integrity or fragmentation), and the potential contribution of identified demographic risks to extinction risk for the species. We then evaluate the potential links between these demographic risks and the causative impacts and threats identified in section 4(a)(1).

Many petitions identify risk classifications made by nongovernmental organizations, such as the International Union on the Conservation of Nature (IUCN), the American Fisheries Society, or NatureServe, as evidence of extinction risk for a species. Risk classifications by such organizations or made under other Federal or state statutes may be informative, but such classification alone will not provide sufficient basis for a 90-day finding under the ESA. For example, as explained by NatureServe, their assessments ''have different criteria, evidence requirements, purposes, and taxonomic coverage than official lists of endangered and threatened species,'' and therefore, these two types of lists ''do not necessarily coincide'' (*https://explorer.natureserve.org/AboutTheData/DataTypes/ConservationStatusCategories*). Additionally, species classifications under IUCN and the ESA are not equivalent; data standards, criteria used to evaluate species, and treatment of uncertainty are also not necessarily the same. Thus, when a petition cites such classifications, we will evaluate the source of information that the classification is based upon in light of the standards on extinction risk and impacts or threats discussed above.

Regardless of the petition process, the ESA also requires the Secretary to conduct a review of listed species at least once every five years, and to determine on the basis of such reviews whether any such species should be delisted or the listing status should be changed (16 U.S.C. 1533(c)(2)).

Previous Federal Actions

On March 28, 2008, we initiated status reviews of ringed, bearded, and spotted seals under the ESA (73 FR 16617). On May 28, 2008, we were petitioned to list these same species as threatened or endangered under the ESA. On September 4, 2008, we published a 90-day finding that the petitioned action may be warranted (73 FR 51615). On December 10, 2010, we published a 12-month petition finding and proposed to list the Arctic, Okhotsk (*Pusa hispida ochotensis*), Baltic (*Pusa hispida botnica*), and Ladoga (*Pusa hispida ladogensis*) subspecies of the ringed seal as threatened under the ESA (75 FR 77476). We published a final rule to list the Arctic, Okhotsk, and Baltic subspecies of the ringed seal as threatened and the Ladoga subspecies of the ringed seal as endangered under the ESA on December 28, 2012, primarily due to threats associated with ongoing and projected changes in sea ice and on-ice snow depths stemming from climate change within the foreseeable future (77 FR 76706; referred to hereafter as the final listing rule). On March 17, 2016, the listing was vacated by the U.S. District Court for the District of Alaska (*Alaska Oil and Gas Ass'n* v. *Nat'l Marine Fisheries Serv.,* 2016 WL 1125744 (D. Alaska 2016)). This decision was reversed by the U.S. Court of Appeals for the Ninth Circuit on February 12, 2018 (*Alaska Oil and Gas Ass'n* v. *Ross,* 722 Fed. Appx. 666 (9th Cir. 2018)) and the listing was reinstated on May 15, 2018.

Although four subspecies of the ringed seal were listed under the ESA on December 28, 2012, we have not yet conducted a review of these subspecies pursuant to 16 U.S.C. 1533(c)(2). Such reviews are required every five years and more than five years have passed since these subspecies were listed. Accordingly, concurrent with the present determination regarding this petition but in a separate action, we are initiating a review of these four subspecies of the ringed seal, including whether the best scientific and commercial data available, particularly new data that has become available since the listing decision, indicate delisting is warranted.

Analysis of Petition

According to the petition, information newly available since the time the Arctic ringed seal was listed as threatened and a reanalysis of the information considered in our listing determination for this species demonstrates that our 2012 listing decision was in error. As discussed above, we evaluate any petition seeking to delist a species in light of any prior reviews or findings we have already made on the listing status of the species that is the subject of the petition. Because our previous review resulted in a final agency action listing the species as threatened, the petitioned action will generally not be considered to present substantial scientific or commercial information indicating that the action may be warranted unless the petition provides new information or a new analysis not previously considered. *See* 50 CFR 424.14(h)(1)(iii). Therefore, unless the petition provides credible new information, or identifies errors or provides a credible new analysis that suggests the species was listed due to an

error in information and delisting may be warranted, we may find that the petition does not present substantial information indicating that the petitioned action may by warranted. A synopsis of our analysis of the petition is provided below.

Species Description

A review of the taxonomy, life history, and ecology of the Arctic ringed seal is presented in the ''Status Review of the Ringed Seal'' (Kelly *et al.,* 2010) (referred to hereafter as the ''Status Review Report''), and relevant updates to this information were included in the preamble to the final listing rule. As discussed in detail in those documents, the principal threat to ringed seals identified at the time of listing was habitat loss and modification stemming from climate change. A specific habitat requirement of Arctic ringed seals is adequate snow depths on sea ice for the formation and occupation of lairs, in particular birth lairs, where pups are nursed and grow in this protected setting. Early break-up of sea ice and early snow melt have been associated with increased pup mortality from premature weaning, hypothermia, and predation. Moreover, the high fidelity to birth sites shown by Arctic ringed seals makes the seals more susceptible to localized degradation of snow cover.

Although the petition cites references related to the Arctic ringed seal's genetic diversity, abundance, movements, habitat use, and diet that became available after the final listing rule was issued, in reviewing the supporting documents we found that these references were consistent with the information considered in our listing determination for this species. For example, the petition cites Crawford *et al.* (2015), who reported, among other findings, that cod were the most common fish taxa identified in the stomachs of ringed seals harvested in two locations in Alaska. The Status Review Report similarly indicated that from late autumn through spring, fishes of the cod family tend to dominate the diets of ringed seals in many areas. As another example, the petition cites Lydersen *et al.* (2017), who reported that several ringed seals tagged in a fjord in Svalbard hauled out on shore during a recent summer while also using glacier ice to some extent. This was in contrast to exclusive use of glacier ice as a haul-out platform by several ringed seals tagged in the same fjord in a prior year. The Status Review Report similarly noted that Lukin *et al.* (2006) reported observation of ringed seals on offshore islands and sand bars in the White Sea during summer months. Lydersen *et al.* (2017) suggested that although the use of terrestrial sites illustrates some of the adaptive flexibility of this species, because of the vulnerability of young pups to predation and thermoregulatory stress it ''is unlikely to overcome the catastrophic consequences of loss of sea-ice breeding habitats on ringed seal pup survival and population health,'' consistent with the information considered in our listing determination for this species.

We identified several instances in the ''Species and Habitat Description'' section of the petition where the information presented, or interpretation of information was incomplete, inaccurate, or was not supported by appropriate documentation (*e.g.,* literature citations, publications, reports, letters from authorities, per 50 CFR 424.14(c)(5)–(6)). Conclusions drawn without the support of credible scientific or commercial information are not considered ''substantial information.'' *See* 50 CFR 424.14(h)(1)(i). For example, the petition states that ringed seals generally use sea ice, when it is available, as a platform for pupping and nursing, implying that ring seals may pup or nurse on land at other times. However, we are not aware of any documented observations of ringed seals giving birth or nursing pups on land. In addition, the petition cites the Status Review Report in stating that snow depth over birth lairs of 20–30 cm may be sufficient to adequately protect pups from predation. However, the Status Review Report did not indicate that such snow depths would be sufficient for the formation of birth lairs. Rather, the Status Review Report indicated that snow drifts of sufficient depths to support birth lair formation typically occur only where average snow depths on sea ice are at least 20–30 cm and where drifting has taken place along pressure ridges or ice hummocks (Lydersen *et al.,* 1990; Hammill and Smith, 1991; Lydersen and Ryg, 1991; Smith and Lydersen, 1991). The Status Review Report stated that snow drifted to 45 cm or more is needed for excavation and maintenance of simple lairs, and birth lairs require depths of 50 cm (Lukin *et al.,* 2006) to 65 cm or more (Smith and Stirling, 1975; Lydersen and Gjertz, 1986; Kelly, 1988; Furgal *et al.,* 1996; Lydersen, 1998). The Status Review Report also noted that Ferguson *et al.* (2005) observed evidence that pup survival dropped sharply when snow depths were less than 32 cm, and that those authors suggested reduced recruitment in the more recent years of the study resulted from low snow fall yielding lairs excavated in drifts too shallow to protect against predators.

Foreseeable Future

As stated above, under the ESA, a ''threatened species'' is defined as any species which is likely to become endangered within the foreseeable future throughout all or a significant portion of its range. In the final listing rule, we stated that the foreseeability of a species' future status is case specific and depends upon both the foreseeability of threats to the species and the foreseeability of the species' response to those threats (77 FR 76707; December 28, 2012). Therefore, in our listing determination for the Arctic ringed seal, we used a threat-specific approach to analyze foreseeable future threats and the species' responses to those threats, based on the best scientific and commercial data available for each respective threat. The climate projections in the Intergovernmental Panel on Climate Change's (IPCC's) ''Fourth Assessment Report'' (AR4) (IPCC, 2007) which extended through the end of the century, as well as the scientific papers used in that report or resulting from that report, were determined to represent the best scientific and commercial data available to inform our analysis of the potential impacts to this species from climate change. As we explained in the final listing rule in response to comments received regarding the timeframe used in our analysis, we considered the projections through the end of the 21st century to analyze the threats stemming from climate change. We recognized that the farther into the future the analysis extends, the greater the inherent uncertainty, and we incorporated that consideration into our assessments of the threats and the species' responses to the threats (77 FR 76723; December 28, 2012).

The petition contends that the model projections of future climate developed for the IPCC's Fifth Assessment Report, ''Climate Change 2013: The Physical Science Basis'' (IPCC, 2013) (referred to hereafter as AR5), provide new information indicating that climate model projections diverge considerably after mid-century, especially in high-latitude areas. The petition also claims that in the final listing rule, NMFS based its foreseeable future on the IPCC AR4 projections of climate-related habitat decline through the end of the century, but lacked the requisite scientific data to make reliable predictions about how the Arctic ringed seal would respond to that threat. The petition cites the USFWS's October 5, 2017, 12-month ''not warranted'' finding

on a petition to list the Pacific walrus (*Odobenus rosmarus divergens*) under the ESA (82 FR 46618) to support the assertion that new information and scientific methodologies have been developed since the final listing rule was issued that further demonstrate NMFS cannot rely upon the duration of climate projections alone to establish the foreseeable future. Based on these arguments, the petition asserts that the time period for projections about effects to habitat from climate change and the responses of the Arctic ringed seal to those potential effects does not extend beyond 2055.

The climate projections discussed in the AR5 are based on a set of scenarios that describe several possible alternative trajectories of greenhouse gas (GHG) emissions and atmospheric concentrations, air pollutant emissions, and land use. Current trends in global annual emissions have been described as consistent with high-end emissions scenarios (U.S. Global Climate Change Research Program (USGCRP, 2017).

According to the petition, by mid-century (2036–2055) the difference between model projections in the Alaska region is about 1.0°–1.5°C, and beyond mid-century for the Alaska region the AR5 projects surface temperature increases with a spread in range from about 2°C to 5–7°C by the late 21st century. The petition asserts that these data demonstrate that there is considerable variability in future climate scenarios, and that there is greater uncertainty in any projection of high-latitude surface temperatures compared to the rest of the globe, especially for the late 21st century.

Although the climate projections discussed in the AR5 became available after the Arctic ringed seal was listed as threatened in 2012, we do not agree that the divergence in the climate model projections after about mid-century is new information not previously considered in our listing determination, which focused on climate model projections developed for the AR4. As we explained in the final listing rule in response to comments expressing similar views regarding divergence of the climate model projections beyond mid-century (77 FR 76722–76723; December 28, 2012), before mid-century, model projections of conditions such as increases in surface air temperature primarily reflect emissions of long-lived GHGs that have already occurred and those that will occur in the near-term, and are thus largely independent of the assumed emissions scenario. In contrast, the model projections become increasingly subject to the assumed emissions scenarios in the longer-term projections for the latter half the 21st century, and thus the projections diverge depending on the emissions scenario. As we explained in the final listing rule, although the magnitude of the warming depends somewhat on the assumed emissions scenario, the trend is clear and unidirectional (77 FR 76723; December 28, 2012). This is also the case for climate model projections under the scenarios considered in the AR5, aside from a scenario that assumes unprecedented global GHG emissions reductions and new technologies (and has no equivalent in the AR4 scenarios). Therefore, we conclude that the information presented in the petition about divergence beyond about mid-century in the climate model projections developed for the AR5 does not constitute new information or a new analysis not previously considered in our listing determination for the Arctic ringed seal.

Regarding the USFWS's 12-month ''not warranted'' finding on a petition to list the Pacific walrus under the ESA (82 FR 46618; October 5, 2017), the USFWS explained that although projections out to 2100 were included in the analysis, it considered 2060 (approximately three Pacific walrus generation lengths from the time of the analysis) to be the foreseeable future as it relates to the status of this species (82 FR 46643; October 5, 2017). USFWS explained that it had high certainty that sea ice availability will decline as a result of climate change, but it had less certainty, particularly further into the future, about the magnitude of effect that climate change will have on the full suite of environmental conditions (*e.g.,* benthic production), or how the species will respond to those changes (82 FR 46643; October 5, 2017). Assuming an Arctic ringed seal generation length of approximately 12 years, the petition contends that applying a similar three-generation-length approach to determining the foreseeable future for this species should yield a foreseeable future timeframe of 2055 (*i.e.,* 36 years beyond 2019), which the petition states also corresponds to the time period when the IPCC AR5 climate projections are most reliable, with the least amount of variability between projection scenarios.

We do not find the USFWS approach taken to analyzing the foreseeable future in the 12-month finding for the Pacific walrus to be new information not previously considered in our listing determination for the Arctic ringed seal. We considered comments received on the proposed listing determination for Arctic ringed seals that our assessment of impacts to ringed seals from climate change through the end of this century differs from the IUCN red list process, which uses a timeframe of three generation lengths (77 FR 76722; December 28, 2012). However, we concluded in the final listing rule that the foreseeability of threats to the species and the species' response is case-specific, and takes into consideration factors such as the species' life history and habitat characteristics and threat projection timeframes. As we explained above, in our risk assessment for ringed seals, we considered the projections through the end of the 21st century to analyze the threats stemming from climate change. We recognized that the farther into the future the analysis extends, the greater the inherent uncertainty, and we incorporated that consideration into our assessments of the threats and the species' responses to the threats (77 FR 76723; December 28, 2012).

Moreover, considering the case-specific nature of evaluating the foreseeable future, it also warrants mention that the Pacific walrus has distinctly different life history and habitat characteristics as compared to the Arctic ringed seal. For example, in its ''Species Assessment and Listing Priority Assignment Form'' for the Pacific walrus (USFWS, 2017) the USFWS explained that, given the ability of the Pacific walrus to change its behavior and/or adapt to environmental stressors, there was much less confidence in predicting Pacific walruses' behavioral responses under increasing environmental stressors out to 2100, noting that changes in the timing of migration, amount of time spent on land, and time spent swimming to access foraging grounds are some of the changes in behavior that have already been observed. We did not cite a similar observed adaptability for Arctic ringed seals in the final listing rule, aside from the observations noted above of ringed seals on offshore islands and sand bars in the White Sea during summer months. Nor does the petition present new information to indicate such adaptability. We concluded in the final listing rule that, because ringed seals stay with the ice as it annually advances and retreats, the southern edge of the ringed seal's range may initially shift northward. Whether ringed seals will continue to move north with retreating ice cover over the deeper, less productive Arctic Basin waters and whether the species that they prey on will also move north is uncertain (77 FR 76716; December 28, 2012). In addition, we discussed that the ability of ringed seals to adapt to earlier snow melts by

advancing the timing of reproduction will be limited by snow depths, which we explained would be unlikely to be improved for birth lairs earlier in the spring, because most of the snow accumulation occurs earlier in the season. In addition we noted that the pace at which snow melts are advancing is rapid relative to the generation time of ringed seals, further challenging the potential for an adaptive response (77 FR 76710; December 28, 2012). The petition presents no new information regarding these conclusions.

Finally, we note that, in support of its assertions regarding analysis of the foreseeable future, the petition cites the 2018 proposed revision of the ESA implementing regulations at 50 CFR 424 that sets out a regulatory framework for determining the foreseeable future (83 FR 35193; July 25, 2018). This framework, which was revised in the final regulation (84 FR 45020; August 27, 2019), is part of a rulemaking that revises and clarifies requirements regarding factors for listing, delisting, or reclassifying species ''to reflect agency experience and to codify current agency practices'' (84 FR 45050; August 27, 2019). Our interpretation of the foreseeable future in the final listing rule is consistent with this regulatory framework. Specifically, we considered conditions only so far into the future as we could reasonably determine that both the future threats and the species' responses to those threats were likely, based on the best available data and taking into account considerations such as the species' life-history characteristics, threat-projection timeframes, and environmental variability.

In summary, we conclude that the petition does not present new information or a new analysis not previously considered in our listing determination for the Arctic ringed seal regarding our assessment of the foreseeable future.

ESA Section 4(a)(1) Factors

As explained above, pursuant to the ESA and our implementing regulations, we determine whether a species is threatened or endangered based on any one or a combination of the five section 4(a)(1) factors (16 U.S.C. 1533(a)(1), 50 CFR 424.11(c)). Because the petition disagrees with some of the conclusions in the final listing rule with respect to these factors, in the following sections we summarize our evaluation of whether the petition presents substantial new information, provides credible new analysis of information previously considered, or identifies errors in the final listing rule regarding these factors that would support a conclusion that delisting may be warranted.

Factor A: The Present or Threatened Destruction, Modification, or Curtailment of the Species' Habitat or Range

As was discussed in detail in the Status Review Report and the final listing rule and noted above, a specific habitat requirement for ringed seals is adequate snow for the formation and occupation of subnivean lairs, especially in spring when pups are born and nursed. Snow depths on the sea ice were projected to decrease substantially by mid-century throughout much of the range of the Arctic ringed seal, and by the end of this century, snow depths adequate for the formation and occupation of birth lairs were projected to occur in only parts of the Canadian Arctic Archipelago, a portion of the central Arctic, and a few small isolated areas in other regions (see Kelly *et al.,* 2010; and 77 FR 76706, December 28, 2012). The petition asserts that new information demonstrates that the 2012 listing decision overestimated the magnitude of future declines in snow cover. However, none of the studies cited in the petition in support of this claim (IPCC, 2013; Nitta *et al.,* 2014; Thackeray *et al.,* 2015; Littell *et al.,* 2018) investigated the effectiveness of climate models in projecting the accumulation of snow (snow depth) on sea ice. Instead, these studies addressed modeling of snow-related parameters (usually percent area covered by any snow) on land surfaces. Of importance to Arctic ringed seals is the available area of sea ice with average snow depths that are sufficient for the formation and maintenance of birth lairs. Therefore, in our listing determination for this species, we considered climate model projections of snow depth on Arctic sea ice during the birth lair period in April (*e.g.,* 77 FR 76708, 76710; December 28, 2012). Although winter precipitation was projected to increase in a warming Arctic, later open-water freeze-up was also projected, and this contributed to the projected decreases in snow accumulation on the ice (because snow falls into the ocean until sea ice forms) (75 FR 77483; December 10, 2010). Future snow depths on sea ice cannot be inferred from the studies discussed in the petition regarding snow on land surfaces. Thus, although the petition cites studies regarding modeling of future snow-related parameters on land that became available after the final listing rule was issued, we conclude that this information does not support the assertion in the petition that the 2012 listing decision overestimated future declines in snow depths on Arctic sea ice, and therefore does not address the concern in the final listing rule that habitat suitability for Arctic ringed seals was likely to decline. These cited studies therefore do not present substantial scientific or commercial information indicating that the petitioned action may be warranted.

The petition also asserts that the scenarios used in the climate model projections considered in our listing determination for the Arctic ringed seal assumed status quo GHG emissions, which, according to the petition, correspond to climate projections in the AR5 reflecting a scenario with a continued increase in emissions. The petition claims that the latest published research indicates that international and domestic policy commitments will result in the climate system following a trajectory more closely corresponding to the intermediate stabilization scenario considered in the AR5 (in which emissions peak around 2040 and then decline and stabilize), but the analysis cited in the petition to support this assertion (Salawitch *et al.,* 2017) does not, in fact, reach that conclusion. Rather, Salawitch *et al.* (2017) assessed the reductions in emissions of GHGs that will be needed to achieve the goal of the United Nations Framework Convention on Climate Change (UNFCCC) Paris Agreement to limit GHG emissions such that warming in this century remains below 2°C, and to pursue efforts to limit warming to 1.5°C. The authors concluded, based on projections from an independently derived climate model (Empirical Model of Global Climate Change), that GHG emissions will remain below the intermediate stabilization scenario out to 2060 if: (1) Conditional as well as unconditional pledges are met; and (2) reductions in GHG emissions needed to achieve the Paris commitments, which generally extend to 2030, are propagated forward to 2060. The authors did not, however, opine as to how likely it is that such actions would occur. The authors also stated that global climate models used in the AR5 indicate that future emissions will instead need to follow the aggressive mitigation scenario involving rapid reductions in GHGs for warming to remain below 2°C. In addition, we note that the United States subsequently announced that it intended to withdraw from the Paris Agreement (see Factor E: The Inadequacy of Existing Regulatory Mechanisms), and current global annual emissions trends have been described as consistent with high-end emissions

scenarios (USGCRP, 2017). Therefore, although the publication by Salawitch *et al.* (2017) became available after the final listing rule was issued, we conclude that the cited study does not support the assertion in the petition that the latest published research indicates the climate system will follow the trajectory of the intermediate stabilization scenario.

Citing a study by Crawford *et al.* (2015), the petition also asserts that observed changes in sea ice extent and duration have not resulted in detectable corresponding reductions in ringed seal population size or effects on ringed seal population health, which the petition claims contradicts the assumptions made in the listing decision. However, our listing of Arctic ringed seals as threatened was not based on evidence indicating that population size or health had declined, nor was it based on a presumption that a climate driven decline would be detectable at that time or shortly thereafter. Rather, as explained in the final listing rule, it was based primarily on the conclusion that continuing Arctic warming would cause substantial reductions in sea ice and on-ice snow depths, two key elements of Arctic ringed seal breeding habitat, and that these habitat changes were expected to lead to decreased survival of pups and a substantial decline in the number of Arctic ringed seals, such that they would no longer persist in substantial portions of their range within the foreseeable future (77 FR 76716, 76731; December 28, 2012).

Regarding new abundance data, the petition cites an estimate of Arctic ringed seals in the U.S. portion of the Bering Sea that was calculated by Conn *et al.* (2014) based on data obtained in 2012. We note that the petition mistakenly cites Conn *et al.* (2014) for an abundance estimate in the U.S. portions of the Chukchi and Beaufort Seas. However, this estimate was not reported by Conn *et al.* (2014). Rather, it was presented in the Status Review Report that informed our listing determination for the Arctic ringed seal. As such, the abundance estimate is not new information but is information that was actually considered in the listing decision.

The petition also extrapolates a total worldwide population estimate for this species from a worldwide estimate of mature Arctic ringed seals reported by Lowry (2016). This petition's extrapolation was based on an assumption that the proportion of pups in ''a stable population'' is about 54 percent. However, because a mature female produces only one pup per year, it is impossible for the pup proportion to be as high as 50 percent of the total population because such a population would consist only of pups and their mothers. Although the abundance estimate for the U.S. Bering Sea reported by Conn *et al.* (2014) (as well as the estimate reported by Lowry, 2016) became available after the final listing rule was issued, this information is consistent with the data considered in our listing determination for the Arctic ringed seal. In the final listing rule we concluded that there are no specific estimates of worldwide population size available for the Arctic subspecies, but most experts postulate that it numbers in the millions (77 FR 76716; December 28, 2012). As we explained in withdrawing the proposed ESA section 4(d) protective regulations for ringed seals, foreseeable habitat changes in the future pose a long-term threat and the consequences for ringed seals will manifest themselves over the next several decades (77 FR 76718; December 28, 2012). Therefore, we conclude that the petition does not present new information on the worldwide or Alaska-specific abundance of this species.

As noted above regarding ringed seal population health, the petition cites a study by Crawford *et al.* (2015) that analyzed data collected from the Alaska Native subsistence harvest to support the assertions in the petition that ringed seals in the Bering and Chukchi Seas have not exhibited declines in body condition, growth, or pregnancy rate, and the age at maturity is younger than in previous decades, and that these observations are all indications of a positive response to environmental conditions. The petition also references Bryan *et al.* (2019), who analyzed data from the same harvest monitoring program collected through 2016. We considered and addressed similar assertions in the final listing rule in reference to a report by Quakenbush *et al.* (2011) that included data from the same Alaska Native subsistence harvest monitoring program collected through 2010. The authors concluded in that report that data from the most recent decade indicated ringed seals were growing faster, had average blubber thickness, were maturing at the youngest age to date, and had the second highest pregnancy rate to date. The authors stated that these factors indicated environmental conditions were currently as favorable (or better) than they were in the 1960s or 1970s (the authors did not comment on the 1980s and 1990s because they had little data for those decades). As we explained in the final listing rule in response to comments received related to the report by Quakenbush *et al.* (2011), healthy individual animals are not inconsistent with a population facing threats that would cause it to become in danger of extinction in the foreseeable future. In the case of ringed seals, substantial losses due to predation and hypothermia associated with reduced snow cover could not be detected by assessing the health of survivors. In fact, survivors might be expected to fare well for a period of time as a consequence of reduced competition (77 FR 76720; December 28, 2012). We also noted in response to a similar comment received regarding observed Arctic sea ice changes relative to effects on ringed seals that indices of condition, such as those indices reported by Quakenbush *et al.* (2011), are available for only a limited portion of the Arctic ringed seal's range, and would not be expected to reflect certain detrimental effects, such as an increase in pup mortality by predation (77 FR 76729; December 28, 2012).

As noted above, the study by Crawford *et al.* (2015) cited in the petition is an update to the report by Quakenbush *et al.* (2011) based on data collected through 2012, and includes analyses that were not presented in the 2011 report, such as comparisons of ringed seal growth measurements with annual variations in sea ice area. Also, Bryan *et al.* (2019) updated several of the demographic parameters analyzed in those studies based on data collected through 2016. However, for the reasons discussed below, we conclude that the updates and new analyses cited in the petition do not constitute new information or new analysis that is inconsistent with the analysis in the final listing rule.

Crawford *et al.* (2015) reviewed published reports on responses of ringed seal demographic indicators (*e.g.,* age of maturation, recruitment, and proportion of pups in the harvest) to interannual variation in sea ice. Although the discussion of this information in Crawford *et al.* (2015) focused on negative effects on ringed seal demography in relatively cold years of extensive spring sea ice (which were also discussed in the Status Review Report), the authors also indicated that their data suggested there might be an optimal amount of spring ice for ice seals, noting that while the residual growth of ringed seals increased as the area of sea ice decreased, this trend began to reverse as the area of sea ice approached zero. The authors discussed that Chambellant *et al.* (2012), a publication previously considered in our listing determination for the Arctic

ringed seal, found similar patterns in the way that the proportion of ringed seal pups in the fall harvest, pup body condition, and adult female body condition varied over the observed range of maximum snow depth for February–May and the ice break-up date. These findings have been explained based on expectations that very cold years are likely to be characterized by late break-up of sea ice and short open-water periods that could result in shorter foraging seasons, lower prey productivity, and longer periods of on-ice predation by polar bears and foxes (*e.g.,* Chambellant *et al.,* 2012). Warmer years that are around the long-term average to which ringed seals have adapted would be expected to have more suitable foraging season length, productivity of prey, and predation pressure. However, the observed changes in sea ice extent and duration cited in the petition are minor compared to the changes that are projected to occur later in this century. As explained in the final listing rule and the Status Review Report, earlier warming and break-up of ice and inadequate snow for lairs are expected to lead to poor survival of young seals and cause consequent demographic impacts within the foreseeable future (77 FR 76710, 76714–76716, 76721; December 28, 2012). Thus, we conclude that the above information does not constitute new information not previously considered or new analysis concerning the Arctic ringed seal's likely response to Arctic warming within the foreseeable future.

The petition also cites Crawford *et al.* (2015) in claiming that the proportion of pups occurring in the harvest is high, and that these studies provide an index for assessing pup survival in changing sea-ice conditions that demonstrates pups are surviving to weaning in current ice and snow conditions. Similarly, Bryan *et al.* (2019) reported that the proportion of pups in the harvest since 2000 was high based on data from the same harvest-based sampling program collected through 2016. However, high proportions of pups in the harvest during the 2000s were also evident in the report by Quakenbush *et al.* (2011), which was considered in the final listing rule, and as explained above, included data through 2010. Thus, this information is not materially new.

The assertion that pup survival and the proportion of pups in the population is high in current snow and ice conditions is based on the comparison in Crawford *et al.* (2015) of the proportion of pups in the Alaska Native subsistence harvest sampled between two time periods: A historical period from 1975–1984 and a recent period from 2003–2012, which had fewer years with extensive May sea ice in the Bering Sea. The petition also references Bryan *et al.* (2019), who similarly reported that the proportion of pups in the harvest in the 2000s and 2010s was high based on data collected through 2016. Because Crawford *et al.* (2012) numerically summarized the proportions of pups harvested, we focus our discussion on those data. Although the overall average proportion of pups in the harvest, 27.4 percent, was within a reasonable range for the population proportion of pups in a species with the life-history characteristics of ringed seals (high adult survival and only one offspring per mature female annually), the average proportion of pups in the harvest during 2003–2012, 51.1 percent, cannot be representative of the actual proportion of pups in the population, as we explained above. Typically, for a long-lived species that produces single offspring annually, the proportion of pups in the population just after the birth season will not be greater than about 33 percent, as would occur if all mature females give birth and the number of mature females is equal to the number of males plus immature females. Pup proportions substantially higher than 33 percent would indicate substantial perturbation to the age and/or sex composition, such as very high male mortality leading to low numbers of males in the population; values approaching 50 percent would require extreme perturbation. This indicates that the index used by Crawford *et al.* (2015) (and similarly by Bryan *et al.,* 2019) is biased in some way, perhaps differently between the two periods, and may not be a reliable measure of pup survival.

Moreover, there are problems with the petition's characterization of the historical (1975–1984), recent (2003–2012), and current periods analyzed by Crawford *et al.* (2015)—it is not clear that the recent period was significantly warmer or lower in sea ice than the historical period. In March–May, when ringed seal pupping and nursing are concentrated, there was not very much difference between these two time periods in the mean sea ice extent in the Bering Sea for May, and there was considerable overlap in the range of sea ice extents (Crawford *et al.,* 2015, Fig. 10). The recent period, which ended in 2012 with very high May ice extent in in the Bering Sea (National Snow and Ice Data Center (NSIDC), 2012), was certainly not an analog for the warm conditions expected later in this century, and this is also the case with respect to the updated information reported by Bryan *et al.* (2019).

Based primarily on the study by Crawford *et al.* (2015) discussed above, the petition concludes that: (1) The 2012 listing decision was based on erroneous assumptions because there is no direct correlation between observed habitat declines and detrimental effects on the health of Arctic the ringed seal population; and (2) ringed seals have greater resilience to environmental changes than anticipated. The information reported by Crawford *et al.* (2015) and Bryan *et al.* (2019) is useful in documenting an apparent optimum range of climatic conditions for ringed seal condition and reproduction, consistent with several other studies that have made similar findings. However, as explained above, this information updates the report by Quakenbush *et al.* (2011), which was cited and considered in the final listing rule, and it does not present substantial new information or a new analysis that might alter the conclusions of our 2012 listing determination regarding the Arctic ringed seal's likely response to Arctic warming within the foreseeable future. Thus, the ''observed habitat declines'' discussed in the petition do not represent the magnitude of anticipated 21st century warming, loss of sea ice, and reduced on-ice snow depths that were the primary concern in listing the Arctic ringed seal. The correlation between habitat declines and detrimental effects on Arctic ringed seals was expected to manifest over a much more extreme range of conditions than was addressed in the updated information that the petition cites.

The petition also claims that, although, in some areas of the Bering Sea, snow depths are currently assumed to be insufficient for ringed seal lair formation and therefore pup survival, observations indicate ringed seals in the Kotzebue Sound region may sometimes give birth on the surface of the sea ice. But the petition does not provide any supporting documentation for these observations as required by 50 CFR 424.14(c)(5)–(6) and 424.14(h)(1)(ii)) and does not present information regarding the survival of any such pups. As we explained in the final listing rule, substantial data indicate survival of prematurely exposed pups tends to be low due to hypothermia and predation (77 FR 76709–76710, 76724; December 28, 2012).

According to the petition, new information since the final listing rule was issued also indicates that the waters of the Arctic and adjacent seas remain vulnerable to ocean acidification.

However, the petition asserts that there is a significant degree of uncertainty regarding the impacts of ocean acidification on Arctic ringed seals and other species, and the magnitude of any potential impacts on the species at issue—or their responses—is unknown. In support of this assertion, the petition quotes an excerpt from the ''Final Species Status Assessment for the Pacific Walrus'' (MacCracken *et al.,* 2017) that cites two publications (Bates and Mathis, 2009; Steinacher *et al.,* 2009) referenced in the Status Review Report, as well as three other publications (Cai *et al.,* 2010; Mathis *et al.,* 2015; Qi *et al.,* 2017), two of which became available after the Arctic ringed seal was listed as threatened. This excerpt, which discusses factors that contribute to uncertainty regarding the potential impacts of ocean acidification on Pacific walrus prey, is largely in agreement with the information compiled in the Status Review Report and the reasoning and conclusions made in our listing determination for the Arctic ringed seal. However, we note that the Status Review Report also reviewed substantial information indicating ocean acidification's potential to disrupt marine ecosystems and food webs, including cascading effects.

We concluded in the final listing rule that Arctic ringed seals will face an increasing degree of habitat modification through the foreseeable future, primarily as a result of the direct effects of diminishing sea ice and on-ice snow, but also from changes in ocean conditions, including acidification; and we explained that the impact of ocean warming and acidification on ringed seals was expected to be primarily through changes in community composition (77 FR 76711; December 28, 2012). Citing diet information reported by Quakenbush *et al.* (2011) and Crawford *et al.* (2015) for ringed seals in Alaska, the petition also asserts that the breadth of the ringed seal's diet increases the likelihood that the species will be resilient to changing environmental conditions and potential shifts in prey populations, which will moderate any impacts associated with ocean acidification. However, the breadth of the Arctic ringed seal's diet was well documented in the Status Review Report, and the report by Quakenbush *et al.* (2011) was considered directly in the final listing rule. The study by Crawford *et al.* (2015) which reported updated results from the same harvest-based sampling program as Quakenbush *et al.* (2011), simply provides additional evidence of the wide variety of prey consumed by these seals. After reviewing the information presented in the petition, we conclude that the petition does not present substantial new information or a new analysis inconsistent with the analysis of the potential for ocean acidification to impact Arctic ringed seals contained in the final listing rule.

In summary, we conclude that the petition does not present substantial new information or new analysis of information considered in the final listing rule regarding this ESA section 4(a)(1) factor that would support a conclusion delisting may be warranted.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

According to the petition, a recent analysis by Nelson *et al.* (2019) for 55 villages in western and northern Alaska estimated that subsistence harvest is well below the sustainable harvest level for Arctic ringed seals in U.S. waters, which is consistent with our conclusion in the final listing rule that there is no evidence that overutilization of ringed seals is occurring at present (77 FR 76711; December 28, 2012). Thus, we conclude that the petition does not present substantial new information or new analysis of information considered in the final listing rule regarding this ESA section 4(a)(1) factor.

Factor C: Disease or Predation

According to the petition, there is no current evidence that disease is a threat to the species. In the final listing rule we similarly concluded that abiotic and biotic changes to ringed seal habitat potentially could lead to exposure to new pathogens or new levels of virulence, but concluded that the potential threats to ringed seals from disease was low (77 FR 76711; December 28, 2012). We also concluded in the final listing rule that the threat posed to ringed seals by predation was currently moderate, but predation risk was expected to increase as snow and sea ice conditions change with a warming climate (77 FR 76711; December 28, 2012). The petition asserts that there is no information indicating a future increase in the likelihood or severity of ringed seal predation, and therefore, predation does not pose a threat to the Arctic ringed seal. However, the petition does not provide any supporting documentation for these assertions as required by 50 CFR 424.14(c)(5)–(6) and 424.14(h)(1)(ii)). The Status Review Report discussed substantial data indicating high ringed seal pup mortality as a consequence of inadequate snow depths for lairs. For example, we noted in the final listing rule that Hammill and Smith (1991) found that polar bear predation on ringed seal pups increased 4-fold in a year when average snow depths in their study area decreased from 23 cm to 10 cm. They concluded that while a high proportion of pups born each year are lost to predation, without the protection provided by the subnivean lair, pup mortality (from polar bears) would be much higher (77 FR 76711; December 28, 2012). In summary, we conclude that the petition does not present substantial new information or new analysis of information considered in the final listing rule regarding this ESA section 4(a)(1) factor.

Factor D: The Inadequacy of Existing Regulatory Mechanisms

Under this factor, in the final listing rule, we evaluated whether existing regulatory mechanisms may be inadequate to address threats to the species identified under the other ESA section 4(a)(1) factors. We concluded that current mechanisms do not effectively regulate GHG emissions, which are contributing to global climate change and associated modifications to ringed seal habitat (77 FR 76712; December 28, 2012). The petition asserts that since the final listing rule was published there have been significant new efforts to address GHGs and climate change at both international and domestic levels, and as a result the potential climate-based threats to the Arctic ringed seal that were identified at the time of listing have been reduced. To support these claims, the petition notes that for example, the Paris Agreement to address global GHG emissions was ratified and entered into force in November 2016. However, the petition does not provide any evidence that the goals of the Paris Agreement will be met, and on November 4, 2019, the U.S. Secretary of State submitted formal notification to the United Nations of United States' intent to withdraw from the Paris Agreement (*https://www.state.gov/on-the-u-s-withdrawal-from-the-paris-agreement/*).

In addition, according to the petition, domestically, a wide range of policies have been adopted at the state and regional levels to reduce GHGs and, to date, twenty states and the District of Columbia have adopted GHG emissions targets. Such state and regional measures may represent policies that could be applied at a national or international level in the future, but we find that this is not substantially new information, because it does not change the overall conclusion in the final listing rule that current mechanisms do

not effectively regulate GHG emissions, which are contributing to global climate change and associated modifications to ringed seal habitat (77 FR 76712; December 28, 2012). In the final listing rule, we expressly acknowledged in response to comments on our assessment of existing regulatory mechanisms in the proposed listing determination that there is some progress addressing anthropogenic GHG emissions (77 FR 76734; December 28, 2012). As such, we conclude that the petition does not present substantial new information or new analysis of the information considered in the final listing rule regarding this ESA section 4(a)(1) factor.

Factor E: Other Natural or Manmade Factors Affecting Its Continued Existence

We concluded in the final listing rule that the threats posed by pollutants, oil and gas activities, fisheries, and shipping do not individually or collectively place Arctic ringed seals at risk of becoming endangered in the foreseeable future. We recognized, however, that the significance of these threats would likely increase for populations diminished by the effects of climate change or other threats (77 FR 76714; December 28, 2012). The petition asserts that there is no information indicating that any of these factors constitute a threat to this species. Related to this, the petition notes that in 2017, nine countries and the European Union agreed not to conduct commercial fishing in the Central Arctic Ocean for at least the next 16 years. We are aware of this agreement, and note that the United States made a similar commitment in 2009 (prior to issuance of the final listing rule) and prohibited commercial fishing in the Arctic portion of the U.S. Exclusive Economic Zone. Thus, we do not believe this represents substantial new information regarding this ESA section 4(a)(1) factor.

Petition Finding

We thoroughly reviewed the information presented in the petition, and found that this information largely reiterates previous arguments expressed in comments received regarding the proposed listing determination for the Arctic ringed seal that were addressed in the final listing rule. The petition does not present substantial new information or new analysis indicating that the scientific and commercial data considered in our listing determination, or the analytic methodology used in the determination, were in error. Therefore, we find that the petition does not present substantial scientific or commercial information indicating that the petitioned action may be warranted. Nevertheless, as stated above, we are separately initiating a review of the status of the Arctic ringed seal pursuant to 16 U.S.C. 1533(c)(2), including whether the best scientific and commercial data available indicate delisting is warranted.

References Cited

A complete list of all references is available upon request from the Protected Resources Division of the NMFS Alaska Region Office in Juneau, Alaska (see **ADDRESSES**).

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: November 23, 2020.

Samuel D. Rauch III,

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

[FR Doc. 2020–26211 Filed 11–25–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA667]

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 72 Pre-workshop Webinar for Gulf of Mexico gag grouper.

SUMMARY: The SEDAR 72 assessment of Gulf of Mexico gag grouper will consist of a series of data and assessment webinars. See **SUPPLEMENTARY INFORMATION.**

DATES: The SEDAR 72 Pre-workshop Webinar will be on December 15, 2020, from 2 p.m. to 4 p.m., Eastern.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Pre-workshop Webinar is as follows:

Panelists will review the data sets available for the assessment and discuss initial modeling efforts.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been

notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: November 23, 2020.

Diane M. DeJames-Daly,

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

[FR Doc. 2020–26237 Filed 11–25–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA659]

South Atlantic Fishery Management Council (Council); Public Meetings

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

ACTION: Notice of Gulf of Mexico Fishery Management Council (GMFMC) and South Atlantic Fishery Management Council (SAFMC) informational webinars.

SUMMARY: The GMFMC and SAFMC will host informational webinars on behalf of NOAA Fisheries regarding the implementation of the Southeast For-Hire Electronic Reporting Program.

DATES: The GMFMC will host two For-Hire Electronic Reporting informational webinars on December 15, 2020, from 10 a.m. until 12 p.m. and from 6 p.m. until 8 p.m. The SAFMC will host two For-Hire Electronic Reporting informational webinars on December 16, 2020, from 10 a.m. until 12 p.m. and from 6 p.m. to 8 p.m.

ADDRESSES: The meetings will be held via webinar.

FOR FURTHER INFORMATION CONTACT: Cameron Rhodes, Outreach Program Manager, SAFMC; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *Cameron.rhodes@safmc.net.*

SUPPLEMENTARY INFORMATION: The GMFMC and SAFMC on behalf of NOAA Fisheries will each host informational webinars regarding the upcoming implementation of the Southeast For-Hire Electronic Reporting Program. Requirements for South Atlantic federal permit holders become effective January 4, 2020 and requirements for Gulf of Mexico federal permit holders become effective January 5, 2020. The informational webinars will provide hands-on training from staff with the Southeast For-Hire Electronic Reporting Program and provide opportunities for participants to ask questions about the program and approved software.

The webinars are open to the public. Registration is required. Additional information, including links to registration for each informational webinar is available at: *https://www.fisheries.noaa.gov/southeast/southeast-electronic-reporting-technologies.*

Special Accommodations

The meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The end times specified for these webinars are subject to change.

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

Dated: November 23, 2020.

Diane M. DeJames-Daly,

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

[FR Doc. 2020–26242 Filed 11–25–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA640]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public workshops.

SUMMARY: The Pacific Fishery Management Council's (Council) is conducting four online workshops as part of its Fishery Ecosystem Plan Climate and Communities Initiative. Each workshop will have a regional focus (see Supplementary Information).

DATES: The online workshops will begin at 9 a.m. Pacific Standard Time and continue each day until the conclusion of business for the day. The online workshops will occur on the following days:

- *Southern California region:* Wednesday–Thursday, December 16–17, 2020
- *Northern California region:* Wednesday–Thursday, January 13–14, 2021
- *Washington region:* Wednesday–Thursday, January 20–21, 2021
- *Oregon region:* Tuesday–Wednesday, February 2–3, 2021

ADDRESSES: These workshops will be held online. Specific meeting information, including directions on how to join the workshops and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2280, extension 412 for technical assistance.

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

FOR FURTHER INFORMATION CONTACT: Kit Dahl, Staff Officer, Pacific Council; telephone: (503) 820–2422.

SUPPLEMENTARY INFORMATION: The Council is conducting a climate change scenario planning exercise as part of its Fishery Ecosystem Plan Climate and Communities Initiative. The workshops will be open to the public. As part of this exercise, four climate change scenarios were developed in January 2020. Based on these four scenarios, workshop participants will identify specific challenges that could be faced by West Coast fishing communities, regions, and participants. These challenges will then be used to formulate potential solutions and actions that the Council and other stakeholders could take to respond to the effects of climate change in the California Current Ecosystem. The results of these workshops are tentatively scheduled to be reported to the Council in March 2021. Participants will be invited to each workshop, representing a range of West Coast fishery stakeholders within each region.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

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

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

Dated: November 23, 2020.

Diane M. DeJames-Daly,

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

[FR Doc. 2020–26238 Filed 11–25–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA655]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council.

DATES: The meetings will be held Monday, December 14, 2020, from 1:30 p.m. to 4 p.m.; Tuesday, December 15, 2020, from 9 a.m. to 5:45 p.m.; Wednesday, December 16, 2020, from 9 a.m. to 4:30 p.m.; and, Thursday, December 17, 2020, from 9 a.m. to 1 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: Due to public health concerns related to the spread of COVID–19 (coronavirus), the Mid-Atlantic Fishery Management Council's December meeting will be conducted by webinar only. This webinar-based meeting replaces the in-person meeting previously scheduled to be held in Baltimore, MD. Please see the Council's website (*www.mafmc.org*) for log-in procedures.

Council address: Mid-Atlantic Fishery Management Council, 800 N State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D. Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's website, *www.mafmc.org* also has details on the meeting location, proposed agenda, webinar listen-in access, and briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's website when possible.)

Monday, December 14, 2020

Executive Committee (CLOSED)

Ricks E Savage Award.

2021 Implementation Plan

Review and approve 2021 Implementation Plan.

Tuesday, December 15, 2020

SSC Economic Work Group Report

Review and select economic case study for development in 2021.

Council Recusal Process

Update on Habitat Activities

NMFS Habitat Conservation Division review of regional projects of interest, including offshore wind projects and aquaculture and an update on the Regional Offshore Science Alliance.

Scup 2021 Recreation Specifications

Review recent fishery performance and recommendations from the Monitoring Committee and Advisory Panel and adopt recommendations for 2021 federal waters recreational management measures.

Black Sea Bass 2021 Recreational Specifications

Review recent fishery performance and recommendations from the Monitoring Committee and Advisory Panel and recommend federal waters recreational management measures or Conservation Equivalency and associated measures for 2021.

Summer Flounder 2021 Recreational Specifications

Review recent fishery performance and recommendations from the Monitoring Committee and Advisory Panel and recommend Conservation Equivalency or coastwide management and associated measures for 2021.

Bluefish 2021 Recreational Specifications

Review recent fishery performance and recommendations from the Monitoring Committee and Advisory Panel and adopt recommendations for 2021 federal waters recreational management measures.

Bluefish Board Only: Technical Committee Report on Biological Monitoring Program

Review effectiveness of the Addendum 1 sampling design.

Wednesday, December 16, 2020

Recreational Reform Initiative

Update and discuss next steps.

Summer Flounder, Scup, and Black Sea Bass Commercial/Recreational Allocation Amendment

Review and approve joint draft public hearing document for public comment and (Board only) approve draft Commission amendment document for public comment.

Black Sea Bass Commercial State Allocation Amendment and Draft Addendum XXXIII for Final Action

Review public comment summary and AP input and consider for final action.

Thursday, December 17, 2020

Update on Atlantic Right Whale Issues

Preliminary 2019 population estimate; Atlantic Large Whale Take Reduction Plan Draft Environmental Impact Statement and proposed rule; and Draft Batched Biological Opinion.

Business Session

Committee Reports (SSC and Executive Committee); Executive Director's Report; Organization Reports; and Liaison Reports.

Continuing and New Business

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: November 20, 2020.

Rey Israel Marquez,

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

[FR Doc. 2020–26142 Filed 11–25–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA630]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 73 post workshop webinar for South Atlantic Red Snapper.

SUMMARY: The SEDAR 73 assessment of the South Atlantic stock of red snapper will consist of a data scoping webinar, a workshop, and a series of assessment webinars. See **SUPPLEMENTARY INFORMATION.**

DATES: The SEDAR 73 post workshop webinar will be held via webinar December 16, 2020, from 9 a.m. until 12 p.m. EST. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice. Additional SEDAR 73 workshops and webinar dates and times will publish in a subsequent issue in the **Federal Register**.

ADDRESSES: The SEDAR 73 post workshop webinar will be held via webinar. The webinar is open to members of the public. Registration is available online at: *https://attendee.gotowebinar.com/register/5228135319828971790.*

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Kathleen Howington, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4373; email: *Kathleen.howington@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the post workshop webinar are as follows:

- Review any data issues remaining.
- Finalize any data decisions remaining.
- Continue discussion on modelling issues and decisions.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SAFMC office (see **ADDRESSES**) at least 10 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: November 23, 2020.

Diane M. DeJames-Daly,

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

[FR Doc. 2020–26240 Filed 11–25–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA619]

Atlantic Highly Migratory Species; Exempted Fishing, Scientific Research, Display, and Shark Research Fishery Permits; Letters of Acknowledgment

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

ACTION: Notice of intent; request for comments.

SUMMARY: NMFS announces its intent to issue exempted fishing permits (EFPs), scientific research permits (SRPs), display permits, letters of acknowledgment (LOAs), and shark research fishery permits for Atlantic highly migratory species (HMS) in 2021. EFPs and related permits would authorize collection of a limited number of Atlantic HMS, including tunas, swordfish, billfishes, and sharks, from Federal waters in the Atlantic Ocean, Caribbean Sea, and Gulf of Mexico for the purposes of scientific research, data collection, the investigation of bycatch, and public display, among other things. LOAs acknowledge that scientific research activity aboard a scientific research vessel is being conducted. Generally, EFPs and related permits would be valid from the date of issuance through December 31, 2021, unless otherwise specified in the permit, subject to the terms and conditions of individual permits.

DATES: Written comments received in response to this notice will be considered by NMFS when issuing EFPs and related permits, and must be received on or before *December 28, 2020.*

ADDRESSES: Comments may be submitted electronically via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0145,* click the ''Comment Now'' icon, complete the required fields, and enter or attach your comments.

FOR FURTHER INFORMATION CONTACT: Craig Cockrell, phone: (301) 427–8503, email: *craig.cockrell@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS issues EFPs and related permits where Atlantic HMS regulations (*e.g.,* fishing seasons, prohibited species, authorized gear, closed areas, and minimum sizes) may otherwise prohibit the collection of live animals and/or biological samples for data collection and public display purposes or may otherwise prohibit certain fishing activities that NMFS has an interest in permitting or acknowledging. Pursuant to 50 CFR parts 600 and 635, NMFS Regional Administrator or Director may authorize, for limited testing, public display, data collection, exploratory fishing, compensation fishing, conservation engineering, health and safety surveys, environmental cleanup, and/or hazard removal purposes, the target or incidental harvest of species managed under a fishery management plan (FMP) or fishery regulations that would otherwise be prohibited. These permits exempt permit holders from the specific portions of the regulations that may otherwise prohibit the collection of Atlantic HMS for public education, public display, or scientific research. Collection of Atlantic HMS under EFPs, SRPs, display permits, and shark research fishery permits represents a small portion of the overall fishing mortality for Atlantic HMS, and this mortality is counted against the relevant quota, as appropriate and applicable. The terms and conditions of individual permits are unique; however, all permits will include reporting requirements, limit the number and/or species of Atlantic HMS to be collected, and only authorize collection in Federal waters of the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea.

EFPs and related permits are issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act (Magnuson-Stevens Act) (16 U.S.C. 1801 *et seq.*) and/or the Atlantic Tunas Convention Act (ATCA) (16 U.S.C. 971 *et seq.*). Regulations at 50 CFR 600.745 and 635.32 govern specifically authorized activities, including scientific research activity, exempted fishing, and exempted public display and educational activities with respect to Atlantic HMS. The Magnuson-Stevens Act exempts scientific research conducted by a scientific research vessel from the definition of ''fishing.'' NMFS issues LOAs acknowledging such bona fide research activities involving species that are only regulated under the Magnuson-Stevens Act (*e.g.,* most species of sharks) and not under ATCA. NMFS generally does not consider recreational or commercial vessels to be bona fide research vessels. However, if the vessels have been contracted only to conduct research and not participate in any commercial or recreational fishing activities during that research, NMFS may consider those vessels as bona fide research platforms while conducting the specified research. For example, in the past, NMFS has determined that commercial pelagic longline vessels assisting with population surveys for sharks may be considered ''bona fide research vessels'' while engaged only in the specified research. For such activities, NMFS reviews scientific research plans and may issue an LOA acknowledging that the proposed activity is scientific research for purposes of the Magnuson-Stevens Act. Examples of research acknowledged by LOAs include tagging and releasing sharks during bottom longline surveys to understand the distribution and seasonal abundance of different shark species, and collecting and sampling sharks caught during trawl surveys for life history and bycatch studies.

While scientific research is not defined as ''fishing'' subject to the MSA, scientific research is not exempt from regulation under ATCA. Therefore, NMFS issues SRPs that authorize researchers to collect HMS from bona fide research vessels for collection of species managed under this statute (*e.g.,* tunas, swordfish, and billfish). One example of research conducted under SRPs consists of scientific surveys of tunas, swordfish, and billfish conducted from NOAA research vessels.

EFPs are issued for activities conducted from commercial or recreational fishing vessels. Examples of activities conducted under EFPs include collection of young-of-the-year bluefin tuna for genetic research from recreational fishing vessels; conducting billfish larval tows from private vessels to determine billfish habitat use, life history, and population structure; and tagging sharks caught on commercial or recreational fishing gear to determine post-release mortality rates.

NMFS also intends to issue display permits for the collection of sharks and other HMS for public display in 2021. Collection of sharks and other HMS sought for public display in aquaria often involves collection when the commercial fishing seasons are closed, collection of otherwise prohibited species (*e.g.,* sand tiger sharks), and collection of fish below the regulatory minimum size. Under Amendment 2 to the 2006 Consolidated Atlantic HMS FMP, NMFS determined that dusky sharks cannot be collected for public display.

The majority of EFPs and related permits described in this annual notice relate to scientific sampling and tagging of Atlantic HMS within existing quotas, and the impacts of the activities to be conducted usually have been previously analyzed in various environmental assessments and environmental impact statements for Atlantic HMS management. In most such cases, NMFS intends to issue these permits without additional opportunity for public comment beyond what is provided in this notice. Occasionally, NMFS receives applications for research activities that were not anticipated, or for research that is outside the scope of general scientific sampling and tagging of Atlantic HMS, or rarely, for research that is particularly controversial. Should NMFS receive such applications, NMFS will provide additional opportunity for public comment, consistent with the regulations at 50 CFR 600.745.

On December 4, 2019, NMFS received an application for an EFP requesting an exemption from the regulations that prohibit the retention of bluefin tuna with unauthorized gear onboard. See 50 CFR 635.19(b). This application was submitted by the Cape Cod Commercial Fishermen's Alliance (CCCFA). The applicants suggested that, with the use of electronic monitoring and through issuance of an EFP, there would be sufficient at-sea monitoring to verify that the catch of bluefin tuna occurred with authorized gear (*i.e.,* rod and reel and harpoon gear) and not with the unauthorized gear onboard the vessel (*i.e.,* benthic longline, jigging machines, handgear, demersal gillnet, or otter trawl). An EFP was issued to the CCCFA on April 28, 2020 that exempted 10 vessels from regulations at 50 CFR 635.19(b). Since issuance of the permit, nine trips have been taken from July through August in New England, four bluefin tuna were retained, and four bluefin tuna were lost at the boat. Harpoon gear was not used for any of the nine trips. There were no shark interactions that occurred during fishing activities in 2020. Comments are invited specifically on these issues related to potential issuance of a similar permit to the CCCFA in 2021.

In addition, this notice invites comments on the shark research fishery

first implemented through Amendment 2 to the 2006 Consolidated Atlantic HMS FMP. This research fishery is conducted under the auspices of the EFP program. Shark research fishery permit holders assist NMFS in collecting valuable shark life history and other scientific data required in shark stock assessments. Since the shark research fishery was established in 2008, the research fishery has allowed for: The collection of fishery dependent data for current and future stock assessments; the operation of cooperative research to meet NMFS' ongoing research objectives; the collection of updated life-history information used in the sandbar shark (and other species) stock assessment; the collection of data on habitat preferences that might help reduce fishery interactions through bycatch mitigation; the evaluation of the utility of the mid-Atlantic closed area on the recovery of dusky sharks; the collection of hook-timer and pop-up satellite archival tag information to determine at-vessel and post-release mortality of dusky sharks; and the collection of sharks to update the weight conversion factor from dressed weight to whole weight. In 2021, NMFS intends to examine the feasibility of using electronic monitoring to accurately measure soak times of bottom longline sets. Fishermen who wish to participate must fill out an application for a shark research fishery permit under the EFP program. Shark research fishery participants are subject to 100-percent observer coverage. In recent years, all non-prohibited shark species brought back to the vessel dead have been required to be retained and were counted against the appropriate quotas of the shark research fishery participant. Additionally, in recent years, all participants of the shark research fishery were limited to a very small number of dusky shark mortalities on a regional basis. Once the designated number of dusky shark mortalities occurs in a specific region, certain terms and conditions are applied (*e.g.,* soak time limits). If subsequent interactions occur in the region all shark research fishery activities must stop within that region. Participants would continue to be limited in the number of sets allowed on each trip and the number of hooks allowed on each set. All participants are also limited to a maximum of 500 hooks onboard the vessel while on a shark research fishery trip. A **Federal Register** notice describing the specific objectives for the shark research fishery in 2021 and requesting applications from interested and eligible shark fishermen is expected to publish in the near future. NMFS requests public comment regarding NMFS' intent to issue shark research fishery permits in 2021 during the comment period of this notice.

The number of specimens that have been authorized thus far under EFPs and other related permits for 2020, as well as the number of specimens collected in 2019, is summarized in Table 1. The total amount of collections in 2019 were within the analyzed quotas for all quota managed Atlantic HMS species. The number of specimens collected in 2020 will be available when all 2020 interim and annual reports are submitted to NMFS.

In all cases, mortalities associated with EFPs, SRPs, or display permits (except for larvae) are counted against the appropriate quota. NMFS issued a total of 40 EFPs, SRPs, display permits, and LOAs in 2019 for the collection of HMS and 5 shark research fishery permits. As of October 20, 2020, NMFS has issued a total of 31 EFPs, SRPs, display permits, and LOAs and 8 shark research fishery permits.

TABLE 1—SUMMARY OF HMS EXEMPTED FISHING PERMITS ISSUED IN 2019 AND 2020, OTHER THAN SHARK RESEARCH FISHERY PERMITS

["HMS" refers to multiple species being collected under a given permit type]

Permit type	2019			2020	
	Permits issued**	Authorized fish (num) **	Fish kept/ discarded dead (num)	Permits issued **	Authorized fish (num) **
EFP					
HMS	7	120	0	10	550
Shark	4	20	6	3	0
Tuna	2	750	0	2	750
SRP					
HMS					
Shark	4	549	0	1	50
	1	486	145	2	1,325
Display					
HMS	2	82	0	2	82
Shark	5	193	56	6	321
Total	25	2,200	716	28	3,078
LOA *					
Shark	15	0	839	5	0

* LOAs acknowledge, but do not authorize, scientific research activity. Thus, the number of sharks in the authorized fish column are in part estimates of harvest under LOAs. LOA holders are either required or encouraged to report all fishing activities in a timely manner.

** Some shark EFPs, SRPs, and LOAs were issued for the purposes of tagging and the opportunistic sampling of sharks and were not expected to result in large amounts of mortality, thus no limits on sampling were set. Some mortality may occur throughout 2020, and will be accounted for under the 60 metric ton shark research and display quota.

Final decisions on the issuance of any EFPs, SRPs, display permits, and shark research fishery permits will depend on the submission of all required information about the proposed activities, NMFS' review of public comments received on this notice, an applicant's reporting history on past permits, if vessels or applicants were issued any prior violations of marine resource laws administered by NOAA, consistency with relevant National Environmental Policy Act (NEPA) documents, and any consultations with appropriate Regional Fishery

Management Councils, states, or Federal agencies. NMFS does not anticipate any significant environmental impacts from the issuance of these EFPs, consistent with the assessment of such activities within the environmental impacts analyses in existing HMS actions, including the 1999 FMP, the 2006 Consolidated Atlantic HMS FMP and its amendments, Amendment 2 to the Consolidated Atlantic HMS FMP, the Environmental Assessment for the 2012 Swordfish Specifications, and the Environmental Assessment for the 2015 Final Bluefin Tuna Quota and Atlantic Tuna Fisheries Management Measures.

(Authority: 16 U.S.C. 971 *et seq.* and 16 U.S.C. 1801 *et seq.*)

Dated: November 23, 2020.

Jennifer M. Wallace,

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

[FR Doc. 2020–26193 Filed 11–25–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA665]

Fisheries of the Gulf of Mexico and Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 68 Assessment Webinar I for Gulf of Mexico and Atlantic scamp grouper.

SUMMARY: The SEDAR 68 assessment process of Gulf of Mexico and Atlantic scamp will consist of a series of data and assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 68 Assessment Webinar I will be held December 14, 2020, from 1 p.m. until 4 p.m., Eastern Time.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop, (2) a series of assessment webinars, and (3) A Review Workshop. The product of the Data Workshop is a report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The assessment webinars produce a report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The product of the Review Workshop is an Assessment Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion during the Assessment Webinar are as follows:

- Using datasets and initial assessment analysis recommended from the data webinars, panelists will employ assessment models to evaluate stock status, estimate population benchmarks and management criteria, and project future conditions.
- Participants will recommend the most appropriate methods and configurations for determining stock status and estimating population parameters.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 3 business days prior to each webinar.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: November 23, 2020.

Diane M. DeJames-Daly,

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

[FR Doc. 2020–26241 Filed 11–25–20; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to the Procurement List.

SUMMARY: The Committee is proposing to add product(s) and service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: December 27, 2020.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this

notice will be required to procure the product(s) and service(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following product(s) and service(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Product(s)

NSN(s)—Product Name(s):
6505–01–420–9275—Rehydration Salts, Oral, Lemon, 50g
6505–01–562–3894—Rehydration Salts, Oral, Modified, Lemon, 10g
6505–01–491–7131—Rehydration Salts, Oral, Modified, Mixed Berry, 10g
6505–01–491–8351—Rehydration Salts, Oral, Modified, Citrus, 21g
6505–01–525–8930—Rehydration Salts, Oral, Modified, Fruit Punch, 21g
6505–01–575–8540—Rehydration Salts, Oral, Orange, 12.5g
6505–01–575–8568—Rehydration Salts, Oral, Lime, 12.5g
6505–01–575–8578—Rehydration Salts, Oral, Pomegranate Acai Blueberry, 12.5g
Designated Source of Supply: Alphapointe, Kansas City, MO
Contracting Activity: Defense Logistics Agency, DLA Troop Support

Service(s)

Service Type: Contractor Operated Civil Engineer Supply Store
Mandatory for: U.S. Air Force, Whiteman AFB, MO
Designated Source of Supply: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: Dept of the Air Force, FA4625 509 CONS CC

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2020–26235 Filed 11–25–20; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds product(s) and service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) and service(s) from the Procurement List previously furnished by such agencies.

DATES: *Date added to and deleted from the Procurement List:* December 27, 2020.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 7/10/2020, 8/21/2020 and 9/4/2020, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the product(s) and service(s) and impact of the additions on the current or most recent contractors, the Committee has determined that the product(s) and service(s) listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the product(s) and service(s) to the Government.

2. The action will result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) proposed for addition to the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are added to the Procurement List:

Product(s)

NSN(s)—Product Name(s):
8415–00–NIB–1374—Face Covering/Mask, Universally Sized, Olive Green, PG/5
8415–00–NIB–1375—Face Covering/Mask, Universally Sized, Brown, PG/5
8415–00–NIB–1376—Face Covering/Mask, Universally Sized, Tan, PG/5
8415–00–NIB–1378—Face Covering/Mask, Universally Sized, Camo, PG/5
8415–00–NIB–1379—Face Covering/Mask, Universally Sized, Black, PG/5
8415–00–NIB–1380—Face Covering/Mask, Universally Sized, Olive Green, PG/50
8415–00–NIB–1381—Face Covering/Mask, Universally Sized, Brown, PG/50
8415–00–NIB–1382—Face Covering/Mask, Universally Sized, Tan, PG/50
8415–00–NIB–1383—Face Covering/Mask, Universally Sized, Camo, PG/50
8415–00–NIB–1384—Face Covering/Mask, Universally Sized, Black, PG/50
Designated Source of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC; Industries of the Blind, Inc., Greensboro, NC; Blind Industries & Services of Maryland, Baltimore, MD; Alphapointe, Kansas City, MO; Southeastern Kentucky Rehabilitation Industries, Inc., Corbin, KY
Mandatory For:
Contracting Activity: Committee for Purchase From People Who Are Blind or Severely Disabled

Service(s)

Service Type: Janitorial Service
Mandatory for: FAA, Denver Air Traffic Control Tower/Base Building and TRACON/Generator Building, Denver, CO
Designated Source of Supply: Bayaud Industries, Inc., Denver, CO
Contracting Activity: Federal Aviation Administration, 697DCK Regional Acquisitions SVCS

Service Type: Laundry Service
Mandatory for: Pennsylvania Air National Guard, 171st Air Refueling Wing, Aircrew Alert Facility, Coraopolis, PA
Designated Source of Supply: Hancock County Sheltered Workshop, Inc., Weirton, WV
Contracting Activity: Dept of the Army, W7NX USPFO Activity PA ARNG

Deletions

On 10/23/2020, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the

product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
6505–01–121–2336—Sunscreen, Lotion, SPF–15
Designated Source of Supply: SMA Healthcare, Inc., Daytona Beach, FL
Contracting Activity: DLA Troop Support, Philadelphia, PA

Service(s)

Service Type: Janitorial/Custodial
Mandatory for: U.S. Federal Building: 88 West 100 North, Provo, UT
Contracting Activity: General Services Administration, FPDS Agency Coordinator

Service Type: Food Service Attendant
Mandatory for: Air National Guard, 179AW, Ohio Air National Guard Base, Mansfield, OH
Designated Source of Supply: The Center for Individual and Family Services, Mansfield, OH
Contracting Activity: Dept of the Army, W7NU USPFO Activity OH ARNG

Service Type: Custodial Services
Mandatory for: USDA, #257 Aduana Street, Mayaguez, PR
Designated Source of Supply: The Corporate Source, Inc., Garden City, NY
Contracting Activity: Animal and Plant Health Inspection Service, USDA APHIS MRPBS

Service Type: Custodial Services
Mandatory for: USDA, Eugenio Maria de Hostos International Airport: Main Terminal Building Mayaguez Airport, Mayaguez, PR
Designated Source of Supply: The Corporate Source, Inc., Garden City, NY
Contracting Activity: Animal and Plant Health Inspection Service, USDA APHIS MRPBS

Service Type: Janitorial/Custodial
Mandatory for: DOT Murphy Building: Bradley International Airport, Floors 2, 3 & 4, Windsor Locks, CT
Contracting Activity: Transportation, Department of, Dept of Trans

Service Type: Janitorial/Custodial
Mandatory for: U.S. Army Reserve Center: Fort Dix
Designated Source of Supply: Occupational Training Center of Burlington County, Burlington, NJ
Contracting Activity: Dept of the Army, W6QM MICC CTR–FT DIX (RC)

Service Type: Janitorial & Grounds Service
Mandatory for: GSA PBS Region 9, Alan Bible Federal Building, Las Vegas, NV
Designated Source of Supply: Opportunity Village Association for Retarded Citizens, Las Vegas, NV
Contracting Activity: Public Buildings Service, PBS R9

Service Type: Food Service Attendant
Mandatory for: Base Miami Beach, Miami Beach, FL
Designated Source of Supply: Goodwill Industries of South Florida, Inc., Miami, FL
Contracting Activity: U.S. Coast Guard, DOL–9

Service Type: Data Entry/Data Base Management
Mandatory for: GSA, Paints and Chemicals Commodity Center: 400 15th Street, SW, Auburn, WA
Designated Source of Supply: JobOne, Independence, MO
Contracting Activity: Public Buildings Service, PBS R6

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2020–26236 Filed 11–25–20; 8:45 am]

BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Global Markets Advisory Committee; Meeting

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of meeting.

SUMMARY: The Commodity Futures Trading Commission (CFTC) announces that on December 17, 2020, from 9:15 a.m. to 12:00 p.m. (Eastern Standard Time), the Global Markets Advisory Committee (GMAC) will hold a public meeting via teleconference. At this meeting, the GMAC will hear presentations on issues affecting international central counterparties and the global clearing ecosystem.

DATES: The meeting will be held on December 17, 2020, from 9:15 a.m. to 12:00 p.m. (Eastern Standard Time). Members of the public who wish to submit written statements in connection with the meeting should submit them by December 24, 2020.

ADDRESSES: The meeting will take place via teleconference. You may submit public comments, identified by ''Global Markets Advisory Committee,'' via the CFTC website, *http://comments.cftc.gov.* If you are unable to submit comments via the CFTC website, contact Andree Goldsmith, Designated Federal Officer, via the contact information listed below to discuss alternate means of submitting your comments. Any statements submitted in connection with the committee meeting will be made available to the public, including publication on the CFTC website, *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Andree Goldsmith, GMAC Designated Federal Officer, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW, Washington, DC 20581; (202) 418–6624; *agoldsmith@cftc.gov.*

SUPPLEMENTARY INFORMATION: Members of the public may listen to the meeting by telephone by calling a domestic toll-free telephone or international toll or toll-free number to connect to a live, listen-only audio feed. Call-in participants should be prepared to provide their first name, last name, and affiliation.

Domestic Toll Free: 1–877–951–7311.

International Toll and Toll Free: Will be posted on the CFTC's website, *http://www.cftc.gov,* on the page for the meeting, under Related Links.

Pass Code/Pin Code: 4883840.

The meeting time and agenda may change to accommodate other GMAC priorities. For time and agenda updates, please visit the GMAC committee website at: *https://www.cftc.gov/About/CFTCCommittees/GlobalMarketsAdvisory/gmac_meetings.html.*

After the meeting, a transcript of the meeting will be published through a link on the CFTC's website at: *http://www.cftc.gov.* All written submissions provided to the CFTC in any form will also be published on the CFTC's website. Persons requiring special accommodations to attend the meeting because of a disability should notify the contact person above.

(Authority: 5 U.S.C. App. 2.)

Dated: November 23, 2020.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–26220 Filed 11–25–20; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Copies of Crop and Market Information Reports

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is announcing an opportunity for public comment on the extension of a proposed collection of certain information by the agency. In

compliance with the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments, as described below, on the proposed Information Collection Request (''ICR'') titled: Copies of Crop and Market Information Reports.

DATES: Comments must be submitted on or before January 26, 2021.

ADDRESSES: You may submit comments, identified by OMB Control No. 3038–0015 by any of the following methods:

- The Agency's website, at *http://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, 1155 21st Street NW, Washington, DC 20581.
- *Hand delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Adam Charnisky, Division of Market Oversight, U.S. Commodity Futures Trading Commission, 525 West Monroe, Chicago, IL 60661; (312) 596–0630; FAX: (312) 596–0711; email: *acharnisky@cftc.gov* and refer to OMB Control No. 3038–0015.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below.

Title: ''Copies of Crop and Market Information Reports,'' OMB Control No. 3038–0015. This is a request for extension of a currently approved information collection.

Abstract: The information collected pursuant to this rule, 17 CFR 1.40, is in the public interest and is necessary for market surveillance. Manipulation of commodity futures prices is a violation of the Commodity Exchange Act (Act). Section 9(a)(2) of the Act (7 U.S.C. 13(a)(2)) prohibits the dissemination of false or misleading or knowingly inaccurate reports that affect or tend to affect the prices of commodities. In order to facilitate the enforcement of this provision, Commission regulation 1.40 requires that members of an exchange and FCMs provide upon request copies of any report published or given general circulation which concerns crop or market information that affects or tends to affect the price of any commodity.

With respect to the following collection of information, the CFTC invites comments on:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- Evaluate the accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, usefulness, and clarity of the information to be collected; and
- Minimize the burden of 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.

You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse, or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

Affected Entities: Entities potentially affected by this action include future commission merchants (''FCMs'') and members of contract markets.

Burden statement: The respondent burden for this collection is estimated to average 0.17 hours per response.

- *Respondents/Affected Entities:* 10.
- *Estimated number of responses:* 10.
- *Estimated total annual burden on respondents:* 1.7 hours.
- *Frequency of collection:* On occasion.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: November 23, 2020.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–26198 Filed 11–25–20; 8:45 am]

BILLING CODE 6351–01–P

[1] 17 CFR 145.9.

COMMODITY FUTURES TRADING COMMISSION

Technology Advisory Committee

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Meeting.

SUMMARY: The Commodity Futures Trading Commission (CFTC) announces that on December 14, 2020, from 9 a.m. to 12 p.m., the Technology Advisory Committee (TAC) will hold a public meeting via teleconference. At this meeting, the TAC will hear presentations from the TAC subcommittees on Distributed Ledger Technology and Market Infrastructure and Virtual Currencies. The TAC also plans to vote on a recommendation from the Cyber Security subcommittee.

DATES: The meeting will be held on December 14, 2020, from 9 a.m. to 12 p.m. Members of the public who wish to submit written statements in connection with the meeting should submit them by December 21, 2020.

ADDRESSES: The meeting will take place via teleconference. You may submit public comments, identified by ''Technology Advisory Committee,'' by any of the following methods:

- *CFTC website: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Comments Online process on the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission,

Commodity Futures Trading Commission, Three Lafayette Center, 1155 21st Street NW, Washington, DC 20581.

• *Hand Delivery/Courier:* Same as Mail, above.

Any statements submitted in connection with the committee meeting will be made available to the public, including publication on the CFTC website, *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Meghan Tente, TAC Designated Federal Officer, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581; (202) 418–5785.

SUPPLEMENTARY INFORMATION: Members of the public may listen to the meeting by telephone by calling a domestic toll-free telephone or international toll or toll-free number to connect to a live, listen-only audio feed. Call-in participants should be prepared to provide their first name, last name, and affiliation.

• *Domestic Toll Free:* 877–951–7311.

• *International Toll and Toll Free:* Will be posted on the CFTC's website, *http://www.cftc.gov,* on the page for the meeting, under Related Links.

• *Pass Code/Pin Code:* 6754747.

The meeting agenda may change to accommodate other TAC priorities. For agenda updates, please visit the TAC committee website at: *https://www.cftc.gov/About/CFTCCommittees/TechnologyAdvisory/tac_meetings.html.* After the meeting, a transcript of the meeting will be published through a link on the CFTC's website at: *http://www.cftc.gov.* All written submissions provided to the CFTC in any form will also be published on the CFTC's website. Persons requiring special accommodations to attend the meeting because of a disability should notify the contact person above.

(Authority: 5 U.S.C. app. 2 section10(a)(2)).

Dated: November 23, 2020.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–26173 Filed 11–25–20; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent to Renew Collection 3038–0026, Gross Collection of Exchange-Set Margins for Omnibus Accounts

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (CFTC) is announcing an opportunity for public comment on the proposed renewal of a collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments on requirements relating to Gross Collection of Exchange-Set Margins for Omnibus Accounts.

DATES: Comments must be submitted on or before January 26, 2021.

ADDRESSES: You may submit comments, identified by OMB Control Number 3038–0026, by any of the following methods:

• *Agency website, via its Comments Online process: http://comments.cftc.gov.* Follow the instructions for submitting comments through the website.

• *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

• *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Mark Bretscher, Special Counsel, Market Participants Division, Commodity Futures Trading Commission, (312) 353–0529; email: *mbretscher@cftc.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.,* Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Title: Gross Collection of Exchange-Set Margins for Omnibus Accounts (OMB Control Number 3038–0026). This is a request for extension of a currently approved information collection.

Abstract: Commission Regulation 1.58 requires that FCMs margin omnibus accounts on a gross, rather than a net, basis. The regulation provides that the carrying FCM need not collect margin for positions traded by a person through an omnibus account in excess of the amount that would be required if the same person, instead of trading through an omnibus account, maintained its own account with the carrying FCM. To prevent abuse of this exception to the regulation, a carrying FCM must maintain a written representation from the originating FCM or foreign broker that the particular positions held in the omnibus account are part of a hedge or spread transaction. This rule is promulgated pursuant to the Commission's rulemaking authority contained in Sections 4c, 4d, 4f, 4g and 8a of the Commodity Exchange Act, 7 U.S.C. 6c, 6d, 6f, 6g and 12a (2000).

With respect to the following collection of information, the CFTC invites comments on:

• Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;

• The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Ways to enhance the quality, usefulness, and clarity of the information to be collected; and

• Ways to minimize the burden of 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.

You should submit only information that you wish to make available publically. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according

to the procedures established in Section 145.9 of the Commissions regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it any deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

Burden Statement: The Commission is revising its estimate of the burden due to the reduced number of futures commission merchants in the industry. The respondent burden for this collection is estimated to be as follows:

- *Estimated number of respondents:* 53.
- *Total annual responses:* 212.
- *Estimated Total Annual Burden Hours:* 17.
- *Frequency of Collection:* On occasion.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.)*

Dated: November, 20, 2020.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–26170 Filed 11–25–20; 8:45 am]

BILLING CODE 6351–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Instructions for Commission Support Grants: How To Apply for State Service Commission Support Grants

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Corporation for National and Community Service (CNCS) has submitted a public information collection request (ICR) entitled Application Instructions for Commission Support Grants: How to Apply for State Service Commission Support Grants for review and approval in accordance with the Paperwork Reduction Act.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by December 28, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Arminda Pappas, at 202–606–6659 or by email to *apappas@cns.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, 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;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose 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

A 60-day Notice requesting public comment was published in the **Federal Register** on July 6, 2020 at 85 FR 40266. This comment period ended September 4, 2020. One public comment was received from this Notice. The comment was nonresponsive to the request for comment.

Title of Collection: Application Instructions for Commission Support Grants: How to Apply for State Service Commission Support Grants.

OMB Control Number: 3045–0099.

Type of Review: Renewal.

Respondents/Affected Public: Organizations OR State Governments.

Total Estimated Number of Annual Responses: 52.

Total Estimated Number of Annual Burden Hours: 1,924.

Abstract: The application instructions conform to the Corporation for National and Community Service's online grant application system, eGrants, which applicants must use to respond to CNCS Commission Support Grant funding opportunities. CNCS seeks to renew the current information collection. The revisions are intended to streamline the application process. The information collection will otherwise be used in the same manner as the existing application. CNCS also seeks to continue using the current application until the revised application is approved by OMB.

Dated: November 20, 2020.

Arminda Pappas,

Grant Review Manager.

[FR Doc. 2020–26187 Filed 11–25–20; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of Defense Science and Technology Reinvention Laboratory (STRL) Personnel Demonstration (Demo) Project in the U.S. Army Research Institute for the Behavioral and Social Sciences (ARI)

AGENCY: Under Secretary of Defense for Research and Engineering (USD(R&E)), Department of Defense (DoD).

ACTION: Personnel demonstration project notice.

SUMMARY: This **Federal Register** Notice (FRN) serves as notice of the adoption by the U.S. Army Research Institute for the Behavioral and Social Sciences (ARI) of the personnel demonstration project flexibilities implemented by the Combat Capabilities Development Command (CCDC) Command, Control, Communications, Computers, Cyber, Intelligence, Surveillance, and Reconnaissance (C5ISR) Center (previously designated as the U.S. Army Communications—Electronics Research, Development and Engineering Center and the U.S. Army Communications—Electronics Command, Research, Development and Engineering), the CCDC Chemical Biological Center (CBC) (previously designated as the Edgewood Chemical Biological Center), and the CCDC Soldier Center (SC) (previously designated as the Natick Soldier Research, Development and Engineering Center). The majority of flexibilities and administrative procedures are adopted without changes. However, modifications were made when necessary to address ARI's specific

[1] 17 CFR 145.9.

organizational, management structure, workforce, and approval needs and to conform to changes in applicable law and regulations after the publication of the adopted personnel demonstration project flexibilities. In addition, changes were made based on current law, best practices, and administrative guidance.

DATES: Implementation of this demonstration project will begin no earlier than November 27, 2020.

FOR FURTHER INFORMATION CONTACT:

• ARI: Dr. Scott Shadrick, 254–288–3800, *Scott.B.Shadrick.civ@mail.mil.*

• *DoD*: Dr. Jagadeesh Pamulapati, Director, Laboratories and Personnel Office, 571–372–6372, *Jagadeesh.Pamulapati.civ@mail.mil*

SUPPLEMENTARY INFORMATION: Section 342(b) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 1995, Public Law (Pub. L.) 103–337, as amended, authorizes the Secretary of Defense (SECDEF), through the USD(R&E), to conduct personnel demonstration projects at DoD laboratories designated as STRLs.

1. Background

Since 1966, many studies of DoD laboratories have been conducted on laboratory quality and personnel. Most of these studies have recommended improvements in civilian personnel policy, organization, and management. Pursuant to the authority provided in section 342(b) of the NDAA for FY 1995, as amended, a number of DoD STRL personnel demonstration projects were approved. These projects are ''generally similar in nature'' to the Department of Navy's ''China Lake'' Personnel Demonstration Project. The terminology, ''generally similar in nature,'' does not imply an emulation of various features, but rather implies a similar opportunity and authority to develop personnel flexibilities that significantly increase the decision authority of laboratory commanders and/or directors.

ARI conducted a thorough review of the personnel practices of existing DoD laboratories designated as STRLs and applicable laws, regulations, and guidance to identify potential flexibilities that would allow ARI to (1) improve effectiveness through a more flexible, responsive personnel system; (2) increase management authority over human resources management; (3) recruit, develop, motivate, and retain a high quality workforce; and (4) adjust workforce levels to meet strategic program and organizational needs.

This demonstration project involves:

(1) New appointment authorities;

(2) Extended probationary periods;

(3) Supervisory probationary periods;

(4) Pay banding;

(5) Streamlined delegated examining;

(6) Simplified job classification;

(7) A pay-for-performance based appraisal system;

(8) A sabbatical program;

(9) Academic degree and certificate training;

(10) A Volunteer Emeritus Corps; and

(11) Senior Scientific Technical Manager (SSTM) positions.

The demonstration project also involves the use of numerous direct hire authorities, as appropriate and in accordance with guidance. Many aspects of a demonstration project are experimental. Modifications may be made from time to time as we gain experience, analyze results, and reach conclusions on how the system is working. The provisions of Department of Defense Instruction (''DoDI'') 1400.37, ''Science and Technology Reinvention Laboratory (STRL) Personnel Demonstration Projects'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/140037p.pdf*) (including subsequently issued or superseding instructions), will be followed to modify, supplement through adoption, or otherwise change this demonstration project plan.

2. Overview

ARI intends to build its demonstration project using flexibilities adopted from existing STRL demonstration programs with significant overlap with the CCDC C5ISR, CCDC CBC, and CCDC SC.

As described in 73 FR 73248, December 2, 2008, flexibilities are defined as those features described in a STRL FRN; amendments thereto published in an FRN; minor changes made within the authorities of a demonstration project plan, documented in laboratory internal issuances and disseminated to employees; and official laboratory implementing issuances that have been distributed.

3. Access to Flexibilities for Other STRLs

Flexibilities published in this FR will be available for use by all STRLs listed enumerated in section 1105(a) of Public Law 111–84, as amended, in accordance with DoDI 1400.37 (including revised or superseded instructions) and after the fulfillment of any collective bargaining obligations.

4. Summary of Comments

Thirteen commenters provided comments and questions regarding the ARI Personnel Demonstration Project, **Federal Register**, 84 FR 64469, dated November 22, 2019. The following is a summary of these written questions by topical area and a response to each.

(1) Pay Banding

Comment: Five commenters expressed concern about allowing all positions to advance, ''unconstrained,'' to the top of a given pay band. One of the comments referenced language that was included in a draft version of the **Federal Register** Notice that was provided to the ARI workforce for review prior to publication. The language stated that, ''Not all positions in a given pay band will be able to progress to the top of that band if the duties and responsibilities of the specific position do not warrant such a progression.'' Another commenter recommended adopting a minor modification used by other laboratories to provide the STRL Director with the ''authority to insert 'control points' for any identified position in any demo pay band and/or occupational family.'' The commenter suggested that the control points would enable the Director to maintain cost discipline while ''ensuring salary increases reflect appropriate levels of performance and/or responsibility.'' Additionally, one commenter asked how control points would impact the midpoint and asked about the potential negative impact of control points on the demonstration performance system. Finally, one commenter questioned the use of linking the top of each pay band the GS Step 10 pay level and not raising the pay caps above the GS Step 10 level.

Response: This **Federal Register** Notice is revised to provide the STRL Director with the ability to insert control points, consistent with the minor modification adopted by Combat Capabilities Development Command (CCDC) Command, Control, Communications, Computers, Cyber, Intelligence, Surveillance, and Reconnaissance (C5ISR) Center, to maintain budget control and flexibility in using the pay banding system. The flexibility provides a tool for managing organization workforce structure and pay and will ensure employees are compensated commensurate with their duties and performance. The use of control points does not negatively impact the midpoint nor the demonstration performance system. The following are examples for use of control points. If an ARI employee in the DB–02 pay band (GS–05 to GS–11) is required to perform duties at the GS–07 equivalent level, and there is no organizational requirement for progressive duties and responsibilities in the career series beyond the GS–07

equivalent level, then the employee's salary would not progress beyond the appropriate equivalent level control point. If an ARI employee in the DE–03 pay band (GS–12 to GS–13) is required to perform duties at the GS–12 equivalent level, and ARI has an organizational requirement for progressive duties and responsibilities in the career series beyond the GS–12 equivalent level, then the employee's salary could progress to the appropriate equivalent level control point as performance requirements dictate.

The pay band structure in this personnel demonstration project was adopted from the U.S. Army Armament Research, Development, and Engineering Center (currently referred to as CCDC Armaments Center). The structure links the pay band's lower and upper limits to the GS pay scales. As the rates of the GS pay scale increase with annual general pay increases, the upper and lower base pay rates of the demonstration project's pay bands also will increase. This allows the laboratory to more effectively compensate high performance while also maintaining necessary cost controls.

(2) Award Timeline

Comment: One comment was received concerning the timing or timeline for payout of awards.

Response: The post-implementation/regular rating period will be from 1 February to 31 January. However, the implementation/initial rating period may be shorter to allow for a paced and orderly transition from the current DPMAP evaluation system to the demonstration project pay for performance system. During the post-implementation/regular performance rating cycle, employees will submit their accomplishments by 31 January of the rating period. Raters will then conduct initial ratings and submit those ratings for review during reconciliation meetings conducted by the pay pool panel(s). Ratings will be finalized and personnel actions submitted for processing at the end of March. During April, employees and supervisors will participate in performance review discussions. Payouts would be effective in May, generally by the first pay period in the month.

(3) Pay for Performance

Comment: Two comments addressed the use of time off awards as a part of the performance payout in lieu of cash bonus. A third comment addressed employees at the GS step 10 equivalent pay level.

Response: Initially, time off awards will not be used as a performance payout in the demonstration project but this may change as experience is gained. Time-off awards may still be awarded in accordance with the Army incentive awards program.

Employees at the top of the pay band (GS step 10 equivalent level) are eligible to receive a pay for performance payout equivalent to the combination of any base pay increase and bonus payout, in the form of a bonus ONLY.

(4) Performance Management Board and Pay Pool Panel Membership

Comment: One commenter questioned whether or not ARI's Scientific and Professional (ST) position would be required to serve on the Performance Management Board (PMB) or Pay Pool Panels in any capacity. A second commenter questioned how many individuals would be appointed to the PMB, how many ad hoc members would be appointed, what roles members perform, and whether there would be term limits. The same commenter asked about the full membership of the pay pool panel.

Response: Performance Management Board (PMB) and Pay Pool Panel members will be appointed by the Director, ARI, consistent with governing regulations and practices. To ensure confidence in a fair and equitable performance management process, appointments will be made in a manner that avoids conflicts of interest. There are no term limits or a fixed number of members for the PMB. The workforce will be informed of the PMB and Pay Pool Panel's composition prior to the start of a new rating cycle, and upon any mid-cycle change. Ad hoc PMB members are non-voting members and serve in an advisory role regarding functional or administrative matters impacting the performance management system.

(5) Personnel Requirements

Comment: Two commenters asked what additional staffing requirements are required to implement the project.

Response: Currently one ARI employee is assigned responsibility for management of ARI's demonstration project. This employee is assisted by other ARI employees as needed. Staffing requirements may be adjusted over the course of the project as necessary.

(6) Details and Temporary Promotions

Comment: Two commenters asked multiple questions concerning details and temporary promotions. The series of comments and questions requested clarification on pay setting, travel, and pay for details and temporary promotions. Comments also addressed the ability to temporarily promote an employee to a different pay band.

Response: This **Federal Register** Notice has been revised to include additional provisions regarding details and temporary promotions. An employee may be detailed or temporarily promoted to a position in a pay band with a higher maximum salary. A base pay increase may be granted for details and temporary promotions when the position significantly increases the complexity, responsibility, or authority of the employee's work, or for other compelling reasons. The PMB will establish guidelines regarding pay increases associated with details and temporary promotions. Details and temporary promotions may be determined by a competitive or a non-competitive process. The **Federal Register** Notice allows ARI, to the extent required, to extend the length of details and temporary promotions for a period up to two years. Existing laws and regulations pertaining to temporary duty status, travel, and tax requirements remain applicable. Eligibility for details or temporary promotions will be documented in ARI's internal operating procedures or business rules.

(7) Occupational Series and Occupational Families

Comment: One commenter questioned the occupational series included in the Engineering & Science (E&S) occupational family.

Response: ARI's current table of distribution and allowances has two occupational series that qualify for the E&S family. Therefore, only those two occupational series (psychologist and statisticians) were included. As noted in Appendix B, additional occupational series may be added in the future, as needed, to support mission requirements.

(8) Classification

Comment: One commenter asked about the appropriate level of delegated classification authority and necessary qualifications. They also asked how individuals with delegated classification authority will interact with the Director.

Response: Classification authority will be delegated to the ARI Director, but it is not anticipated that classification authority will be further delegated in the near-term. Unless otherwise delegated, ARI will rely on classification specialists at the Civilian Human Resources Agency (or other supporting human resources entity) to perform classification functions. Any delegated authority will require demonstrated competence in the

technical principles, policies, and standards for classifying positions based on the duties and responsibilities assigned and the qualifications required to do the work. Any individual with delegated classification authority will be required to complete training prior to any classification activities and will be responsible to the Director.

(9) Pay Pools Compositions

Comment: One commenter asked for more specificity on the composition of the pay pool panels in the **Federal Register** Notice. Two commenters discussed the size of ARI and suggested that the pay pool panels would be too small to allow for a fair and equitable system.

Response: As noted in the initial **Federal Register** Notice (page 64471, section G, paragraph 2), the Performance Management Board will determine the composition of the pay-for-performance pay pools in accordance with the guidelines of the IOP (Internal Operating Procedures). Additionally, the names of the pay pool manager and pay pool members will be published prior to each new performance rating period. When necessary, changes to pay pools may be made based on organizational structure, the number of employees and their occupational composition, work levels and work categories, and the size and manageability of pay pools.

Pay pools will generally be between 25 and 75 employees; however, smaller or larger pay pools may be appropriate where organization and mission dictate.

(10) Significant Accomplishment Rule

Comment: Two comments were related to the significant accomplishment rule. One comment requested that the rule be eliminated and a second suggested that non-E&S employees would not fare well under the system due, for example, to the Significant Accomplishment/ Contribution Rule.

Response: The significant accomplishment rule is designed to ensure a high level of performance to advance within the high end of the pay band for E&S occupations in the DB–03 band given the number of employees assigned to that particular pay band. Consistent with other labs utilizing the significant accomplishment rule, it will be appropriately used to maintain pay-for-performance cost/pay discipline within the pay band. The rule prevents DB–03 employees from progressing to the highest salary in the band without performing at increased levels of performance or responsibility. The rule does not apply to non-E&S employees.

(11) Grievances

Comment: One commenter suggested, ''It was previously agreed that a grievance would be to someone above the Director'' and wanted to know why that was not included in the notice.

Response: Grievances filed by individuals who are not rated by the Director will be acted on by the Director because the Director is not involved in the rating of those employees. Grievances filed by individuals who are rated by the Director will be acted on by a higher authority. For bargaining unit employees, the negotiated grievance procedure (NGP) will be followed.

(12) Direct Hires

Comment: One commenter asked why scientists and engineers were the only group listed for direct hire. The commenter noted that Business and Technical and General Support are equally as important and should be included in the direct hire.

Response: The designation of career series eligible for direct hire authority does not diminish the importance and value of each career series in the organization's mission success. In this instance, use of the direct hire authority is limited to the flexibilities afforded by Congress in various National Defense Authorization Acts (NDAA). The direct hire authorities listed in the notice are those that STRLs are authorized by Congress to utilize; and are currently allowed for (1) candidates with advanced degrees to scientific and engineering positions; (2) candidates with bachelor's degrees to scientific and engineering positions; (3) veteran candidates to scientific, technical, engineering, and mathematics positions (STEM); and (4) student candidates enrolled in a program of instruction leading to a bachelors or advanced degree in a STEM discipline.

(13) Supervisory Probationary Periods and Performance Improvement Plans

Comment: One commenter asked for clarification on probationary periods for supervisors new to the government and performance improvement plans for supervisors.

Response: Supervisors new to the government must complete a three-year new employee probationary period. Supervisors who have previously completed a new employee probationary period in a government position must complete a two-year supervisory probationary period as a supervisor. Supervisors, as with any employee, can be placed on a performance improvement plan when appropriate, to include during the probationary period.

(14) Demotions to a Lower Pay Band

Comment: One commenter suggested that demotions for reason other than cause should not be allowed and asked about recourse or grievance procedures employees might have.

Response: Demotions to a lower pay band are a necessary element of the pay-for-performance system. Demotions for reasons other than cause can occur due to erosion of duties, reclassification of duties to a lower pay band, an employee's request, or for other reasons to preserve equity in pay and/or job requirements. Employees retain the ability to request reconsideration and/or file an appeal with the U.S. Merit Systems Protection Board. Employees will be provided notice and an opportunity to respond prior to such action being taken.

Identical or nearly identical provisions are found in other **Federal Register** Notices, including (organizations as designated in the original **Federal Register** Notice): Tank Automotive Research, Development and Engineering Center (76 FR 12508); Communications-Electronics Research, Development, and Engineering Center (66 FR 54872); Edgewood Chemical Biological Center (74 FR 68936); Natick Soldier Research, Development and Engineering Center (74 FR 68448); Army Research Laboratory (63 FR 10680), and non-Army laboratories such as: Naval Air System Command, Naval Air Warfare Center, Aircraft Division (76 FR 8530), and Naval Air Warfare Center, Weapons Division (76 FR 8529). These same flexibilities have been utilized in multiple laboratories without issue and are another tool the Director could utilize as the situation and organizational requirements merit.

(15) Exceptions to Competitive Procedures for Assignment to a Position

Comment: One commenter questioned whether or not one of the exceptions to competitive assignment procedures, promotion due to the reclassification of a position based on accretion of duties, could be used to circumvent competitive hiring.

Response: Permitting exceptions to competitive procedures for assignment to a higher position within a pay band aligns with ARI's workforce and organizational structure. Most positions in ARI have a natural progression. For example, a majority of the research personnel are in the DB–03 pay band and perform similar work. Those at the high end of the band who perform more complex work requiring high levels of expertise or who have substantively greater workload move toward the top of

their band as their performance dictates. Generally, movement to a vacant position in a pay band would require use of competitive procedures. The same is true of a promotion from one pay band to another. However, there may be situations where accretion of duties resulting from new requirements may be appropriate for newly reclassified positions. In those instances, the Director must have the ability to take appropriate action.

(16) Evaluation

Comment: Three commenters asked questions about the STRL evaluation requirement concerning who will gather evaluation data, how the unit climate and professional work environment will be assessed, and whether the results will be shared with the workforce?

Response: ARI will evaluate the project within five years of implementation of the project in accordance with Chapter 47 of 5 U.S.C. Data will be collected internally and externally based on standards and guidelines currently being developed by the USD(R&E). Additionally, ARI will collect climate survey data throughout the life of the project. Results of evaluation data will be provided to the USD(R&E) and the ARI workforce, as appropriate.

(17) Performance Elements

Comment: One commenter recommended removing training from the technical rigor performance element and recommended making unspecified changes to the Driving Organization Results element.

Response: Technical rigor is a critical element required for high-performing organizations. A high level of technical rigor in individual performance is critical to achieving many of the goals of the demonstration performance project outlined in section II (C). Those goals include: Increased quality of the workforce, and resultant research products and outcomes; more effective, efficient, and adaptable organizational systems required to respond to Army needs; increased retention of excellent performers; and increased workforce satisfaction with the personnel management system. Additionally, it is important to retain training as a legitimate component of the technical rigor element in developing and advancing the technical competence of employees and the organization at large.

ARI will conduct a data-driven review of the performance elements after implementation. The PMB will review the performance elements annually and make any necessary changes prior to the start of a new rating period; and as stated in the FRN, performance elements may evolve over time to ensure individual and organizational success.

(18) Performance Management System and Supervisor Ratings

Comment: One commenter made a positive statement about the performance management system but noted that the system would not work any better than TAPES or DPMAP if supervisors fail to accurately evaluate performance. Another commenter questioned the objectivity of the performance system. Another commenter suggested that a summary of accomplishments, provided by the employee, should not be mandatory. One commenter asked if midterm reviews were formal, documented reviews.

Response: Supervisors will receive training on the performance management system and rating processes to support an accurate evaluation of performance. Additionally, the performance management system's use of benchmark performance criteria establishes a common set of standards for evaluating performance and assigning ratings. The benchmark performance criteria will be published annually and whenever changes are made. Finally, the use of a pay pool panel and reconciliation process provides additional objectivity to the evaluation process.

Midterm reviews are mandatory documented reviews. The midterm reviews are not meant to be time-consuming, but are intended to be productive performance meetings used to address any concerns the employee or supervisor might have prior to the end of the rating period.

To support the rating process, employees are encouraged, but not required, to provide input on their accomplishments during the performance period. Employee input allows the employee to describe their accomplishments and any unique circumstances regarding their performance. Employee input should provide the rater and pay pool panel with a clear, concise, and accurate picture of their performance during the rating cycle. Ratings for employees who do not provide input on their accomplishments will be based on the supervisor's observations of employee performance.

(19) Internal Operating Procedures (IOP)

Comment: One commenter asked when the IOP would be available for employees.

Response: Once the final **Federal Register** Notice is published, and before implementation of the demonstration project, the IOP will be distributed to the workforce.

(20) Mid-Point Rule

Comment: Two commenters asked about the mid-point rule and whether the initial score of 30 would need to be changed.

Response: The purpose of the mid-point rule is to help provide cost discipline to the personnel system. The mid-point rule stipulates that an employee must receive a performance score of 30 or higher for his/her base pay to cross the mid-point of the pay band. The performance score of 30 also has been established as the initial, minimum score to be eligible for promotion opportunities.

With respect to the mid-point rule, setting a performance score too high or low can have a negative impact on the workforce and the laboratory. A score of 30 has been established initially for the mid-point rule because it represents successful performance and is comparable to what other laboratories have used. However, future assessments of the personnel demonstration project may indicate a different performance evaluation score is more appropriate for applying the mid-point rule within ARI. For example, if it is determined that the performance evaluation system consistently results in performance ratings that are lower than anticipated across the laboratory, then it may be necessary to establish a lower performance score for applying the mid-point rule. This would ensure the laboratory maintains a system that allows some employees to advance beyond the mid-point of the pay band or to be eligible for promotion opportunities. Conversely, if the score used to apply the midpoint rule is too low relative to the typical evaluation score received by employees, then it will be difficult for the laboratory to maintain appropriate cost controls. Having the ability to adjust the minimum score associated with the mid-point rule will allow the PMB to achieve the goals of providing appropriate payment and promotion opportunities for employees, increasing laboratory performance, and providing cost discipline to the system.

(21) Additional Comments

Comment: One commenter recommended a minor word change from ''Center'' to ''laboratory.'' The change was appropriate and was made in the notice. Another commenter asked

if employees would be queried during exit interviews.

Response: While not a part of the demonstration project, the Director has used exit interviews to collect information to address organizational concerns. It is expected that the Director, to the extent possible, will continue to conduct exit interviews.

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I. Executive Summary

ARI operates as a Field Activity of the Deputy Chief of Staff, G–1. As a Science and Technology (S&T) lab, ARI has the core mission of inventing for the future while maintaining an organizational culture of action in support of emerging Army needs. ARI's S&T program is focused on developing innovative measures and methods to optimize the Soldier lifecycle and talent management, developing theories and investigating new domains in the behavioral and social sciences, conducting scientific assessments, providing behavioral and social science advice to human resource authorities and informing human resource policies.

To sustain these unique capabilities, ARI must be able to hire, retain, and continuously motivate enthusiastic, innovative, and highly-educated scientists, supported by skilled business management and administrative professionals, as well as a skilled administrative and technical support staff.

The goal of the current project is to enhance the quality and professionalism of the ARI workforce through improvements in the efficiency and effectiveness of the human resource system. The project interventions will strive to achieve the best workforce for the ARI mission, adjust the workforce for change, and improve workforce satisfaction. This demonstration project extends the CCDC C5ISR/CCDC CBC/CCDC SC demonstration projects to ARI. The CCDC C5ISR/CCDC CBC/CCDC SC projects built on the concepts, and use much of the same language, as the demonstration projects developed by the CCDC Army Research Laboratory (ARL) (previously designated as the ARL); the CCDC Aviation and Missile Center (previously designated as the Aviation and Missile Research, Development, and Engineering Center); the Navy's ''China Lake;'' as well as other laboratories designated as an STRL. The results of this project will be evaluated by ARI within five years of implementation.

II. Introduction

A. Purpose

The purpose of the project is to demonstrate that the effectiveness of DoD STRLs can be enhanced by expanding opportunities available to employees and by allowing greater managerial control over personnel functions through a more responsive and flexible personnel system. Federal laboratories need more efficient, cost effective, and timely processes and methods to acquire and retain a highly creative, productive, educated, and trained workforce. This project, in its entirety, attempts to improve employees' opportunities and provide managers, at the lowest practical level, the authority, control, and flexibility needed to achieve the highest quality organization and hold them accountable for the proper exercise of this authority within the framework of an improved personnel management system.

While many aspects of a demonstration project were once considered experimental, many have been implemented in various DoD laboratories for a number of years. Modifications have been made based on the implementation experience of other DoD laboratories, best practices, and formative evaluation efforts. Additional modifications may be needed from time to time as additional experience is gained during this specific implementation based on evaluations of how the system is working to meet the goals and objectives of the personnel demonstration project.

B. Problems With the Present System

The current Civil Service GS system has existed in essentially the same form since the 1920s. Work is classified into one of fifteen overlapping pay ranges that correspond with the fifteen grades. Base pay is set at one of those fifteen grades and the ten interim steps within each grade. The Classification Act of 1949 rigidly defines types of work by occupational series and grade, with very precise qualifications for each job. This system does not quickly or easily respond to new ways of designing work and changes in the work itself. In addition, the GS system makes it difficult for the DoD labs to recruit and retain the best and the brightest scientists.

The need to change the current hiring system is essential, as ARI must be able to recruit and retain professional scientific researchers, support staff, and other professionals and skilled technicians. ARI must be able to compete with the private sector for the best talent and be able to make job offers in a timely manner with the attendant bonuses and incentives to attract high-quality employees.

Finally, current limitations on training, retraining, and otherwise developing employees make it difficult to correct skill imbalances and to prepare current employees for new lines of research needed to meet the Army's changing missions and emerging technology requirements.

C. Changes Required/Expected Benefits

The primary benefit expected from this demonstration project is greater organizational effectiveness through increased employee satisfaction. The long-standing Department of the Navy ''China Lake'' and subsequent demonstration projects have produced impressive statistics on increased job satisfaction and quality of employees versus that for the Federal workforce in general. Similar results have been demonstrated in more recent STRL demonstration projects and other alternative personnel systems implemented in the DoD and other agencies.

This project will demonstrate that a human resource system tailored to the mission and needs of the ARI workforce will facilitate:

(1) Increased quality in the workforce and resultant research products and outcomes,

(2) More effective, efficient, and adaptable organizational systems required to respond to Army needs,

(3) Increased timeliness of key personnel processes,

(4) Increased retention of excellent performers,

(5) Increased success in recruitment of personnel with critical skills,

(6) Increased management authority and accountability,

(7) Simpler and more effective human resources management process, and

(8) Increased workforce satisfaction with the personnel management system.

D. Participating Organizations

ARI is comprised of the ARI Headquarters located at Fort Belvoir, Virginia, and ARI research, technical, and support personnel located at Fort Belvoir, with geographically dispersed research units located at key strategic locations at Fort Benning, Georgia; Fort Hood, Texas; and Fort Leavenworth, Kansas. ARI also has a small number of employees dispersed at other locations in small numbers required to meet Army needs and mission requirements. As in the past and as expected in the future, there may be modifications to organizational structure and locations based on changing needs.

E. Participating Employees and Union Representation

This demonstration project will cover approximately 113 ARI civilian employees under Title 5 U.S.C. in the occupations listed in Appendix B. Additional employees and other occupations may be added after implementation of the project. The project plan does not cover members of the Senior Executive Service (SES), Senior Level (SL), Scientific and Professional (ST) employees, Federal Wage System (FWS) employees, and employees presently covered by the Defense Civilian Intelligence Personnel System (DCIPS).

Department of the Army, Army Command centrally funded, local interns, and Pathways Program employees (hired prior to implementation of the project) will not be converted to the demonstration project until they reach their full performance level. Pathways employees will continue to follow the Defense Performance Management and Appraisal Program (DPMAP) until they have reached their full performance level and are transitioned to the STRL personnel system.

The American Federation of Government Employees (AFGE) Local 1920 represents a small percentage of ARI's workforce located at one research location. Those represented employees may or may not participate in the personnel demonstration project depending on negotiations with the Union, specific hiring actions, and other factors. Of those employees assigned to ARI, approximately seven percent are represented by a labor union.

F. Project Design

Upon notification of the initial authority granted by Congress designating ARI as an STRL, the ARI Director assigned an experienced and tenured leader within the organization to contact appropriate agencies to develop the project plan. Initial guidance was provided by the DoD, Defense Civilian Personnel Advisory Services (DCPAS) and HQDA, Office of the Assistant Chief of Staff, G–1, Civilian Personnel Staffing and Classification Division. As a result of those initial discussions, ARI conducted a comprehensive review of the personnel practices of existing DoD laboratories designated as STRLs. That review resulted in a detailed list of personnel flexibilities adopted by the various DoD laboratories. As a part of the initial review, the Laboratory Quality Enhancement Program (LQEP)—Personnel Subpanel was contacted. The LQEP—Personnel Subpanel (LQEP–P) consists of STRL/Personnel Management Demonstration professionals and experts. LQEP–P members provided extensive advice and example materials for consideration. Detailed discussions with LQEP–P members focused on the capabilities provided by the various flexibilities employed, lessons learned and best practices, and implementation guidance. Concurrent to the review of existing flexibilities, a review of ARI's specific organizational personnel needs and requirements was conducted. Finally, a review of innovative personnel practices used outside of the federal government was conducted.

The initial set of existing flexibilities, with descriptions, waiver requirements, and expected benefits was briefed to ARI leadership and supervisors. Detailed discussion focused on how the proposed flexibility would help ARI accomplish its personnel management goals and how it would impact the workforce. The briefing and subsequent discussions resulted in a set of flexibilities for further research and consideration that were aligned with ARI personnel management needs. Those flexibilities were then extensively researched and discussed with LQEP–P members to determine if the proposed flexibility would meet those needs and to determine the cost and benefit of implementing the specific flexibility. The LQEP–P members were invaluable in this process. This resulted in a subset of personnel demonstration flexibilities that were best matched to ARI personnel needs and requirements. A team of senior leaders reviewed the potential flexibilities and provided recommendations for further consideration.

This preparatory work resulted in a proposed IOP that fully described how the proposed personnel management program would be implemented in ARI. The IOP was reviewed by and discussed with senior managers and supervisors to determine if the proposed system would meet ARI needs and workforce expectations. Following these internal reviews, final changes were made to the IOP and the associated FRN.

G. Personnel Management Board

ARI will create a Personnel Management Board (PMB) to oversee and monitor the fair, equitable, and consistent implementation of the provisions of the demonstration project to include establishment of internal controls and accountability. Members of the board will be senior ARI managers/supervisors and independent contributors appointed by the ARI Director. As needed, ad hoc members (such as Human Resources representatives), will serve as advisory members to the board.

Based on guidance and consistent interaction with the ARI Director, the board will execute the following:

(1) Carry out the guidance and procedures in all aspects of the personnel demonstration program in accordance with the direction given by the ARI Director.

(2) Determine the composition of the pay-for-performance pay pools in accordance with the guidelines of the IOP;

(3) Review operation of pay pools and provide guidance to pay pool managers;

(4) Oversee disputes in pay pool issues;

(5) Formulate and execute the civilian pay budget;

(6) Manage the awards pools;

(7) Determine hiring and promotion base pay as well as exceptions to pay-for-performance base pay increases;

(8) Conduct classification review and oversight, monitoring, and adjusting

classification practices and deciding broad classification issues;

(9) Approve major changes in position structure;

(10) Address issues associated with multiple pay systems during the demonstration project;

(11) Establish Standard Performance Elements and Benchmarks;

(12) Assess the need for changes to demonstration project procedures and policies;

(13) Review requests for Supervisory/Team Leader Base Pay Adjustments and provide recommendations to the ARI Director;

(14) Ensure in-house personnel budget discipline;

(15) Develop policies and procedures for administering Developmental Opportunity Programs;

(16) Ensure all employees are treated in a fair and equitable manner in accordance with all policies, regulations, and guidelines covering this demonstration project; and

(17) Conduct a formative evaluation of the project.

In executing these duties and responsibilities, the board will keep in close contact and consultation with the ARI Director to ensure policies and procedures are executed consistently across the organization and aligned with the Director's guidance.

H. Organizational Structure and Design

To optimize the effectiveness and efficiency of ARI during the adoption of the new STRL personnel system, the ARI Director will review and realign the organization structure to best meet mission needs and requirements. Realignment may include removing limitations in terms of supervisory ratios consistent with section 342(b) of the NDAA for FY 1995 as amended by section 1109 of the NDAA for FY 2000, and the alignment and organization of the workforce required to accomplish the mission of the STRL consistent with 10 U.S.C. 2358a.

The ARI Director will manage workforce strength, structure, positions, and compensation without regard to any limitation on appointments, positions, or funding in a manner consistent with the budget available in accordance with 10 U.S.C. 2358a.

I. Funding Levels

The Under Secretary of Defense (Personnel & Readiness), may, at his/her discretion, adjust the minimum funding levels to take into account factors such as the Department's fiscal condition, guidance from the Office of Management and Budget, and equity in circumstances when funding is reduced or eliminated for GS pay raises or awards

III. Personnel System Changes

A. Pay Banding

The design of the ARI pay banding system takes advantage of the many reviews performed by DA and DoD. The design has the benefit of being preceded by exhaustive studies of pay banding systems currently practiced in the Federal sector, to include those practiced by the Navy's ''China Lake'' experiment and subsequent demo/STRL demonstration projects. In addition, the pay plans, occupational families, pay bands, and general schedule equivalent grade structures for all the existing DoD laboratories were reviewed. ARI's pay banding system will replace the current GS structure. Currently, the fifteen grades of the GS are used to classify positions and, therefore, to set pay. The GS covers all white-collar work: Administrative, technical, clerical and professional. Changes in this rigid structure are required to allow flexibility in hiring, developing, retaining, and motivating the workforce. The pay banding structure adopted by ARI's STRL is similar to the one employed by the U.S. Army Armament Research, Development, and Engineering Center as well as other DoD laboratories.

1. Occupational Families

Occupations with similar characteristics will be grouped together into one of three occupational families with pay band levels designed to facilitate pay progression. The naming structure and other occupational family features adopted for ARI's STRL are consistent with other Army laboratories implementing a similar system. Each occupational family will be composed of pay bands corresponding to recognized advancement and career progression expected within the occupations. These pay bands will replace individual grades and will not be the same for each occupational family. Each occupational family will be divided into three to six pay bands with each pay band covering the same pay range now covered by one or more GS grades. Employees track into an occupational family based on their current series as provided in Appendix B. The upper and lower pay rate for base pay of each pay band is defined by the GS rate for the grade and step as indicated in Figure 1 except for Pay Band VI of the Engineering & Scientist (E&S) occupational family. Comparison to the GS grades was used in setting the upper and lower base pay dollar limits of the pay band levels. However, once employees are moved into the demonstration project, GS grades will no longer apply. The current occupations have been examined, and their characteristics and distribution have served as guidelines in the development of the following three occupational families: Engineering and Science (E&S), Business & Technical (B&T), and General Support (GEN).

Engineering and Science (E&S) (Pay Plan DB): This occupational family includes technical professional positions, such as psychologist and statisticians. Additional occupational series may be added in the future. Specific course work or educational degrees are required for these occupations. Six pay bands have been established for the E&S occupational family:

(1) Band I is a student trainee track covering GS–1, step 1 through GS–4, step 10.

(2) Band II is a developmental track covering GS–5, step 1 through GS–11, step 10.

(3) Band III is a full-performance technical track covering GS–12, step 1 through GS–13, step 10.

(4) Band IV includes senior technical/team leader positions covering GS–14, step 1 through GS–14, step 10.

(5) Band V includes supervisor/manager/senior technical positions covering GS–15, step 1 through GS–15, step 10.

(6) Band VI includes SSTM positions. The pay range is: Minimum base pay is 120 percent of the minimum base pay of GS–15; maximum base pay is Level IV of the Executive Schedule (EX–IV); and maximum adjusted base pay is Level III of the Executive Schedule (EX–III).

Business & Technical (B&T) (Pay Plan DE): This occupational family includes such positions as procurement specialists, finance, accounting, management analysis, computer specialists, and quality assurance specialists. Employees in these positions may or may not require specific course work or educational degrees. Five pay bands have been established for the B&T occupational family:

(1) Band I is a student trainee track covering GS–1, step 1 through GS–4, step 10.

(2) Band II is a developmental track covering GS–5, step 1 through GS–11, step 10.

(3) Band III is a full performance track covering GS–12, step 1 through GS–13, step 10.

(4) Band IV includes first-level supervisors and senior technical

personnel covering GS–14, step 1 through GS–14, step 10.

(5) Band V is a supervisor/manager track covering GS–15, step 1 through GS–15, step 10.

General Support (GEN) (Pay Plan DK): This occupational family is composed of positions for which specific course work or educational degrees are not required. Clerical work usually involves the processing and maintaining of records. Assistant work requires knowledge of methods and procedures within a specific administrative area. This family includes such positions as secretaries, office automation clerks, and budget/program/computer assistants. Three pay bands have been established for the GEN occupational family:

(1) Band I includes entry-level positions covering GS–1, step 1 through GS–4, step 10.

(2) Band II includes full-performance positions covering GS–5, step 1 through GS–8, step 10.

(3) Band III includes senior technicians/assistants/secretaries covering GS–9 step 1 through GS–10, step 10.

2. Pay Band Design

The pay bands for the occupational families and how they relate to the current GS framework are shown in Figure 1.

FIGURE 1—PAY BAND CHART

	Equivalent GS grades					
	I	II	III	IV	V	VI
Engineering & Science (DB)	GS-01 to 04	GS-05 to 11	GS-12 & 13	GS-14	GS-15	Above GS-15
Business & Technical (DE)	GS-01 to 04	GS-05 to 11	GS-12 & 13	GS-14	GS-15	
General Support (DK)	GS-01 to 04	GS-05 to 08	GS-9 & 10			

Employees will be converted into the occupational family and pay band that corresponds to their GS series and grade. Each employee converted to the demonstration project is assured, upon conversion, an initial place in the system without loss of pay. However, exceptional qualifications or other compelling reasons based on specific criteria may lead to a higher entrance base pay within a band, commensurate with the employee's experience and qualifications. As the pay rates of the GS scale are increased due to the annual general pay increases, the upper and lower base pay rates of the pay bands will also increase. Since pay progression through the bands depends directly on performance, there will be no scheduled Within-Grade Increases (WGIs) or Quality Step Increases (QSIs) for employees once the pay banding system is in place.

3. Pay Band VI

The pay banding plan expands the pay banding concept used at ''China Lake'' and other laboratories by creating Pay Band VI for the E&S occupational family. The band is designed for SSTM as authorized in 10 U.S.C. 2358a and described in 79 FR 43722. Pay Band VI will apply exclusively to positions designated as SSTMs.

The primary function of these positions is to engage in research and development in the physical, biological, medical, or engineering sciences, or another field closely related to the ARI mission and to carry out technical supervisory responsibilities.

As a part of the initial implementation of the STRL, the Director will review organizational and mission requirements to determine appropriate use of available SSTM positions and, if appropriate, will establish SSTM positions consistent with long-term organizational plans and limitations set forth by Congress (*e.g.,* number of SSTM positions based on percent of workforce requirements). The pay range for SSTM positions is as follows: Minimum base pay is 120 percent of the minimum base pay of GS–15, maximum rate of base pay is Level IV of the Executive Schedule (EX– IV), and maximum adjusted base pay is Level III of the Executive Schedule (EX– III). Adjusted base pay is base rate plus locality or supervisory pay differential as appropriate.

After full implementation of the STRL, newly vacant SSTM positions will be filled competitively. Panels will be created to assist in the review of candidates for SSTM positions. Panel members typically will be SES members, ST employees, and, after full implementation, those employees designated as SSTMs. In addition, General Officers and recognized technical experts from outside ARI may serve, as appropriate. The panel will apply criteria developed largely from the OPM Research Grade Evaluation Guide for positions exceeding the GS–15 level and other OPM guidance related to positions exceeding the GS–15 level. The purpose of the panel is to ensure impartiality and a rigorous and demanding review.

Consistent with 10 U.S.C. 2358a, the demonstration project will implement SSTM flexibilities described in 79 FR 43722.

B. Classification

1. Occupational Series

The present GS classification system has over 400 occupational series, which are divided into 23 occupational groupings. ARI currently has positions in fewer than 20 occupational series. All positions listed in Appendix B will be in the classification structure. Provisions will be made for including other occupations in response to

changing missions and agency requirements.

2. Classification Standards and Position Descriptions

If available, ARI will use a fully automated classification system modeled after the Navy's ''China Lake'' and ARL's automated systems. The Web-based automation tool is a fully integrated classification system that can create standardized, classified position descriptions under the new pay banding system. The present system of OPM classification standards will be used for the identification of proper series and occupational titles of positions within the demonstration project. Current OPM position classification standards, in some cases, will not be used to grade positions in this project. However, the grading criteria in those standards will be used as a framework to develop new and simplified standards for the purpose of pay band determinations. The objective is to record the essential criteria for each pay band within each occupational family by stating the characteristics of the work, the responsibilities of the position, and the competencies required. The classification standard for each pay band will serve as an important component to update existing position descriptions, which will include position-specific information, and provide data element information pertinent to the job. The computer-assisted process will produce information necessary for position descriptions. The new descriptions will be easier to prepare, minimize the amount of writing time and make the position description a more useful and accurate tool for other personnel management functions.

Specialty work codes (narrative descriptions) will be used to further differentiate types of work and the competencies required for particular positions within an occupational family and pay band. Each code represents a specialization or type of work within the occupation.

3. Fair Labor Standards Act

Fair Labor Standards Act (FLSA) exemption and non-exemption determinations will be consistent with criteria found in 5 CFR part 551. All employees are covered by the FLSA unless they meet the criteria for exemption. The duties and responsibilities outlined in the classification standards for each pay band will be compared to the FLSA criteria. As a general rule, the FLSA status can be matched to occupational family and pay band as indicated in Figure 2. For example, positions classified in Pay Band I of the E&S occupational family are typically nonexempt, meaning they are covered by the overtime entitlements prescribed by the FLSA. An exception to this guideline includes supervisors/managers whose primary duties meet the definitions outlined in the OPM GS Supervisory Guide. Therefore, supervisors/managers in any of the pay bands who meet the foregoing criteria are exempt from the FLSA. The Director/manager/or supervisor with classification authority will make the determinations on a case-by-case basis by comparing assigned duties and responsibilities to the classification standards for each pay band and the 5 CFR part 551 FLSA criteria. Additionally, the advice and assistance of the servicing Civilian Personnel Advisory Center (CPAC) will be obtained in making determinations. The benchmark position descriptions will not be the sole basis for the determination. Basis for exemption will be documented and attached to each position description. Exemption criteria will be narrowly construed and applied only to those employees who clearly meet the spirit of the exemption. Changes will be documented and provided to the CPAC.

FIGURE 2—FLSA STATUS

[Pay bands]

Occupational Family	I	II	III	IV	V	VI
E&S.....	N	N/E	E	E	E	E
B&T.....	N	N/E	E	E		
GEN.....	N	N	E			

N—Non-Exempt from FLSA; E—Exempt from FLSA.

N/E—Exemption status determined on a case-by-case basis.

Note: Although typical exemption status under the various pay bands is shown in the above table, actual FLSA exemption determinations are made on a case-by-case basis.

4. Classification Authority

The ARI Director will have classification authority and may, in turn, delegate this authority to appropriate levels. Any individual with delegated classification authority must complete required training. Position descriptions will be developed to assist in exercising delegated position classification authority. Those leaders with classification authority will identify the occupational family, job series, functional code, specialty work code, pay band level, and other critical information. Personnel specialists will provide ongoing consultation and guidance to managers and supervisors throughout the classification process. These decisions will be documented in the position description.

5. Classification Appeals

Classification appeals under this demonstration project will be processed using the following procedures:An employee may appeal the determination of occupational family, occupational series, position title, and pay band of his/her position at any time. An employee must formally raise the area of concern to supervisors in the immediate chain of command, either verbally or in writing. If the employee is not satisfied with the supervisory response, he/she may then appeal to the Personnel Management Board. A final appeal may be made to the DoD appellate level. Appeal decisions rendered by DoD will be final and binding on all administrative, certifying, payroll, disbursing, and accounting officials of the government. Classification appeals are not accepted on positions which exceed the equivalent of a GS–15 level. Time periods for cases processed under 5 CFR part 511 apply.

An employee may not appeal the accuracy of the position description, the demonstration project classification criteria, or the pay-setting criteria; the assignment of occupational series to the occupational family; the propriety of a pay schedule; or matters grievable under an administrative or negotiated grievance procedure, or an alternative dispute resolution procedure.

The evaluations of classification appeals under this demonstration project are based upon the demonstration project classification criteria. Prior to forwarding appeals to the decision authority, the servicing human resources entity will provide a recommendation and ensure that the case file includes copies of appropriate demonstration project criteria.

C. Pay for Performance

1. Overview

The purpose of the pay-for-performance system is to provide an effective, efficient, and flexible method for assessing, compensating, and managing the ARI workforce. It is essential for the development of a highly productive workforce and to provide management at the lowest practical level, the authority, control, and flexibility needed to achieve a quality organization and meet mission requirements. The pay-for-performance system allows for greater employee involvement in the assessment process, strives to increase communication between supervisor and employee, promotes a clear accountability of performance, facilitates employee career progression, and provides an understandable and rational basis for pay changes by linking pay and performance.

The pay-for-performance system uses annual performance payouts based on the employee's total performance score rather than within-grade increases, quality step increases, promotions from one grade to another where both grades are now in the same pay band (*i.e.,* there are no within-band promotions), and performance awards. The standard rating period will be one year. The minimum rating period will be 120 days. Pay-for-performance payouts can be in the form of increases to base pay, cash bonuses and time off awards; the bonuses are not added to base pay but, rather, are given as a lump sum bonus. Other awards, such as Special Acts, will be retained separately from the pay-for-performance payouts.

The system will have the flexibility to be modified, if necessary, as more experience is gained under the project.

2. Performance Objectives

Performance objectives define a target level of activity, expressed as tangible, measurable objective statements against which actual achievement can be compared. These objectives will specifically identify what is expected of the employee during the rating period and will typically consist of three to ten results-oriented statements. Employees are encouraged to participate in developing their performance objectives with their supervisor at the beginning of the rating cycle. These are to be reflective of the employee's duties/responsibilities and pay band along with the mission/organizational goals and priorities. Objectives will be reviewed annually and revised upon changes in pay reflecting increased responsibilities commensurate with pay increases. Supervisors will make the final decision for approving their employee's performance objective. Use of generic one-size-fits-all objectives will be avoided, as performance objectives are meant to define an individual's specific responsibilities and expected accomplishments. While generic objectives will be avoided, objectives will be commensurate to the employees pay and employees at similar positions in the pay band are expected to have objectives of similar complexity, responsibility, and/or another defining characteristic. Thus, exemplar, baseline, objectives will be developed and provided to supervisors and employees to highlight appropriate performance requirements at various pay levels. These exemplars will be used to help define performance expectations commensurate to employee pay.

In contrast, performance elements as described in the next paragraph will identify generic performance characteristics, against which the accomplishment of objectives will be measured. As a part of this demonstration project, training focused on overall organizational objectives and the development of performance objectives will be held for both supervisors and employees. Performance objectives may be jointly modified, changed, or deleted as appropriate during the rating cycle. However, additional objectives may not be added within the last 120 days of the rating cycle, given the minimum period of performance. Changes initiated by employees must be approved by their supervisor. As a general rule, performance objectives should only be changed when the employee successfully meets or exceeds the original objectives or circumstances outside the employee's control prevent or hamper the accomplishment of the original objectives. It is also appropriate to change objectives when mission or workload shifts occur. Objectives will not be changed when an employee's lack of performance prevents or hinders successful performance.

3. Performance Elements

Performance elements define generic performance characteristics that will be used to evaluate the employee's success in accomplishing his/her performance objectives. The use of generic characteristics for scoring purposes helps to ensure comparable scores are assigned while accommodating diverse individual objectives. This pay-for-performance system will utilize those performance elements provided in Appendix C; as adapted from the system

of performance elements implemented at other DoD Labs designated as STRLs.

All elements are critical. A critical performance element is defined as an attribute of job performance that is of sufficient importance that performance below the minimally acceptable level requires remedial action and may be the basis for removing an employee from his/her position. Non-critical elements will not be used. Each of the performance elements will be assigned a weight, which reflects its importance in accomplishing an individual's performance objectives. A minimum weight (expressed as a percentage) is set for each performance element. The sum of the weights for all of the elements must equal 100.

A single set of performance elements will be used for evaluating the annual performance of all ARI personnel covered by this plan. This set of performance elements may evolve over time, based on experience gained during each rating cycle. This evolution is essential to capture the critical competencies that enable the workforce to meet individual and organizational performance objectives. The evolving nature of performance elements may be particularly necessary in an environment where mission requirements, technology, and work processes are changing at an increasingly rapid pace. Thus, the ARI Personnel Management Board will annually review the set of performance elements and set them for the entire organization before the beginning of the rating period. The following is an initial set of performance elements:

(1) Technical Rigor
(2) Interpersonal Effectiveness
(3) Managing Time and Other Resources
(4) Driving Organizational Success
(5) Team Leadership
(6) Supervision/Leadership, and Equal Employment Opportunity (EEO).

All employees will be rated against the first four (Core) performance elements. Team Leadership is mandatory for team leaders (within this document ''team leader'' refers to non-supervisory team leaders as determined by the OPM GS Leader Grade Evaluation Guide).

Supervision/Leadership, and Equal Employment Opportunity is mandatory for all managers/supervisors. At the beginning of the rating period, pay pool managers will review the objectives and weights assigned to employees within the pay pool, to verify consistency and appropriateness across the organization.

4. Performance Feedback and Formal Ratings

The most effective means of communicating job requirements, performance goals, and desired results is person-to-person discussion between supervisors and employees. Employees and supervisors alike are expected to actively participate in these discussions to clarify expectations and identify potential obstacles to meeting performance goals. To the extent possible, employees should describe what they need from their supervisors to support goal accomplishment. The timing of performance feedback and discussions will vary based on the nature of work performed, but at a minimum will occur formally at the beginning, mid-point, and end of the rating period. If employees are unsure of their performance goals or quality at any time, they are encouraged to initiate discussions with their supervisor. In addition, supervisors will initiate discussions at the earliest possible sign of unacceptable performance or as needed to maintain successful performance. The supervisor and employee will discuss job performance and accomplishments in relation to the performance objectives and performance elements. At least two reviews, normally the mid-point review and annual review, will be documented as a formal progress review. More frequent informal task-specific discussions may be appropriate in certain circumstances. In cases where work is accomplished by a team, team discussions regarding goals and expectations may also be conducted as appropriate.

Employees will be requested to provide a summary of their accomplishments to their supervisor to highlight their most important performance outcomes, at both the mid-point and at the end of the rating period. Space limitations may be imposed in the performance management system to limit the length of the employee's self-summary of their accomplishments. The goal of employee self-reports is to highlight significant employee accomplishments rather than to describe job processes at a granular level of detail.

At the end of the rating period and following a review of the employee's accomplishments, the supervisor will rate each performance element by assigning a score between 0 and 50. Supervisors will use benchmark performance standards that describe the level of performance associated with a score. Benchmark standards ensure the employee's performance is accurately captured and ensures different supervisors apply a similar rating standard and scoring approach to their employees during the rating process. During the rating and point assignment process, the supervisor reflects on the specific objectives for each employee and rates the individual on each performance element using specific descriptors of performance related to the benchmark performance criteria. It should be noted these scores are not discussed with the employee or considered final until scores for all employees are reconciled and approved by the Pay Pool Manager. The element scores will then be multiplied by the element-weighting factor to determine the weighted score expressed to two decimal points. The weighted scores for each element will then be totaled to determine the employee's overall appraisal score and rounded to a whole number as follows: If the digit to the right of the decimal is between five and nine, it should be rounded to the next higher whole number; if the digit to the right of the decimal is between one and four, it should be dropped.

For each performance element, a total, unweighted score of 10 or above will result in a rating of acceptable. A total, unweighted score of 9 or below, or an unweighted score of 9 or below in a single performance element, will result in a rating of unacceptable. An unacceptable rating requires action to be taken by management to address deficient performance in accordance with Section 5 below.

5. Unacceptable Performance

Formal corrective action, to include placing an employee on a PIP, may be taken at any time during the rating cycle and must be taken following an unacceptable rating. Whenever a supervisor recognizes an employee's performance on one or more performance elements is unacceptable, the supervisor will immediately inform the employee. Efforts will be made to identify the possible reasons for the unacceptable performance. An employee who is on a PIP is not eligible to receive the general pay increase.

If an employee performs at an unacceptable level or has received an unacceptable rating, and the supervisor chooses to initiate a PIP, the following steps will be followed. The supervisor will identify the items/actions that need to be corrected or improved, outline required time frames (generally 30 days) for such improvement, and provide the employee with available assistance as appropriate. Progress will be monitored during the PIP, and all counseling/feedback sessions will be documented.

If the employee's performance is acceptable at the conclusion of the PIP, no further action is necessary. If a PIP ends prior to the end of the annual performance cycle and the employee's performance improves to, and remains at, an acceptable level, the employee is appraised at the end of the annual performance cycle. If the employee's performance deteriorates to an unacceptable level in any element within two years from the beginning of a PIP, follow-on actions may be initiated with no additional opportunity to improve. If an employee's performance is at an acceptable level for two years from the beginning of the PIP, and performance once again declines to an unacceptable level, the employee will be given an additional opportunity to improve before management proposes follow-on actions.

If the employee fails to improve at the conclusion of the PIP, the employee will be given notice of proposed appropriate action. This action can include removal from the Federal service, placement in a lower pay band or grade level with a corresponding reduction in pay (demotion), reduction in pay within the same pay band, or change in position or occupational family. In many situations, employees with an unacceptable rating will not be permitted to remain at their current pay and may be reduced in pay band.

Reductions in base pay within the same pay band or changes to a lower pay band will be accomplished with a minimum of a five-percent decrease in an employee's base pay.

Note: Nothing in this subsection will preclude action under 5 U.S.C. chapter 75 [Adverse Actions], when appropriate.

All relevant documentation concerning a reduction in pay or removal based on unacceptable performance will be preserved and made available for review by the affected employee or a designated representative. At a minimum, the record will consist of a copy of the notice of proposed personnel action, the employee's written reply, if provided, or a summary when the employee makes an oral reply. Additionally, the record will contain the written notice of decision and the reasons therefore along with any supporting material (including documentation regarding the opportunity afforded the employee to demonstrate improved performance).

6. Reconciliation Process

Following the initial scoring of each employee by the supervisor, a panel of rating officials and supervisors will meet in a structured review and reconciliation process panel managed by the Pay Pool Manager. In this step, each employee's performance objectives, accomplishments, preliminary scores, and pay are compared. Through discussion and consensus building, consistent and equitable ratings are reached. There will not be a prescribed distribution of total scores. The Pay Pool Manager will chair a final review with the rating officials/supervisors to validate these ratings and resolve any remaining scoring issues. If consensus on scoring cannot be reached for one or more employees in this process, the Pay Pool Manager makes all final decisions. IOPs will provide details on this process to employees and supervisors.

Given the unique organizational structure of ARI, the reconciliation process of employees who report directly to the ARI Director may be different from the procedures described above. In those cases, the ARI Director will review and resolve all ratings as pay pool manager for those direct reports. Should the organization's structure change to allow for a pay pool process comparable to the one previously described, the procedures for the ARI Director's direct reports are likely to change to incorporate pay pool panel participation and reconciliation.

After the reconciliation process is complete, scores are finalized. Payouts proceed according to each employee's final score and adjusted base pay. Information pertaining to the reconciliation process will be made available to all employees.

7. Pay Pools

ARI will have one or more pay pools, and each ARI employee will be placed into one of these pools. Pay pools are combinations of organizational elements that are defined for the purpose of determining performance payouts under the pay-for-performance system. The next paragraph provides the guidelines for determining pay pools. These guidelines will normally be followed, but deviations may occur if there is a compelling need. The rationale for any deviations will be documented in writing, and final procedures will be published prior to start of the rating period.

The ARI Director will establish pay pools. A pay pool should be large enough to encompass a reasonable distribution of ratings but not so large as to compromise rating consistency. Supervisory personnel will be placed in a pay pool separate from subordinate non-supervisory personnel. Neither the Pay Pool Manager nor supervisors within a pay pool will recommend or set their own individual pay. Decisions regarding the amount of the performance payout are based on the established formal payout calculations.

Funds within a pay pool available for performance payouts are calculated from anticipated pay increases under the existing system and divided into two components, base pay and bonus. The funds within a pay pool used for base pay increases are those that would have been available from within-grade increases, quality step increases, and promotions. This amount will be defined based on historical data and will be set at no less than two percent of total adjusted base pay annually. The funds available to be used for bonus payouts are funded separately within the constraints of the organization's overall award budget. This amount will be defined based on historical data and at no less than one percent of total adjusted base pay annually. The pay pool funding percentages are the same for all pay pools. The sum of these two factors is referred to as the pay pool percentage factor.

The ARI Personnel Management Board will annually review the pay pool funding and recommend adjustments to the ARI Director to ensure cost discipline over the life of the demonstration project. The ARI Director makes the final decision on pay pool funding.

8. Performance Payout Determination

The performance payout an employee will receive is based on the total performance score from the pay for performance assessment process. An employee will receive a performance payout as a percentage of adjusted base pay. This percentage is based on the number of shares that equates to an employee's final appraisal score. Shares will be awarded on a continuum as follows:

Total Performance Score = Share
50 = 3
40 = 2
30 = 1
21 = 0.1
10 – 20 = 0
< = 9 = 0 (Performance Improvement Plan required).

Fractional shares will be awarded for scores that fall between these scores. For example, a score of 38 will equate to 1.8 shares, and a score of 44 will equate to 2.4 shares.

The value of a share cannot be exactly determined until the rating and reconciliation process is completed and scores for all employees are finalized. The share value is expressed as a percentage. The formula that computes the value of each share uses base pay rates and is based on (1) the sum of the base pay of all employees in the pay pool times the pay pool percentage factor, (2) the employee's base pay, (3) the number of shares awarded to each employee in the pay pool, and (4) the total number of shares awarded in the pay pool. This formula assures that each employee within the pool receives a share amount equal to other employees in the same pool who are at the same rate of base pay and receive the same score. The formula is shown in Figure 3.

FIGURE 3—SHARE VALUE FORMULA

$$\text{Share value} = \frac{\text{Sum of base pay of employees in pool} * \text{pay pool percentage factor}}{\text{Sum of (base pay} * \text{shares earned) for each employee}}$$

An individual payout is calculated by first multiplying the shares earned by the share value and multiplying that product by base pay. An adjustment is then made to account for locality pay.

A pay pool manager is accountable for staying within pay pool limits. The pay pool manager makes the final decision on base pay increases and/or bonuses to individuals based on rater recommendation, the final score, the pay pool funds available, and the employee's pay.

9. Base Pay Increases and Bonuses

The amount of money available for performance payouts is divided into two components: Base pay increases and bonuses. The base pay and bonus funds are based on the pay pool funding formula established annually. Once the individual performance amounts have been determined, the next step is to determine what portion of each payout will be in the form of a base pay increase as opposed to a bonus payment. The payouts made to employees from the pay pool may be a mix of base pay and bonus as determined by the rules set forth in this FRN and IOPs, such that all the allocated funds are disbursed. To provide performance incentives while ensuring cost discipline, base pay increases may be limited or capped.

Certain employees will not be able to receive the projected base pay increase due to base pay caps. Base pay is capped when an employee reaches the maximum rate of base pay in an assigned pay band, when the mid-point rule applies (see below), when the Significant Accomplishment/Contribution rule applies (see below), or otherwise subject to other salary control point established by the STRL Director. Prior to implementing, modifying, or terminating any new control point, appropriate notice will be provided to the workforce. Also, for employees receiving retained rates above the applicable pay band maximum, the entire performance payout will be in the form of a bonus payment.

When capped, the payout an employee receives will be in the form of a bonus versus the combination of base pay and bonus. Bonuses are cash payments and are not part of the base pay for any purpose (*e.g.,* lump sum payments of annual leave on separation, life insurance, and retirement). The maximum base pay rate under this personnel demonstration project will be the unadjusted base pay rate of GS–15/step 10, except for employees in Pay Band VI of the E&S occupational family.

Based on pay pool operating procedures and business rules, the organization may re-allocate a portion (up to the maximum possible amount) of the unexpended base pay funds. This re-allocation will be determined by the Pay Pool Manager. Any dollar increase in an employee's projected base pay increase will be offset, dollar for dollar, by an accompanying reduction in the employee's projected bonus payment. Thus, the employee's total performance payout is unchanged. This re-allocation could be required for a number of reasons to include the use of re-allocation of to reduce extreme pay-for-performance gaps.

In addition, the pay pool manager may request approval from the PMB for use of an Extraordinary Achievement Recognition. Such recognition grants a base pay increase and/or bonus to an employee that is higher than the one generated by the compensation formula for that employee. The funds available for an Extraordinary Achievement Recognition are separately funded within the constraints of the organization's budget. Extraordinary Achievement Recognition, if warranted, will be determined by the Review and Reconciliation Panel, and the pay pool manager will provide the request to the PMB who will make the final decision based on the merits and funds available.

10. Mid-Point Rule

To provide added performance incentives as an employee progresses through a pay band, a mid-point rule will be used to determine base pay increases. The mid-point rule dictates that any employee must receive a score of 30 or higher for his/her base pay to cross the mid-point of the base pay range for his/her pay band. Also, once an employee's base pay exceeds the mid-point, the employee must receive a score of 30 or higher to receive any additional base pay increases. Any amount of an employee's performance payout, not paid in the form of a base pay increase because of the mid-point rule, will be paid as a bonus. This rule effectively raises the standard of performance expected of an employee once the mid-point of a band is crossed. This applies to all employees in every occupational family and pay band. The performance rating of 30 is set as an initial value and may be changed by the PMB, as necessary, with a goal of continuously increasing employee and organizational performance.

11. Significant Accomplishment/ Contribution Rule

The purpose of this rule is to maintain cost discipline while ensuring that employee payouts are in consonance with accomplishments and levels of responsibility. The rule will apply only to employees in E&S Pay Band III whose base pay would fall within the top 15 percent of the band. For employees meeting these criteria, the following provisions will apply:

(1) If an employee's score falls in the top third of scores received in his/her pay pool, he/she will receive the full allowable base pay increase portion of the performance payout. The balance of the payout will be paid as a lump sum bonus.

(2) If an employee's score falls in the middle third of scores received in his/her pay pool, the base pay increase portion will not exceed one percent of base pay. The balance of the payout will be paid as a lump sum bonus.

(3) If an employee's appraisal score falls in the bottom third of scores received in his/her pay pool, the full payout will be paid as a lump sum bonus.

12. Awards

In addition to the annual performance evaluation and payout process, the ARI Director may recognize outstanding individual or group achievements as they occur. Awards may include, but are not limited to, honorary, special act or on-the-spot monetary awards, and time-off awards. The ARI Director may re-delegate this authority. The ARI Director will have the authority to grant special act awards to covered employees of up to $10,000 IAW the criteria of AR 672–20, Incentive Awards. The funds available to be used for traditional 5 U.S.C. awards are separately funded within the constraints of the organization's budget.

13. General Pay Increase—Limitations for Unacceptable Performance

Employees on a PIP at the time pay determinations are made do not receive performance payouts or the annual general pay increase. An employee who receives an unacceptable rating of record will not receive any portion of the general pay increase until such time as his/her performance improves to the acceptable level and remains acceptable for at least 90 days. When the employee has performed acceptably for at least 90 days, the general pay increase will not be retroactive but will be granted at the beginning of the next pay period after the supervisor authorizes its payment. These actions may result in a base pay that is identified in a lower pay band. This occurs because the minimum rate of base pay in a pay band increases as the result of the general pay increase (5 U.S.C. 5303). This situation (a reduction in band level with no reduction in pay) will not be considered an adverse action, nor will band retention provisions apply.

14. Retention Counteroffers

The Director, working with the PMB, may offer a retention counteroffer to retain high performing employees with critical scientific or technical skills who present evidence of an alternative employment opportunity with higher compensation. Such employees may be provided increased base pay (up to the ceiling of the pay band) and/or a one-time cash payment that does not exceed 50 percent of one year of base pay. Further details will be published in the IOP. This flexibility addresses the expected benefits described in paragraph II. C, particularly ''increased retention of high-quality employees.'' Retention allowances, either in the form of a base pay increase and/or a bonus, count toward the Executive Level I aggregate limitation on pay consistent with 5 U.S.C. 5307 and 5 CFR part 530, subpart B. Further details will be published in the IOP.

15. Grievances

An employee may grieve the performance rating/score received under the pay-for-performance system through the administrative grievance procedure. Bargaining unit employees may not file a negotiated grievance disputing their rating/score unless the applicable collective bargaining agreement permits it.

16. Adverse Actions

Except where specifically waived or modified in this plan, adverse action procedures under 5 CFR part 752 remain unchanged.

D. Hiring Authority

1. Qualifications

A candidate's basic eligibility will be determined using OPM's Qualification Standards Handbook for General Schedule Positions. Candidates must meet the minimum standards for entry into the pay band. For example, if the pay band includes positions in grades GS–5 and GS–7, the candidate must meet the qualifications for positions at the GS–5 level. Specific experience/ education requirements will be determined based on whether a position to be filled is at the lower or higher end of the band. Selective placement factors can be established in accordance with the OPM Qualification Handbook, when judged to be critical to successful job performance. These factors will be communicated to all candidates for particular position vacancies and must be met for basic eligibility. Restructuring the examining process and providing an authority to appoint candidates meeting distinguished scholastic achievements will allow the laboratory to compete more effectively for high quality personnel and strengthen the manager's role in personnel management as well as the goals of the demonstration project.

2. Delegated Examining

Competitive service positions will be filled through Merit Staffing, and through direct-hire authority or under Delegated Examining. Section 1108 of the NDAA for FY 2009, as amended by

section 1103 of the NDAA for FY 2012, provides for delegation of direct-hire authority for qualified candidates with an advanced degree to scientific and engineering positions within STRL laboratories designated under section 1105 of NDAA FY2010. Direct-hire authority will be exercised in accordance with the requirements of the delegation of authority.

When there are no more than 15 qualified applicants and no preference eligibles, all eligible applicants are immediately referred to the selecting official without rating and ranking. Rating and ranking may occur when the number of qualified candidates exceeds 15 or there is a mix of preference and non-preference applicants. Category rating may be used to provide for a more streamlined and responsive hiring system to increase the number of eligible candidates referred to selecting officials. This provides for the grouping of eligible candidates into quality categories and the elimination of consideration according to the ''rule of three.'' This includes the coordination of recruitment and public notices, the administration of the examining process, the administration of veterans' preference, the certification of candidates, and selection and appointment consistent with merit principles. Specific procedures used for competitive examining authority will be detailed in the IOP.

Statutes and regulations covering veterans' preference will be observed in the selection process when rating and ranking are required. Veterans with preference will be referred ahead of non-veterans with the same score/category.

3. Direct Hire

ARI will use the direct-hire authorities authorized by section 1108 of the NDAA for FY 2009, as amended by section 1103 of the NDAA for FY 2012, the direct hire authorities published in 79 FR 43722, and the direct hire authorities in 10 U.S.C. 2358a, as appropriate, to appoint the following:

(1) Candidates with advanced degrees to scientific and engineering positions;

(2) Candidates with bachelor's degrees to scientific and engineering positions;

(3) Veteran candidates to scientific, technical, engineering, and mathematics positions (STEM), including technicians; and

(4) Student candidates enrolled in a program of instruction leading to a bachelors or advanced degree in a STEM discipline.

In addition, other Direct Hire authorities, documented in FRNs and available to all DoD STRL laboratories, may be utilized, as appropriate.

4. Legal Authority

For actions taken under the auspices of the demonstration project, the first legal authority code (LAC)/legal authority Z2U/Public Law 103–337 will be used. The second LAC/legal authority may identify the authority utilized (*e.g.,* Direct Hires). For all other actions, the nature of action codes and legal authority codes prescribed by OPM, DoD, or DA will continue to be used.

5. Revisions to Term Appointments

ARI will continue to have career and career-conditional appointments and temporary appointments not to exceed one year. These appointments will use existing authorities and entitlements. Under the demonstration project, ARI will have the added authority to hire individuals under a modified term appointment, and the Flexible Length and Renewable Term Technical Appointments authorized by section 1109(b)(1) of the NDAA for FY 2016, as amended by section 1106 of the NDAA for FY 2019, and published in 82 FR 43339.

Employees hired under the modified term appointment authority are in a non-permanent status in the competitive service for up to five years. The ARI Director is authorized to extend a modified term appointment for up to one additional year. Employees on modified term appointments may be eligible for conversion to career conditional appointments. To be converted, the employee must (1) have been selected for the term position under competitive procedures, with the announcement specifically stating that the individual(s) selected for the term position may be eligible for conversion to a career-conditional appointment at a later date; (2) have served two years of continuous service in the term position; (3) be selected under merit promotion procedures for the permanent position; and (4) be performing at the acceptable level of performance with a current score of 30 or greater.

The Flexible Length and Renewable Term Technical Appointment authority will allow ARI to appoint qualified candidates who are not currently DoD civilian employees, or who are DoD civilian employees in term appointments, into any scientific, technical, engineering, and mathematic positions, including technicians, for a period of more than one year but not more than six years. The appointment of any individual under this authority may be extended without limit in up to six year increments at any time during any term of service under conditions set forth by the ARI Director. These appointments will allow ARI to dynamically shape the workforce to respond to mission requirements. Consistent with section 1109(b)1) of the NDAA for FY 2016, as amended, employees hired under this provision will be counted as fractional employees of the laboratory for the purpose of determining workforce size of the laboratory. All waivers published in 82 FR 43339 apply to this demonstration project.

Employees appointed under Flexible Length and Renewable Term Technical Appointments may be eligible for noncompetitive conversion to a permanent appointment if the job announcement clearly states the possibility of being made permanent, in addition to any other provision in the STRL's modified term appointment authority. Unless otherwise eligible for a noncompetitive hiring authority, positions filled under this authority must be competed. Job opportunity announcements must clearly identify the type of appointment and the expected duration of initial appointment (up to six years). Appointees will also be afforded the opportunity to apply for vacancies that are otherwise limited to ''status'' candidates as described in 82 FR 43339.

Employees serving under term appointments will be covered by the plan's pay-for-performance system.

6. Extended Probationary or Trial Period

The current two-year probationary period (Pub. L. 114–92) for DoD employees will be extended to three years for all newly hired permanent career-conditional employees. Trial periods for term appointments will also be extended to three years. The purpose of extending the probationary period is to allow supervisors an adequate period of time to fully evaluate an employee's ability to complete cycles of work and to fully assess an employee's contribution and conduct. The three-year probationary period will apply only to new hires subject to a probationary period.

Aside from extending the time period for probationary or trial periods, all other features of the current probationary and trial period are retained including the potential to remove an employee without providing the full substantive and procedural rights afforded a non-probationary employee. Any employee appointed prior to the implementation date will not be affected.

7. Termination of Probationary Employees

Probationary employees may be terminated when they fail to demonstrate proper conduct, technical competency, and/or acceptable performance for continued employment, and for conditions arising before employment. When a supervisor decides to terminate an employee during the probationary period because his/her work performance or conduct is unacceptable, the supervisor will terminate the employee's services by written notification stating the reasons for termination and the effective date of the action. The information in the notice will, at a minimum, consist of the supervisor's conclusions as to the inadequacies of the employee's performance or conduct, or those conditions arising before employment that support the termination.

8. Supervisory Probationary Periods

Supervisory probationary periods will be consistent with 5 CFR part 315, subpart I. Existing Federal employees who are competitively selected or reassigned to a supervisory position will be required to complete a two-year supervisory probationary period for initial appointment to a supervisory position. Newly appointed supervisors, new to Federal service, must complete the probationary periods in accordance with section III.D.6 of this FRN for Extended Probationary Periods. Consistent with 5 U.S.C. 3321, if, during this supervisory probationary period, the decision is made to return the employee to a non-supervisory position for reasons related to supervisory performance, the employee will be returned to a position comparable in pay and job duties to the position from which they were originally promoted or reassigned. A return to a non-supervisory position will result in a return to the employees' salary immediately prior to the appointment to a supervisory position, plus any increases that would have been afforded to the employee if the employee had remained in the position.

Supervisors hired, new to the Government, who have not demonstrated successful performance in a lower position at ARI and who do not successfully complete their probationary period may be terminated when they fail to demonstrate proper conduct, technical competency, and/or acceptable performance for continued employment, and for conditions arising before employment. As with non-supervisors and consistent with 5 U.S.C. 3321, a supervisor who is not performing at an acceptable level may be moved to another position in a different pay band. Such a move would result in a reduction of pay of no less than 6 percent or to the top of the lower pay band, whichever reduction is greater.

The ARI Director may place the supervisor on a PIP at any time during the supervisory probationary period to help improve performance to a successful level.

9. Volunteer Emeritus Program (VEP)

The ARI Director will have the authority to offer former Federal employees who have retired or separated from the Federal service, voluntary assignments in ARI. VEP assignments are not considered ''employment'' by the Federal government. Thus, such assignments do not affect an employee's entitlement to buyouts or severance payments based on an earlier separation from Federal service. The VEP will ensure continued quality research while reducing the overall salary line by allowing higher paid individuals to accept retirement incentives with the opportunity to retain a presence in the scientific community. The program will be of most benefit during manpower reductions as senior employees could accept retirement and return to provide valuable on-the-job training or mentoring to less experienced employees. Volunteer service will not be used to replace any employee, or interfere with career opportunities of employees. The VEP may not be used to replace or substitute for work performed by civilian employees occupying regular positions required to perform the ARI's mission.

To be accepted into the VEP, a candidate must be recommended by an ARI manager to the ARI Director. Everyone who applies is not entitled to participate in the program. The Director will document the decision process for each candidate and retain selection and non-selection documentation for the duration of the assignment or two years, whichever is longer.

To ensure success and encourage participation, the volunteer's federal retirement pay (whether military or civilian) will not be affected while serving in a volunteer capacity. Retired or separated federal employees may accept an emeritus position without a break or mandatory waiting period.

Volunteers will not be permitted to monitor contracts on behalf of the government or to participate on any contracts or solicitations where a conflict of interest exists. The same rules that currently apply to source selection members will apply to volunteers.

An agreement will be established between the volunteer and the ARI Director. The agreement will be reviewed by the servicing legal office. The agreement must be finalized before the assumption of duties and will include:

(1) A statement that the service provided is gratuitous, that the volunteer assignment does not constitute an appointment in the civil service and is without compensation or other benefits except as provided for in the agreement itself, and that, except as provided in the agreement regarding work-related injury compensation, any and all claims against the Government (stemming from or in connection with the volunteer assignment) are waived by the volunteer;

(2) a statement that the volunteer will be considered a federal employee for the purpose of:

(a) 18 U.S.C. 201, 203, 205, 207, 208, 209, 603, 606, 607, 643, 654, 1905, and 1913;

(b) 31 U.S.C. 1343, 1344, and 1349(b);

(c) 5 U.S.C. chapters 73 and 81;

(d) The Ethics in Government Act of 1978;

(e) 41 U.S.C. chapter 21;

(f) 28 U.S.C. chapter 171 (tort claims procedure), and any other Federal tort liability statute;

(g) 5 U.S.C. 552a (records maintained on individuals); and

(3) The volunteer's work schedule;

(4) The length of agreement (defined by length of project or time defined by weeks, months, or years);

(5) The support to be provided by ARI (travel, administrative, office space, supplies);

(6) The volunteer's duties;

(7) A provision that states no additional time will be added to a volunteer's service credit for such purposes as retirement, severance pay, and leave as a result of being a participant in the VEP;

(8) A provision allowing either party to void the agreement with 10 working days written notice;

(9) The level of security access required (any security clearance required by the assignment will be managed by ARI while the volunteer is a participant in the VEP);

(10) A provision that any written products prepared for publication that are related to VEP participation will be submitted to the ARI Director for review and must be approved prior to publication;

(11) A statement that the volunteer accepts accountability for loss or damage to Government property

occasioned by the volunteer's negligence or willful action;

(12) A statement that the volunteer's activities on the premises will conform to the ARI's regulations and requirements;

(13) A statement that the volunteer will not improperly use or disclose any non-public information, to include any pre-decisional or draft deliberative information related to DoD programming, budgeting, resourcing, acquisition, procurement or other matter, for the benefit or advantage of the VEP participant or any non-Federal entities. VEP participants will handle all non-public information in a manner that reduces the possibility of improper disclosure.

(14) A statement that the volunteer agrees to disclose any inventions made in the course of work performed at ARI. The ARI Director will have the option to obtain title to any such invention on behalf of the U.S. Government. Should the Director elect not to take title, the laboratory will retain a non-exclusive, irrevocable, paid up, royalty-free license to practice or have practiced the invention worldwide on behalf of the U.S. Government.

(15) A statement that the VEP participant must complete either a Confidential or Public Financial Disclosure Report, whichever applies, and ethics training in accordance with office of Government Ethics regulations prior to implementation of the agreement; and

(16) A statement that the VEP participant must receive post-government employment advice from a DoD ethics counselor at the conclusion of program participation. VEP participants are deemed Federal employees for purposes of post-government employment restrictions.

E. Internal Placement

1. Promotion

A promotion is the movement of an employee to a higher pay band in the same occupational family or to another pay band in a different occupational family, wherein the band in the new family has a higher maximum base pay than the band from which the employee is moving. Positions with known promotion potential to a specific band within an occupational family will be identified when they are filled. Movement from one occupational family to another will depend upon individual competencies, qualifications, and the needs of the organization.

Progression within a pay band is based upon performance-based pay increases; as such, these actions are not considered promotions and are not subject to the provisions of this section. Except as specified below, promotions will be processed under competitive procedures in accordance with Merit System Principles and requirements of the local merit promotion plan.

To be promoted competitively or non-competitively from one band to the next, an employee must meet the minimum qualifications for the job and have a current performance rating of 30 or better, or equivalent under a different performance appraisal system. The minimum performance rating of 30 is set as an initial value and may be changed by the PMB, as necessary, with a goal of continuously increasing employee and laboratory performance. If an employee does not have a current performance rating, the employee will be treated the same as an employee with an ''acceptable'' rating as long as there is no documented evidence of unacceptable performance.

2. Reassignment

A reassignment is the movement of an employee from one position to a different position within the same occupational family and pay band or to another occupational family and pay band wherein the band in the new family has the same maximum base pay. The employee must meet the qualifications requirements for the occupational family and pay band.

3. Demotion or Placement in a Lower Pay Band or Grade

A demotion is a placement of an employee into a lower pay band within the same occupational family or placement into a pay band in a different occupational family with a lower maximum base pay. Demotions may be for cause (performance or conduct) or for reasons other than cause (*e.g.,* erosion of duties, reclassification of duties to a lower pay band, application under competitive announcements, at the employee's request—if approved, placement actions resulting from reduction-in-force ((RIF) procedures). Such actions will be executed using the applicable adverse action procedures in Title 5, U.S.C., Chapter 43 or Chapter 75.

4. Simplified Assignment Process

Today's environment of downsizing and workforce fluctuations mandates that the organization have maximum flexibility to assign duties and responsibilities to individuals. Pay banding can be used to address this need, as it enables the organization to have maximum flexibility to assign an employee with no change in base pay, within broad descriptions, consistent with the needs of the organization and the individual's qualifications and level. Subsequent assignments to projects, tasks, or functions anywhere within the organization requiring the same level, area of expertise, and qualifications would not constitute an assignment outside the scope or coverage of the current position description. For instance, a Research Psychologist could be assigned to any project, task, or function requiring similar expertise. Likewise, a manager/supervisor could be assigned to manage any similar function or organization consistent with that individual's qualifications. This flexibility allows broader latitude in assignments and further streamlines the administrative process and system. Execution of such actions may require fulfilling labor obligations, where applicable.

5. Details and Expanded Temporary Promotions

Employees may be detailed to a position at the same or similar level (position in a pay band with the same maximum salary). Additionally, employees may be temporary promoted to a position in a pay band with a higher maximum salary. Details and temporary promotions may be for up to two years. A detail or temporary promotion may be effected without a change in pay or may result in a base pay increase when the detail or temporary assignment significantly increases the complexity, responsibility, authority, or for other compelling reasons. Such an increase is subject to the specific guidelines established by the PMB. Details and temporary promotions may be determined by a competitive or a non-competitive process. The specifics of these authorities will be stipulated by local business rules, policies, or procedures as organizational experience dictates. Execution of such actions may require fulfilling labor obligations, where applicable.

6. Exceptions to Competitive Procedures for Assignment to a Position

The following actions are excepted from competitive procedures:

(1) Re-promotion to a position which is in the same pay band or GS equivalent and occupational family as the employee previously held on a permanent basis within the competitive service.

(2) Promotion, reassignment, demotion, transfer, or reinstatement to a position having promotion potential no greater than the potential of a position an employee currently holds or

previously held on a permanent basis in the competitive service.

(3) A position change permitted by RIF procedures.

(4) Promotion without current competition when the employee was appointed through competitive procedures to a position with a documented career ladder.

(5) A temporary promotion, or detail to a position in a higher pay band, of two years or less.

(6) A promotion due to the reclassification of positions based on accretion (addition) of duties.

(7) A promotion resulting from the correction of an initial classification error or the issuance of a new classification standard.

(8) Consideration of a candidate who did not receive proper consideration in a competitive promotion action.

F. Pay Setting

1. General

Pay administration policies will be established by the PMB. These policies will be exempt from Army Regulations or local pay fixing policies. Employees whose performance is acceptable will receive the full annual general pay increase and the full locality pay. The ARI Director shall have delegated authority to may make full use of recruitment, retention, and relocation payments as currently provided for by OPM.

Grade and pay retention will follow current law and regulations at 5 U.S.C. 5362, 5363, and 5 CFR part 536, except as waived or modified in Section IX, the waiver section of this plan. The ARI Director may also grant pay retention to employees who meet general eligibility requirements, but do not have specific entitlement by law, provided they are not specifically excluded.

2. Pay and Compensation Ceilings

A demonstration project employee's total monetary compensation paid in a calendar year may not exceed the base pay of Level I of the Executive Schedule consistent with 5 U.S.C. 5307 and 5 CFR part 530 subpart B. In addition, each pay band will have its own pay ceiling, just as grades do in the GS system. Base pay rates for the various pay bands will be directly keyed to the GS rates, except as noted for the Pay Band VI of the Engineer and Scientist occupational family. Other than where retained rate applies, base pay will be limited to the maximum base pay payable for each pay band.

3. Pay Setting for Appointment

For initial appointments to Federal service, the individual's pay may be set at the lowest base pay in the pay band or anywhere within the band level consistent with the special qualifications of the individual, specific organizational requirements, the unique requirements of the position, or other compelling reason. These special qualifications may be in the form of education, training, experience or any combination thereof that is pertinent to the position in which the employee is being placed. Guidance on pay setting for new hires will be established by the PMB and documented in IOPs.

Highest Previous Rate (HPR) may be considered in placement actions authorized under rules similar to the HPR rules in 5 CFR 531.221. Request to use HPR must be made to the PMB and is subject to policies established by the PMB, as approved by the ARI Director. To maintain consistent application of pay setting decisions, the PMB will collect and track pay setting data, qualifications, and other relevant information.

4. Pay Setting for Promotion

The minimum base pay increase upon promotion to a higher pay band will be six percent or the minimum base pay rate of the new pay band, whichever is greater. The maximum amount of a pay increase for a promotion is 20 percent but will not normally exceed $10,000 or other such amount as established by the Personnel Management Board. The maximum base pay increase for promotion may be exceeded when necessary to allow for the minimum base pay increase. For employees assigned to occupational categories and geographic areas covered by special rates, the minimum base pay rate in the pay band to which promoted is the minimum base pay for the corresponding special rate or locality rate, whichever is greater. For employees covered by a staffing supplement (described in III.F.9.), the demonstration staffing supplement adjusted pay is considered base pay for promotion calculations. When a temporary promotion is terminated, the employee's pay entitlements will be re-determined based on the employee's position of record, with appropriate adjustments to reflect pay events during the temporary promotion, subject to the specific policies and rules established by the PMB. In no case may those adjustments increase the base pay for the position of record beyond the applicable pay range maximum base pay rate.

5. Pay Setting for Reassignment

A reassignment may be effected without a change in base pay. However, a base pay increase may be granted where a reassignment significantly increases the complexity, responsibility, authority, or for other compelling reasons. Such an increase is subject to the specific guidelines established by the PMB.

6. Pay Setting for Demotion or Placement in a Lower Pay Band

Employees demoted for cause (performance or conduct) are not entitled to pay retention and will receive a minimum of a five percent decrease in base pay. Employees demoted for reasons other than cause (*e.g.,* erosion of duties, reclassification of duties to a lower pay band, or placement actions resulting from RIF procedures) may be entitled to pay and grade retention in accordance with the provisions of 5 U.S.C. 5363 and 5 CFR part 536, except as waived or modified in Section IX of this plan.

Employees who receive an unacceptable rating or who are on a PIP at the time pay determinations are made do not receive performance payouts or the general pay increase. This action may result in a base pay that is identified in a lower pay band. This occurs because the minimum rate of base pay in a pay band increases as the result of the general pay increase (5 U.S.C. 5303). This situation (a reduction in band level with no reduction in pay) will not be considered an adverse action, nor will band retention provisions apply.

A supervisor who fails to successfully complete a supervisory probationary period will no longer receive a supervisory pay adjustment (supervisory differential/adjustment).

7. Supervisory and Team Leader Pay Adjustments

Supervisory and team leader pay adjustments may be approved by the ARI Director at his/her discretion, based on the recommendation of the PMB, to compensate employees with supervisory or team leader responsibilities. Supervisory and team leader pay adjustments are a tool that may be implemented at the discretion of the ARI Director and are not to be considered an employee entitlement due solely to his/her position as a supervisor or team leader. Only employees in supervisory or team leader positions as defined by the OPM GS Supervisory Guide or GS Leader Grade Evaluation Guide may be considered for the pay adjustment. These pay adjustments are funded separately from performance pay pools. These pay adjustments are increases to base pay, ranging up to 10 percent of that pay rate

for supervisors and for team leaders. Pay adjustments are subject to the constraint that the adjustment may not cause the employee's base pay to exceed the pay band maximum base pay. Criteria to be considered in determining the pay increase percentage include:

(1) Needs of the organization to attract, retain, and motivate high-quality supervisors/team leaders;

(2) Budgetary constraints;

(3) Years and quality of related experience;

(4) Relevant training;

(5) Performance appraisals and experience as a supervisor/team leader;

(6) Unique requirements of a specific position or level of complexity compared to other positions of a similar nature,

(7) Organizational level of position; and

(8) Impact on the organization.

A pay adjustment may be considered under the following conditions:

(1) New supervisory/team leader positions will have their initial rate of base pay set within the pay range of the applicable pay band and rules established by the PMB. Request for initial rate of pay will be made to the PMB and approved by the ARI Director or delegated official. This rate of pay may include a pay adjustment determined by using the ranges and criteria outlined above.

(2) A career employee selected for a supervisory/team leader position may also be considered for a base pay adjustment. If a supervisor/team leader is already authorized a base pay adjustment and is subsequently selected for another supervisor/team leader position, then the base pay adjustment will be re-determined. Upon initial conversion into the demonstration project into the same or substantially similar position, supervisors/team leaders will be converted at their existing base rate of pay and will not be eligible for a base pay adjustment.

(3) The supervisory/team leader pay adjustment will be reviewed annually, or more often as needed, and may be increased or decreased by a portion or by the entire amount of the supervisory/team leader pay adjustment based upon the employee's performance appraisal score for the performance element, Team Project Leadership or Supervision/EEO, needs of the organization, and/or criteria outlined above. If the entire portion of the supervisory/team leader pay adjustment is to be decreased, the initial dollar amount of the supervisory/team leader pay adjustment will be removed. A decrease to the supervisory/team leader pay adjustment as a result of the annual review or when an employee voluntarily leaves a position is not an adverse action and is not subject to appeal.

8. Supervisory/Team Leader Pay Differentials

Supervisory and team leader pay differentials may be used by the ARI Director to provide an incentive and reward supervisors and team leaders. Supervisory and team leader pay differentials are a tool that may be implemented at the discretion of the ARI Director and is not to be considered an entitlement due to an employee solely due to their position as a supervisor or team leader. Pay differentials are not funded from performance pay pools. A pay differential is a cash incentive that may range up to 10 percent of base pay for supervisors and for team leaders. It is paid on a pay period basis with a specified not-to-exceed (NTE) of one year or less and is not included as part of the base pay. Criteria to be considered in determining the amount of the pay differential are the same as those identified for Supervisory/Team Leader Pay Adjustments.

The pay differential may be considered, either during conversion into or after initiation of the demonstration project. The differential must be terminated if the employee is removed from a supervisory/team leader position, regardless of cause.

After initiation of the demonstration project, all personnel actions involving a supervisory/team leader differential will require a statement signed by the employee acknowledging that the differential may be terminated or reduced at the discretion of the ARI Director. The termination or reduction of the supervisory differential is not considered an adverse action under Chapter 75, of Title 5, U.S.C. and 5 CFR 752, and is not subject to appeal with the Merit Systems Protection Board.

9. Staffing Supplements

Employees assigned to occupational categories and geographic areas covered by special rates will be entitled to a staffing supplement if the maximum adjusted base pay for the banded GS grades (*i.e.,* the maximum GS locality rate) to which assigned is a special rate that exceeds the maximum GS locality rate for the banded grades. Specific provisions will be described in IOPs.

G. Employee Development

1. Expanded Developmental Opportunity Program

The Expanded Developmental Opportunity Program will be available to all demonstration project employees. Expanded developmental opportunities complement existing developmental opportunities such as long-term training; rotational job assignments; developmental assignments to ARI, Army, or DoD; and self-directed study via correspondence courses, local colleges, and universities. Each developmental opportunity must result in a product, service, report, or study that will benefit ARI or customer organization as well as increase the employee's individual effectiveness. The PMB will provide written guidance for employees on application procedures and develop a process that will be used to review and evaluate applicants for development opportunities. These expanded developmental opportunities may be made available when there is a critical skill, need, or gap that must be filled for organizational success. Determinations for sabbaticals and critical skills training shall be made based on the needs of ARI and the relationship to the research mission, merit, organization fill rates, current, near- and mid-term workload requirements, budget, and employee performance scores.

(1) *Sabbatical.* The ARI Director has the authority to grant paid or unpaid sabbaticals to all career employees. The purpose of a sabbatical will be to permit employees to engage in study or uncompensated work experience that will benefit the organization and contribute to the employee's development and effectiveness. Each sabbatical must result in a product, service, report, or study that will benefit the ARI mission as well as increase the employee's individual effectiveness. Various learning or developmental experiences may be considered, such as research, self-directed or guided study, and on-the-job work experience. Limitations and eligibility requirements for sabbaticals will be published in the IOP. Employees approved for a paid sabbatical must sign a service obligation agreement to continue in service in ARI for a period of three times the length of the sabbatical. If an employee voluntarily leaves ARI before the service obligation is completed he/she is liable for repayment of expenses incurred by ARI that are associated with the sabbatical. Expenses do not include salary costs. The ARI Director has the authority to waive this requirement. Criteria for such waivers will be addressed in the operating procedures. Specific procedures will be developed for processing sabbatical applications upon implementation of the demonstration project.

(2) *Critical Skills Training.* The ARI Director has the authority to approve academic degree training where consistent with a current employee's current line of work, and where it provides a clear benefit to the organization. Training is an essential component of an organization that requires continuous acquisition of advanced and specialized knowledge. Degree training is also a tool for maintaining required knowledge and skills critical to the present and future requirements of the organization. Degree or certificate payment may not be authorized where it would result in a tax liability for the employee without the employee's express and written consent. Any variance from this policy must be rigorously determined and documented. Guidelines will be developed to ensure a fully competitive approval process for expanded critical skills training. Employees approved for degree training must sign a service obligation agreement to continue service in the ARI for a period three times the length of the training period commencing after the completion of the entire degree program. If an employee voluntarily leaves ARI before the service obligation is completed, he/she is liable for repayment of expenses incurred by ARI that are related to the critical skills training. Expenses do not include salary costs. The ARI Director has the authority to waive this requirement. Criteria for such waivers will be addressed in the operating procedures.

IV. Implementation Training

Critical to the success of the demonstration project is the training developed to promote understanding of the broad concepts and finer details needed to implement and successfully execute this project. Training will be tailored to address employee concerns and to encourage comprehensive understanding of the demonstration project. Training will be required both prior to implementation and at various times during the life of the demonstration project.

A training program will begin prior to implementation and will include modules tailored for employees, supervisors, and administrative staff. Typical modules are:

(1) An overview of the demonstration project personnel system.

(2) How employees are converted into and out of the system.

(3) Pay banding.

(4) The pay-for-performance system.

(5) Defining performance objectives.

(6) How to assign weights to performance elements.

(7) Assessing performance and giving feedback.

(8) New position descriptions.

(9) Demonstration project administration and formal evaluation.

Various types of training are being considered, including videos, video-teleconference tutorials, and train-the-trainer concepts. To the extent possible, materials already developed from other STRLs will be utilized when appropriate to reduce implementation cost and to maintain consistency in application of similar procedures across laboratories.

V. Conversion

A. Conversion to the Demonstration Project

Conversion from current GS grade and pay into the new pay band system will be accomplished during implementation of the demonstration project. Initial entry into the demonstration project will be accomplished through a full employee-protection approach that ensures each employee an initial place in the appropriate pay band without loss of pay on conversion.

Under the GS pay structure, employees progress through their assigned grade in step increments. Since this system is being replaced under the demonstration project, employees will be awarded that portion of the next higher step they have completed up until the effective date of conversion. As under the current system, supervisors will be able to withhold these partial step increases if the employee's performance is below an acceptable level of competence.

Rules governing WGIs will continue in effect until conversion. Adjustments to the employee's base salary for WGI equity will be computed as of the effective date of conversion. WGI equity will be acknowledged by increasing base pay by a prorated share based upon the number of full weeks an employee has completed toward the next higher step. Payment will equal the value of the employee's next WGI times the proportion of the waiting period completed (weeks completed in waiting period/weeks in the waiting period) at the time of conversion. Employees at step 10, or receiving retained rates, on the day of implementation will not be eligible for WGI equity adjustments since they are already at or above the top of the step scale. Employees serving on retained grade will receive WGI equity adjustments provided they are not at step 10 or receiving a retained rate.

Employees who enter the demonstration project after initial implementation by lateral transfer, reassignment, or realignment will be subject to the same pay conversion rules as above. If conversion into the demonstration project is accompanied by a geographic move, the employee's GS pay entitlements in the new geographic area must be determined before performing the pay conversion.

B. Conversion or Movement From a Project Position to a General Schedule Position

If a demonstration project employee is moving to a GS position not under the demonstration project, or if the project ends and each project employee must be converted back to the GS system, the following procedures will be used to convert the employee's project pay band to a GS-equivalent grade and the employee's project rate of pay to GS equivalent rate of pay. The converted GS grade and GS rate of pay must be determined before movement or conversion out of the demonstration project and any accompanying geographic movement, promotion, or other simultaneous action. For conversions upon termination of the project and for lateral reassignments, the converted GS grade and rate will become the employee's actual GS grade and rate after leaving the demonstration project (before any other action). For employee movement from within DoD (transfers), promotions, and other actions, the converted GS grade and rate will be used in applying any GS pay administration rules applicable in connection with the employee's movement out of the project (*e.g.,* promotion rules, highest previous rate rules, pay retention rules), as if the GS converted grade and rate were actually in effect immediately before the employee left the demonstration project.

1. Grade-Setting Provisions

An employee in a pay band corresponding to a single GS grade is converted to that grade. An employee in a pay band corresponding to two or more grades is converted to one of those grades according to the following rules:

(1) The employee's adjusted rate of basic pay under the demonstration project (including any locality payment or staffing supplement) is compared with step four rates on the highest applicable GS rate range. (For this purpose, a ''GS rate range'' includes a rate in (1) the GS base schedule, (2) the locality rate schedule for the locality pay area in which the position is located, or (3) the appropriate special rate schedule for the employee's occupational series, as applicable.) If the series is a two-grade interval series, only

odd-numbered grades are considered below GS–11.

(2) If the employee's adjusted project rate equals or exceeds the applicable step four rate of the highest GS grade in the band, the employee is converted to that grade.

(3) If the employee's adjusted project rate is lower than the applicable step four rate of the highest grade, the adjusted rate is compared with the step four rate of the second highest grade in the employee's pay band. If the employee's adjusted rate equals or exceeds step four rate of the second highest grade, the employee is converted to that grade.

(4) This process is repeated for each successively lower grade in the band until a grade is found in which the employee's adjusted project rate equals or exceeds the applicable step four rate of the grade. The employee is then converted at that grade. If the employee's adjusted rate is below the step four rate of the lowest grade in the band, the employee is converted to the lowest grade.

(5) Exception: An employee will not be converted to a lower grade than the grade held by the employee immediately preceding a conversion, lateral reassignment, or transfer from within DoD into the project, unless since that time the employee has undergone a reduction in band or accepted a lower grade/band position.

2. Pay-Setting Provisions

An employee's pay within the converted GS grade is set by converting the employee's demonstration project rate of pay to GS rate of pay in accordance with the following rules:

(1) The pay conversion is done before any geographic movement or other pay-related action that coincides with the employee's movement or conversion out of the demonstration project.

(2) An employee's adjusted rate of basic pay under the project (including any locality payment or staffing supplement) is converted to the GS adjusted rate on the highest applicable rate range for the converted GS grade. (For this purpose, a ''GS rate range'' includes a rate range in (1) the GS base schedule, (2) an applicable locality rate schedule, or (3) an applicable special rate schedule.)

(3) If the highest applicable GS rate range is a locality pay rate range, the employee's adjusted project rate is converted to a GS locality rate of pay. If this rate falls between two steps in the locality-adjusted schedule, the rate must be set at the higher step. The converted GS unadjusted rate of basic pay would be the GS base rate corresponding to the converted GS locality rate (*i.e.,* same step position). (If this employee is also covered by a special rate schedule as a GS employee, the converted special rate will be determined based on the GS step position. This underlying special rate will be basic pay for certain purposes for which the employee's higher locality rate is not basic pay.)

(4) If the highest applicable GS rate range is a special rate range, the employee's adjusted project rate is converted to a special rate. If this rate falls between two steps in the special rate schedule, the rates must be set at the higher step. The converted GS unadjusted rate of basic pay will be the GS rate corresponding to the converted special rate (*i.e.,* same step position).

3. E&S Pay Band III Employees

An employee in Pay band III of the E&S Occupational family will convert out of the demonstration project at no higher than the GS–13, step 10 level. ARI, in consultation with the CPAC, will develop a procedure to ensure that employees entering E&S Pay band III understand that if they leave the demonstration project and their adjusted pay exceeds the GS–13, step 10 rate, there is no entitlement to retained pay; their GS-equivalent rate will be deemed to be the rate for GS–13, step 10. These procedures will be documented in IOPs.

4. E&S Pay Band VI Employees

E&S Pay Band VI Employees: An employee in Pay Band VI of the E&S occupational family will convert out of the demonstration project at the GS–15 level. Procedures will be documented in IOPs to ensure that employees entering Pay Band VI understand that if they leave the demonstration project and their adjusted base pay under the demonstration project exceeds the highest applicable GS–15, step 10 rate, there is no entitlement to retained pay. However, consistent with 79 FR 43722, July 28, 2014, pay retention may be provided to SSTM members under criteria established by the PMB (and approved by the Director) who are impacted by a reduction in force, work realignment, or other planned management action that would necessitate moving the incumbent to a position in a lower pay band within the STRL. Pay retention may also be provided under criteria established when an SES or ST employee is placed in a SSTM position as a result of reduction in force or other management action. SSTM positions not entitled to pay retention above the GS–15, step 10 rate will be deemed to be the rate for GS–15, step 10. For those Pay Band VI employees paid below the adjusted GS–15, step 10 rate, the converted rates will be set in accordance with paragraph 2.

5. Employees With Band or Pay Retention

(1) If an employee is retaining a band level under the demonstration project, apply the procedures in paragraphs 1.a. and 1.b. (Grade-Setting Provisions) above, using the grades encompassed in the employee's retained band to determine the employee's GS-equivalent retained grade and pay rate. The time in a retained band under the demonstration project counts toward the 2-year limit on grade retention in 5 U.S.C. 5382.

(2) If an employee is retaining rate under the demonstration project, the employee's GS-equivalent grade is the highest grade encompassed in his or her band level. ARI will coordinate with DoD to prescribe a procedure for determining the GS-equivalent pay rate for an employee retaining a rate under the demonstration project.

6. Within-Grade Increase

Equivalent Increase Determinations: Service under the demonstration project is creditable for within-grade increase purposes upon conversion back to the GS pay system. Performance pay increases (including a zero increase) under the demonstration project are equivalent increases for the purpose of determining the commencement of a within-grade increase waiting period under 5 CFR 531.405(b).

C. Personnel Administration

All personnel laws, regulations, and guidelines not waived by this plan will remain in effect. Basic employee rights will be safeguarded and Merit System Principles will be maintained. Servicing CPAC(s) will continue to process personnel-related actions and provide consultative and other appropriate services.

D. Automation

ARI will use the DoD approved automated personnel system for the processing of personnel-related data. Payroll servicing will continue from the respective payroll offices.

An automated tool or other appropriate procedures will be used to support computation of performance related pay increases and awards and other personnel processes and systems associated with this project.

E. Revision

Constant assessment and refinement is needed to maximize the effectiveness of the system. Modifications may be

made from time to time as experience is gained, results are analyzed, and conclusions are reached on how the new system is working. Modifications will be made in accordance with the provisions of DoDI 1400.37, or applicable superseding instructions.

VI. Project Duration

Public Law 103–337 removed any mandatory expiration date for this demonstration project. ARI, DA, and DoD will ensure this project is evaluated for the first five years after implementation in accordance with 5 U.S.C. 4703. Modifications to the original evaluation plan or any new evaluation will ensure the project is evaluated for its effectiveness, its impact on mission, and any potential adverse impact on any employee groups.

VII. Evaluation Plan

A. Overview

Chapter 47 of 5 U.S.C. requires that an evaluation be performed to measure the effectiveness of the demonstration project, and its impact on improving public management. A comprehensive evaluation plan for the entire demonstration program, originally covering 24 DoD laboratories, was developed by a joint OPM/DoD Evaluation Committee in 1995. This plan was submitted to the Office of Defense Research & Engineering and was subsequently approved. The main purpose of the evaluation is to determine whether the waivers granted result in a more effective personnel system and improvements in ultimate outcomes (*i.e.,* organizational effectiveness, mission accomplishment, and customer satisfaction). That plan, while useful, is dated and does not fully afford the laboratories the ability to evaluate all aspects of the demonstration project in a way that fully facilitates assessment and effective modification based on actionable data. Therefore, in conducting the evaluation ARI will ensure USD(R&E) evaluation requirements are met in addition to applying knowledge gained from other DoD laboratories and their evaluations to ensure a timely, useful evaluation of the demonstration project.

B. Method of Data Collection

Data from a variety of different sources will be used in the evaluation. Information from existing management information systems supplemented with perceptual survey data from employees will be used to assess variables related to effectiveness. Multiple methods provide more than one perspective on how the demonstration project is working. Information gathered through one method will be used to validate information gathered through another. Confidence in the findings will increase as they are substantiated by the different collection methods. The following types of qualitative and/or quantitative data will be collected as part of the evaluation: (1) Workforce data; (2) personnel office data; (3) employee attitudes and feedback using surveys, structured interviews, and focus groups; (4) local activity histories; and, (5) core measures of laboratory effectiveness.

VIII. Demonstration Project Costs

A. Cost Discipline

An objective of the demonstration project is to ensure in-house cost discipline. A baseline will be established at the start of the project and labor expenditures will be tracked yearly. Implementation costs (including project development, automation costs, step buy-in costs, and evaluation costs) are considered one-time costs and will not be included in the cost discipline.

The Personnel Management Board will track personnel cost changes and recommend adjustments if required to achieve the objective of cost discipline.

B. Developmental Costs

Costs associated with the development of the personnel demonstration project include software automation, training, and project evaluation. All funding will be provided through the organization's budget. The projected annual expenses are summarized in Table 1. Project evaluation costs are not expected to continue beyond the first five years unless the results warrant further evaluation. Additional cost may be incurred as a part of the implementation and operation of the project.

TABLE 1—PROJECTED DEVELOPMENTAL COSTS

[In thousands of dollars]

	FY20	FY21	FY22	FY23	FY24
Training	15K	15K	10K	10K	5K
Project Evaluation	0K	0K	5K	5K	30K
Automation	15K	25K	25K	25K	25K
	30K	40K	40K	40K	60K

IX. Required Waivers to Law and Regulation

Public Law 106–398 gave the DoD the authority to experiment with several personnel management innovations. In addition to the authorities granted by the law, the following are waivers of law and regulation that will be necessary for implementation of the demonstration project. In due course, additional laws and regulations may be identified for waiver request.

The following waivers and adaptations of certain Title 5 U.S.C. provisions are required only to the extent that these statutory provisions limit or are inconsistent with the actions contemplated under this demonstration

project. Nothing in this plan is intended to preclude the demonstration project from adopting or incorporating any law or regulation enacted, adopted, or amended after the effective date of this demonstration project.

A. Waivers to Title 5, United States Code

Chapter 5, section 552a: Records maintained on individuals. This section is waived only to the extent required to clarify that volunteers under the Volunteer Emeritus Corps are considered employees of the Federal government for purposes of this section.

Chapter 31, section 3104: Employment of specially qualified scientific and professional personnel. Waived to allow SSTMs.

Chapter 31, section 3132: The Senior Executive Service: Definitions and exclusions. Waived as necessary to allow for the Pay Band VI of the E&S Occupational Family.

Chapter 33, section 3317(a): Competitive Service; certification from registers. Waived insofar as ''rule of three'' is eliminated under the demonstration projects.

Chapter 33, section 3318(a): Competitive Service, selection from certificate. Waived to the extent necessary to eliminate the requirement for selection using the ''Rule of Three'' and other limitations on recruitment list.

Chapter 33, section 3321: Competitive service; probationary period. This section waived only to the extent necessary to replace grade with ''pay band.''

Chapter 33, section 3324 and section 3325: Appointments to positions classified above GS–15. Waived in entirety to fully allow for positions above GS–15.

Chapter 33, section 3341: Details. Waived as necessary to extend the time limits for details.

Chapter 41, section 4107(a) (1), (2), (b) (1), (3): Pay for Degrees. Waived to the extent required to allow ARI to pay for all courses related to a degree program approved by the ARI Director.

Chapter 41, section 4108(a)–(c): Employee agreements; service after training. Waived to the extent necessary to require the employee to continue in the service of ARI for the period of the required service and to the extent necessary to permit the Director, ARI, to waive in whole or in part a right of recovery.

Chapter 43, sections 4301–4305: Related to performance appraisal. These sections are waived to the extent necessary to allow provisions of the performance management system as described in this FRN.

Chapter 51, sections 5101–5112: Classification. Waived as necessary to allow for the demonstration project pay banding system.

Chapter 53, sections 5301–5307: Related to pay comparability system and GS pay rates. Waived to the extent necessary to allow demonstration project employees, including SSTM employees, to be treated as GS employees, and to allow basic rates of pay under the demonstration project to be treated as scheduled rates of pay. SSTM pay will not exceed EX–IV and locality adjusted SSTM rates will not exceed EX III.

Chapter 53, sections 5331–5336: GS pay rates. Waived in its entirety to allow for the demonstration project's pay banding system and pay provisions.

Chapter 53, sections 5361–5366: Grade and pay retention. Waived to the extent necessary to allow pay retention provisions described in this FR notice and to allow SSTMs to receive pay retention as described in 79 FR 43722.

Chapter 55, section 5545(d): Hazardous duty differential. Waived to the extent necessary to allow demonstration project employees to be treated as GS employees. This waiver does not apply to employees in Pay Band VI of the E&S occupational family.

Chapter 57, section 5753, 5754, and 5755: Recruitment and relocation, bonuses, retention allowances and supervisory differentials. Waived to the extent necessary to allow (1) employees and positions under the demonstration project to be treated as employees and positions under the GS, (2) employees in Pay Band VI of the E&S occupational family to be treated as ST and/or GS employees as appropriate, (3) previsions of the retention counteroffer and incentives as described in this FRN, and (4) to allow SSTMs to receive supervisory pay differentials as described in 79 FR 43722.

Chapter 59, section 5941: Allowances based on living costs and conditions of environment; employees stationed outside continental U.S. or Alaska. Waived to the extent necessary to provide that cost-of-living allowances paid to employees under the demonstration project are paid in accordance with regulations prescribed by the President (as delegated to OPM).

Chapter 75, sections 7501(1), 7511(a)(1)(A)(ii), and 7511(a)(1)(C)(ii): Adverse actions—definitions. Waived to the extent necessary to allow for up to a three-year probationary period and to permit termination during the extended probationary period without using adverse action procedures for those employees serving a probationary period under an initial appointment except for those with veterans' preference. Waived to the extent necessary to allow for two-year supervisory probationary periods and to permit re-assignment of supervisors during the probationary period without adverse action procedures for those employees serving in a supervisory probationary period.

Chapter 75, section 7512(3): Adverse actions. Waived to the extent necessary to replace ''grade'' with ''pay band.''

Chapter 75, section 7512(4): Adverse actions. Waived to the extent necessary to provide that adverse action provisions do not apply to (1) reductions in pay due to the removal of a supervisory or team leader pay adjustment/differential upon voluntary movement to a non-supervisory or non-team leader position or (2) decreases in the amount of a supervisory or team leader pay adjustment/differential during the annual review process.

B. Waivers to Title 5, Code of Federal Regulations

Part 300–330: Employment (general) other than subpart G of 300. Waived to the extent necessary to allow provisions of the direct hire authorities as described in 79 FR 43722 and 82 FR 29280.

Part 300, sections 300.601 through 605: Time-in-grade restrictions. Waived to eliminate time-in-grade restrictions in the demonstration project.

Part 315, section 315.801(a), 315.801(b)(1), (c), and (e) and 315.802(a) and (b)(1): Probationary period and length of probationary period. Waived to the extent necessary to (1) allow for up to a three-year probationary period and to permit termination during the extended probationary period without using adverse action procedures for those employees serving a probationary period under an initial appointment except for those with veterans' preference and (2) to the extent necessary to allow for supervisory probationary periods to permit reassignment during the supervisory probationary period without using adverse action procedures for employees serving a probationary period.

Part 315, section 315.804: Termination of probationers for unsatisfactory performance or conduct. Waived to the extent necessary to reduce a supervisor who fails to successfully complete a supervisory probationary period to a lower grade/band.

Part 315, section 315.805: Termination of probationers for

conditions arising before appointment. Waived to the extent necessary to permit termination during the extended probationary period without using adverse procedures.

Part 315, section 315.901–315.909: Statutory requirement. Waived to the extent necessary to (1) replace ''grade'' with ''pay band;'' (2) establish a two-year supervisory probationary period; and (3) allow the movement of a newly hired supervisor who fails to meet requirements to a lower grade/band.

Part 316, sections 316.301, 316.303, and 316.304: Term employment. Waived to the extent necessary to allow modified term appointments and Flexible Length and Renewable Term Technical Appointments as described in this FRN and in 82 FR 43339.

Part 332, section 332.401, 332. 402 and 332.404: Order of selection from certificates. Waived to the extent necessary to eliminate the requirement for selection using the ''Rule of Three'' or other procedures to limit recruitment lists.

Part 335, section 335.103: Agency promotion programs. Waived to the extent necessary to extend the length of details and temporary promotions without requiring competitive procedures.

Part 337, section 337.101(a): Rating applicants. Waived to the extent necessary to allow referral without rating when there are 15 or fewer qualified candidates and no qualified preference eligibles.

Part 340, subpart A, subpart B, and subpart C: Other than full-time career employment. These subparts are waived to the extent necessary to allow a Volunteer Emeritus Corps.

Part 359, section 359.705: Pay. Waived to allow demonstration project rules governing pay retention to apply to a former SES or ST placed on an SSTM position.

Part 410, section 410.308(a–e): Training to obtain an academic degree. Waived to the extent necessary to allow provisions described in this FR.

Part 410, section 410.309: Agreements to continue in service. Waived to the extent necessary to allow the ARI Director to determine requirements related to continued service agreements.

Part 430, subpart B: Performance appraisal for GS, prevailing rate, and certain other employees. Waived to the extent necessary to be consistent with the demonstration project's pay-for-performance system.

Part 432, section 432.102–432.106: Performance based reduction in grade and removal actions. Waived to the extent necessary to allow provisions described in the FRN.

Part 511: Classification under the general schedule. Waived to the extent necessary to allow classification provisions outlined in this FR to include the list of issues that are neither appealable nor reviewable, the assignment of series under the project plan to appropriate occupational families; and to allow appeals to be decided by the ARI Director. If the employee is not satisfied with the ARI Director's response to the appeal, he/she may then appeal to the DoD appellate level.

Part 530, subpart C: Special rate schedules for recruitment and retention. Waived in its entirety to allow for staffing supplements, if applicable.

Part 531, subpart B: Determining rate of basic pay. Waived to the extent necessary to allow for pay setting and pay-for-performance under the provisions of the demonstration project.

Part 531, subparts D and E: Within-grade increases and quality step increases. Waived in its entirety.

Part 531, subpart F: Locality-based comparability payments. Waived to the extent necessary to allow (1) demonstration project employees, except employees in Pay Band VI of the E&S occupational family, to be treated as GS employees; and (2) base rates of pay under the demonstration project to be treated as scheduled annual rates of pay.

Part 536: Grade and pay retention. Waived to the extent necessary to (1) replace ''grade'' with ''pay band;'' (2) provide that pay retention provisions do not apply to conversions from GS special rates to demonstration project pay, as long as total pay is not reduced, and to reductions in pay due solely to the removal of a supervisory pay adjustment upon voluntarily leaving a supervisory position; (3) allow demonstration project employees to be treated as GS employees; (4) provide that pay retention provisions do not apply to movements to a lower pay band as a result of not receiving the general increase due to an annual performance rating of ''Unacceptable;'' (5) provide that an employee on pay retention whose rating of record is ''Unacceptable'' is not entitled to 50 percent of the amount of the increase in the maximum rate of base pay payable for the pay band of the employee's position; (6) ensure that for employees of Pay Band VI in the E&S occupational family, pay retention provisions are modified so that no rate established under these provisions may exceed the rate of base pay for GS–15, step 10 (*i.e.,* there is no entitlement to retained rate); and (7) provide that pay retention does not apply to reduction in base pay due solely to the reallocation of demonstration project pay rates in the implementation of a staffing supplement. This waiver applies to ST employees only if they move to a GS-equivalent position within the demonstration project under conditions that trigger entitlement to pay retention.

Part 536, section 536.306(a): Limitation on retained rates. Waived to the extent necessary to allow SSTMs to receive pay retention as described in 79 FR 43727.

Part 550, section 550.703: Definitions. Waived to the extent necessary to modify the definition of ''reasonable offer'' by replacing ''two grade or pay levels'' with ''one band level'' and ''grade or pay level'' with ''band level.''

Part 550, section 550.902: Definitions. Waived to the extent necessary to allow demonstration project employees to be treated as GS employees. This waiver does not apply to employees in Pay Band VI of the E&S occupational family.

Part 575, subparts A, B, C, and D: Recruitment incentives, relocation incentives, retention incentives and supervisory differentials. Waived to the extent necessary to allow (1) employees and positions under the demonstration project covered by pay banding to be treated as employees and positions under the GS system, (2) to allow SSTMs to receive supervisory pay differentials as described in 73 FR 43727, and (3) to allow the Director to pay an offer up to 50 percent of basic pay of either a base pay and/or a cash payment to retain quality employees; and to the extent necessary to allow SSTMs to receive supervisory pay differentials. Criteria for retention determination and preparing written service agreements will be as prescribed in 5 U.S.C. 5754 and as waived herein.

Part 591, subpart B: Cost-of-living allowance and post differential—Non-foreign Areas. Waived to the extent necessary to allow demonstration project employees to be treated as employees under the GS system.

Part 752, sections 752.101, 752.201, 752.301 and 752.401: Principal statutory requirements and coverage. Waived to the extent necessary to (1) allow for up to a three-year probationary period; (2) permit termination during the extended probationary period without using adverse action procedures for those employees serving a probationary period under an initial appointment except for those with veterans' preference; (3) allow for supervisory probationary periods and to permit reassignment during the supervisory probationary period without use of adverse action procedures for those employees serving a probationary

period under a supervisory probationary period; (4) replace ''grade'' with ''pay band;'' and (5) provide that a reduction in pay band level is not an adverse action if it results from the employee's rate of base pay being exceeded by the minimum rate of base pay for his/her pay band. Waived to the extent necessary to provide that adverse action provisions do not apply to (1) conversions from GS special rates to demonstration project pay, as long as total pay is not reduced and (2) reductions in pay due to the removal of a supervisory or team leader pay adjustment/differential upon voluntary movement to a non-supervisory or non-team leader position or decreases in the amount of a supervisory or team leader pay adjustment based on the annual review.

APPENDIX A: ARI EMPLOYEES BY DUTY LOCATION

[Totals exclude SES and ST]

Duty Location	Employees
Fort Belvoir, VA	78
Fort Benning, GA	12
Fort Eustis, VA	1
Fort Hood TX	11
Fort Leavenworth, KS	12
Total All Employees	114

APPENDIX B: OCCUPATIONAL SERIES BY OCCUPATIONAL FAMILY

I. Engineering & Science (DB)

0180 Psychologist Series

1530 Statistics Series

II. Business/ Technical (DE)

0301 Miscellaneous Administration and Program Series

0340 Program Management Series

0341 Administrative Officer Series

0343 Management and Program Analysis Series

0560 Budget Analysis Series

1410 Librarian Series

2001 General Supply Series

2210 Information Technology Management Series

III. General Support (DK)

0303 Miscellaneous Clerk and Assistant Series

0318 Secretary Series

NOTE: Additional occupational series may be added as needed to support mission requirements.

APPENDIX C: PERFORMANCE ELEMENTS

Each performance element is assigned a minimum weight. The total weight of all elements in a performance plan must equal 100. The supervisor assigns each element a weight represented as a percentage of the 100 in accordance with individual duties/ responsibilities, objectives, and the organization's mission and goals. All employees will be rated against the first four performance elements listed below. Those employees whose duties require team leader responsibilities will be rated on element five. All supervisors will be rated on element six.

1. Technical Rigor

The extent to which an employee applies professional and technical rigor (i.e., knowledge, skills, abilities, and other attributes) to work products and processes. An employee demonstrates technical rigor by producing products that rise to the standards of one's profession or job series. Technical rigor embodies both the quality/accuracy of work produced and the approach used to accomplish the work. Technical rigor also is demonstrated through innovative approaches to technical challenges, technically sound decisions and recommendations, the ability and initiative to recognize and solve technical problems, and the initiative to maintain and improve one's technical skills through professional growth, training, and developmental assignments.

2. Interpersonal Effectiveness

The extent to which an employee is effective in his or her interpersonal interactions with others, promotes a professional and positive work environment, and works effectively with others in group contexts. An employee demonstrates interpersonal effectiveness through treating others with courtesy and respect, communicating information and ideas through verbal and written channels, and understanding how to convey information effectively to different types of audiences. An interpersonally effective employee builds and maintains relationships with others within and outside the organization to accomplish one's work and the goals of the organization.

3. Managing Time and Other Resources

The extent to which an employee effectively manages resources (e.g., time, finances, projects, government assets) and creates efficiencies to accomplish his or her work and achieve objectives. An employee demonstrates effective management of his or her resources by meeting schedules and milestones, prioritizing and balancing tasks, and utilizing and properly controlling resources. Effective resource management also includes adapting to changing requirements, determining and obtaining the resources needed to complete a task/project, and creating or implementing new ideas to improve work efficiencies.

4. Driving Organizational Success

The extent to which an employee effectively understands, contributes to, and promotes the effective performance of ARI's mission within the Army S&T enterprise. An employee demonstrates effective performance in this element by understanding his or her internal and external stakeholder's needs and being responsive to the needs of the organization and relevant stakeholders. Additionally, an employee can help drive the success of the organization by lending his or her expertise to coworkers, management, organizational efforts, and Army initiatives.

5. Team Leadership

The extent to which a Team Leader guides a team to produce plans and products in alignment with the organization and unit's strategic plan, mission, and vision. An effective Team Leader communicates the organization and unit's strategic vision to his/her team and helps translate strategic vision into meaningful actions at the team member level. Team leaders are responsible for proactively identifying new projects, tasks, and actions collaboratively to enable the unit to accomplish its mission. An effective Team Leader also ensures both the quality and timeliness of team member work by monitoring and coordinating team activities. A Team Leader will resolve simple, informal complaints of team members and inform the supervisor of any performance management issues and/or problems. (This performance element is mandatory for

all non-supervisory Team Leaders, but can be used also for an employee who is temporarily assigned to lead a large-scale project and team commensurate with work performed by a Team Leader.)

6. Supervision and EEO

The extent to which a supervisor leads, manages, plans, communicates, and assures implementation of strategic/operational goals and objectives of the organization. An effective supervisor manages and monitors employee performance by developing employee performance objectives and communicating performance expectations, evaluating employee performance, providing timely feedback, and recognizing exceptional performance throughout the performance period. An effective supervisor develops and sustains a positive unit climate and professional work environment. An effective supervisor also develops and grows the skills of his or her employees by ensuring employees complete training requirements, providing developmental tasks and activities, and maintaining a technically challenging work environment. Effective supervision and leadership also require proactive action to recruit and staff the unit with employees who possess the potential to perform well. Importantly, an effective supervisor is one who adheres to EEO and Merit principles, creates a physically safe work environment, and ensures proper management controls to prevent fraud, waste, or abuse. (Mandatory for managers/supervisors.)

Dated: November 20, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–26165 Filed 11–25–20; 8:45 am]

BILLING CODE 5001–06–C

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2020–OS–0096]

Proposed Collection; Comment Request

AGENCY: Pentagon Force Protection Agency, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Assistant Secretary of Defense for Health Affairs announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 26, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* The DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should

be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Pentagon Force Protection Agency, 9000 Defense Pentagon, Suite 5B890, ATTN: Christopher Layman, Washington, DC 20301–9000, or call 703–692–9101.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Computer Aided Dispatch and Record Management System (CAD/RMS); OMB Control Number 0704–0522.

Needs and Uses: The information collection requirement is necessary to obtain information regarding incidents that occur at the Pentagon and other facilities under the jurisdiction of the Pentagon Force Protection Agency.

Affected Public: Individuals or households

Annual Burden Hours: 231.

Number of Respondents: 693.

Responses per Respondent: 1.

Annual Responses: 693.

Average Burden per Response: 20 minutes.

Frequency: On occasion.

Dated: November 23, 2020.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–26205 Filed 11–25–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2020–OS–0067]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD)

ACTION: 30-Day information collection notice.

SUMMARY: The DoD 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 December 28, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION: Title; Associated Form; and OMB Number: Postsecondary Education Complaint Intake System; DD–2961; OMB Control Number 0704–0501.

Type of Request: Revision of a currently approved collection.

Number of Respondents: 917.

Responses per Respondent: 1.

Annual Responses: 917.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 229.25 hours.

Needs and Uses: The Postsecondary Education Complaint information collection is necessary to meet the requirements of the E.O. and to obtain, document, and respond to complaints, questions, and other issues concerning educational programs and services provided to military students, and their adult Family members. It allows DoD to monitor and track the types of complaint issues that are submitted, the complaint content, the educational institutions the complaints have been filed against, the type of education benefits being used, and the branch of the military Service. The information collected via the DoD Intake form is used to assist in further developing and shaping of relevant mitigating and preventative measures concerning abusive, deceptive, and fraudulent practices against Service members and Spouses who are pursuing higher education utilizing TA and MyCAA.

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: November 23, 2020.

Kayyonne T. Marston,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2020–26206 Filed 11–25–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Notice of Request for Information (RFI) on Offshore Wind Transmission System Integration Research Needs

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy (DOE).

ACTION: Request for information.

SUMMARY: The U.S. Department of Energy (DOE) invites public comment on its Request for Information (RFI) number DE–FOA–0002389 regarding offshore wind transmission system integration research needs. The DOE's Wind Energy Technologies Office (WETO) is seeking information from the public on research needs regarding the integration of large-scale offshore wind energy generation into the transmission grid. In addition to input on overall research priorities, focus areas include considerations of technical means to

enhance transmission utilization and mitigate congestion; updates to system integration studies and analyses in view of anticipated offshore wind additions; and priorities for improvements to data, models, and analytical tools. This RFI is intended to inform WETO's strategic planning on research aimed at lowering the cost of integrating offshore wind power into the grid, while enhancing system reliability and resiliency.

DATES: Responses to the RFI must be received no later than 5:00pm (ET) on January 24, 2021.

ADDRESSES: Interested parties are to submit comments electronically to *WindEnergyRFI@ee.doe.gov.* Include WETO OSW Integration RFI in the subject line of the email. Responses must be provided as attachments to an email. It is recommended that attachments with file sizes exceeding 25MB be compressed (*i.e.,* zipped) to ensure message delivery. Responses must be provided as a Microsoft Word (.docx) attachment to the email, and no more than 10 pages in length, 12 point font, 1 inch margins. Only electronic responses will be accepted. The complete RFI document is located at *https://eere-exchange.energy.gov/.*

FOR FURTHER INFORMATION CONTACT: Question may be addressed to Jian Fu at *WindEnergyRFI@ee.doe.gov* or (202) 586–9136. Further instruction can be found in the RFI document posted on EERE Exchange.

SUPPLEMENTARY INFORMATION: The purpose of this RFI is to solicit information from electric utilities, academia, research laboratories, government agencies, and other stakeholders on research needs regarding the integration of large-scale offshore wind generation into the transmission grid. The responses will inform WETO's strategic and research planning in the general area of offshore wind and systems integration. WETO is specifically interested in information on: (a) Overall offshore wind systems integration research and development priorities; (b) means to enhance transmission utilization and mitigate congestion; (c) transmission system integration studies and analysis related to offshore wind; and (d) data, models and analytic tools to support offshore wind grid integration. The questions are meant to stimulate thoughts and comments in the identified areas, but may not be exhaustive. As such, responders may offer additional relevant comments in the topic areas even though a question is not specifically asked. The RFI is available at *https://eere-exchange.energy.gov/.*

Confidential Business Information

Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Signing Authority

This document of the Department of Energy was signed on November 19, 2020, by Robert C. Marlay, Director, Wind Energy Technologies Office, Office of Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 20, 2020.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2020–26149 Filed 11–25–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR21–2–000]

Coffeyville Resources Refining & Marketing, LLC v. TransCanada Keystone Pipeline, LP; Notice of Complaint

Take notice that on November 18, 2020 pursuant to Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 (2020), sections 343.1(a) and 343.2(c) of the Commission's Procedural Rules Applicable to Oil Pipeline Proceedings, 18 CFR 343.1(a) and 343.2(c) (2020), and sections 1(5), 3(1), 6, 13, 15(9) and 16 of the Interstate Commerce Act (ICA), 49 U.S.C. App. 1(5), 3(1), 6, 13, 15(9), 16, Coffeyville Resources Refining & Marketing, LLC (Coffeyville or Complainant) filed a formal complaint against TransCanada Keystone Pipeline, LP (Keystone or Respondent) challenging the lawfulness of rates charged by Keystone for the transportation of crude oil within the United States under committed rates calculated pursuant to terms contained in a Transportation Service Agreement between Keystone and Coffeyville, all as more fully explained in the complaint.

The Complainants certifies that a copy of the complaint was served on the contacts listed for the Respondent in the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued

by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov,* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on December 18, 2020.

Dated: November 20, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–26190 Filed 11–25–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG21–38–000.

Applicants: RE Slate 1 LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of RE Slate 1 LLC.

Filed Date: 11/19/20.

Accession Number: 20201119–5161.

Comments Due: 5 p.m. ET 12/10/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–1858–009.

Applicants: NorthWestern Corporation.

Description: Notice of Change in Status of Northwestern Corporation.

Filed Date: 11/19/20.

Accession Number: 20201119–5203.

Comments Due: 5 p.m. ET 12/10/20.

Docket Numbers: ER11–4443–002.

Applicants: AK Electric Supply LLC.

Description: Notice of Non-Material Change in Status, et al. of AK Electric Supply LLC.

Filed Date: 11/19/20.

Accession Number: 20201119–5200.

Comments Due: 5 p.m. ET 12/10/20.

Docket Numbers: ER20–945–002.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing: Deficiency Response—Compliance Filing in Response to June 30 Order to be effective 4/4/2020.

Filed Date: 11/20/20.

Accession Number: 20201120–5049.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER20–3040–001.

Applicants: Southwestern Electric Power Company.

Description: Tariff Amendment: Hope PSA to be effective 1/1/2020.

Filed Date: 11/20/20.

Accession Number: 20201120–5135.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER20–3042–001.

Applicants: Southwestern Electric Power Company.

Description: Tariff Amendment: Bentonville PSA to be effective 1/1/2020.

Filed Date: 11/20/20.

Accession Number: 20201120–5092.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER20–3043–001.

Applicants: Southwestern Electric Power Company.

Description: Tariff Amendment: ETEC and NTEC PSA to be effective 1/1/2020.

Filed Date: 11/20/20.

Accession Number: 20201120–5143.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER20–3044–001.

Applicants: Southwestern Electric Power Company.

Description: Tariff Amendment: NTEC PSA to be effective 1/1/2020.

Filed Date: 11/20/20.

Accession Number: 20201120–5142.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER20–3045–001.

Applicants: Southwestern Electric Power Company.

Description: Tariff Amendment: Prescott PSA to be effective 1/1/2020.

Filed Date: 11/20/20.

Accession Number: 20201120–5124.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER21–254–001.

Applicants: Harmony Florida Solar, LLC.

Description: Tariff Amendment: Harmony Florida Solar, LLC Supplement to Application for MBR Authority to be effective 10/30/2020.

Filed Date: 11/19/20.

Accession Number: 20201119–5120.

Comments Due: 5 p.m. ET 12/10/20.

Docket Numbers: ER21–443–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2236R14 Golden Spread Electric Cooperative, Inc. NITSA NOA to be effective 11/1/2020.

Filed Date: 11/20/20.

Accession Number: 20201120–5019.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER21–444–000.

Applicants: Southern California Edison Company.

Description: Tariff Cancellation: Notice of Cancellation of Letter Agreement sPower Development SA No. 234 to be effective 11/21/2020.

Filed Date: 11/20/20.

Accession Number: 20201120–5060.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER21–445–000.

Applicants: Hill Top Energy Center LLC.

Description: Baseline eTariff Filing: Application For Market Based Rate Authority to be effective 1/15/2021.

Filed Date: 11/20/20.

Accession Number: 20201120–5067.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER21–446–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Service Agreement Nos. 344 and 345, Agreement with CSE and S&R to be effective 11/5/2020.

Filed Date: 11/20/20.

Accession Number: 20201120–5107.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER21–447–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2020–11–20 Pseudo-Ties of Shared Resources to be effective 1/30/2021.

Filed Date: 11/20/20.

Accession Number: 20201120–5108.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER21–448–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA, SA No. 4588; Queue No. AB2–027 re: suspension to be effective 10/26/2020.

Filed Date: 11/20/20.

Accession Number: 20201120–5128.

Comments Due: 5 p.m. ET 12/11/20.

Docket Numbers: ER21–449–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Notice of Cancellation of WMPA SA No. 5460; Queue No. AE2–304 to be effective 12/25/2020.

Filed Date: 11/20/20.

Accession Number: 20201120–5145.

Comments Due: 5 p.m. ET 12/11/20.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 20, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–26186 Filed 11–25–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2020–0585; FRL–10017–03]

Glyphosate Registration Review; Draft Endangered Species Act Biological Evaluations; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of the Environmental Protection Agency's (EPA or the Agency) draft biological evaluation (BE) for the registration review of the pesticide glyphosate and opens a public comment period on this document.

DATES: Comments must be received on or before January 26, 2021.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2020–0585, through the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Tracy Perry, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 308–0128; email address: *perry.tracy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides and/or the potential impacts of pesticide use on threatened or endangered (listed) species and designated critical habitat. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

A. Authority

The Endangered Species Act (ESA) requires federal agencies, such as EPA, to ensure that their actions are not likely to jeopardize the continued existence of species listed as threatened or endangered under the ESA or destroy or adversely modify the designated critical habitat of such species. The final registration review determination of reevaluating a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) constitutes an EPA ''action'' under the ESA. If EPA determines a pesticide may affect a listed species or its designated critical habitat, EPA must initiate informal or formal consultation with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service (collectively referred to as the Services), as appropriate. EPA initiates formal consultation with the Services through the conduct and transmittal of a biological evaluations (BE) with its findings.

B. Background

The schedule for conducting the atrazine and simazine BEs was negotiated as part of a partial settlement agreement pursuant to a joint stipulation filed on October 18, 2019 and entered by the court on October 22, 2019, in Center for Biological Diversity *et al.* v. EPA *et al.* (N.D. Ca) (3:11–cv–00293). EPA stated in this settlement that it would also include the herbicides propazine and glyphosate in this group of effects determinations. The Agency has completed a comprehensive, nationwide draft BE for the use of glyphosate relative to the potential effects on listed species and their designated critical habitats.

The glyphosate BE follows the *Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides* (see docket ID number EPA–HQ–OPP–2019–0185–0084 at *www.regulations.gov*). EPA utilized the Revised Method for the first time when conducting the methomyl and carbaryl draft BEs, which were posted for public comment on March 17, 2020 (85 FR 15168). EPA is currently evaluating public comments received and will take them into consideration for the final BEs for these pesticides. Comments received on carbaryl and methomyl that are applicable to the broader BE methodology will also be incorporated into the final BE for glyphosate as applicable.

After reviewing comments received during the public comment period on the glyphosate draft BE, EPA will issue a final BE and a response to public comments document. If EPA determines that glyphosate may affect listed species and/or their designated critical habitats, EPA will initiate consultation with the

Services. Based on the BE, the Services will then develop a Biological Opinion for glyphosate.

C. Public Comments Sought

Pursuant to 40 CFR 155.53(c) and consistent with the enhanced stakeholder engagement practices (see docket ID number EPA–HQ–OPP–2012–0442), EPA is providing an opportunity, through this notice of availability, for interested parties to provide comments and input concerning the Agency's draft BE for glyphosate. Such comments could address, among other things, the application of the Agency's revised risk assessment methodologies to and assumptions for this draft BE.

The file size of the glyphosate draft BE exceeds the docket system's file size limitation, therefore it is not posted to this BE docket. Instead, the BE is posted on EPA's endangered species web page (see web link provided in the Table below). Commenters are instructed to post comments on the BE to this BE docket (EPA–HQ–OPP–2020–0585) in *www.regulations.gov,* as indicated in the Table below.

TABLE—PESTICIDE DOCKET ID NUMBER FOR POSTING COMMENTS ON THE GLYPHOSATE DRAFT BE AND LINK TO THE DRAFT BE

Document	Pesticide docket ID No. for public comments	Link to the draft BE
Glyphosate BE	EPA–HQ–OPP–2020–0585	*https://www.epa.gov/endangered-species/draft-national-level-listed-species-biological-evaluation-glyphosate.*

1. *Other related information.* Additional information on endangered species risk assessment and the National Academy of Sciences report recommendations are available at *https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-risk-assessment-methodology-endangered.* Information on the Agency's registration review program and its implementing regulation is available at *https://www.epa.gov/pesticide-reevaluation.*

2. *Information submission requirements.* Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted later.
- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audio graphic or video graphic record. Written material may be submitted in paper or electronic form.
- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 18, 2020.

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2020–26184 Filed 11–25–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2018–0436; FRL–10017–15]

Di-isononyl Phthalate (DINP); Draft Scope of the Risk Evaluation To Be Conducted Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on the draft scope document for the risk evaluation to be conducted for di-isononyl phthalate (DINP) (1,2-benzene-dicarboxylic acid, 1,2-diisononyl ester, and 1,2-benzenedicarboxylic acid, di-C8–10-branched alkyl esters, C9-rich; Chemical Abstracts Service Registry Number (CASRN) 28553–12–0 and CASRN 68515–48–0) a category of chemical substances for which EPA received a manufacturer request for risk evaluation. The draft scope document for this category of chemical substances includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA plans to consider in conducting the risk evaluation for this category of chemical substances. EPA is also asking the public to provide additional data or information that could be useful to the Agency in finalizing the scope of the risk evaluations; comments may be submitted to this docket.

DATES: Comments must be received on or before January 11, 2021.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0436, through the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Collin Beachum, Existing Chemical Risk Assessment Division (Mailcode E205–02), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 109 T.W. Alexander Drive,

RTP, NC 27711; telephone number: (919) 541–7554; email address: *beachum.collin@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to entities that manufacture (including import) a chemical substance regulated under TSCA (*e.g.,* entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). The action may also be of interest to chemical processors, distributors in commerce, and users; non-governmental organizations in the environmental and public health sectors; state and local government agencies; and members of the public. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

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

The draft scope document is issued pursuant to TSCA section 6(b) and EPA's implementing regulations at 40 CFR 702.41(c)(7).

C. What action is the Agency taking?

EPA is publishing the draft scope of the risk evaluation for DINP under TSCA. Through the risk evaluation process, EPA will determine whether the category of chemical substances presents an unreasonable risk of injury to health or the environment under the conditions of use, as determined by the Administrator, in accordance with TSCA section 6(b)(4).

II. Background

TSCA allows chemical manufacturers to request an EPA-conducted risk evaluation of a chemical under 40 CFR 702.37. On May 24, 2019, EPA received a manufacturer request for a risk evaluation of DINP (Ref. 1). On December 20, 2019, the Agency granted the request, and subsequently initiated the scoping process for the risk evaluation for this category of chemical substances. The purpose of a risk evaluation is to determine whether a chemical substance, or group of chemical substances, presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation (15 U.S.C. 2605(b)(4)(A)). As part of this process, EPA must evaluate both hazards and exposures for the conditions of use; describe whether aggregate or sentinel exposures were considered and the basis for consideration; not consider costs or other nonrisk factors; take into account where relevant, likely duration, intensity, frequency, and number of exposures; and describe the weight of the scientific evidence for hazards and exposures (15 U.S.C. 2605(b)(4)(F)). This process will culminate in a determination of whether or not the category of chemical substances presents an unreasonable risk of injury to health or the environment under the conditions of use (15 U.S.C. 2605(b)(4)(A); 40 CFR 702.47).

III. Draft Scope of the Risk Evaluation for Di-isononyl phthalate (DINP)

The category of chemical substances for which EPA is publishing the draft scope of the risk evaluation includes the following chemical substances: 1,2-benzene-dicarboxylic acid, 1,2-diisononyl ester (CASRN 28553–12–0), and 1,2-benzenedicarboxylic acid, di-C8–10-branched alkyl esters, C9-rich; (CASRN 68515–48–0). The draft scope of the risk evaluation for this category of chemical substances includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA plans to consider in the risk evaluation (15 U.S.C. 2605(b)(4)(D)). Development of the scope is the first step of a risk evaluation. The draft scope of the risk evaluation will include the following components (40 CFR 702.41(c)):

- The conditions of use, as determined by the Administrator, that EPA plans to consider in the risk evaluation.
- The potentially exposed populations that EPA plans to evaluate; the ecological receptors that EPA plans to evaluate; and the hazards to health and the environment that EPA plans to evaluate.
- A description of the reasonably available information and the science approaches that the Agency plans to use.
- A conceptual model that will describe the actual or predicted relationships between the chemical substance, the conditions of use within the scope of the evaluation and the receptors, either human or environmental, with consideration of the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, use, to release or disposal—and identification of human and ecological health hazards EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.
- An analysis plan, which will identify the approaches and methods EPA plans to use to assess exposure, hazards, and risk, including associated uncertainty and variability, as well as a strategy for using reasonably available information and best available science approaches.
- A plan for peer review.

EPA encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. EPA will publish a notice in the **Federal Register** announcing the availability of the final scope within three months of publishing the draft scope.

IV. References

The following is a listing of the documents that are specifically referenced in this **Federal Register** notice. The docket for this action includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket. For assistance in locating these referenced documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Di-isononyl Phthalate (DINP) (1,2-Benzene- dicarboxylic acid, 1,2-diisononyl ester); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments. **Federal Register**. (84 FR 42912, August 19, 2019) (FRL–9998–25).

(Authority: 15 U.S.C. 2601 *et seq.*)

Andrew Wheeler,

Administrator.

[FR Doc. 2020–26204 Filed 11–25–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R06–OW–2020–0608; FRL–10017–34-Region 6]

Public Notice of State of Texas' Submittal to EPA of Request for Partial National Pollutant Discharge Elimination System (NPDES) Program Authorization for Oil and Gas Discharges

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability; request for comment; notice of public hearing.

SUMMARY: The United States Environmental Protection Agency (EPA), Region 6 is requesting comments on and will hold a public hearing for the State of Texas' application for National Pollutant Discharge Elimination System (NPDES) authority for discharges from produced water, hydrostatic test water and gas plant effluent, hereafter referred to as oil and gas discharges, within the State of Texas (''application for NPDES oil and gas authorization'' or ''the application''). The Governor of Texas submitted the application for NPDES oil and gas authorization, seeking approval for the Texas Commission on Environmental Quality (TCEQ) to implement a major category partial NPDES program as provided for under the Clean Water Act (CWA or ''the Act''). Today, the EPA is providing public notice of the State's submittal of the application for NPDES oil and gas authorization and of both a public hearing and public comment period on the State's submission. The EPA will either approve or disapprove the State's request for program authorization after considering all comments received. If approved, the NPDES authority for oil and gas discharges within the State of Texas will transfer from the EPA to the TCEQ upon the date of program approval.

DATES: Comments must be received on or before January 11, 2021. The EPA Region 6 will hold a virtual informational public meeting, followed by a virtual public hearing no sooner than 30 days after the date of this notice. Please refer to the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section for additional information on how to submit comments and for specifics regarding the date, times, and how to register for the public meeting and public hearing.

ADDRESSES: You may submit comments identified by Docket No. EPA–R06–OW–2020–0608 at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

To View and/or Obtain Copies of Documents. A copy of the application and related documents may be viewed or downloaded, at no cost, from the EPA website at *https://www.epa.gov/publicnotices/notices-search/location/Texas* or *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Kilty Baskin, EPA Region 6 Office, NPDES/Wetland Review Section (R6 WD–PN), 214–665–7500, *baskin.kilty@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. Public Participation

1. How can I get copies of this document and other related information?

You may access this **Federal Register** Notice document electronically at the EPA's website, *https://www.epa.gov/publicnotices/notices-search/location/Texas* or *https://www.regulations.gov.*

2. How and to whom do I submit comment?

We encourage the public to submit comments electronically as described in the **ADDRESSES** Section of this notice, as there may be a delay in processing mail and hand deliveries will be accepted by appointment only due to public health concerns related to COVID–19.

Please submit your comments within the specified time period cited in the **DATES** section of this document. Comments received after the close of the comment period will be marked ''late''. The EPA is not required to consider these late comments. All comments received by the EPA in accordance with this section by the ending date of the comment period and/or presented at the public hearing will be considered by the EPA before a final decision is made regarding program approval.

3. How do I participate in the informational public meeting and/or public hearing?

Informational Public Meeting: The informational public meeting will be held virtually and will include a technical overview of the State's proposed NPDES oil and gas program, as well as an opportunity for questions and answers. The TCEQ will participate with the EPA during this meeting. Questions or comments made during the informational meeting will not be entered into the official record. Comments for the official record must be made in accordance with the public hearing procedures and/or submitted to the EPA as written comments before the end of the comment period. To register to attend the virtual public meeting, please refer to the online registration form available via links regarding the Texas Program Authorization notice at *https://www.epa.gov/publicnotices/notices-search/location/Texas.* The last day to pre-register for the public meeting will be 3 working days prior before the meeting date

Public Hearing: Please note that the EPA is deviating from its typical approach because the President has declared a national emergency. Because of current CDC recommendations, as well as state and local orders for social distancing to limit the spread of COVID–19, the EPA cannot hold in-person public meetings at this time. As a result, the public hearing will be held virtually. The public hearing will be conducted in accordance with the provisions of 40 CFR 124.12, and will provide interested parties with the opportunity to give written and/or oral testimony into the official record.

The EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**. To register to attend or speak at the virtual public hearing, please refer to the online registration form available via links regarding the Texas Program Authorization notice at *https://www.epa.gov/publicnotices/notices-search/location/Texas* to register to speak at the virtual hearing. The last day to pre-register to speak at the hearing will be 3 working days prior before the hearing date. Prior to the hearing, EPA will post a general agenda for the hearing that will list pre-registered speakers in approximate order at the Texas Program Authorization Notice page accessible from: *https://www.epa.gov/publicnotices/notices-search/location/Texas*

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

The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to *rosborough.evelyn@epa.gov.* The EPA also recommends submitting the text of your oral

comments as written comments to the official docket.

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

Please note that any updates made to any aspect of the hearing is posted online at *https://www.epa.gov/publicnotices/notices-search/location/Texas.* While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact Ms. Evelyn Rosborough, 214–665- 7515, or email: *rosborough.evelyn@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or a special accommodation such as audio description, please pre-register for the hearing at *https://www.epa.gov/publicnotices/notices-search/location/Texas,* and describe your needs one week before the date of the hearing. Please note that the EPA may not be able to arrange accommodations.

B. General Information

1. Does this action apply to me?

Entities potentially affected by this action include the regulated oil and gas community and citizens within the State of Texas. If authorized, the TCEQ will implement the NPDES permitting, compliance monitoring and enforcement program for oil and gas activities in Texas. The TCEQ's authority will apply on land within the State of Texas and extend 3.0 statute miles (1 statute mile equals 5280 feet) offshore into the Gulf of Mexico. The EPA retains jurisdiction for discharges more than 3 statute miles offshore in the Gulf of Mexico. Thus, CWA oil and gas exploration and production related discharges in these waters remain subject to the EPA's Outer Continental Shelf of the Gulf of Mexico General Permit (GMG290000). In addition, spills or releases of hydrocarbons subject to the Oil Pollution Act are not subject to the NPDES program. The EPA's authority to address releases of hydrocarbons to waters of the United States under the Oil Pollution Act cannot be delegated to states and TCEQ will continue to refer incidents to EPA as the regulatory authority for the Oil Pollution Act. The TCEQ NPDES program does not apply in areas of Indian country as defined in 18 U.S.C. 1151. The EPA retains jurisdiction over discharges in these areas. If you have any questions regarding the applicability of this action to a particular entity, please contact Ms. Kilty Baskin at 214–665–7500, *baskin.kilty@epa.gov.*

2. What action is the EPA taking?

The EPA is providing notice of the State of Texas' request for partial NPDES program authorization for oil and gas discharges within the State. The Governor of Texas submitted the application for NPDES oil and gas authorization pursuant to Section 402(b) of the CWA, seeking approval for the TCEQ to implement a major category partial NPDES program under Section 402(n)(3) of the Act. In accordance with CWA section 402(b), 33 U.S.C. 1342(b), and NPDES regulations at 40 CFR part 123, the EPA shall approve a State's application for program approval unless adequate authority does not exist as required by the CWA.

3. What is the EPA's authority for taking this action?

CWA section 402 established the NPDES permitting program and gives the EPA authority to approve state NPDES programs. 33 U.S.C. 1342(b). CWA section 402(n)(3) authorizes the EPA to approve a Major Category Partial Permit Program covering administration of a major category of discharges if ''(A) such program represents a complete permit program and covers all of the discharges under the jurisdiction of a department or agency of the State; and (B) the Administrator determines that the partial program represents a significant and identifiable part of the State program required by subsection (b).'' 33 U.S.C. 1342(n)(3).

State Permit Program Approval: Section 402 of the CWA, 33 U.S.C. 1342, created the NPDES program under which the EPA may issue permits authorizing the point source discharge of pollutants to waters of the United States under conditions required by the Act. CWA Section 402(b), 33 U.S.C. 1342(b), provides that the EPA shall approve a State's request to administer its own permit program provided the State has appropriate legal authority and a state program that meets the Act's requirements. The regulatory requirements for state program submissions and for EPA state program approval are set forth in 40 CFR part 123 (*https://www.ecfr.gov/*).

Decision Process: Pursuant to 40 CFR 123.61(b), the EPA must approve or disapprove Texas' application for NPDES oil and gas authorization within 90 days of receipt of a complete program submission, unless this review period is extended by mutual agreement between the EPA and the State pursuant to 40 CFR 123.21(d). Under CWA § 402(b) and 40 CFR part 123, the State must show, among other things that it has the authority to issue permits that comply with the Act, authority to impose civil and criminal penalties for permit violations, and authority to ensure that the public is given notice and an opportunity for a hearing on each proposed permit. Once the State's request for program approval is declared complete, the CWA and its implementing regulations require the EPA to provide notice of the State's application and allow a comment period of at least 45 days during which the public may express their views on the proposed State program. The EPA's public notice of the application must also provide notice of a public hearing to be held no less than 30 days after publication of the notice. See 40 CFR 123.61.

After the close of the public comment period, the EPA will determine whether to approve or disapprove the State's application based on the requirements of section 402(b) of the CWA and 40 CFR part 123. If the EPA approves the State's program, the Regional Administrator of EPA Region 6 will so notify the State and sign the proposed Memorandum of Agreement between the EPA and the TCEQ (MOA). If approved, notice of the approval will be published in the **Federal Register** and, as of the date of program approval, the EPA will suspend issuance of NPDES permits for oil and gas discharges in Texas. If the EPA disapproves Texas' application for NPDES oil and gas authorization, the State will be notified of the reasons for disapproval and of any revisions or modifications to the program that are necessary to obtain approval. The EPA will not make a final decision on whether to approval or disapprove Texas' application until after: (1) Consideration of all public comments provided during the public comment period, including those submitted at the public hearing, and the preparation of a responsiveness summary and (2) completion of government to government tribal consultations, as requested, with federally recognized tribes in Texas.

Summary of the State's Application/Proposed Program: By letter dated October 9, 2020, and received by the EPA on October 12, 2020, the Governor of the State of Texas submitted a request for NPDES program authorization for oil and gas discharges in Texas. The request is for approval of a Major Category

Partial Permit Program under CWA section 402(n)(3) covering administration of a major category of discharges within the State. The State's NPDES oil and gas program, if approved, would be administered by the TCEQ. The TCEQ currently implements an approved partial NPDES permitting program, the Texas Pollutant Discharge Elimination System (TPDES) program, for discharges to waters of the State in accordance with Clean Water Act § 402(n)(3). However, when TCEQ was granted authority by the EPA in 1998 to administer the NPDES program for discharges under its jurisdiction, oil and gas discharges were regulated by the Railroad Commission of Texas (RRC) and thus were not included as part of the approved TPDES program. As a result, EPA is the permitting authority for oil and gas discharges in Texas. In 2019, House Bill 2771, 86th Texas Legislature, amended Texas Water Code § 26.131 to transfer jurisdiction of discharges of produced water, hydrostatic test water, and gas plant effluent into water in the state from the RRC to the TCEQ upon NPDES program authorization from the EPA for such discharges. A copy of Texas Water Code § 26.131 is attached as Attachment A to the State's application.

In accordance with 40 CFR 123.21, the State's application includes the following 5 elements: (1) A letter from the Governor requesting program approval; (2) A complete program description, as required by 40 CFR 123.22, describing how the State intends to carry out its responsibilities under the Act and its implementing regulations; (3) An Attorney General's statement as required by 40 CFR 123.23; (4) A Memorandum of Agreement (MOA) with the Regional Administrator as required by 40 CFR 123.24; and (5) Copies of all applicable State statutes and regulations, including those governing State administrative procedures.

A complete program description is included as Attachment E to the State's submission. The program description is divided into four (4) chapters:

- Overview of the TCEQ, as required by 40 CFR 123.22(a) and (b);
- Oil and Gas Permitting Program Description, as required by 40 CFR 123.22(c), (d) and (g);
- Oil and Gas Enforcement Program Description, as required by 40 CFR 123.22(d), (e) and (g); and
- Program Costs and Funding Description, as required by 40 CFR 123.22(b)(1)-(3).

A Statement of Legal Authority, signed by the Texas Attorney General, is included as Attachment C to the State's submission. The Statement of Legal Authority outlines the TCEQ's legal authority to regulate the discharge of produced water, hydrostatic test water, and gas plant effluent into water in the state resulting from oil and gas activities upon NPDES program authorization from the EPA. The Statement of Legal authority notes that when House Bill 2771 became effective, the term ''produced water'' was not defined in State rules or statutes. For the purposes of the TCEQ's implementation of amended Tex. Water Code § 26.131, the TCEQ defined the term ''produced water'' in 30 Tex. Admin. Code § 305.541(b) as ''all wastewater associated with oil and gas exploration, development, and production activities, except hydrostatic test water and gas plant effluent, that is discharged into water in the state, including waste streams regulated by 40 CFR part 435.'' Through the Statement of Legal Authority, the Texas Attorney General certifies that amended Tex. Water Code **§ 26.131,** in conjunction with the definition of produced water in 30 Tex. Admin. Code § 305.541(b) and the TCEQ's existing authority to issue permits for the discharge of pollutants into water in the state in Tex. Water Code § 26.121, provides the TCEQ with authority to issue TPDES permits for the discharge of all oil and gas wastewater into water in the State in Texas.

The MOA between the TCEQ and the EPA Region 6 concerning the TPDES program and a MOA Addendum to address oil and gas discharges are included as Attachment D to the State's submission. The MOA Addendum recognizes that one of the most important goals for transferring NPDES program authority to Texas for oil and gas discharge permitting, compliance monitoring and enforcement is to promote and facilitate the expeditious transformation of federal NPDES and state permits into one TPDES permit. The MOA Addendum describes in detail the permitting, compliance monitoring and enforcement authority that will transfer to the TCEQ on the date of program authorization. Upon authorization, jurisdiction for EPA issued oil and gas permits and primary enforcement authority for oil and gas discharges within the State will be transferred to the TCEQ, with certain limited exceptions. The MOA Addendum describes in detail those exceptions, *i.e.,* permits and enforcement actions for which the EPA will initially retain jurisdiction, such as permits for which appeals are pending or enforcement actions that are currently ongoing. The MOA Addendum also details the actions that will trigger transfer of jurisdiction for those permits and enforcement actions to TCEQ, for example resolution of the permit appeal or resolution of the ongoing enforcement action.

Copies of all applicable State statutes and regulations, as well as TCEQ Operating Policies and Procedures, are included as Attachment F to the State's submission. Please note that TCEQ adopted by reference EPA's Oil and Gas Effluent Limitation Guidelines (40 Code of Federal Regulations (CFR) Part 435).

On November 5, 2020, the TCEQ submitted revised language to Attachment E—Ch 3 Enforcement Program Description for clarification purposes. The revised language does not affect substantive changes to the State's program submission. The revised language clarifies that TCEQ's existing spill response program has been evaluated and determined to be adequate for the inclusion of wastewater spills from oil and gas operations subject to the NPDES program. Upon the EPA's approval of the State's request for NPDES authority for oil and gas discharges, primary enforcement authority for such spills and releases will transfer to the TCEQ. Spills or releases of hydrocarbons subject to the Oil Pollution Act are not subject to the NPDES program. The EPA's authority to address releases of hydrocarbons to waters of the United States under the Oil Pollution Act cannot be delegated to states and the TCEQ will continue to refer incidents to the EPA as the regulatory authority for the Oil Pollution Act.

The EPA determined that the State's October 12, 2020 program submission, including the November 5, 2020 clarification, constituted a complete package under 40 CFR 123.21, and a letter of completeness was sent to the State on November 12, 2020. Pursuant to 40 CFR 123.21, within 90 days of the EPA's receipt of the State's complete program submission, or by January 11, 2021, the EPA must approve or disapprove the program based on the requirements of CWA § 402(b) and 40 CFR part 123 and taking into consideration all comments received, unless this review period is extended by mutual agreement between the EPA and the State pursuant to 40 CFR 123.21(d).

Authority: This action is taken under the authority of section 402 of the Clean Water Act as amended, 33 U.S.C. 1342. I hereby provide public notice of the application by the State of Texas for approval to administer the NPDES program for discharges from oil and gas activities within the State, in accordance with 40 CFR 123.61.

Dated: November 19, 2020.

David Gray,

Acting Regional Administrator, Region 6.

[FR Doc. 2020–26038 Filed 11–25–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9054–1]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed November 16, 2020 10 a.m. EST Through November 20, 2020 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20200238, Draft, USFS, OR, Stella Restoration Project, Comment Period Ends: 01/12/2021, Contact: Elizabeth Bly 541–560–3465.

EIS No. 20200239, Draft, USCG, TX, Texas Gulflink Deepwater Port License Application, Comment Period Ends: 01/11/2021, Contact: Brad McKitrick 202–372–1443.

EIS No. 20200240, Final, USFWS, REG, Regulations Governing Take of Migratory Birds, Review Period Ends: 12/28/2020, Contact: Lesley Kordella 703–963–1729.

EIS No. 20200241, Final, BLM, PRO, Final Programmatic EIS for Fuels Reduction and Rangeland Restoration in the Great Basin, Review Period Ends: 12/28/2020, Contact: Shannon Bassista 208–373–3845.

EIS No. 20200242, Draft, USACE, VA, Surry To Skiffes Creek To Whealton Transmission Project, Comment Period Ends: 01/11/2021, Contact: Randy Steffey 757–201–7579.

Dated: November 20, 2020.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2020–26179 Filed 11–25–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2018–0435; FRL–10017–14]

Di-isodecyl Phthalate (DIDP); Draft Scope of the Risk Evaluation to be Conducted Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on the draft scope document for the risk evaluation to be conducted for di-isodecyl phthalate (DIDP) (1,2-benzenedicarboxylic acid, 1,2-diisodecyl ester and 1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich; Chemical Abstracts Service Registry Number (CASRN) 26761–40–0 and CASRN 68515–49–1), a category of chemical substances for which EPA received a manufacturer request for risk evaluation. The draft scope document for this category of chemical substances includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA plans to consider in conducting the risk evaluation for this category of chemical substances. EPA is also asking the public to provide additional data or information that could be useful to the Agency in finalizing the scope of the risk evaluation.

DATES: Comments must be received on or before January 11, 2021.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0435, through the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Collin Beachum, Existing Chemical Risk Assessment Division (Mailcode E205–02), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 109 T.W. Alexander Drive, RTP, NC 27711; telephone number: (919) 541–7554; email address: *beachum.collin@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to entities that manufacture (including import) a chemical substance regulated under TSCA (*e.g.,* entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). The action may also be of interest to chemical processors, distributors in commerce, and users; non-governmental organizations in the environmental and public health sectors; state and local government agencies; and members of the public. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

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

The draft scope document is issued pursuant to TSCA section 6(b) and EPA's implementing regulations at 40 CFR 702.41(c)(7).

C. What action is the Agency taking?

EPA is publishing the draft scope of the risk evaluation for DIDP under TSCA. Through the risk evaluation process, EPA will determine whether the category of chemical substances presents an unreasonable risk of injury to health or the environment under the conditions of use, as determined by the Administrator, in accordance with TSCA section 6(b)(4).

II. Background

TSCA allows chemical manufacturers to request an EPA-conducted risk evaluation of a chemical under 40 CFR 702.37. On May 24, 2019, EPA received a manufacturer request for a risk

evaluation of DIDP. On December 20, 2019, the Agency granted the request, and subsequently initiated the scoping process for a risk evaluation for this category of chemical substances. The purpose of a risk evaluation is to determine whether a chemical substance, or group of chemical substances, presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation (15 U.S.C. 2605(b)(4)(A)). As part of this process, EPA must evaluate both hazards and exposures for the conditions of use; describe whether aggregate or sentinel exposures were considered and the basis for consideration; not consider costs or other nonrisk factors; take into account where relevant, likely duration, intensity, frequency, and number of exposures and describe the weight of the scientific evidence for hazards and exposures (15 U.S.C. 2605(b)(4)(F)). This process will culminate in a determination of whether or not the category of chemical substances presents an unreasonable risk of injury to health or the environment under the conditions of use (15 U.S.C. 2605(b)(4)(A); 40 CFR 702.47).

III. Draft Scope of the Risk Evaluation for Di-isodecyl phthalate (DIDP)

The category of chemical substances for which EPA is publishing the draft scope of the risk evaluation includes the following chemical substances: 1,2-benzenedicarboxylic acid, 1,2-diisodecyl ester (CASRN 26761–40–0) and 1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich; (CASRN 68515–49–1). The draft scope of the risk evaluation for this category of chemical substances includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations EPA plans to consider in the risk evaluation (15 U.S.C. 2605(b)(4)(D)).

Development of the scope is the first step of a risk evaluation. The draft scope of the risk evaluation will include the following components (40 CFR 702.41(c)):

- The conditions of use, as determined by the Administrator, that EPA plans to consider in the risk evaluation.
- The potentially exposed populations that EPA plans to evaluate; the ecological receptors that EPA plans to evaluate; and the hazards to health and the environment that EPA plans to evaluate.
- A description of the reasonably available information and the science approaches that the Agency plans to use.
- A conceptual model that will describe the actual or predicted relationships between the chemical substance, the conditions of use within the scope of the evaluation and the receptors, either human or environmental, with consideration of the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, use, to release or disposal—and identification of human and ecological health hazards EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.
- An analysis plan, which will identify the approaches and methods EPA plans to use to assess exposure, hazards, and risk, including associated uncertainty and variability, as well as a strategy for using reasonably available information and best available science approaches.
- A plan for peer review.

EPA encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. EPA will publish a notice in the **Federal Register** announcing the availability of the final scope within three months of publishing the draft scope.

IV. References

The following is a listing of the documents that are specifically referenced in this **Federal Register** notice. The docket for this action includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket. For assistance in locating these referenced documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Di-isodecyl Phthalate (DIDP) (1,2-Benzene-dicarboxylic acid, 1,2-diisodecyl ester); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments. **Federal Register**. (84 FR 42914, August 30, 2019) (FRL–9998–26).

(Authority: 15 U.S.C. 2601 *et seq.*)

Andrew Wheeler,

Administrator.

[FR Doc. 2020–26203 Filed 11–25–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10292 and CMS–R–65]

Agency Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 26, 2021.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–

05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*.

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10292 State Medicaid HIT Plan, Planning Advance Planning Document, and Implementation Advance Planning Document for Section 4201 of the Recovery Act

CMS–R–65 Final Peer Review Organizations Sanction Regulations

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Medicaid HIT Plan, Planning Advance Planning Document, and Implementation Advance Planning Document for Section 4201 of the Recovery Act; *Use:* To assess the appropriateness of state requests for the administrative Federal financial participation for expenditures under their Medicaid Electronic Health Record Incentive Program related to health information exchange, our staff will review the submitted information and documentation to make an approval determination of the state advance planning document. *Form Number:* CMS–10292 (OMB control number: 0938–1088); *Frequency:* Once and occasionally; *Affected Public:* State, Local, and Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 896. (For policy questions regarding this collection contact Edward Dolly at 410–786–8554.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Final Peer Review Organizations Sanction Regulations; *Use:* The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act (the Act), creating the Utilization and Quality Control Peer Review Organization Program. Section 1156 of the Act imposes obligations on health care practitioners and others who furnish or order services or items under Medicare. This section also provides for sanction actions, if the Secretary determines that the obligations as stated by this section are not met. Quality Improvement Organizations (QIOs) are responsible for identifying violations. The QIOs may allow practitioners or other entities, opportunities to submit relevant information before determining that a violation has occurred. The information collection requirements contained in this information collection request are used by the QIOs to collect the information necessary to make their decision. *Form Number:* CMS–R–65 (OMB control number: 0938–0444); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 18; *Total Annual Responses:* 18; *Total Annual Hours:* 4,716. (For policy questions regarding this collection contact Kimberly Harris at 401–837–1118.)

Dated: November 23, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–26223 Filed 11–25–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10443, CMS–10558 and CMS–287–21]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS)

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (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 December 28, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* . Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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*

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:* Extension of a previously approved collection: *Title of Information Collection:* Transcatheter Valve Therapy (TVT) Registry; *Use:* The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, ''Transcatheter Aortic Valve Replacement (TAVR)''. The TAVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all cause mortality and quality of life. CMS finds that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TAVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TAVR technologies for the treatment of aortic stenosis.

The data will also include the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ–10) to assess heath status, functioning and quality of life. In the KCCQ, an overall summary score can be derived from the physical function, symptoms (frequency and severity), social function and quality of life domains. For each domain, the validity, reproducibility, responsiveness and interpretability have been independently established. Scores are transformed to a range of 0–100, in which higher scores reflect better health status.

The conduct of the STS/ACC TVT Registry and the KCCQ–10 is in accordance with Section 1142 of the Social Security Act (the Act) that describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TAVR is reasonable and necessary (*e.g.,* improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Act. Furthermore, data from the Registry will assist the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat aortic stenosis. For purposes of the TAVR NCD, The TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, data will be made available for research purposes under the terms of a data use agreement that only provides de-identified datasets. *Form Number:* CMS–10443 (OMB control number: 0938–1202); *Frequency:* Annual; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 37,221; *Total Annual Responses:* 148,884; *Total Annual Hours:* 47,765. (For policy questions regarding this collection contact Sarah Fulton at 410–786–2749.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs; *Use:* Under 45 CFR 156.122(d)(1)(2), 156.230(b), and 156.230(c), and in the final rule, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018 (CMS–9934–F), standards for qualified health plan (QHP) issuers (including Small Business Health Options Program (SHOP) issuers and stand-alone dental plans (SADP) issuers) are established for the submission of provider and formulary data in a machine- readable format to the Department of Health and Human Services (HHS) and for posting on issuer websites. These standards provide greater transparency for consumers, including by allowing software developers to access formulary and provider data to create innovative and informative tools. The Centers for Medicare and Medicaid Services (CMS) is continuing an information collection request (ICR) in connection with these standards. *Form Number:* CMS–10558 (OMB control number 0938–1284); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 376; *Number of Responses:* 376; *Total Annual Hours:* 10,495. (For questions regarding this collection, contact Joshua Van Drei at 410–786–1659).

3. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Home Office Cost Statement; *Use:* The primary function of the home office cost statement is to provide the documentary support required for a Medicare provider to claim reimbursement for HO/CO costs in their Medicare cost report. A HO/CO must submit an acceptable home office cost statement directly to the servicing contractors for its providers that received a home office cost allocation for reimbursement determinations. Section 1874A of the Act describes the functions of the contractor.

The home office cost statement schedules collect the cost data required to support home office costs claimed in a provider's Medicare cost report. The Schedule S includes the certification statement where the HO/CO attests to the accuracy of the information and allows the HO/CO the opportunity to electronically sign and electronically submit the home office cost statement. The Schedule S–1 collects identifying data about the home office and key officers/employees of the home office. The Schedule S–2 collects identifying information for healthcare provider components, non-healthcare components, and region/division components of the HO/CO, and provides the structure for reporting

costs for those components throughout the cost statement. The A series of schedules collects the HO/CO trial balance of expenses, reclassifications, and adjustments, for allocation of the HO/CO costs to its components. On the B series of schedules, the home office directly allocates costs directly attributable to specific components. On the C and D series of schedules, the HO/CO functionally allocates costs to components in a manner that reasonably relates to the services provided to the components. On the E series of schedules, the HO/CO allocates pooled costs (costs not directly assigned or functionally allocated) to the components. On the F series of schedule, the HO/CO summarizes the cost allocations by component. On the G series of schedules, the HO/CO reports financial data from their balance sheet and income statement. *Form Number:* CMS–287–21 (OMB control number 0938–0202); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 1,626; *Number of Responses:* 1,626; *Total Annual Hours:* 757,716. (For questions regarding this collection, contact Gail Duncan at 410–786–7278.)

Dated: November 20, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–26156 Filed 11–25–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1736]

Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice announcing a public meeting and requesting comments that appeared in the **Federal Register** of October 13, 2020. In that notice, FDA announced a public meeting, held on November 16, 2020, and requested public input on a potential revised approach for considering the human medical importance of antimicrobial new animal drugs when assessing and managing the antimicrobial resistance risks associated with the use of antimicrobial drugs in animals. Specifically, the Agency requested comments on the potential revised process for ranking antimicrobials according to their relative importance in human medicine, on the potential criteria for their ranking, and on the resulting ranked list of antimicrobial drugs. FDA is taking this action in response to several requests for extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period announced in the notice of public meeting and request for comments published October 13, 2020 (85 FR 64481). Submit either electronic or written comments by March 16, 2021, to ensure that the Agency considers your comments regarding this public meeting and request for comments.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1736 for ''Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts

and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5661, *Kelly.Covington@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 13, 2020, FDA published a notice announcing a public meeting and requesting comments on a concept paper entitled ''Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs'' with a 94-day comment period.

Interested persons were originally given until January 15, 2021, to comment on the public meeting and request for comments. The Agency received several requests to allow interested persons additional time to comment. The requests conveyed concern that the initial 94-day comment period did not allow sufficient time to develop a comprehensive response. FDA believes that an extension of 60 days allows adequate time for interested persons to submit comments.

Dated: November 20, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26182 Filed 11–25–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1898]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document. Consistent with FDA's regulations, this notice is being published with less than 15 days prior to the date of the meeting based on a determination that convening a meeting of the Vaccines and Related Biological Products Advisory Committee as soon as possible is warranted. This **Federal Register** notice could not be published 15 days prior to the date of the meeting due to a recent submission of a request for Emergency Use Authorization (EUA) for an investigational vaccine to prevent Coronavirus Disease 2019 (COVID–19) and the need for prompt discussion of such submission, given the COVID–19 pandemic.

DATES: The meeting will be held on December 10, 2020, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions including information regarding special accommodations due to a disability may be accessed at: *https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings.* The online web conference meeting will be available at the following link on the day of the meeting: *https://fda.yorkcast.com/webcast/Play/d75d80a3eb6e419986181c1a881fe2671d.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1898. The docket will close on December 9, 2020. Submit either electronic or written comments on this public meeting by December 9, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 9, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 9, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before December 4, 2020 will be provided to the committee. Comments received after December 4, 2020, and by December 9, 2020, will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications, submissions, or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1898 for ''Vaccines and Related Biological Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT: Prabhakara Atreya or Kathleen Hayes, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993–0002, 240–506–4946 or 301–796–7864, respectively; *CBERAdvisoryCommittees@fda.hhs.gov;* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/advisory-committees* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before joining the meeting.

SUPPLEMENTARY INFORMATION: *Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The Committee will meet in open session to discuss EUA of the Pfizer-BioNTech COVID–19 Vaccine for the prevention of COVID–19 in individuals 16 years of age and older. EUA authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, nuclear (CBRN) threats by facilitating the availability and use of Medical Countermeasures (MCMs) needed during public health emergencies. Under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), FDA may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives. Additional information about EUAs can be found at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/advisory-committees/advisory-committee-calendar.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before December 4, 2020, will be provided to the committee. Comments received after December 4, 2020, and by December 9, 2020, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 12 p.m. Eastern Time and 1 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 2, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 3, 2020.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Prabhakara Atreya or Kathleen Hayes (*CBERAdvisoryCommittees@fda.hhs.gov*) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26229 Filed 11–25–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1347]

Michael L. Babich: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Michael L. Babich from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Babich was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Babich was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred. As of September 2, 2020 (30 days after receipt of the notice), Mr. Babich had not responded. Mr. Babich's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable November 27, 2020.

ADDRESSES: Submit applications for special termination of debarment to Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, *debarments@fda.hhs.gov,* or at 240–402–8743.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On January 22, 2020, Mr. Babich was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against him in the U.S. District Court for the District of Massachusetts, after his plea of guilty, to one count of conspiracy in violation of 18 U.S.C. 371 and one count of wire fraud in violation of 18 U.S.C. 1341.

The factual basis for this conviction is as follows: Mr. Babich was the President and Chief Executive Officer of Insys Therapeutics, Inc. (Insys), a Delaware Corporation, with headquarters in Chandler, Arizona. Insys developed and owned a drug called SUBSYS, a liquid formulation of fentanyl to be applied under the tongue. FDA approved SUBSYS for the management of breakthrough pain in adult cancer patients who are already receiving and are already tolerant to opioid therapy for their underlying persistent cancer pain. From May 2012 and continuing until December 2015, Mr. Babich conspired with other employees of Insys to bribe and provide kickbacks, often mailed through the U.S. Postal service, to medical practitioners in various states to get those practitioners to increase prescribing SUBSYS to their patients, many of whom did not have cancer. The bribes and kickbacks took various forms, including honoraria for the practitioners' participation in educational events and payment of the practitioner's staff salaries. To further this conspiracy, Mr. Babich along with his co-conspirators devised a scheme whereby Insys executives conspired to mislead and defraud health insurance providers to ensure those providers approved payment for SUBSYS when it was prescribed for non-cancer patients.

As a result of this conviction FDA sent Mr. Babich, by certified mail on July 16, 2020, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Babich was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Babich an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Babich received the proposal on August 3, 2020. Mr. Babich did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Babich has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Babich is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see DATES) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Babich, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Babich provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Babich during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Babich for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2020–N–1347 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26226 Filed 11–25–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4437]

In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry (GFI) #242 entitled ''In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products.'' The purpose of in-use stability testing is to establish a period of time during which a multiple-dose drug product may be used while retaining acceptable quality specifications once the container is opened (*e.g.,* after a container has been needle-punctured). This guidance reflects the Agency's current thinking on how to formulate in-use statements, as well as how to design and carry out in-use stability studies to support these in-use statements, for multiple-dose injectable drug products intended for use in animals. This current thinking pertains to both generic drug products and pioneer drug products regardless of whether the pioneer reference listed new animal drug (RLNAD) currently has an in-use statement on the labeling.

DATES: The announcement of the guidance is published in the **Federal Register** on November 27, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–4437 for ''In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Kevin Rice, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–402–0680, *kevin.rice@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 4, 2017 (82 FR 851), FDA published the notice of availability for a draft GFI #242 entitled ''In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products.'' The purpose of in-use stability testing is to establish a period of time during which a multiple-dose drug product may be used while retaining acceptable quality specifications once the container is opened (*e.g.,* after a container has been needle-punctured).

FDA received two comments on the draft guidance and those comments were considered as the guidance was

finalized. FDA made changes to provide additional clarification, including adding information regarding in-use labeling language that we recommend for multi-dose animal drug products (mostly food animal drugs) for which less than the theoretical maximum number of punctures are used for the in-use stability study; providing examples of adverse trending that may lead us to recommend the use of aged product for in-use stability studies; and clarifying that if changes are made to the storage temperature or expiry period that would impact a current in-use statement on an approved animal drugs, that we recommend sponsors reassess the in-use statement and submit revised labeling for review.

This final guidance reflects the Agency's current thinking on how to formulate in-use statements, as well as how to design and carry out in-use stability studies to support these in-use statements, for multiple-dose injectable drug products intended for use in animals. This current thinking pertains to both generic drug products and pioneer drug products regardless of whether the pioneer RLNAD currently has an in-use statement on the labeling.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; and the collections of information in sections 512(b) and 512(n) of the Federal Food, Drug, and Cosmetic Act have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: November 20, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26183 Filed 11–25–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by communicating with Betty B. Tong, Ph.D., National Institute of Diabetes and Digestive and Kidney Diseases, Technology Advancement Office, 12A South Drive Suite 3011, Bethesda, MD 20892; telephone: 301–451–7836; email: *tongb@mail.nih.gov.* A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

P2Y14 Receptor Antagonists Containing A Biaryl Core

The technology discloses composition of compounds that fully antagonize the human P2Y14 receptor, with moderate affinity with insignificant antagonism of other P2Y receptors. Therefore, they are highly selective P2Y14 receptor antagonists. Even though there is no P2Y14 receptor modulators in clinical use currently, selective P2Y14 receptor antagonists are sought as potential therapeutic treatments for asthma, cystic fibrosis, inflammation and possibly diabetes and neurodegeneration.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications

Development of P2Y14 receptor antagonist for treatment of disorders, such as:

- Inflammation
- diabetes
- cystic fibrosis
- asthma
- neurodegeneration

Development Stage:

- Early stage

Inventors: Kenneth A. Jacobson (NIDDK), Jinha Yu (NIDDK), Antonella Ciancetta (NIDDK), Zhiwei Wen (NIDDK), Young-Hwan Jung (NIDDK)

Publications: Yu J, Ciancetta A, Dudas S, *et al.,* Structure-guided modification of heterocyclic antagonists of the P2Y14 receptor. J. Med. Chem., 2018, 61: 4860–4882, Jung YH, Yu J, Wen Z, *et al.,* Exploration of alternative scaffolds for P2Y14 receptor antagonists containing a biaryl core. J. Med. Chem., 2020, 63:9563–9589.

Intellectual Property: HHS Reference No. E–028–2018–0/1, US Provisional Patent Application 62/628,699 filed 09 Feb 2018, International Patent Application PCT/US2019/17422, filed 11 Feb 2019.

Licensing Contact: Betty B. Tong, Ph.D.; 301–451–7836; *tongb@mail.nih.gov. This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404.*

Dated: November 19, 2020.

Bei Tong,

Senior Licensing and Patenting Manager, National Institute of Diabetes and Digestive and Kidney Diseases, Technology Advancement Office.

[FR Doc. 2020–26168 Filed 11–25–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the National Toxicology Program Board of Scientific Counselors was renewed for an additional two-year period on November 14, 2020.

It is determined that the National Toxicology Program Board of Scientific Counselors is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed

through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail Stop Code 4875), Telephone (301) 496–2123, or *harriscl@mail.nih.gov*.

Dated: November 20, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–26167 Filed 11–25–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Vaccine Research Center Board of Scientific Counselors, NIAID. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Vaccine Research Center Board of Scientific Counselors, NIAID.

Date: December 15–16, 2020.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 40 Convent Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John R. Mascola, MD, Director, Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 40 Convent Drive, Bethesda, MD 20892, (301) 496–1852, *jmascola@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 20, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–26150 Filed 11–25–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Initial Review Group; Behavior and Social Science of Aging Review Committee NIA–S.

Date: February 4–5, 2021.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Carmen Moten, Ph.D., MPH, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, (301) 402–7703, *cmoten@mail.nih.gov.*

Name of Committee: National Institute on Aging Initial Review Group; Biological Aging Review Committee NIA–B.

Date: February 11–12, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bita Nakhai, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 402–7701, *nakhaib@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: November 24, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–26369 Filed 11–25–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by communicating with Betty B. Tong, Ph.D., National Institute of Diabetes and Digestive and Kidney Diseases, Technology Advancement Office, 12A South Drive Suite 3011, Bethesda, MD 20892; telephone: 301–451–7836; email: *tongb@mail.nih.gov.* A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Triazole Derivatives as P2Y14 Receptor Antagonists

The technology describes the composition of small molecule compounds that are antagonists of the P2Y14 receptor. Also provided are methods of using the compounds, including a method of treating a disorder, such as inflammation, diabetes, insulin resistance, hyperglycemia, a lipid disorder, obesity, a condition associated with metabolic syndrome, and asthma, and a method of antagonizing P2Y14 receptor activity in a cell. This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

Development of P2Y14 receptor antagonist for treatment of disorders, such as:

- Inflammation
- diabetes
- obesity
- asthma

- lipid disorder
- metabolic syndrome

Development Stage

- Early stage

Inventors: Kenneth A. Jacobson (NIDDK), Anna Junker, Elisa Uliassi (NIDDK), Evgeny Kiselev (NIDDK)

Publications: Junker A, Balasubramanian R, Ciancetta A, *et al.,* Structure-based design of 3-(4-aryl-1H–1,2,3-triazol-1-yl)-biphenyl derivatives as $P2Y_{14}$ receptor antagonists. J. Med. Chem., 2016, 59:6149 − 6168.

Intellectual Property: HHS Reference No. E–213–2015–0, U.S. Patent No. 10,683,277, issued June 16, 2020, EP Patent Application 16774825.0, filed Sept. 23, 2016, Chinese Patent Application 201680064441.5, filed Sept. 23, 2016.

Licensing Contact: Betty B. Tong, Ph.D.; 301–451–7836; *tongb@mail.nih.gov. This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404.*

Dated: November 19, 2020.

Bei Tong,

Senior Licensing and Patenting Manager, National Institute of Diabetes and Digestive and Kidney Diseases, Technology Advancement Office.

[FR Doc. 2020–26169 Filed 11–25–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44 Clinical Trial Required).

Date: December 18, 2020.

Time: 2:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20892, (Virtual Meeting).

Contact Person: Cynthia L. De La Fuente, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20852, 240–669–2740, *delafuentecl@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 20, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–26152 Filed 11–25–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6236–N–01]

Notice of Certain Operating Cost Adjustment Factors for 2021

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice establishes operating cost adjustment factors (OCAFs) for project-based assistance contracts issued under Section 8 of the United States Housing Act of 1937 and renewed under the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA) for eligible multifamily housing projects having an anniversary date on or after February 11, 2021. OCAFs are annual factors used to adjust Section 8 rents renewed under section 515 or section 524 of MAHRA.

DATES: Applicability Date: February 11, 2021.

FOR FURTHER INFORMATION CONTACT: Carissa Janis, Program Analyst, Office of Asset Management and Portfolio Oversight, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; telephone number 202–402–2487 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. OCAFs

Section 514(e)(2) and section 524(c)(1) of MAHRA (42 U.S.C. 1437f note) require HUD to establish guidelines for the development of OCAFs for rent adjustments. Sections 524(a)(4)(C)(i), 524(b)(1)(A), and 524(b)(3)(A) of MAHRA, all of which prescribe the use of the OCAF in the calculation of renewal rents, contain similar language. HUD has therefore used a single methodology for establishing OCAFs, which vary among states and territories.

MAHRA gives HUD broad discretion in setting OCAFs, referring, for example, in sections 524(a)(4)(C)(i), 524(b)(1)(A), 524(b)(3)(A), and 524(c)(1), to simply ''an operating cost adjustment factor established by the Secretary.'' The sole limitation to this grant of authority is a specific requirement in each of the foregoing provisions that application of an OCAF ''shall not result in a negative adjustment.'' Contract rents are adjusted by applying the OCAF to that portion of the rent attributable to operating expenses exclusive of debt service.

The OCAFs provided in this notice are applicable to eligible projects having a contract anniversary date of February 11, 2021, or after and were calculated using the same method as those published in HUD's 2020 OCAF notice published on November 22, 2019 (84 FR 64553). Specifically, OCAFs are calculated as the sum of weighted component cost changes for wages, employee benefits, property taxes, insurance, supplies and equipment, fuel oil, electricity, natural gas, and water/sewer/trash, using publicly available indices. The weights used in the OCAF calculations for each of the nine cost component groupings are set using current percentages attributable to each of the nine expense categories. These weights are calculated in the same manner as in the November 22, 2019, notice. Average expense proportions were calculated using three years of audited Annual Financial Statements from projects covered by OCAFs. The expenditure percentages for these nine categories have been found to be very stable over time but using three years of data increases their stability. The nine cost component weights were calculated at the state level, which is the lowest level of geographical aggregation with enough projects to permit statistical analysis. These data were not available for the Western Pacific Islands, so data for Hawaii were used as the best available indicator of OCAFs for these areas.

The best current price data sources for the nine cost categories were used in calculating annual change factors. State-

level data for fuel oil, electricity, and natural gas from Department of Energy surveys are relatively current and continue to be used. Data on changes in employee benefits, insurance, property taxes, and water/sewer/trash costs are available only at the national level. The data sources used for the selected nine cost indicators are as follows:

- *Labor Costs:* First quarter, 2020 Bureau of Labor Statistics (BLS) ECI, Private Industry Wages and Salaries, All Workers (Series ID CIU2020000000000I) at the national level and Private Industry Benefits, All Workers (Series ID CIU2030000000000I) at the national level.
- *Property Taxes:* Census Quarterly Summary of State and Local Government Tax Revenue—Table 1 *https://www.census.gov/econ/currentdata/dbsearch?program=QTAX&startYear=2018&endYear=2020&categories=QTAXCAT1&dataType=T01&geoLevel=US&notAdjusted=1&submit=GET+DATA&releaseScheduleId=.* Twelve-month property taxes are computed as the total of four quarters of tax receipts for the period from April through March. Total 12-month taxes are then divided by the number of occupied housing units to arrive at average 12-month tax per housing unit. The number of occupied housing units is taken from the estimates program at the Bureau of the Census. *http://www.census.gov/housing/hvs/data/histtab8.xlsx.*
- *Goods, Supplies, Equipment:* May 2019 to May 2020 Bureau of Labor Statistics (BLS) Consumer Price Index, All Items Less Food, Energy and Shelter (Series ID CUUR0000SA0L12E) at the national level.
- *Insurance:* May 2019 to May 2020 Bureau of Labor Statistic (BLS) Consumer Price Index, Tenants and Household Insurance Index (Series ID CUUR0000SEHD) at the national level.
- *Fuel Oil:* October 2019–March 2020 U.S. Weekly Heating Oil and Propane Prices report. Average weekly residential heating oil prices in cents per gallon excluding taxes for the period from October 7, 2019, through the week of March 30, 2020, are compared to the average from October 1, 2018, through the week of March 25, 2019. For the States with insufficient fuel oil consumption to have separate estimates, the relevant regional Petroleum Administration for Defense Districts (PADD) change between these two periods is used; if there is no regional PADD estimate, the U.S. change between these two periods is used. *http://www.eia.gov/dnav/pet/pet_pri_wfr_a_EPD2F_prs_dpgal_w.htm.*
- *Electricity:* Energy Information Agency, February 2020 ''Electric Power Monthly'' report, Table 5.6.B. *http://www.eia.gov/electricity/monthly/epm_table_grapher.cfm?t=epmt_5_06_b.*
- *Natural Gas:* Energy Information Agency, Natural Gas, Residential Energy Price, 2018–2019 annual prices in dollars per 1,000 cubic feet at the state level. Due to EIA data quality standards several states were missing data for one or two months in 2019; in these cases, data for these missing months were estimated using data from the surrounding months in 2019 and the relationship between that same month and the surrounding months in 2018. *http://www.eia.gov/dnav/ng/ng_pri_sum_a_EPG0_PRS_DMcf_a.htm.*
- *Water and Sewer:* May 2019 to May 2020 Consumer Price Index, All Urban Consumers, Water and Sewer and Trash Collection Services (Series ID CUUR0000SEHG) at the national level.

The sum of the nine cost component percentage weights equals 100 percent of operating costs for purposes of OCAF calculations. To calculate the OCAFs, state-level cost component weights developed from AFS data are multiplied by the selected inflation factors. For instance, if wages in Virginia comprised 50 percent of total operating cost expenses and increased by 4 percent from 2019 to 2020, the wage increase component of the Virginia OCAF for 2021 would be 2.0 percent (50% * 4%). This 2.0 percent would then be added to the increases for the other eight expense categories to calculate the 2021 OCAF for Virginia. For states where the calculated OCAF is less than zero, the OCAF is floored at zero. The OCAFs for 2021 are included as an Appendix to this Notice.

II. MAHRA OCAF Procedures

Sections 514 and 515 of MAHRA, as amended, created the Mark-to-Market program to reduce the cost of federal housing assistance, to enhance HUD's administration of such assistance, and to ensure the continued affordability of units in certain multifamily housing projects. Section 524 of MAHRA authorizes renewal of Section 8 project-based assistance contracts for projects without restructuring plans under the Mark-to-Market program, including projects that are not eligible for a restructuring plan and those for which the owner does not request such a plan. Renewals must be at rents not exceeding comparable market rents except for certain projects. As an example, for Section 8 Moderate Rehabilitation projects, other than single room occupancy projects (SROs) under the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11301 *et seq.*), that are eligible for renewal under section 524(b)(3) of MAHRA, the renewal rents are required to be set at the lesser of: (1) The existing rents under the expiring contract, as adjusted by the OCAF; (2) fair market rents (less any amounts allowed for tenant-purchased utilities); or (3) comparable market rents for the market area.

III. Findings and Certifications Environmental Impact

This notice sets forth rate determinations and related external administrative requirements and procedures that do not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

IV. Paperwork Reduction Act

This notice does not impact the information collection requirements already submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

V. Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number for this program is 14.195.

Dana T. Wade,

Assistant Secretary for Housing—Federal Housing Commissioner.

APPENDIX

OPERATING COST ADJUSTMENT FACTORS FOR 2021

Alabama	2.6
Alaska	2.3
Arizona	2.1
Arkansas	2.4
California	2.7
Colorado	2.4
Connecticut	2.6
Delaware	2.2
District of Columbia	2.7
Florida	2.5
Georgia	2.5
Hawaii	2.0
Idaho	2.5
Illinois	2.6
Indiana	2.5
Iowa	2.7

OPERATING COST ADJUSTMENT FACTORS FOR 2021—Continued

Kansas	2.0
Kentucky	2.4
Louisiana	2.2
Maine	2.2
Maryland	2.5
Massachusetts	2.3
Michigan	2.5
Minnesota	2.4
Mississippi	2.4
Missouri	2.0
Montana	2.0
Nebraska	2.5
Nevada	2.7
New Hampshire	2.6
New Jersey	2.8
New Mexico	2.2
New York	2.0
North Carolina	2.6
North Dakota	2.5
Ohio	2.3
Oklahoma	2.2
Oregon	2.4
Pacific Islands	2.0
Pennsylvania	2.4
Puerto Rico	2.5
Rhode Island	2.4
South Carolina	2.6
South Dakota	2.3
Tennessee	2.4
Texas	2.8
Utah	2.3
Vermont	1.8
Virgin Islands	2.0
Virginia	2.6
Washington	2.3
West Virginia	2.2
Wisconsin	2.8
Wyoming	2.2
US	2.5

[FR Doc. 2020–26192 Filed 11–25–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7024–N–48]

30-Day Notice of Proposed Information Collection: HUD-Owned Good Neighbor Next Door Program; OMB Control No.: (2502–0570)

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date: December 28, 2020.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/Start* Printed Page 15501PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: 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. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on June 1, 2020 at 85 FR 33188.

A. Overview of Information Collection

Title of Information Collection: HUD-Owned Good Neighbor Next Door Program.

OMB Approval Number: 2502–0570.

Type of Request: Extension of currently approved collection.

Form Number: HUD–9549, HUD–9549–A, HUD–9549–B, HUD–9549–C, HUD–9549–D, HUD–9549–E.

Description of the need for the information and proposed use: The information collected will be used to administer the Good Neighbor Next Door Sales program and to determine and document the eligibility to participate in the program. The forms are used in addition to the sales contracts and addenda that are used in binding contracts between purchasers of acquired single family assets and HUD through the Good Neighbor Next Door Sales program.

Respondents: law enforcement officers, teachers or firefighters/emergency medical Technicians.

Estimated Number of Respondents: 738.

Estimated Number of Responses: 1,806.

Frequency of Response: 2.44715.

Average Hours per Response: 0.08582.

Total Estimated Burdens: 155.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond,; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) Ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority: Section 2 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2020–26234 Filed 11–25–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7024–N–49]

30-Day Notice of Proposed Information Collection: Exigent Health and Safety Deficiency Correction Certification; OMB Control No.: 2577–0241

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* December 28, 2020.

ADDRESSES: Interested persons are invited to submit comments regarding

this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/Start* Printed Page 15501PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: 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. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on September 4, 2020 at 85 FR 55312.

A. Overview of Information Collection

Title of Information Collection: Exigent Health and Safety Deficiency Correction Certification.

OMB Approval Number: 2577–0241.

Type of Request: Extension of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: HUD's Uniform Physical Condition Standards (UPCS) regulation (24 CFR part 5, subpart G) provides that HUD housing must be decent, safe, sanitary, and in good repair. The UPCS regulation also provides that all area and components of the housing must be free of health and safety hazards. HUD conducts physical inspections of the HUD housing to compliance with the UPCS standards. Pursuant to the UPCS inspection protocol, at the end of the inspection (or at the end of each day of a multi-day inspection) the inspector provides the property representative with a copy of the ''Notification of Exigent and Fire Safety Hazards Observed'' form. Each exigent health and safety (EHS) deficiency that the inspector observed that day is listed on the form. The property representative signs the form acknowledging receipt. PHAs are to correct/remedy/act abate all EHS deficiencies within 24 hours. Using the electronic format, PHAs are to notify HUD within three business days of the date of inspection—the date the PHA was provided notice of these deficiencies—that the deficiencies were corrected/remedied/acted on to abate within the prescribed time frames (per 24 CFR part 902).

Respondents: Public Housing Agencies.

Estimated Number of Respondents: 976.

Estimated Number of Responses: 976.

Frequency of Response: Once per year.

Average Hours per Response: 0.3333.

Total Estimated Burdens: 325.30.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2020–26243 Filed 11–25–20; 8:45 am]

BILLING CODE 4210–67–P

HOUSING AND URBAN DEVELOPMENT

[Docket No FR–6178–D–02]]

Delegations of Authority for the Office of Housing—Federal Housing Administration (FHA); Redelegations of Authority Regarding Multifamily Housing Programs

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of revocation and redelegation of authority.

SUMMARY: On June 20, 2012, the Assistant Secretary for Housing—Federal Housing Commissioner published comprehensive redelegations of authority for the Office of Multifamily Housing Programs. Today's notice of redelegations of authority updates and amends the notice that was published on June 20, 2012. This notice reflects changes that have been made to the redelegations of authority regarding multifamily housing programs since the June 2012 Delegations. In general, these changes reflect the Multifamily for Tomorrow (MFT) Transformation, which has: Transitioned existing Multifamily Hubs and Program Centers into five (5) Multifamily Regional Centers and seven (7) Multifamily Satellite Offices. In addition, the MFT Transformation reorganized HUD Headquarters offices to expand the Office of Affordable Housing Preservation and rename it as the Office of Recapitalization; rename the Office of Multifamily Development as the Office of Multifamily Production; create a new Office of Field Support and Operations; and expand the Office of Asset Management to incorporate the Office of Housing Assistance and Grants Administration and the Office of Housing Assistance Contract Administration Oversight, and rename the expanded office the Office of Asset Management and Portfolio Oversight.

DATES: November 23, 2020.

FOR FURTHER INFORMATION CONTACT: Jeffrey D. Little, Associate Deputy Assistant Secretary for Office of Multifamily Housing Programs, Office of Housing, U.S. Department of Housing and Urban Development, 451 Seventh Street SW, Room 6112, Washington, DC 20410–8000, telephone 202–402–5647. (This is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the Federal Relay Service number at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Section I. Multifamily Housing Programs: Office of Housing Organization

A. Office of Multifamily Housing Programs—Headquarters

In general, all Headquarters and field managers and staff of the Office of Multifamily Housing Programs report to the Deputy Assistant Secretary for Multifamily Housing Programs. In Headquarters, there are now four (4) major Multifamily Housing program offices. These offices and a general description of each appear below.

1. Office of Multifamily Production

The Office of Multifamily Production develops and implements policies and guidelines for the loan origination aspects of Federal Housing Administration (FHA) multifamily housing mortgage insurance programs from pre-application to final endorsement of the mortgage note. The Office is responsible for Traditional Application Processing (TAP), Multifamily Accelerated Processing (MAP), and Section 542 Risk-Sharing mortgage insurance policies and procedures. The Office of Multifamily Production staff provides technical guidance to the HUD/FHA multifamily housing field staff, the industry, and other Headquarters offices. The Office is headed by a Director and a Deputy Director.

2. Office of Asset Management and Portfolio Oversight

The Office of Asset Management and Portfolio Oversight (OAMPO), which was formed from the merger of the Office of Asset Management, the Office of Housing Assistance and Grant Administration, and the Office of Housing Assistance Contract Administration Oversight, is primarily responsible for strategic planning, guidance, lender approval, and lender monitoring, and oversight of HUD's multifamily housing portfolio of project assets after final endorsement of the mortgage note and upon occupancy. The Office is headed by a Director and a Deputy Director.

a. Asset Management Functions

OAMPO develops policy for, and oversees, field office asset management operations. OAMPO is responsible for oversight of regulated property ownership and management, routine mortgage servicing, default servicing, partial payment of claims, acquisition and/or disposition of loans and properties, lender approval and monitoring, the Flexible Subsidy Program, and management of properties where the Secretary is the owner (as a result of default and foreclosure) or mortgagee-in-possession. OAMPO serves as Multifamily Housing's liaison with the Real Estate Assessment Center (REAC) and the Departmental Enforcement Center (DEC). In addition, OAMPO oversees field office and lender servicing activities for HUD-assisted and HUD-insured properties. By means of the Property Disposition Division in Fort Worth, OAMPO oversees and implements HUD's property disposition efforts through the foreclosure sale process, property management, relocation of tenants, and sale of HUD-owned properties. With respect to the disposition of properties under the originating authorities of the Office of Healthcare Programs, the Property Disposition Division will follow policies and procedures as may be established in guidance developed by the Office of Housing describing specific actions between the Office of Healthcare Programs and the Office of Multifamily Housing. The two offices must work together to decide which office is responsible for a particular function associated with such dispositions.

b. Housing Assistance and Grant Administration Functions

Additionally, OAMPO is responsible for directing and overseeing housing assistance programs and housing production and development functions administered by the Office of Multifamily Housing Programs. OAMPO's programs include post-award implementation of project-based Section 8 housing assistance, Section 202 and Section 811 programs, the Emergency Capital Repair Grants program, Service Coordinators in Multifamily Housing Programs, the Assisted Living Conversion program, and Congregate Housing Services programs. OAMPO is also involved with other project-based assistance programs, including Rent Supplement, Rental Assistance Payments, Section 236 Rental Assistance Payments, Project Rental Assistance Contracts, and Senior Preservation Rental Assistance Contracts. In addition, the Office provides occupancy policy guidance and supports the Rental Housing Integrity Improvement Initiative and Enterprise Income Verification in connection with HUD efforts to reduce improper payments. With respect to competitive grant programs, OAMPO is solely responsible for Section 811 programs, the Emergency Capital Repair Grants program, Service Coordinators in Multifamily Housing Programs, with the exception of grants under Section 514, the Assisted Living Conversion program, and Congregate Housing Services programs. OAMPO is jointly responsible for competitive grant programs with respect to Section 202 and Section 514 programs, as such activities may be allocated among offices by the Deputy Assistant Secretary.

c. Housing Assistance Contract Administration Oversight Functions

Furthermore, OAMPO is responsible for policies, procedures, guidelines, performance assessment, and technical and general compliance under the terms of the respective Annual Contributions Contracts for Section 8 Contract Administrators (CAs). This Section 8 contract administration oversight ensures that properties continue to meet the Department's standards for providing decent, safe, and sanitary housing to low-income families. Additionally, OAMPO is responsible for assuring that the Department meets its financial obligations to owners, as specified in the various subsidy contracts, by ensuring availability of subsidy payments and overseeing ongoing funding of project-based assistance contracts.

3. Office of Recapitalization

The Office of Recapitalization was originally established within the Office of Multifamily Housing Programs as the Office of Affordable Housing Preservation (OAHP), which primarily administered the Mark-to-Market Program. OAHP was renamed the Office of Recapitalization (Recap) and expanded as part of the MFT Transformation to process financial transactions that recapitalize and preserve federally-assisted affordable housing units and thus ensure long-term physical and financial viability. Recap is responsible for developing policies and procedures and providing oversight for the programs administered by Recap. Recap is involved with project-based assistance programs, including converting Public Housing projects to the Section 8 platform via the Rental Assistance Demonstration (RAD), Section 8 Project Based Rental Assistance, Rent Supplement, Rental Assistance Payments, Section 236 Rental Assistance Payments, Project Rental Assistance Contracts, and Senior Preservation Rental Assistance Contracts. Recap is jointly responsible for competitive grant programs with respect to Section 202 and Section 514 programs, as such activities may be allocated among the offices by the Deputy Assistant Secretary. The programs administered by Recap are described in Section II.D,

Recapitalization, below. The Office is headed by a Director and a Deputy Director. Other leadership of the Office includes the Director of the Affordable Housing Transaction Division, the Director of the Closing and Post-Closing Division, the Director of the Recapitalization Program Administration Office (Division), and subordinate branch chiefs.

Redelegations of authority to the Director and Deputy Director of the Office of Recapitalization and other Office of Recapitalization officials are set forth in Section IV of this notice.

4. Office of Field Support and Operations

The Office of Field Support and Operations (OFSO) is a new office created from the MFT Transformation. OFSO is responsible for the field management and operations of multifamily programs in the five Regional Centers (Atlanta, Chicago, Fort Worth, New York, and San Francisco), and seven Satellite Offices (collectively ''the field''). The office provides oversight and direction at the field level in the execution of Multifamily goals as well as other departmental goals and initiatives.

B. Office of Multifamily Housing Programs—Field Office Structure

The new field office organization now consists of twelve (12) offices, including five (5) Regional Centers and seven (7) Satellite Offices.

The highest-ranking official in a Regional Center is the Regional Director. The immediate deputies of the Regional Director are the Production Division Director, Asset Management Division Directors, and the Operations Officer in the Regional Center and in the region's Satellite Office(s), the Satellite Office Asset Management Division Director/ Satellite Office Coordinator. The Satellite Office Asset Management Division Director/Satellite Office Coordinator is both an Asset Management Division Director and the head of that Satellite Office. The chart below identifies each Regional Center, the Satellite Office(s) that report to it, and the geographic area served by the Regional Center and its respective Satellite Office(s). The MFT Transformation also includes initiatives that require Multifamily Housing Programs staff to perform duties outside their geographic jurisdictions identified in the chart below (''Workload Sharing'').

MULTIFAMILY HOUSING PROGRAMS REGIONAL STRUCTURE

Regional center	Satellite office(s)	Geographic area serviced
Atlanta	Jacksonville	HUD Region IV: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virgin Islands.
Chicago	Detroit, Minneapolis	HUD Region V: Ohio, Illinois, Indiana, Michigan, Minnesota, Wisconsin.
Fort Worth	Kansas City	HUD Regions VI and VII: Arkansas, Iowa, Kansas, Louisiana, Missouri, Nebraska, New Mexico, Oklahoma, Texas.
New York City	Boston, Baltimore	HUD Regions I, II, and III: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, West Virginia.
San Francisco	Denver	HUD Regions VIII, IX, and X: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming.

In summary, certain Multifamily Housing Programs officials in Regional Centers, Satellite Offices, and Headquarters, acting within the scope of their redelegated authorities and applicable law, have independent authority, through the delegation process, to make binding decisions on behalf of the Department. Production Division Directors, Asset Management Division Directors, and Satellite Office Asset Management Division Directors/ Satellite Office Coordinators report to Regional Directors.

Section II. Multifamily Housing Programs—Functions

The Office of Multifamily Housing Programs is charged with carrying out duties on behalf of the Assistant Secretary for Housing—Federal Housing Commissioner, Chief of Staff for Housing, General Deputy Assistant Secretary for Housing, and Associate General Deputy Assistant Secretary for Housing as they relate to multifamily programs set forth in HUD's governing legislation, as described in the Consolidated Delegation of Authority for the Office of Housing—Federal Housing Administration (FHA). This broad range of programs enables HUD, in concert with the private and public sectors, to provide safe, decent, and affordable multifamily housing to millions of American families. The programs include mortgage insurance, rental assistance programs, and programs to improve and preserve affordable housing. Under this delegation, the Assistant Secretary for Housing—Federal Housing Commissioner, Chief of Staff for Housing, General Deputy Assistant Secretary for Housing, and Associate General Deputy Assistant Secretary for Housing redelegate broad program authority to the Deputy Assistant Secretary for Multifamily Housing Programs and to particular Multifamily Housing Programs officials in Headquarters and the field.

Characterizing the authority that is being redelegated in broad or general terms in this Section II will enable the Deputy Assistant Secretary for Multifamily Housing Programs, Associate Deputy Assistant Secretary for Multifamily Housing Programs, and Multifamily Housing Program Office Directors to perform all functions necessary to accomplish Multifamily Housing Programs tasks and objectives.

Section II of this delegation sets forth functions in general terms, while the preamble provides insights into the nature of the work performed by officials with delegated authority under each category. The basic multifamily housing functions and a brief description of each are as follows:

A. General Authority

This authority allows certain officials in the Office of Multifamily Housing Programs, designated in this notice, to sign any and all documents necessary to carry out business within their program and geographic jurisdictions, except for any authorities retained exclusively by the Assistant Secretary for Housing—Federal Housing Commissioner, Chief of Staff for Housing, General Deputy Assistant Secretary for Housing, and Associate General Deputy Assistant Secretary for Housing, as described in the Consolidated Delegation of Authority for the Office of Housing—Federal Housing Administration (FHA). Designated field officials and their staffs are authorized to engage in Workload Sharing across regional lines when their

staffs are performing production and/or asset management/portfolio oversight functions that are otherwise consistent with limitations established in these redelegations. In addition, this authority allows such officials, when considering a proposal, to waive, for good cause and with written justification, any directives that are not mandated by statute or regulation or reserved to Headquarters.

B. Multifamily Production

This authority allows an official with delegated authority to make all necessary determinations that relate to the FHA-insured mortgage underwriting process and the risk-sharing programs, except as may be limited by internal controls. Essentially, this category of authority begins with a pre-application or application for mortgage insurance and ends with the Department's endorsement of an insured mortgage and related documentation. For all mortgage insurance programs, it includes, but is not limited to, such activities as determining the acceptability of project sites; issuing firm commitments for FHA insurance; issuing initial or final endorsements for FHA insurance; executing regulatory agreements; requiring corrective actions and escrow accounts as needed; and wherever applicable, overseeing the actions of HUD's program participants in connection with a project's development (*e.g.,* authorizing a housing finance agency to process risk sharing loans or to conduct a subsidy layering review).

C. Asset Management and Portfolio Oversight

Functions carried out under this category involve HUD's continuing relationship with a multifamily project after it has been added to the HUD portfolio through either FHA mortgage insurance, co-insurance, or risk-sharing programs; direct loan; capital advance or grant programs; other subsidy programs; and combinations thereof. Under this category, ongoing decision-making relates to an insured or subsidized project's occupancy, operations, and physical and financial condition from the time of occupancy through final disposition, including, but not limited to, prepayment, repayment of the loan or end of the subsidy contract, foreclosure, and/or termination of the subsidy contract. In addition, functions involve the renewal of Section 8 contracts and other project-based assistance, and imposing sanctions upon project owners that, for example, violate the terms of their regulatory agreement and/or Section 8 Housing Assistance Payments contract. Further, functions involve the oversight of use agreements and contractual restrictions, including consents to liens, approval of changes in ownership, amendment or release (in part or in full) of use agreements or contracts, and granting of other consent rights held by HUD. To the extent that these functions overlap authority delegated herein to Recap (for example, with respect to the RAD and Mark-to-Market (M2M) programs), the two offices must work together to decide which office is responsible for a particular function. Included in this category is oversight over housing assistance and competitive grant programs administered by the Office of Multifamily Housing Programs, except for the authority to issue a final Notice of Funding Availability (NOFA) or to make grant awards. Competitive grant programs within the Office of Multifamily Housing typically include those for the Section 202 Supportive Housing for the Elderly Program, Section 811 Project Rental Assistance Program, Section 514 program, and the Multifamily Housing Service Coordinator Program. To the extent that functions with respect to the Section 202 Supportive Housing for the Elderly Program and Section 514 program overlap authority delegated herein to Recap, the two offices must work together to decide which office is responsible for a particular function. In any given year, Congress may authorize additional or alternative programs. Office functions include developing the criteria for applications, rating and ranking applications, and executing grant agreements. Once a grant is awarded, functions include monitoring compliance with the grant agreement, terminating a grant for noncompliance, modifying a grant, and closing out a grant.

Also included are contract administration and oversight. Functions in this area of contract administration and oversight involve activities related to the award of the Contract Administration Contracts (Annual Contribution Contracts), assessment and assignment of Section 8 contracts to Performance-Based Contract Administrators (PBCAs), evaluation of PBCA performance, provision of technical assistance to PBCAs, and prescription of any remedial actions needed to improve PBCA performance. Key functions also involve developing policies and procedures for field offices and coordinating efforts between the PBCAs and the local Multifamily Housing Programs field office staff; monitoring, evaluating, and providing technical guidance relative to field activities; assuring that PBCAs provide data needed to evaluate their performance and the status of contracts they administer; and coordinating audit activities associated with Section 8 Contract Administration. Funding activities involve budget and funding responsibilities associated with various rental assistance programs, including both HUD and third-party administered contracts. Activities also include creating and approving administrative commitments for active contracts; determining funding levels; reserving the subsidy based on funding availability; and monitoring allotments versus annual appropriations, funding assignments versus allotments, reservations versus fund assignments, and actual reservations versus estimated activity. Additional functions include monitoring the timely payment of Section 8 housing assistance to PBCAs and project owners in collaboration with the accounting staff in the Office of the Chief Financial Officer. The funding area also works with the Department's budget and accounting organizations to generate budget authority estimates for the above-referenced subsidy programs, to develop procedures for funding and payment processes, and to integrate systems to support the data.

Property disposition is also included in this category. Property disposition functions consist of foreclosure sales, post sales transaction oversight, tenant relocations, and property management. These functions include notifying an owner; hearing and deciding an owner's appeal to the foreclosure determination; deciding the terms of and directing a foreclosure sale; accepting a deed-in-lieu of foreclosure; managing HUD-owned and HUD-held properties; authorizing any work and related terms required by a project in advance of a sale; advertising a project for sale; approving disposition plans, sales documents, and purchasers; executing rental assistance contracts; and relocating residents as may be necessary.

D. Recapitalization

Functions carried out under this category involve HUD efforts to preserve and recapitalize project-based affordable housing and HUD approvals informed by underwriting of refinancing transactions often involving a variety of public and private sector leverage and other financing sources. Functions primarily involve preservation of affordable housing through two main programs, the Mark-to-Market Program and the Rental Assistance Demonstration.

The Mark-to-Market Program preserves long-term affordability and availability of low-income rental multifamily housing properties by restructuring FHA-insured or formerly insured HUD-held mortgages for eligible multifamily housing projects. The Multifamily Assisted Housing Reform and Affordability Act of 1997, as amended (MAHRA) (42 U.S.C. 1437f note) authorized a Mark-to-Market program designed to preserve low-income rental housing affordability while reducing the long-term costs of Federal rental assistance, including project-based assistance from HUD, for certain multifamily rental projects. The projects involved are projects with (1) HUD-insured or formerly insured HUD-held mortgages; and (2) contracts for project-based rental assistance from HUD, primarily through the Section 8 program, for which the average rents for assisted units exceed the market rents. The program objectives are to (1) preserve housing affordability while reducing the costs of project-based assistance, often by reducing project-based rents to market levels; (2) restructure the HUD-insured or formerly insured HUD-held mortgages so that the monthly payments on the resulting new (or modified) first mortgage can be supported by the adjusted rents; (3) reduce the costs of insurance claims; (4) ensure competent management of the project; and (5) ensure that projects are adequately capitalized to meet future capital improvement needs. The restructured project is subject to long-term use and affordability restrictions. The M2M program's predecessor program was the Portfolio Reengineering Demonstration Project (Demo) originally authorized in 1996 and most recently in 1998 under title V of the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1998 (Pub. L. 105–65).

Related to the M2M program and the Demo program functions are certain post-transaction reviews (Post M2M), which address the processing of an owner's request to extend the maturity date of a HUD-held mortgage on, or to refinance or sell, or to sever excess land from, a property that previously received the benefits of a debt restructuring under the M2M program or the Demo program. Post M2M transactions may also include applications for debt assumption, modification, or forgiveness of M2M debt for a non-profit qualified by HUD as being eligible to receive such benefit. In addition, under the American Recovery and Reinvestment Act of 2009 (Recovery Act), OAHP was charged with providing grants and loans (Green Retrofit Program Loans or GRP Loans) for energy retrofit and green investments in assisted housing projects (Green Retrofit Program or GRP) through the policies, procedures, contracts, and transactional infrastructure authorized for M2M. Functions include the administration of GRP Loans, including an owner's request to extend the maturity date or otherwise modify a GRP Loan, or when a property encumbered by a GRP Loan is being sold or refinanced.

The Rental Assistance Demonstration (RAD) allows properties to be converted from their original regulatory platform to the Section 8 project-based voucher program or the Section 8 project-based rental assistance program, which in turn allows a variety of financing tools to be applied to at-risk public and assisted housing in order to preserve the Nation's stock of deeply affordable rental housing, promote efficiency within and among HUD programs, and build strong, stable communities. RAD allows public housing agencies to leverage public and private debt and equity in order to reinvest in the public housing stock, and gives owners of multifamily housing properties with Rent Supplement (Rent Supp) project-based rental assistance contracts, Section 236 Rental Assistance Payments (RAP) project-based rental assistance contracts, Section 8 Moderate Rehabilitation (Mod Rehab) project-based rental assistance contracts, Section 8 Moderate Rehabilitation Single Room Occupancy (Mod Rehab SRO) project-based rental assistance contracts, and Section 202 project rental assistance contracts (Section 202 PRACs) the opportunity to enter into long-term project-based rental assistance contracts.

Functions related to the RAD, M2M, and Post M2M activities also involve the oversight of RAD and M2M use agreements and contractual restrictions, including consents to additional liens, approval of changes in ownership, amendment or release of use agreements or contracts, and granting of other consent rights held by HUD.

In addition to these two main programs, functions under this heading include the following additional programs: (1) The Section 236 program, under which Recap processes Section 236 preservation transactions in order to recapitalize and/or maintain the affordability of Section 236 projects through refinancing, tax credits, or other forms of assistance; (2) the Senior Preservation Rental Assistance Contract (SPRAC) program, under which new 20-year project-based rental assistance contracts are entered into that prevent displacement of income-eligible elderly residents who reside in Section 202 Direct Loan projects with original interest rates of six (6) percent or less in the case of refinancing or recapitalization of the project; (3) pre-1974 Section 202 Housing for the Elderly preservation activities, which coordinate the issuance of Section 8 tenant protection vouchers upon prepayment or maturity of the Section 202 Direct Loan and the project-basing of such Section 8 rental assistance, either alone or in conjunction with a SPRAC in order to prevent displacement of income-eligible elderly residents who reside in Section 202 Direct Loan projects; and (4) oversight of the Section 202 Supportive Housing for the Elderly and the Section 514 competitive grant programs administered by the Office of Multifamily Housing Programs.

E. Program Demonstrations

Periodically, Congress will enact legislation that authorizes HUD to conduct a multifamily housing program on a demonstration basis. The purpose of a demonstration is essentially to test the viability of a new program on a limited basis, for example, by geography, case volume, or time. Functions related to demonstration programs include developing program criteria, implementing the program, monitoring activities and results, preparing any required reports to Congress, and closing out the program.

F. Coinsurance

In 1990, HUD stopped accepting new applications for multifamily housing coinsurance. However, HUD still carries out multifamily housing coinsurance program functions related to the existing inventory, which include any and all actions necessary to carry out the program authorized under 12 U.S.C. 1715z–9. Functions also include authorizing second mortgage documents in partial payment-of-claims cases, as well as approving requests for the conversion of coinsurance to full mortgage insurance.

G. Portfolio Reengineering

Although all cases under the Portfolio Reengineering Demonstration Project (Demo) program have been closed, there are ongoing asset management functions related to this portfolio of projects.

H. Limited Denials of Participation and Other Available Remedies

A participant, contractor, or affiliate, other than a mortgagee, who fails to

comply with HUD program regulations, rules, and/or procedures can be denied the right to participate in a HUD program or programs. Procedures governing the nature and scope of proceedings for the issuance of a limited denial of participation are set forth in 2 CFR part 2424, subpart J. Only certain officials may issue such limited denials of participation pursuant to the process in the regulations. The issuance of a limited denial of participation does not preclude HUD from initiating additional administrative action (see, *e.g.,* 31 U.S.C. 3081 *et seq.;* 2 CFR part 180, 2 CFR 2424.10 *et seq.,* 24 CFR part 25, 24 CFR part 30, 24 CFR part 200, subpart Y) or referring a matter to the U.S. Department of Justice for civil or criminal enforcement.

Section III. Multifamily Housing Programs—Authority Redelegated

As provided in this Section III, the Assistant Secretary for Housing—Federal Housing Commissioner, Chief of Staff for Housing, General Deputy Assistant Secretary for Housing, and Associate General Deputy Assistant Secretary for Housing retain and redelegate the power and authority (1) to the Deputy Assistant Secretary for Multifamily Housing Programs; (2) through the Deputy Assistant Secretary for Multifamily Housing Programs to the Headquarters Multifamily Program Office Directors listed below; and (3) through the Headquarters Multifamily Program Office Directors to the Headquarters and field Office officials listed below, the following power and authority, as derived from Consolidated Delegation of Authority for the Office of Housing—Federal Housing Administration (FHA).

A. Deputy Assistant Secretary for Multifamily Housing Programs

Authority is redelegated, on a nationwide basis, to take all actions necessary to conduct all multifamily housing programs, including, but not limited to, the exercise of the following functions:

(1) The general power to modify and sign any documents necessary to perform enumerated functions and to waive any directive that is not mandated by a statute or regulation;

(2) All production functions related to mortgage insurance, grants, risk-sharing, or other multifamily programs;

(3) All recapitalization and asset management and portfolio oversight functions related to mortgage insurance, loans, capital advances, or grants, or other programs, including, but not limited to, functions related to Section 8 contract administration and funding, and the renewal of Section 8 contracts and other project-based assistance;

(4) All functions necessary to carry out a competitive grant program;

(5) All functions necessary to carry out a program conducted on a demonstration basis;

(6) All functions necessary to carry out the Rental Assistance Demonstration, Mark-to-Market Program, Green Retrofit Program, and Portfolio Reengineering Demonstration Program;

(7) All property disposition functions;

(8) All functions necessary to the conduct of the Multifamily coinsurance program;

(9) All functions necessary to the conduct of Section 8 contract administration oversight/funding;

(10) All functions necessary to carry out the Self-Help Housing Property Disposition Program;

(11) Authority to issue limited denials of participation; and,

(12) All source selection official functions.

B. Associate Deputy Assistant Secretary for Multifamily Housing Programs

All authority delegated to the Deputy Assistant Secretary for Multifamily Housing Programs under this notice is redelegated to the Associate Deputy Assistant Secretary for Multifamily Housing Programs in the absence or unavailability of the Deputy Assistant Secretary. Further, all authority delegated to the Deputy Assistant Secretary is redelegated to the Associate Deputy Assistant Secretary in those instances where managers and staff of the Office of Multifamily Housing Programs are designated by the Deputy Assistant Secretary to report through the Associate Deputy Assistant Secretary. The authority being redelegated in this subsection is a broad and general authority to take all actions and to perform all functions necessary to conduct all multifamily housing programs on a nationwide basis, including, without limitation, to facilitate Workload Sharing when field staff is required to perform duties outside their geographic jurisdiction, and further, including, without limitation, the authority to redelegate, or withdraw from, any authority delegated under this notice.

C. Director and Deputy Director, Office of Multifamily Production

Authority is redelegated, on a nationwide basis, to take all actions necessary to conduct all multifamily housing programs in relation to the following functions:

(1) The general power to sign any documents necessary to perform enumerated functions and to waive any directive that is not mandated by a statute or regulation;

(2) All production functions related to mortgage insurance or risk-sharing programs; and

(3) All functions necessary to carry out a program conducted on a demonstration basis.

D. Director and Deputy Director, Office of Asset Management and Portfolio Oversight

Authority is redelegated, on a nationwide basis, to take all actions necessary to conduct all multifamily housing programs in relation to the following functions:

(1) The general power to sign any documents necessary to perform enumerated functions and to waive any directive that is not mandated by a statute or regulation;

(2) All asset management and portfolio oversight functions related to mortgage insurance, loans, capital advances, or grants or other programs, including, but not limited to, functions related to Section 8 contract administration and funding, the renewal of Section 8 contracts and other project-based assistance, the transfer of Section 8 budget authority and/or use agreements from one site to another (*e.g.,* pursuant to Section 8bb), and all matters related to Flexible Subsidy Loans;

(3) All functions necessary to carry out competitive grant programs;

(4) All functions necessary to carry out a program conducted on a demonstration basis;

(5) All property disposition functions;

(6) All functions necessary to conduct the multifamily coinsurance program; and

(7) Authority to issue limited denials of participation.

The Deputy Assistant Secretary for Multifamily Housing Programs, through the Director of the Office of Asset Management and Portfolio Oversight further redelegate to the Director of the Field Asset Management and Program Administration Division all powers and authorities to execute any documents necessary to perform enumerated functions related to the modification or release (in part or in full) of regulatory agreement(s) and use agreement(s) for multifamily housing projects and programs.

E. All Regional Directors, Operations Officers, Production Division Directors, Asset Management Division Directors, and Satellite Office Asset Management Division Directors/Satellite Office Coordinators

The authority redelegated authorizes these officials to take all actions necessary to the conduct of all multifamily housing programs, not including the property disposition program, coinsurance program, and M2M, Demo, and Green Retrofit programs. With respect to the M2M, Demo, and Green Retrofit programs, the authority redelegated authorizes these officials to take all actions with respect to an M2M, Demo, or Green Retrofit Program use agreement, loan, or mortgage modification, partial release of security or HUD consent required pursuant to an M2M, Demo, or Green Retrofit transaction document provided that such authority is delegated to such officials by administrative guidance issued from time to time by the Deputy Assistant Secretary or which is consistent with a memorandum issued by the Office of Recapitalization. The authority is further limited in that it may be exercised only within each official's authorized geographic jurisdiction. Accordingly, the Regional Directors, Operations Officers, Production Division Directors, Asset Management Division Directors, and Satellite Office Asset Management Division Directors/Satellite Office Coordinators may exercise the functions enumerated herein with the full geographic jurisdiction of their respective Regional Center, which include all Satellite Office areas under their respective jurisdictions. Designated officials and their staffs are also authorized to engage in Workload Sharing with other jurisdictions when their staffs are performing production and/or asset management/portfolio oversight functions that are otherwise consistent with limitations established in these redelegations. The authority redelegated permits the exercise of the following functions:

(1) Except as specifically stated otherwise in this notice or administrative guidance, the general power to modify and sign any documents necessary to perform functions enumerated herein and to waive any directive that is not mandated by statute or regulation or reserved to Headquarters;

(2) All production functions related to mortgage insurance, grants, or other multifamily housing insurance programs, except as follows:

(a) Operations Officers cannot issue a conditional or firm commitment or endorse FHA notes for insurance;

(b) Production Division Directors, Asset Management Division Directors and Satellite Office Asset Management Division Directors/Satellite Office Coordinators (each a ''Field Division Director'') cannot issue a conditional or firm commitment for mortgage insurance where the principal amount of the mortgage is in excess of $15 million. The Regional Director can issue a firm commitment for mortgage insurance without any limitation related to the principal amount of the mortgage, but such loans may be subject to departmental controls or other required approval(s) before either an application invitation letter or a firm commitment can be issued, depending on program type, project size, loan size, and real estate risk.

(3) The Regional Director may redelegate (and subsequently withdraw), for good cause and with written justification, any authority that may be delegated to a Field Division Director to any Branch Chief within his or her geographic jurisdiction, except that the authority to issue or reissue FHA firm mortgage insurance commitments is limited to no greater than $5 million, and authority to sign firm commitment amendments for commitments greater than $5 million is limited to amendments that do not increase the mortgage amount. Redelegations granted for a limited time period must state either (1) the specific dates or (2) the length of time the redelegated authority will be in effect. Redelegations granted on a case-by-case basis must identify the project, activity, or undertaking involved;

(4) All asset management functions related to mortgage insurance, loans, grants, or other programs, except as follows:

(a) Regional Directors, Operations Officers, Production Division Directors, Asset Management Division Directors and Satellite Office Asset Management Division Directors/Satellite Office Coordinators cannot perform the following functions: (i) authorize the acceleration of the principal debt of a mortgage; (ii) terminate a rent supplement contract or rental assistance contract; (iii) declare a default under an interest reduction payment contract; (iv) authorize a partial payment of claim; (v) authorize a loan or mortgage modification, except a loan or mortgage modification (1) under M2M, Demo, or with respect to a GRP Loan, including a partial release of security under those programs, which is consistent with a memorandum to be issued by the Office of Recapitalization, or in a manner determined by administrative guidance issued from time to time by the Deputy Assistant Secretary, (2)to process an interest rate reduction in accordance with existing or subsequent guidance, or (3) that the Deputy Assistant Secretary for Multifamily Housing Programs may authorize from time to time through the issuance of administrative guidance; (vi) authorize the override of a mortgage lockout provision; or (vii) authorize a prepayment of a HUD-insured or HUD-held mortgage, or voluntary termination of mortgage insurance; except as provided in (v) above or unless specifically authorized to do so by an express redelegation of authority from the Assistant Secretary for Housing—Federal Housing Commissioner, the Chief of Staff for Housing, General Deputy Assistant Secretary for Housing, or Associate General Deputy Assistant Secretary for Housing setting forth any affected programs and terms and conditions applicable thereto.

(b) Operations Officers and Production Division Directors cannot issue (i) a notice of violation under the terms of a regulatory agreement; (ii) a notice of default under the terms of a Section 8 housing assistance payments contract; (iii) an approval of a partial release of security; or (iv) an approval of a release from a residual receipts account.

(5) All functions necessary to carry out competitive capital advance programs;

(6) All functions necessary to carry out a program conducted on a demonstration basis;

(7) Authority to issue limited denials of participation; and

(8) Regional Directors and Satellite Office Asset Management Division Directors/Satellite Office Coordinators are authorized to carry out all source selection official functions for field office-based procurements, provided that the contract amount is less than $10 million.

F. Director of OAMPO Property Disposition Division Only

Authority is redelegated to the Director of Property Disposition Division, on a nationwide basis, to take all actions and perform all functions, including signing any documents in furtherance thereof and issuing waivers of directives not mandated by statute or regulation, necessary to conduct the multifamily and healthcare property disposition program. For the healthcare property program, this authority must be exercised in accordance with guidance established between the Office

of Healthcare Programs and the Office of Multifamily Housing Programs.

Section IV. Office of Recapitalization—Authority Redelegated

A. The Assistant Secretary for Housing—Federal Housing Commissioner, Chief of Staff for Housing, General Deputy Assistant Secretary for Housing, and Associate General Deputy Assistant Secretary for Housing redelegate to the Deputy Assistant Secretary for Multifamily Housing Programs and the Director and Deputy Director of the Office of Recapitalization the following authority:

(1) All authority necessary to carry out the provisions of the Mark-to-Market Program under MAHRA, the Demo Program, the Green Retrofit Program, and Post M2M activities, including shared authority with OAMPO for the sale or disposition of M2M loans, Demo loans, and GRP Loans, and for the full or partial release or amendment of use restrictions associated with M2M, Demo and GRP Loans. The two offices must work together to decide which office is responsible for a particular function associated with such sales, dispositions, or use agreement modifications. The foregoing authorities do not include the authority to issue and/or waive regulations and to sue and be sued.

(2) All asset management functions associated with (i) Section 236 preservation transactions; (ii) the deferral and subordination of the repayment of Operating Assistance Flexible Subsidy Loans and prepayment of Section 236 mortgages (including FHA-insured, non-insured, and HUD-held mortgages), and (iii) other HUD approvals related to Section 236 preservation transactions, including, but not limited to, the following powers and authorities: To process and sign any documents necessary to fulfill the functions associated with Section 236 preservation transactions, including, but not limited to, the following: Prepayments; Interest Reduction Payment (IRP) decouplings and re-decouplings; excess income requirements; modifications to Emergency Low-Income Housing Preservation Act (ELIHPA) and Low-Income Housing Preservation and Resident Homeownership Act (LIHPRHA) use agreements(s); Rent Supplement and Section 236 Rental Assistance Payment contract extensions; unit conversion requests; allowance of nonprofit sales proceeds and distributions; and other related approvals or denials.

(3) To administer all aspects of the Rental Assistance Demonstration (RAD), including, but not limited to, the review of Financing Plans and Conversion Plans, issuance of and amendments to RAD Conversion Commitments (RCCs) and conditional approval letters, amendments to or reissuances of Commitments to enter into Housing Assistance Payments Contracts (CHAPs), multi-phase awards or portfolio awards, execution of RAD conversion transaction documents, and implementation of closings and post-closing activities, with the exception of releases of public housing related Declarations of Trust or Declarations of Restrictive Covenants, which are retained by the Assistant Secretary for Public and Indian Housing and as redelegated under Public Housing delegations of authority, and with the exception of waivers of public housing, Section 8 Project-Based Voucher and/or Section 8 Project-Based Rental Assistance regulations, which are retained by the Assistant Secretary for Housing and/or the Assistant Secretary for Public and Indian Housing, as applicable.

To carry out all functions related to RAD use agreements and contractual restrictions, including consents to liens, approval of changes in ownership, amendment or release of use agreements or contracts, and granting of other consent rights held by HUD. To the extent that these RAD functions overlap authority delegated to OAMPO, the two offices must work together to decide which office is responsible for a particular function.

(4) To execute new project-based rental assistance (PBRA) HAP contracts associated with RAD conversions, including for public housing properties converting under RAD Component 1 and for Rent Supp/RAP, Mod Rehab, Mod Rehab SRO and Section 202 Capital Advance developments with Project Rental Assistance Contracts (202 PRACs), converting under Component 2, and any forthcoming legacy programs for which Congress may create a RAD conversion option. To the extent that these RAD functions overlap authority delegated to OAMPO, the two offices must work together to decide which office is responsible for a particular function.

(5) To release documents related to Section 202 Capital Advance developments with Project Rental Assistance Contracts (202 PRACs), including capital advances and use agreements, to facilitate the execution of new agreements and covenants required for 202 PRAC conversions to RAD.

(6) To administer all aspects of the Senior Preservation Rental Assistance Contract (SPRAC) program, including, but not limited to, the review of submissions requesting SPRAC rental assistance, issuance of conditional and final approval letters, execution of SPRAC transaction documents, and implementation of closings and post-closing activities.

(7) To administer preservation activities with respect to Pre-1974 Section 202 Housing for the Elderly properties, including, but not limited to, review of submissions related to prepayment of the Section 202 Direct Loan, coordination with the Office of Public and Indian Housing regarding the issuance of Section 8 tenant protection vouchers upon prepayment or maturity of the Section 202 Direct Loan and the project-basing of such Section 8 rental assistance, execution of transaction documents, and implementation of closing and post-closing activities.

(8) All functions necessary to carry out competitive grant programs pursuant to the Section 202 Capital Advance program and the Section 514 Tenant Organizing and Education program (including developing the criteria for applications, rating and ranking applications, executing grant agreements, and executing associated project rental assistance contracts), except for the authority to issue a final NOFA or to make grant awards. To the extent the implementation and oversight of the Section 202 Supportive Housing for the Elderly and the Section 514 functions overlap authority delegated herein to the Office of Asset Management and Portfolio Oversight, the two offices must work together to decide which office is responsible for a particular function.

(9) All functions necessary to carry out a program conducted on a demonstration basis.

B. The foregoing redelegations to the Director and Deputy Director of the Office of Recapitalization include, without limitation, the following authority:

(1) To modify and sign any documents necessary to perform enumerated functions and to waive any directive that is not mandated by a statute or regulation.

(2) To administer all provisions of MAHRA, including, but not limited to, the following:

(a) To make eligibility determinations under sections 512 and 516 of MAHRA;

(b) To enter into, modify, and/or extend agreements with participating administrative entities under section 513 of MAHRA;

(c) In connection with a restructuring transaction, to make rent and/or mortgage restructuring determinations under sections 514, 515, 517, and 524 of MAHRA; and

(d) To terminate, modify, or affirm any decision on appeal under MAHRA.

(3) In connection with a restructuring transaction, to modify the principal balance, payments, interest rate, and amortization period and other terms of existing FHA-insured and HUD-held mortgages, including any HUD or Secretary-held subordinate debt encumbering or otherwise related to a project; and to issue restructuring commitments and closing documents relating to such debt.

(4) To issue HUD forms 92264 and 92264A upon approval of a restructuring plan.

(5) In connection with a restructuring transaction, to approve transfers of physical assets.

(6) In connection with a transaction, to approve environmental assessment and compliance findings for related laws report, HUD form 4128 or through the HUD Environmental Review Online System (HEROS).

(7) To issue a commitment to insure and endorse for insurance a mortgage note given to refinance a HUD-insured or HUD-held mortgage, pursuant to sections 223(a)(7) or 223(f) of the National Housing Act (12 U.S.C. 1715n), in accordance with protocol(s) established between the Office of Recapitalization and the Office of Multifamily Production.

(8) For qualified nonprofit entities acquiring projects that are the subject of a restructuring transaction, to modify, assign, or forgive debt created in the restructuring.

(9) To administer escrow accounts and modify the agreement established under the restructuring transaction for the purpose of addressing immediate and near-term rehabilitation needs of a project.

(10) To perform all functions of a source selection official in relation to a procurement under the subject matter jurisdiction of the Office of Recapitalization, subject to laws, regulations, and HUD policies and procedures governing the procurement process.

(11) To administer grant programs, other than selecting a grantee.

(12) To extend the maturity date of and otherwise modify mortgage restructuring notes, contingent repayment notes, Demo notes, and notes evidencing GRP Loans, and approve, in connection with a project's sale or mortgage refinancing, the assumption, modification, and/or subordination of mortgage restructuring notes, contingent repayment notes or Demo notes, previously created during a debt restructuring transaction, and notes evidencing GRP Loans.

(13) To administer all Section 236 prepayments and all processing pursuant to prepayments.

(14) To administer all Rental Assistance Demonstration transactions processed by the Office of Multifamily Housing Programs.

(15) To designate an official to review any appeal, conduct the conference, and issue the written decision in accordance with 24 CFR 401.651.

C. To the Affordable Housing Transaction Division Director and each Affordable Housing Transaction Branch Chief, through the Deputy Assistant Secretary for Multifamily Housing Programs and the Director and Deputy Director of the Office of Recapitalization, the following authority is delegated

(1) To modify and sign any documents necessary to perform enumerated functions and to waive any directive issued by the Office of Recapitalization that is not mandated by a statute or regulation.

(2) To administer the following provisions of MAHRA;

(a) To make eligibility determinations under sections 512 and 516 of MAHRA;

(b) In connection with a restructuring transaction, to make rent and/or mortgage restructuring determinations under sections 514, 515, 517, and 524; and

(c) To reject or hear and decide any appeal made to the transaction branch responsible for M2M under and in accordance with 24 CFR 401.645 or another permissible procedure.

(3) In connection with a restructuring transaction, to modify the principal balance, payments, interest rate, and amortization period and other terms of existing FHA-insured and HUD-held mortgages, including any HUD or Secretary-held subordinate debt encumbering or otherwise related to a project; and to issue restructuring commitments and closing documents relating to such debt.

(4) To issue HUD forms 92264 and 92264A upon approval of a restructuring plan.

(5) In connection with a restructuring transaction, to approve transfers of physical assets.

(6) In connection with a transaction, to approve environmental assessment and compliance findings for related laws report, HUD form 4128 or through the HUD Environmental Review Online System (HEROS).

(7) To issue a commitment to insure and endorse for insurance a mortgage note given to refinance a HUD-insured or HUD-held mortgage, pursuant to sections 223(a)(7) or 223(f) of the National Housing Act (12 U.S.C. 1715n), in accordance with protocol(s) established between the Office of Recapitalization and the Office of Multifamily Production.

(8) To modify and sign any documents necessary to perform enumerated functions related to the rehabilitation needs of a project that was the subject of a restructuring transaction.

(9) To administer escrow accounts and modify the agreement established under the restructuring transaction, for the purpose of addressing immediate and near-term rehabilitation needs of a project.

D. Authority to Redelegate within the Office of Recapitalization. The Director and Deputy Director of the Office of Recapitalization may further redelegate, or withdraw from, any authority delegated to them in this notice to any other Office of Recapitalization official.

Section V. Authority Excepted

The authority redelegated in this notice does not include the authority to issue or to waive HUD regulations. The authority redelegated in this notice does not include the authority to sue or be sued.

Section VI. Further Redelegations

Except as otherwise specified in this notice, the Deputy Assistant Secretary may redelegate, or withdraw from, any authority delegated to the Deputy Assistant Secretary under this notice to any Multifamily Housing Programs official. The Deputy Assistant Secretary for Multifamily Housing Programs is authorized to redelegate authority to Regional Directors outside their geographic jurisdiction, as necessary, to facilitate Workload Sharing when field staff is required to perform duties outside their geographic jurisdiction, but otherwise consistent with the limitations established in this notice. The authority specified in Section III. A, item (10) (the Self-Help Housing Property Disposition Program) may not be further redelegated by the Deputy Assistant Secretary for Multifamily Housing Programs to other officials.

A Regional Director may redelegate to, or withdraw from any official within his or her geographic jurisdiction and expanded geographic jurisdiction as authorized by the Deputy Assistant Secretary for Multifamily Housing Programs, any authority delegated to the Regional Director under this notice except:

(a) A Regional Director has limited authority to redelegate the authority to issue FHA conditional or firm mortgage insurance commitments, as set forth in

Section III(D)(3) of these redelegations; and

(b) a Regional Director may not further redelegate the authority which is delegated to Regional Directors, Asset Management Division Directors, and Satellite Office Asset Management Division Directors/Satellite Office Coordinators to issue: (i) A notice of violation under the terms of a regulatory agreement; (ii) a notice of default under the terms of a Section 8 housing assistance payments contract; (iii) an approval of a partial release of security; or (iv) an approval of a release from a residual receipts account.

Except as stated otherwise herein, the authority redelegated to Operations Officers, Production Division Directors, Asset Management Division Directors, and Satellite Office Asset Management Division Directors/Satellite Office Coordinators may not be further redelegated by those officials.

Section VII. Revocation of Delegations

All prior redelegations of authority to the Deputy Assistant Secretary and other staff in the Office of Multifamily Housing Programs are hereby superseded. The Assistant Secretary for Housing—Federal Housing Commissioner, Chief of Staff for Housing, General Deputy Assistant Secretary for Housing, and Associate General Deputy Assistant Secretary for Housing may, at any time, revoke any of the authority redelegated in this notice. Notice of any revocation will be published in the **Federal Register**.

Section VIII. Ratification

All actions previously taken before publication of this notice by the specified HUD officials consistent with the authorities described herein are ratified.

Authority: Section 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dana T. Wade,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2020–26224 Filed 11–25–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[201A2100DD/AAKC001030/A0A501010.999900 253G; OMB Control Number 1076–0114]

Agency Information Collection Activities; Application for Admission to Haskell Indian Nations University and to Southwestern Indian Polytechnic Institute

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Education (BIE) is proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before January 26, 2021.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Ms. Juanita Mendoza, U.S. Department of the Interior, Bureau of Indian Education, 1849 C Street NW, Washington, DC 20240; fax: (202) 208–3312; email: *Juanita.Mendoza@bie.edu.* Please reference OMB Control Number 1076–0114 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Dr. Sherry Allison, with Southwestern Indian Polytechnic Institute, by email at *Sherry.Allison@bie.edu* or LouEdith Hara, with Haskell Indian Nations University, by email at *lhara@haskell.edu.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the BIE; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BIE enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BIE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The BIE is requesting approval for the admission forms for Haskell Indian Nations University (Haskell) and Southwest Indian Polytechnic Institute (SIPI). These admission forms are used in determining program eligibility of American Indian and Alaska Native students for educational services. These forms are utilized pursuant to the Blood Quantum Act, Public Law 99–228; the Snyder Act, Chapter 115, Public Law 67–85; and, the Indian Appropriations of the 48th Congress, Chapter 180, page 91, For Support of Schools, July 4, 1884. Submission of these eligibility application forms is mandatory in determining a student's eligibility for educational services. The information is collected on three forms: The Application for Admission to Haskell form and the Application for Admission to SIPI form are already approved forms, and the Haskell Dual Enrollment application is a new collection instrument.

Title of Collection: Application for Admission to Haskell Indian Nations University and Southwestern Indian Polytechnic Institute.

OMB Control Number: 1076–0114.

Form Number: None.

Type of Review: Renewal of an information collection with revisions.

Respondents/Affected Public: Students.

Total Estimated Number of Annual Respondents: 4,100 per year, on average (1,000 respondents for the Application for Admission to Haskell Indian Nations University, 100 respondents for the Haskell Indian Nations University Dual Enrollment Application, and 3,000 respondents for the Southwestern Indian Polytechnic Institute application).

Total Estimated Number of Annual Responses: 4,100 per year, on average.

Estimated Completion Time per Response: 20 minutes for the Application for Admission to Haskell Indian Nations University, 20 minutes for the Haskell Indian Nations University Dual Enrollment Application, and 30 minutes for the Southwestern Indian Polytechnic Institute application.

Total Estimated Number of Annual Burden Hours: 1,867 hours.

Respondent's Obligation: Response is required to obtain a benefit.

Frequency of Collection: Each semester for the Application for Admission to Haskell Indian Nations University, each semester for the Haskell Indian Nations University Dual Enrollment Application, and each trimester for the Southwestern Indian Polytechnic Institute application.

Total Estimated Annual Nonhour Burden Cost: $10,000.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2020–26185 Filed 11–25–20; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[19X.LLID930000.L11700000.DF0000. LXSGPL000000.241A.4500132602]

Notice of Availability of the Final Programmatic Environmental Impact Statement for Fuels Reduction and Rangeland Restoration in the Great Basin; Idaho, Washington, Oregon, California, Nevada and Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, the Bureau of Land Management (BLM) has prepared a Final Programmatic Environmental Impact Statement (EIS) for Fuels Reduction and Rangeland Restoration in the Great Basin and by this notice is announcing its availability.

DATES: The BLM will not issue a final decision on the proposal for a minimum of 30 days after the date that the Environmental Protection Agency publishes its Notice of Availability (NOA) in the **Federal Register**.

ADDRESSES: Copies of the Final Programmatic EIS for Fuels Reduction and Rangeland Restoration in the Great Basin are available for public inspection during regular business hours at 1387 South Vinnell Way, Boise ID 83709. Interested persons may also review the Final Programmatic EIS online at: *https://go.usa.gov/x79bp.* Additional copies can be made available at the Oregon/Washington, California, Nevada and Utah BLM State Offices upon request.

FOR FURTHER INFORMATION CONTACT: Shannon Bassista, telephone 208–373–3845; address BLM Idaho State Office, 1387 South Vinnell Way, Boise ID 83709; email *sbassista@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Intact sagebrush communities are disappearing within the Great Basin due to the interactions of increased wildfires, the spread of invasive annual grasses, and the encroachement of pinyon-juniper. Fuels reduction treatments and rangeland restoration treatments are needed to increase intact sagebrush communities and improve their ability to resist annual grass invasion and recover from disturbance such as wildfire. Functioning and viable sagebrush communities provide multiple-use opportunities for all user groups as well as habitat for sagebrush-dependent species.

The Programmatic EIS analzyes the environmental effects of fuels reduction projects, invasive species treatments, and vegetation restoration work within sagebrush communities. The preferred alternative (Alternative B) analyzes a full suite of manual, chemical and mechanical treatments, including prescribed fire, seeding, and targeted grazing, in order to restore degraded vegetative communities within the 38.5 million-acre sagebrush analysis area. The preferred alternative provides a framework under which BLM offices may work to develop site-specific fuels reduction and rangeland restoration treatments within the project area.

The NOA for the Draft Programmatic EIS published on April 3, 2020, initiating a 60-day public comment period. The BLM hosted a virtual public meeting website to share information about the proposed project and alternatives and to answer questions. The public was able to comment online through ePlanning, through the virtual public meeting website, via a project email address, or by postal mail. The BLM received 1,270 comment form letters and 144 unique comment letters. Comments on the Draft Programmatic EIS received from the public and internal BLM review were considered and incorporated as appropriate into the Final Programmatic EIS. Public comments resulted in the addition of clarifying text, but did not significantly change the alternatives or analysis.

(Authority: 40 CFR 1506.6, 40 CFR 1506.11 (2020))

John F. Ruhs,

Idaho State Director, Bureau of Land Management.

[FR Doc. 2020–26146 Filed 11–25–20; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVW01000.L144000000.FR0000.241A; 14110008; TAS: 18X; N–60081 MO#4500145980]

Notice of Realty Action: Non-Competitive Direct Sale of the Reversionary Interest and Mineral Interest in a Recreation and Public Purpose Act Patent, in Pershing County, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action.

SUMMARY: The Bureau of Land Management (BLM) intends to dispose of the reversionary interest held by the United States in a 10-acre parcel of public land in Pershing County, Nevada, pursuant to Section 203 and Section 209 of the Federal Land Policy and Management Act of October 21, 1976 (FLPMA), as amended, through a non-competitive direct sale to Pershing County. The BLM has found the reversionary interest and conveyance of the mineral interest suitable for disposal under the authority of Section 203 and Section 209 of FLPMA.

DATES: Interested parties may submit written comments regarding the direct sale on or before January 11, 2021.

ADDRESSES: Send written comments to the BLM Humboldt River Field Manager, 5100 East Winnemucca

Boulevard, Winnemucca, NV 89445, or by email to *wfoweb@blm.gov.*

FOR FURTHER INFORMATION CONTACT: Realty Specialist Julie McKinnon at the above address, by phone at 775–623–1734, or by email at *jmckinno@blm.gov.* Persons who use telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 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 BLM patented the land to Pershing County under the Recreation and Public Purposes (R&PP) Act on May 29, 2020, with a reversionary interest to maintain, preserve, and improve the cemetery. In March 2020, while that patent was being processed, Pershing County also requested to purchase the reversionary and mineral interest.

The Unionville Cemetery dates to the 1860s when Unionville was a thriving mining camp and the seat of Humboldt County, prior to the division of Humboldt County to create Pershing County in 1919. Although it is a historic cemetery with many marked and unmarked historic graves, the residents of Unionville have used it through the present for the burial of family members.

The parcel is located on the lands described below in Pershing County, Nevada:

Mount Diablo Meridian, Nevada

T. 30 N., R. 34 E.,
Sec. 24, SE¼NW¼SE¼SW¼,
SW¼NW¼SE¼SW¼,
NE¼SW¼SE¼SW¼, and
NW¼SW¼SE¼SW¼.

The area described contains 10-acres.

The proposed non-competitive direct sale of the reversionary interest and conveyance of the mineral interest is consistent with the BLM Winnemucca Resource Management Plan (RMP) and the Record of Decision (ROD) approved in May 2015.

The BLM determined that the 10-acre cemetery parcel is suitable for disposal pursuant to Section 203 and Section 209 of FLPMA, as amended, which authorizes a sale of public lands when the Secretary determines that the proposed sale parcel, ''because of its location or other characteristics is difficult and uneconomic to manage as part of the public lands, and is not suitable for management by another Federal department or agency.'' The parcel is not needed for any Federal purposes; therefore, the BLM believes its disposal is in the public interest.

Pershing County has used a portion of the subject land for purposes of a cemetery, so the BLM would not wish to retain this parcel of land. The BLM determined the parcel met the criteria for disposal set forth in 43 CFR 2710.0–3(a)(3).

The land meets the criteria for direct sale under 43 CFR 2711.3–3(a), ''Direct sales may be utilized, when in the opinion of the Authorized Officer, a competitive sale is not appropriate and the public interest would best be served by a direct sale.'' Consistent with FLPMA Section 203(a)(3), ''Disposal of such tract will serve important public objectives, including but not limited to expansion of communities and economic development . . .'' The land also meets the criteria for conveyance of the Federally owned minerals under 43 CFR 2720.1–1 ''Any existing or prospective record owner of the surface of land in which mineral interests are reserved or otherwise owned by the United State may file an application to purchase such mineral interests if—(1) He has reason to believe there are no known mineral values in the land . . .'' and 2720.1–2 consistent with FLPMA Section 209 (b)(1) ''The Secretary, after consultation with the appropriate department or agency head, may convey mineral interests owned by the United States . . .'' ''. . . if [the Secretary] finds (1) that there are no known mineral values in the land . . .'' The parcel is within the boundaries of the town of Unionville, and Pershing County uses a portion of the subject lands for cemetery purposes. This cemetery use makes it impractical for the BLM to administer the subject lands. Therefore, the BLM believes it is in the best interest of the public to sell the reversionary interest to Pershing County by direct sale procedures pursuant to 43 CFR 2711.3–3 and 2720.1–1 and 2720.1–2.

The BLM will not offer the sale of the reversionary interest and mineral interest to Pershing County until at least January 11, 2021 at no less than the appraised fair market value of $3,250. Conveyance of the identified public land interest would be subject to valid existing rights of record and the following terms, conditions and reservations: The conveyance document issued will only transfer the reversionary interest and mineral interest retained by the United States in Patent No. 27–2020–0026 and will contain the following terms, conditions, and reservations:

1. A right-of-way thereon for ditches and canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945);

2. Right-of-way N–59759 for road purposes, granted to Pershing County, its successor or assigns, pursuant to the Act of October 21, 1976 (43 U.S.C. 1761);

3. An appropriate indemnification clause protecting the United States from claims arising out the patentee's use, occupancy, or occupations on the patented lands; and

4. Additional terms and conditions that the authorized officer deems appropriate.

No warranty of any kind, express or implied, is given by the United States in connection with the sale or release of the reversionary interest and mineral interest. The documentation for land use conformance, NEPA procedures, a map, environmental assessment, and the appraisal report, are available for review at the BLM Winnemucca District Office located at the address listed above. The BLM prepared an Environmental Assessment (EA) document with the number DOI–BLM–NV–W010–2017–0007–EA in connection with the sale of these lands. The following is a link to the EA. *https://eplanning.blm.gov/public_projects/nepa/77517/132167/161291/1-16-18_EA.pdf*

Interested parties may submit written comments on the direct sale of the reversionary interest and conveyance of the mineral interest for the 10-acre parcel. Before including your address, phone number, email address, or other personally identifying information in your comment, you should be aware that your entire comment—including your personally identifying information—may be made publicly available at any time. While you can ask the BLM in your comment to withhold your personally identifying information from public review, we cannot guarantee that we will be able to do so.

Any adverse comments will be reviewed by the BLM Nevada State Director who may sustain, vacate, or modify this realty action. In the absence of timely, filed objections, the decision will become effective on January 11, 2021.

(Authority: 43 CFR 2711.1–2)

Ester M. McCullough,

Winnemucca District Manager.

[FR Doc. 2020–26153 Filed 11–25–20; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–GATE–29632; PPNEGATEB0, PPMVSCS1Z.Y00000]

Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee

AGENCY: National Park Service, Interior.

ACTION: Notice of reestablishment.

SUMMARY: The Secretary of the Interior is giving notice of reestablishment of the Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee. The Committee provides advice on the development of a specific reuse plan and on matters relating to the future uses of the Fort Hancock Historic Landmark District within the Sandy Hook Unit of Gateway National Recreation Area.

FOR FURTHER INFORMATION CONTACT: Daphne Yun, Acting Public Affairs Officer, Gateway National Recreation Area, 210 New York Avenue, Staten Island, New York 10305, or by telephone (718) 815–3651, or by email *daphne_yun@nps.gov.*

SUPPLEMENTARY INFORMATION: This notice is published in accordance with Section 9(a)(2) of the Federal Advisory Committee Act of 1972 (Pub. L. 92–463, as amended).

Certification Statement: I hereby certify that the reestablishment of the Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee is necessary and in the public interest in connection with the performance of duties imposed on the Department of the Interior by the National Park Service Organic Act (54 U.S.C. 100101(a) *et seq.*), and other statutes relating to the administration of the National Park Service.

Dated: November 18, 2020.

David L. Bernhardt,

Secretary of the Interior.

[FR Doc. 2020–26216 Filed 11–25–20; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–463 and 731–TA–1159 (Second Review)]

Oil Country Tubular Goods From China

Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the countervailing and antidumping duty orders on oil country tubular goods from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on April 1, 2020 (85 FR 18268, April 1, 2020) and determined on July 6, 2020 that it would conduct expedited reviews (85 FR 64161, October 9, 2020).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on November 20, 2020. The views of the Commission are contained in USITC Publication 5136 (November 2020), entitled *Oil Country Tubular Goods from China: Investigation Nos. 701–TA–463 and 731–TA–1159 (Second Review).*

By order of the Commission.

Issued: November 20, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–26141 Filed 11–25–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–643 and 731–TA–1493 (Final)]

Small Vertical Shaft Engines From China; Scheduling of the Final Phase of Countervailing and Antidumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–643 and 731–TA–1493 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of small vertical shaft engines from China, provided for in subheadings 8407.90.10, 8409.91.99, 8433.11.00, 8424.30.90, and 8407.90.90 of the Harmonized Tariff Schedule of the United States, preliminarily determined by the Department of Commerce (''Commerce'') to be subsidized and sold at less-than-fair-value.

DATES: October 21, 2020.

FOR FURTHER INFORMATION CONTACT: Charles Cummings ((202) 708–1666), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Scope.— For purposes of these investigations, Commerce has defined the subject merchandise as spark-ignited, nonroad, vertical shaft engines, whether finished or unfinished, whether assembled or unassembled, whether mounted or unmounted, primarily for walk-behind lawn mowers. Engines meeting this physical description may also be for other non-handheld outdoor power equipment, including but not limited to, pressure washers. The subject engines are spark ignition, single-cylinder, air cooled, internal combustion engines with vertical power take off shafts with a minimum displacement of 99 cubic centimeters (cc) and a maximum displacement of up to, but not including, 225cc. Typically, engines with displacements of this size generate gross power of between 1.95 kilowatts (kw) to 4.75 kw. Engines covered by this scope normally must comply with and be certified under Environmental Protection Agency (EPA) air pollution controls title 40, chapter I, subchapter U, part 1054 of the Code of Federal Regulations standards for small nonroad spark-ignition engines and equipment. Engines that otherwise meet the physical description of the scope but are not certified under 40 CFR part 1054 and are not certified under other parts of subchapter U of the EPA air pollution controls are not excluded from the scope of this proceeding. Engines that may be certified under both 40 CFR part 1054 as well as other parts of subchapter U remain subject to the scope of this proceeding.

Certain small vertical shaft engines, whether or not mounted on non-hand-

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

held outdoor power equipment, including but not limited to walk-behind lawn mowers and pressure washers, are included in the scope. However, if a subject engine is imported mounted on such equipment, only the engine is covered by the scope. Subject merchandise includes certain small vertical shaft engines produced in the subject country whether mounted on outdoor power equipment in the subject country or in a third country. Subject engines are covered whether or not they are accompanied by other parts.

For purposes of these investigations, an unfinished engine covers at a minimum a sub-assembly comprised of, but not limited to, the following components: Crankcase, crankshaft, camshaft, piston(s), and connecting rod(s). Importation of these components together, whether assembled or unassembled, and whether or not accompanied by additional components such as a sump, carburetor spacer, cylinder head(s), valve train, or valve cover(s), constitutes an unfinished engine for purposes of these investigations. The inclusion of other products such as spark plugs fitted into the cylinder head or electrical devices (*e.g.,* ignition coils) for synchronizing with the engine to supply tension current does not remove the product from the scope. The inclusion of any other components not identified as comprising the unfinished engine subassembly in a third country does not remove the engine from the scope. Specifically excluded from the scope of these investigations are ''Commercial'' or ''Heavy Commercial'' engines under 40 CFR 1054.107 and 1054.135 that have (1) a displacement of 160 cc or greater, (2) a cast iron cylinder liner, (3) an automatic compression release, and (4) a muffler with at least three chambers and volume greater than 400 cc.

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of affirmative preliminary determinations by Commerce that certain benefits which constitute subsidies within the meaning of § 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in China of small vertical shaft engines, and that such products are being sold in the United States at less than fair value within the meaning of § 733 of the Act (19 U.S.C. 1673b). The investigations were requested in petitions filed on March 18, 2020, by Briggs & Stratton Corporation, Wauwatosa, Wisconsin.

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on February 23, 2021, and a public version will be issued thereafter, pursuant to § 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on Tuesday, March 9, 2021. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.* Interested parties should check the Commission's website periodically for updates. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before Wednesday, March 3, 2021. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on Friday, March 5, 2021, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.23 of the Commission's rules; the deadline for filing is March 2, 2021. Parties may also file written testimony in connection with their presentation at the hearing, as provided in § 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of § 207.25 of the Commission's rules. The deadline for filing posthearing briefs is March 15, 2021. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petitions, on or before March 15, 2021. On March 30, 2021, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before April 1, 2021, but such final comments must not contain new factual information and must otherwise comply with § 207.30 of the Commission's rules. All written submissions must conform with the provisions of § 201.8 of the

Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to § 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: November 20, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–26147 Filed 11–25–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–645 and 731–TA–1495–1501 (Final)]

Mattresses From Cambodia, China, Indonesia, Malaysia, Serbia, Thailand, Turkey, and Vietnam; Scheduling of the Final Phase of Countervailing Duty and Antidumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–645 and 731–TA–1495–1501 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of mattresses from Cambodia, Indonesia, Malaysia, Serbia, Thailand, Turkey, and Vietnam, provided for in subheadings 9404.21.00, 9404.29.10, 9404.29.90, 9401.40.00, and 9401.90.50 of the Harmonized Tariff Schedule of the United States, preliminarily determined by the Department of Commerce (''Commerce'') to be sold in the United States at less than fair value and imports of mattresses from China preliminarily determined by Commerce to be subsidized by the Government of China.

DATES: November 3, 2020.

FOR FURTHER INFORMATION CONTACT: Mary Messer ((202) 205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Scope.—For purposes of these investigations, Commerce has defined the subject merchandise as follows:

''. . . all types of youth and adult mattresses. The term ''mattress'' denotes an assembly of materials that at a minimum includes a ''core,'' which provides the main support system of the mattress, and may consist of innersprings, foam, other resilient filling, or a combination of these materials. Mattresses may also contain: (1) ''Upholstery,'' the material between the core and the top panel of the ticking on a single-sided mattress; or between the core and the top and bottom panel of the ticking on a double-sided mattress; and/or (2) ''ticking,'' the outermost layer of fabric or other material (*e.g.,* vinyl) that encloses the core and any upholstery, also known as a cover.

The scope of this investigation is restricted to only ''adult mattresses'' and ''youth mattresses.'' ''Adult mattresses'' are frequently described as ''twin,'' ''extra-long twin,'' ''full,'' ''queen,'' ''king,'' or ''California king'' mattresses. ''Youth mattresses'' are typically described as ''crib,'' ''toddler,'' or ''youth'' mattresses. All adult and youth mattresses are included regardless of size and size description.

The scope encompasses all types of ''innerspring mattresses,'' ''non-innerspring mattresses,'' and ''hybrid mattresses.'' ''Innerspring mattresses'' contain innersprings, a series of metal springs joined together in sizes that correspond to the dimensions of mattresses. Mattresses that contain innersprings are referred to as ''innerspring mattresses'' or ''hybrid mattresses.'' ''Hybrid mattresses'' contain two or more support systems as the core, such as layers of both memory foam and innerspring units.

''Non-innerspring mattresses'' are those that do not contain any innerspring units. They are generally produced from foams (*e.g.,* polyurethane, memory (viscoelastic), latex foam, gel- infused viscoelastic (gel foam), thermobonded polyester, polyethylene) or other resilient filling.

Mattresses covered by the scope of this investigation may be imported independently, as part of furniture or furniture mechanisms (*e.g.,* convertible sofa bed mattresses, sofa bed mattresses imported with sofa bed mechanisms, corner group mattresses, day-bed mattresses, roll-away bed mattresses, high risers, trundle bed mattresses, crib mattresses), or as part of a set in combination with a ''mattress foundation.'' ''Mattress foundations'' are any base or support for a mattress. Mattress foundations are commonly referred to as ''foundations,'' ''boxsprings,'' ''platforms,'' and/or ''bases.'' Bases can be static, foldable, or adjustable. Only the mattress is covered by the scope if imported as part of furniture, with furniture mechanisms, or as part of a set in combination with a mattress foundation.

Excluded from the scope of this investigation are ''futon'' mattresses. A ''futon'' is a bi-fold frame made of wood, metal, or plastic material, or any combination thereof, that functions as both seating furniture (such as a couch, love seat, or sofa) and a bed. A ''futon mattress'' is a tufted mattress, where the top covering is secured to the bottom with thread that goes completely through the mattress from the top through to the bottom, and it does not contain innersprings or foam. A futon mattress is both the bed and seating surface for the futon.

Also excluded from the scope are airbeds (including inflatable mattresses) and waterbeds, which consist of air- or liquid-filled bladders as the core or main support system of the mattress.

Also excluded is certain multifunctional furniture that is

convertible from seating to sleeping, regardless of filler material or components, where that filler material or components are upholstered, integrated into the design and construction of, and inseparable from, the furniture framing, and the outermost layer of the multifunctional furniture converts into the sleeping surface. Such furniture may, and without limitation, be commonly referred to as ''convertible sofas,'' ''sofabeds,'' ''sofa chaise sleepers,'' ''futons,'' ''ottoman sleepers'' or a like description.

Also excluded from the scope of this investigation are any products covered by the existing antidumping duty orders on uncovered innerspring units from China or Vietnam. See Uncovered Innerspring Units from the People's Republic of China: Notice of Antidumping Duty Order, 74 FR 7661 (February 19, 2009); Uncovered Innerspring Units from the Socialist Republic of Vietnam, 73 FR 75391 (December 11, 2008).

Also excluded from the scope of this investigation are bassinet pads with a nominal length of less than 39 inches, a nominal width less than 25 inches, and a nominal depth of less than 2 inches.

Additionally, also excluded from the scope of this investigation are ''mattress toppers.'' A ''mattress topper'' is a removable bedding accessory that supplements a mattress by providing an additional layer that is placed on top of a mattress. Excluded mattress toppers have a height of four inches or less.

The products subject to this investigation are currently . . . classifiable under HTSUS subheadings: 9404.21.0010, 9404.21.0013, 9404.29.1005, 9404.29.1013, 9404.29.9085, and 9404.29.9087. Products subject to this investigation may also enter under HTSUS subheadings: 9404.21.0095, 9404.29.1095, 9404.29.9095, 9401.40.0000, and 9401.90.5081. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this investigation is dispositive.''

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of affirmative preliminary determinations by Commerce that certain benefits which constitute subsidies within the meaning of § 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in China of mattresses, and that such products imported from Cambodia, Indonesia, Malaysia, Serbia, Thailand, Turkey, and Vietnam are being sold in the United States at less than fair value within the meaning of § 733 of the Act (19 U.S.C. 1673b). The investigations were requested in petitions filed on March 31, 2020, by Brooklyn Bedding (Phoenix, Arizona), Corsicana Mattress Company (Dallas, Texas), Elite Comfort Solutions (Newnan, Georgia), FXI, Inc. (Media, Pennsylvania), Innocor, Inc. (Media, Pennsylvania), Kolcraft Enterprises, Inc. (Chicago, Illinois), Leggett & Platt, Incorporated (Carthage, Missouri), the International Brotherhood of Teamsters (Washington, DC), and United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO (Washington, DC).

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on March 4, 2021, and a public version will be issued thereafter, pursuant to § 207.22 of the Commission's rules.

Hearing.— The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on Thursday, March 18, 2021. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.* Interested parties should check the Commission's website periodically for updates. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before Friday, March 12, 2021. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on Tuesday, March 16, 2021. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.23 of the Commission's rules; the deadline for filing is March 11, 2021. Parties may also file written testimony in connection with their presentation at the hearing, as provided in § 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of § 207.25 of the Commission's rules. The deadline for filing posthearing briefs is March 25,

2021. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before March 25, 2021. On April 14, 2021, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before April 16, 2021, but such final comments must not contain new factual information and must otherwise comply with § 207.30 of the Commission's rules. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to § 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: November 20, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–26164 Filed 11–25–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Open Source Imaging Consortium, Inc.

Notice is hereby given that, on November 13, 2020, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Open Source Imaging Consortium, Inc. (''Open Source Imaging Consortium'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Vida Diagnostics, Inc., Coralville, IA; and University of Genoa, Genoa, ITALY, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Open Source Imaging Consortium intends to file additional written notifications disclosing all changes in membership.

On March 20, 2019, Open Source Imaging Consortium filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 12, 2019 (84 FR 14973).

The last notification was filed with the Department on August 19, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 28, 2020 (85 FR 53402).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2020–26188 Filed 11–25–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–744]

Importer of Controlled Substances Application: Meridian Medical Technologies

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Meridian Medical Technologies has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before December 28, 2020. Such persons may also file a written request for a hearing on the application on or before December 28, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on November 3, 2020, Meridian Medical Technologies, 2555 Hermelin Drive, Saint Louis, Missouri 63144, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Morphine	9300	II

The company manufactures a product containing morphine in the United States. The company exports this product to customers around the world. The company has been asked to ensure that its product, which is sold to

European customers, meets the standards established by the European Pharmacopeia, administered by the Directorate for the quality of Medicines (EDQM). In order to ensure that its product will meet European specifications, the company seeks to import morphine supplied by EDQM for use as reference standards. No other activity for these drug codes is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–26172 Filed 11–25–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–743]

Bulk Manufacturer of Controlled Substances Application: Novitium Pharma LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Novitium Pharma LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before January 26, 2021. Such persons may also file a written request for a hearing on the application on or before January 26, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on November 2, 2020, Novitium Pharma LLC, 70 Lake Drive, East Windsor, New Jersey 08520, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Levorphanol	9220	II

The company plans to bulk manufacture the above-controlled substance to support production of the company's Food and Drug Administration approved drug product. No other activity for this drug code is authorized for this registration.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–26171 Filed 11–25–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–746]

Importer of Controlled Substances Application: Noramco Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Noramco Inc. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before December 28, 2020. Such persons may also file a written request for a hearing on the application on or before December 28, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on October 23, 2020, Noramco Inc., 500 Swedes Landing Road, Wilmington, Delaware, 19801–4417, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Nabilone	7379	II
Phenylacetone	8501	II
Opium, Raw	9600	II
Poppy Straw Concentrate	9670	II
Tapentadol	9780	II

The company plans to import Phenylacetone (8501), and Poppy Straw Concentrate (9670) to bulk manufacture other controlled substances for distribution to its customers. The company plans to import an intermediate form of Tapentadol (9780) to bulk manufacture Tapentadol for distribution to its customers. In reference to drug codes 7360 (Marihuana) and 7370 (Tetrahydrocannabinols), the company plans to import a synthetic cannabidiol and a synthetic Tetrahydrocannabinol. No other activity for these drug codes is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–26174 Filed 11–25–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–742]

Importer of Controlled Substances Application: Lyndra Therapeutics

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Lyndra Therapeutics has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on

or before December 28, 2020. Such persons may also file a written request for a hearing on the application on or before December 28, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on October 22, 2020, Lyndra Therapeutics, 65 Grove Street, Suite 301, Watertown, Massachusetts 02472, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Methadone	9250	II

The company plans to develop the formulation and process, and then manufacture the finished oral dosage form for use in preclinical and human clinical trials under a research grant from National Institute on Drug Abuse. No other activity for these drug codes is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–26175 Filed 11–25–20; 8:45 am]

BILLING CODE P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (20–097)]

NASA Advisory Council; Science Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of revised dates for meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces revised dates for the upcoming meeting of the Science Committee of the NASA Advisory Council (NAC).

DATES: Tuesday, December 1, 2020, 1:00 p.m.–5:00 p.m., and Wednesday, December 2, 2020, 1:00–5:15 p.m., Eastern Time.

FOR FURTHER INFORMATION CONTACT: Ms. KarShelia Henderson, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2355 or *khenderson@nasa.gov.*

SUPPLEMENTARY INFORMATION: The original meeting notice was published in the **Federal Register** on Friday, November 13, 2020 in Vol. 85, No. 220 on page 72703. This meeting will now take place on two days (December 1–2, 2020), rather than on three days (December 1–3, 2020). The Science Committee reports to the NAC. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning. This meeting will be open to the public via Webex and telephonically. Webex connectivity information for each day is provided below. For audio, when you join the Webex event, you may use your computer or provide your phone number to receive a call back, otherwise, call the U.S. toll conference number listed for each day. On Tuesday, December 1, the event address for attendees is: *https://nasaenterprise.webex.com/nasaenterprise/onstage/g.php?MTID=ec9f04af53099d097214a64cf178fc2ed.* The event number is 199 056 0375 and the event password is wfSEe8uH5*3. If needed, the U.S. toll conference number is 1–415–527–5035 and access code is 199 056 0375. On Wednesday, December 2, the event address for attendees is: *https://nasaenterprise.webex.com/nasaenterprise/onstage/g.php?MTID=e51f38c7ac92a01577c5f697d7d1b4c5f.* The event number is 199 748 1916 and the event password is EswGXYZ@742. If needed, the U.S. toll conference number is 1–415–527–5035 and access code is 199 748 1916.

The agenda for the meeting includes the following topics:

—Science Mission Directorate (SMD) Missions, Programs and Activities

It is imperative that the meeting be held on these dates due to the scheduling priorities of the key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2020–26244 Filed 11–25–20; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL LABOR RELATIONS BOARD

Privacy Act of 1974; System of Records

AGENCY: National Labor Relations Board (NLRB).

ACTION: Notice of a new privacy act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the National Labor Relations Board proposes to issue a National Labor Relations Board system of records notice titled ''NLRB iTrak and Banned Entry List'' (NLRB–34) to support the protection of employees, contractors, and property leased, or occupied, by the National Labor Relations Board. This system of records includes the NLRB's iTrak Incident & Security Management Software System (''iTrak''), which is used to manage information on individuals who have been reported to present a threat or potential threat to NLRB employees, contractors, and property, as well as a Banned Entry List, which is a list of individuals banned from entering NLRB facilities based on information in iTrak. The system allows the National Labor Relations Board to collect and maintain records on the results of law enforcement activities concerning individuals maintaining a presence at or who have access to property leased or occupied by the NLRB and who have been reported to present a threat as described above. The NLRB is issuing this system of records notice in compliance with the Privacy Act of

1974. This issued system notice will be included in the NLRB inventory of record systems. All persons are advised that, in the absence of submitted comments considered by the Agency as warranting modification of the notice as here proposed, it is the intention of the Agency that the notice shall be effective upon expiration of the comment period without further action.

DATES: Written comments on the system's routine uses must be submitted on or before December 28, 2020. This system will be effective upon publication. The routine uses in this action will become effective on December 28, 2020 unless written comments are received that require a contrary determination.

ADDRESSES: All persons who desire to submit written comments for consideration by the Agency in connection with this proposed notice of the amended system of records shall mail them to the Agency's Senior Agency Official for Privacy, National Labor Relations Board, 1015 Half Street SE, Third Floor, Washington, DC 20570–0001, or submit them electronically to *privacy@nlrb.gov*. Comments may also be submitted electronically through *http://www.regulations.gov,* which contains a copy of this proposed notice and any submitted comments.

FOR FURTHER INFORMATION CONTACT: For general questions and privacy issues please contact: Virginia Ephraim, Privacy and Information Security Specialist, Office of the Chief Information Officer, National Labor Relations Board, 1015 Half Street SE, Third Floor, Washington, DC 20570–0001, (202) 273–3733, or at *privacy@nlrb.gov*.

SUPPLEMENTARY INFORMATION: The Agency exempts a new system of records, NLRB–34, NLRB iTrak and Banned Entry List, from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I), and (f). The Agency is claiming exemptions pursuant to Section 5 U.S.C. 552a(k)(1), (2), and (5) of that Act. The Agency's Direct Final Rule setting forth these exemptions appears elsewhere in this issue of the **Federal Register**.

In accordance with 5 U.S.C. 552a(r), the NLRB has provided a report of this system of records to Congress and to the Office of Management and Budget.

NLRB–34

SYSTEM NAME:

NLRB iTrak and Banned Entry List.

SECURITY CLASSIFICATION:

Most of the iTrak and Banned Entry List records are not classified. However, limited records of individuals, or portions of records, may be classified in the interest of national security.

SYSTEM LOCATION:

Records are maintained at the National Labor Relations Board Headquarters in Washington, DC and in NLRB field locations, which are available at *https://www.nlrb.gov/who-we-are/regional-offices.*

SYSTEM MANAGER:

For all locations: Chief Security Officer, Security Branch, (202) 273–1990, 1015 Half Street SE, Washington, DC 20570–0001.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Executive Order 12958, as amended by Executive Order 13292; Title 5 U.S.C. 552a(e)(10); Title 44 U.S.C. chapters 21 and 33. These statutes and Executive Orders are directed toward security of United States Government records maintained by federal agencies. Title 40 U.S.C. section 1315, and title 41 CFR 102–81.10 and 81.15. This statute and the federal regulations are directed toward security of United States Government buildings and the people working at and visiting such buildings.

PURPOSES OF THE SYSTEM:

The purpose of this system is to maintain and record the results of law enforcement activities in support of the protection of NLRB employees and contractors and of property leased or occupied by the National Labor Relations Board and its Regional Offices. It will also be used to pursue criminal prosecution or civil penalty actions against individuals or entities suspected of offenses that may have been committed against property owned, occupied, or secured by the NLRB or persons on the property.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include:

Individuals or entities involved in, suspected of being involved in, or who the Agency believes may become involved in criminal acts against the buildings, grounds, and property that are leased or occupied by the National Labor Relations Board, or against persons who are in or on such buildings, grounds, or property.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in the system may include the following types of information about individuals:

- Individual's or entity's name;
- Alias;
- Digital video recordings and Closed Circuit Television (CCTV) recordings;
- Audio recordings;
- Date of birth, place of birth, and age;
- Social Security number;
- Alien File Number (A-Number);
- Duty/work address and telephone number;
- Race and ethnicity;
- Citizenship;
- Sex;
- Marital status;
- Identifying marks (e.g., tattoos, scars);
- Height and weight;
- Eye and hair color;
- Biometric data (e.g., photograph, fingerprints);
- Home address, telephone number, and other contact information;
- Driver's license information and citations issued;
- Vehicle information;
- Date, location, nature and details of the incident/offense;
- Alcohol, drugs, or weapons involvement;
- Bias against any particular group;
- Confinement information to include location of correctional facility;
- Gang/cult affiliation, if applicable;
- Release/parole/clemency eligibility dates;
- Foreign travel notices and reports including briefings and debriefings;
- Notices and reports with foreign contacts;
- Reports of investigation;
- Statements of individuals, affidavits, and correspondence;
- Documentation pertaining to criminal activities;
- Investigative surveys;
- Certifications pertaining to qualifications for employment, including but not limited to education, firearms, first aid, and CPR;
- Technical, forensic, polygraph, and other investigative support to criminal investigations to include source control documentation and regional information;
- Data on individuals to include victims, witnesses, complainants, offenders, and suspects;
- Records of possible espionage, foreign intelligence service elicitation activities, and terrorist collection efforts directed at the U.S. Government or its staff, contractors, or visitors;
- Records of close coordination with the intelligence and law enforcement community.

RECORD SOURCE CATEGORIES:

Records are obtained from sources contacted during investigations; NLRB

employees; state, tribal, international, and local law enforcement; and federal departments and agencies.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records or information contained in this system may be disclosed outside the NLRB as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To the Department of Justice for use in litigation when either (a) the Agency or any component thereof, (b) any employee of the Agency in his or her official capacity, (c) any employee of the Agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or (d) the United States Government is a party to litigation or has an interest in such litigation, and the Agency determines that the records are both relevant and necessary to the litigation.

2. To a court or other adjudicative body before which the Agency is authorized to appear, when either (a) the Agency or any component thereof, (b) any employee of the Agency in his or her official capacity, (c) any employee of the Agency in his or her individual capacity, where the Agency has agreed to represent the employee, or (d) the United States Government is a party to litigation or has an interest in such litigation, and the Agency determines that the records are both relevant and necessary to the litigation.

3. To a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained. However, the investigative file, or parts thereof, will only be released to a Congressional office if the Agency receives a signed statement under 28 U.S.C. 1746 from the subject of the investigation.

4. To the National Archives and Records Administration (NARA) pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

5. To the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures and compliance with the Freedom of Information Act (FOIA), and to facilitate OGIS's offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

6. To appropriate agencies, entities, and persons when:

a. The National Labor Relations Board determines that the use of information from this system of records is reasonably necessary and otherwise compatible with the purpose of collection to assist another federal recipient agency or entity in (a) responding to a suspected or confirmed breach of private information, or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security resulting from a suspected or confirmed breach; or

b. the National Labor Relations Board suspects or has confirmed there has been a breach of this system of records; and (a) the NLRB has determined that as a result of the suspected or confirmed breach, there is a risk of harm to individuals, harm to the NLRB (including its information systems, programs, and operations), the Federal Government, or national security; and (b) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the NLRB's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

7. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for NLRB, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to NLRB employees.

8. To an appropriate federal, state, tribal, or local law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations, and such disclosure is proper and consistent with the official duties of the person making the disclosure.

9. To a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or pursuant to the order of a court of competent jurisdiction.

10. To third parties during the course of a law enforcement investigation to the extent necessary to obtain information pertinent to the investigation, provided disclosure is appropriate to the proper performance of the official duties of the officer making the disclosure.

11. To a federal, state, local agency, or other appropriate entities or individuals, or through established liaison channels to selected foreign governments, in order to provide intelligence, counterintelligence, or other information for the purposes of intelligence, counterintelligence, or antiterrorism activities authorized by United States law, Executive Order, or other applicable national security directive.

12. To a public or professional licensing organization when such information indicates, either by itself or in combination with other information, a violation or potential violation of professional standards, or reflects on the moral, educational, or professional qualifications of an individual who is licensed or who is seeking to become licensed.

13. To individuals involved in incidents occurring on federal facilities, their insurance companies, and their attorneys for the purpose of adjudicating a claim, such as personal injury, traffic accident, or other damage to property. The release of personal information is limited to that required to adjudicate a claim.

14. To the news media and the public, with the approval of the Senior Agency Official for Privacy in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information, when disclosure is necessary to preserve confidence in the integrity of the NLRB, or when disclosure is necessary to demonstrate the accountability of the NLRB's employees or individuals covered by the system, except to the extent the Senior Agency Official for Privacy determines that release of the specific information in the context of a particular case would constitute a clearly unwarranted invasion of personal privacy.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in paper format in file folders, on digital images, and in electronic databases. Any classified information is maintained in a storage container that meets classification requirements.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by individual name or other personal identifier listed in ''Categories of Records,'' when applicable.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained in accordance with NARA General Records Schedule 5.6, Security Records, Item 010 Security Administrative Records, which generally requires destruction after three years, but which also permits longer retention as required for business use. Disposition Authority: DAA–GRS–2017–0006–0001.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Paper—Paper files are stored in a locked file cabinet or a secure facility with an intrusion alarm system at NLRB Headquarters in the Security Branch. Access is limited to security specialists and their duly authorized representatives who have a need to know the information for the performance of their official duties. The U.S. Postal Service and other postal providers are used to transmit hard copy records sent to and from field offices, other agencies, and designated individuals.

Electronic—Comprehensive electronic records are maintained in the Security Branch and on the NLRB network. Electronic records are maintained in computer databases in a secure room accessible only by a personal identity verification card reader which is limited to Office of Chief Information Officer designated employees. Information that is transmitted electronically from field offices is encrypted. Access to the records is restricted to security staff with a specific role in creating and maintaining the Banned Entry List.

NOTIFICATION PROCEDURES:

For records not exempted under 5 U.S.C. 552a(k)(1), (2), and (5), an individual may inquire as to whether this system contains a record pertaining to such individual by sending a request in writing, signed, to the System Manager at the address above, in accordance with the procedures set forth in 29 CFR 102.119(a).

An individual requesting notification of records in person must provide identity documents sufficient to satisfy the custodian of the records that the requester is entitled to such notification, such as a government-issued photo ID. Individuals requesting notification via mail must furnish, at minimum, name, date of birth, and home address in order to establish identity.

RECORD ACCESS PROCEDURES:

For records not exempted under 5 U.S.C. 552a(k)(1), (2), and (5), an individual seeking to gain access to records in this system pertaining to him or her should contact the System Manager at the address above, in accordance with the procedures set forth in 29 CFR 102.119(b) and (c).

An individual requesting access in person must provide identity documents sufficient to satisfy the custodian of the records that the requester is entitled to such access, such as a government-issued photo ID. Individuals requesting access via mail must furnish, at minimum, name, date of birth, and home address in order to establish identity. Requesters should also reasonably specify the record contents being sought. Investigative information created by other agencies remains the property of those agencies and requests regarding such material must be directed to them.

CONTESTING RECORD PROCEDURES:

For records not exempted under 5 U.S.C. 552a(k)(1), (2), and (5), an individual may request amendment of a record pertaining to such individual maintained in this system by directing a request to the System Manager at the address above, in accordance with the procedures set forth in 29 CFR 102.119(d).

An individual seeking to contest records in person must provide identity documents sufficient to satisfy the custodian of the records that the requester is entitled to contest such records, such as a government-issued photo ID. Individuals seeking to contest records via mail must furnish, at minimum, name, date of birth, and home address in order to establish identity. Requesters should also reasonably identify the record, specify the information they are contesting, state the corrective action sought and the reasons for the correction along with supporting justification showing why the record is not accurate, timely, relevant, or complete. Investigative information created by other agencies remains the property of those agencies and requests regarding such material must be directed to them.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(1), (2), and (5), the Agency has exempted portions of this system that relate to providing an accounting of disclosures to the data subject, and access to and amendment of records (5 U.S.C. 552a(c)(3),(d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I), and (f)). This system may contain the following types of information:

1. Properly classified information subject to the provisions of section 552(b)(1), which describes matters that are: (A) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) in fact properly classified pursuant to such Executive order.

2. Investigatory material compiled for law enforcement purposes, other than material within the scope of 5 U.S.C. 552a(j)(2): Provided, however, that if any individual is denied any right, privilege, or benefit to which he would otherwise be entitled by Federal law, or for which he would otherwise be eligible, as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence.

3. Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment and Federal contracts or access to classified information. Materials may be exempted to the extent that release of the material to the individual whom the information is about would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to September 27, 1975, furnished information to the Government under an implied promise that the identity of the source would be held in confidence. When this system receives a record from another system exempted in that source system under 5 U.S.C. 552a(j)(2), the NLRB will claim the same exemptions for those records that are claimed for the original primary systems of records from which they originated and claim any additional exemptions set forth here.

HISTORY:

None.

Dated: November 13, 2020. Washington, DC.

By direction of the Board.

Roxanne L. Rothschild,

Executive Secretary, National Labor Relations Board.

[FR Doc. 2020–25467 Filed 11–25–20; 8:45 am]

BILLING CODE 7545–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Call for Nominations

AGENCY: U.S. Nuclear Regulatory Commission

ACTION: Call for nominations.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is soliciting for nominations for the Patients' Rights Advocate representative position on the Advisory Committee of the Medical Uses of Isotopes (ACMUI). Patients' Rights Advocate nominees should have professional or personal experience with and/or knowledge about patient advocacy. Also, involvement or leadership with patient advocacy organizations is preferred.

DATES: Nominations are due on or before January 26, 2021.

ADDRESSES: *Nomination Process:* Submit an electronic copy of resume or curriculum vitae, along with a cover letter, to Ms. Kellee Jamerson, *Kellee.Jamerson@nrc.gov.* The cover letter should describe the nominee's current involvement with patients' rights advocacy and express the nominee's interest in the position. Please ensure that the resume or curriculum vitae includes the following information, if applicable: Education; certification; professional association membership and committee membership activities; and number of years, timeframe, and type of setting for patient advocacy.

FOR FURTHER INFORMATION CONTACT: Ms. Kellee Jamerson, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards; (301) 415–7408; *Kellee.Jamerson@nrc.gov.*

SUPPLEMENTARY INFORMATION: The ACMUI Patients' Rights Advocate representative provides advice to the NRC staff on patients' issues associated with the regulation of medical applications of byproduct material. This advice includes ensuring patients' rights are represented during the development and implementation of the NRC's medical-use regulations. This individual is appointed based on his or her professional and personal experience with and/or knowledge about patient advocacy, as well as involvement and/or leadership with patient advocacy organizations.

ACMUI members are selected based on their educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained from recommendation letters or during the selection process. Nominees should have the demonstrated ability to establish effective work relationships with peers and implement successful approaches to problem solving and conflict resolution. ACMUI members currently serve a four-year term and may be considered for reappointment to an additional term. The current ACMUI membership is comprised of the following professionals: (a) Nuclear medicine physician; (b) nuclear cardiologist; (c) nuclear medicine physicist; (d) therapy medical physicist; (e) radiation safety officer; (f) nuclear pharmacist; (g) two radiation oncologists; (h) patients' rights advocate; (i) Food and Drug Administration representative; (j) Agreement State representative; (k) healthcare administrator; and (l) diagnostic radiologist. For additional information about membership on the ACMUI, visit the ACMUI Membership web page, *http://www.nrc.gov/about-nrc/regulatory/advisory/acmui/membership.html.*

Nominees must be U.S. citizens and be able to devote up to 160 hours per year to ACMUI business. Members are expected to attend semi-annual meetings in Rockville, Maryland and to participate in teleconferences, as needed. Members who are not Federal employees are compensated for their service. In addition, members are reimbursed for travel (including per diem in lieu of subsistence) and are reimbursed secretarial and correspondence expenses. Full-time Federal employees are reimbursed for travel expenses only.

Security Background Check: The selected nominee will undergo a thorough security background check. Security paperwork may take the nominee several weeks to complete. Nominees will also be required to complete a financial disclosure statement to avoid conflicts of interest.

Dated: November 20, 2020.

Russell E. Chazell,

Advisory Committee Management Officer.

[FR Doc. 2020–26151 Filed 11–25–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–003, 50–247, and 50–286; NRC–2020–0251]

Holtec Decommissioning International, LLC;

Indian Point Nuclear Generating Station, Unit Nos. 1, 2, and 3

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to a February 12, 2020, request from Holtec Decommissioning International, LLC (HDI). The exemption permits HDI to make withdrawals from the Indian Point Nuclear Generating Station, Unit Nos. 1, 2, and 3 (referred to individually as IP1, IP2, and IP3, respectively, and collectively as the Indian Point Energy Center or IPEC) Decommissioning Trust Funds (DTFs) for spent fuel management and site restoration activities for IP1, IP2, and IP3 without prior notification to the NRC. This exemption is effective upon issuance, but only applies to HDI upon the consummation of the transfers of the licenses for IP1, IP2, and IP3 to Holtec International (Holtec) subsidiaries Holtec Indian Point 2, LLC and Holtec Indian Point 3, LLC and the transfer of the operating authority under the licenses to HDI.

DATES: The exemption was issued on November 23, 2020.

ADDRESSES: Please refer to Docket ID NRC–2020–0251 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0251. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR)

reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

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

FOR FURTHER INFORMATION CONTACT: Richard V. Guzman, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1030, email: *Richard.Guzman@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: November 23, 2020.

For the Nuclear Regulatory Commission.

Richard V. Guzman,

Senior Project Manager, Plant Licensing Branch I, Division of Operator Reactor Licensing, Office of Nuclear Reactor Regulation.

Attachment—Exemption.

Nuclear Regulatory Commission

Docket Nos. 50–003, 50–247, and 50–286; Holtec Decommissioning International, LLC Indian Point Nuclear Generating Station, Unit Nos. 1, 2, and 3; Exemption

I. Background.

The Indian Point Energy Center (IPEC) consists of three, four-loop pressurized-water reactors, Indian Point Nuclear Generating Station, Unit Nos. 1, 2, and 3 (IP1, IP2, and IP3, respectively), and an independent spent fuel storage installation (ISFSI), located in Buchanan, New York, in Westchester County, on the east bank of the Hudson River. Operation of IP1 permanently ceased on October 31, 1974 and all fuel was permanently removed from the IP1 reactor vessel by January 1976; operation of IP2 permanently ceased on April 30, 2020 and all fuel was permanently removed from the lP2 reactor vessel on May 12, 2020; and operation of IP3 is scheduled to permanently cease by April 30, 2021.

The U.S. Nuclear Regulatory Commission (NRC, the Commission) licenses for the IPEC are Provisional Operating License No. DPR–5 for IP1, Renewed Facility Operating License Nos. DPR–26 and DPR–64 for IP2 and IP3, respectively, and the general license for the ISFSI. The current licensed owners under these licenses are Entergy Nuclear Indian Point 2, LLC and Entergy Nuclear Indian Point 3, LLC and the current licensed operator under these licenses is Entergy Nuclear Operations, Inc. (ENOI). The IPEC licenses are subject to the rules, regulations, and orders of the NRC.

By application dated November 21, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19326B953), the current licensed owners and operator and Holtec International (Holtec) and Holtec Decommissioning International, LLC (HDI) requested that the NRC consent to the transfer of the ownership of the IPEC licenses to Holtec subsidiaries Holtec Indian Point 2, LLC and Holtec Indian Point 3, LLC and the operating authority under these licenses to Holtec subsidiary HDI.

In support of the license transfer application, by letter dated December 19, 2019 (ADAMS Accession No. ML19354A698), HDI provided to the NRC a post-shutdown decommissioning activities report (PSDAR) and site-specific decommissioning cost estimate (SSCE) for IPEC. These documents reflected HDI's proposed use of the DECON decommissioning method to complete decommissioning over a period (inclusive of 2021) of 43 years if the license transfer application is approved and the proposed license transfer transaction is consummated. The decommissioning of IPEC would begin following the permanent cessation of operations of IP3 in 2021 and the majority of license termination activities would be completed by 2033 (*i.e.,* releasing for unrestricted use the entirety of the site with the exception of the ISFSI). HDI would then remove the fuel and Greater than Class C waste from the site, decommission the ISFSI, terminate the NRC licenses, and release the remainder of the site for unrestricted use by 2063.

II. Request/Action

In support of the license transfer application, in addition to providing a PSDAR and an SSCE, by letter dated February 12, 2020 (ADAMS Accession No. ML20043C539), HDI also submitted to the NRC a request for exemption from specific requirements of 10 CFR 50.82(a)(8)(i)(A) and 10 CFR 50.75(h)(1)(iv). The exemption from 10 CFR 50.82(a)(8)(i)(A) and 10 CFR 50.75(h)(1)(iv) would permit HDI to make withdrawals from the IP1, IP2, and IP3 Decommissioning Trust Funds (DTFs) for spent fuel management and site restoration activities for IP1, IP2, and IP3, respectively, in accordance with HDI's SSCE. The exemption from 10 CFR 50.75(h)(1)(iv) would also permit HDI to make these withdrawals without prior notification to the NRC, similar to withdrawals for decommissioning activities made in accordance with 10 CFR 50.82(a)(8). The exemption would only apply to HDI if and when the proposed license transfer transaction is consummated.

As part of its exemption request, HDI provided Tables 1, 2, and 3 for IP1, IP2, and IP3, respectively, showing the annual cash flows for each unit's DTF while conducting decommissioning activities under the decommissioning method discussed in HDI's PSDAR. Each table contains the projected withdrawals from the unit's DTF needed to cover the estimated costs at that unit for radiological decommissioning, spent fuel management, and site restoration activities in accordance with HDI's SSCE. By letter dated March 26, 2020 (ADAMS Accession No. ML20086Q904), pursuant to 10 CFR 50.75(f)(2), ENOI reported the balances of the IP1, IP2, and IP3 DTFs as of December 31, 2019. The NRC staff considered all of this information in its review of the exemption request.

The requirements of 10 CFR 50.82(a)(8)(i)(A) restrict the use of DTF withdrawals to expenses related to legitimate decommissioning activities consistent with the definition of decommissioning that appears in 10 CFR 50.2, ''Definitions.'' The definition of ''decommission'' in 10 CFR 50.2 is:

> To remove a facility or site safely from service and reduce residual radioactivity to a level that permits—
>
> (1) Release of the property for unrestricted use and termination of the license; or
>
> (2) Release of the property under restricted conditions and termination of the license.

This definition does not include activities associated with spent fuel management and site restoration activities. The requirements of 10 CFR 50.75(h)(1)(iv) also restrict the use of DTF disbursements (other than for ordinary administrative costs and other incidental expenses of the fund in connection with the operation of the fund) to decommissioning expenses until final radiological decommissioning is completed. Therefore, an exemption from 10 CFR 50.82(a)(8)(i)(A) and 10 CFR 50.75(h)(1)(iv) is needed to allow HDI to use funds from the IPEC DTFs for spent fuel management and site restoration activities at IPEC. The requirements of 10 CFR 50.75(h)(1)(iv) further provide that, except for withdrawals being made under 10 CFR 50.82(a)(8) or for payments of ordinary administrative costs and other incidental expenses of the fund in connection with the operation of the fund, no disbursement

may be made from the DTF without written notice to the NRC at least 30 working days in advance. Therefore, an exemption from 10 CFR 50.75(h)(1)(iv) is also needed to allow HDI to use funds from the IPEC DTFs for spent fuel management and site restoration activities at IPEC without prior NRC notification.

III. Discussion.

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 (1) when the exemptions are authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security; and (2) when any of the special circumstances listed in 10 CFR 50.12(a)(2) are present. These special circumstances include, among other things:

(ii) Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule; and

(iii) Compliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated.

A. Authorized by Law

The requested exemption from 10 CFR 50.82(a)(8)(i)(A) and 10 CFR 50.75(h)(1)(iv) would allow HDI to use a portion of the funds from the IPEC DTFs for spent fuel management and site restoration activities at IPEC without prior notice to the NRC in the same manner that withdrawals are made under 10 CFR 50.82(a)(8) for decommissioning activities. As stated above, 10 CFR 50.12 allows the NRC to grant exemptions from the requirements of 10 CFR part 50 when the exemptions are authorized by law. The NRC staff has determined, as explained below, that granting HDI's proposed exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

B. No Undue Risk to Public Health and Safety

The underlying purpose of 10 CFR 50.82(a)(8)(i)(A) and 10 CFR 50.75(h)(1)(iv) is to provide reasonable assurance that adequate funds will be available for the radiological decommissioning of power reactors. Based on HDI's SSCE and the cash flow analyses, use of a portion of the IPEC DTFs for spent fuel management and site restoration activities at IPEC will not adversely impact HDI's ability to complete radiological decommissioning within 60 years and terminate the IPEC licenses. Furthermore, an exemption from 10 CFR 50.75(h)(1)(iv) to allow HDI to make withdrawals from the DTFs for spent fuel management and site restoration activities without prior written notification to the NRC will not affect the sufficiency of funds in the DTFs to accomplish radiological decommissioning, because such withdrawals are still constrained by the provisions of 10 CFR 50.82(a)(8)(i)(B)–(C) and are reviewable under the annual reporting requirements of 10 CFR 50.82(a)(8)(v)–(vii).

Based on the above, there are no new accident precursors created by using the DTFs in the proposed manner. Thus, the probability of postulated accidents is not increased. Also, based on the above, the consequences of postulated accidents are not increased. No changes are being made in the types or amounts of effluents that may be released offsite. There is no significant increase in occupational or public radiation exposure. Therefore, the requested exemption will not present an undue risk to public health and safety.

C. Consistent With the Common Defense and Security

The requested exemption would allow HDI to use funds from the IPEC DTFs for spent fuel management and site restoration activities at IPEC. Spent fuel management under 10 CFR 50.54(bb) is an integral part of the planned HDI decommissioning and license termination process and will not adversely affect HDI's ability to physically secure the site or protect special nuclear material. This change to enable the use of a portion of the funds from the DTFs for spent fuel management and site restoration activities has no relation to security issues. Therefore, the common defense and security is not impacted by the requested exemption.

D. Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the regulation.

The underlying purpose of 10 CFR 50.82(a)(8)(i)(A) and 10 CFR 50.75(h)(1)(iv), which restrict withdrawals from DTFs to expenses for radiological decommissioning activities, is to provide reasonable assurance that adequate funds will be available for radiological decommissioning of power reactors and license termination. Strict application of these requirements would prohibit the withdrawal of funds from the IPEC DTFs for activities other than radiological decommissioning activities at IPEC, such as for spent fuel management and site restoration activities, until final radiological decommissioning at IPEC has been completed.

The DTFs for IP1, IP2, and IP3 contained $555.74 million, $701.30 million, and $929.97 million, respectively, as of December 31, 2019. HDI's analyses project the total radiological decommissioning costs at IP1, IP2, and IP3 to be approximately $485,015,000, $469,456,000, and $583,168,000, respectively (in 2019 dollars), including the costs for decommissioning the ISFSI. As required by 10 CFR 50.54(bb), HDI estimated the costs associated with spent fuel management at IP1, IP2, and IP3 to be $72,381,000, $188,278,000, and $371,370,000, respectively (in 2019 dollars).

The NRC staff performed independent cash flow analyses of the IPEC DTFs over the proposed 43-year DECON period (assuming an annual real rate of return of 2 percent, as allowed by 10 CFR 50.75(e)(1)(ii)) and determined the projected earnings of the DTFs. The NRC staff confirmed that the current funds in the DTFs and projected earnings provide reasonable assurance of adequate funding to complete all NRC-required radiological decommissioning activities at IPEC and also to pay for spent fuel management and site restoration activities. Therefore, the NRC staff finds that HDI has provided reasonable assurance that adequate funds will be available for the radiological decommissioning of IPEC, even with the disbursement of funds from the DTFs for spent fuel management and site restoration activities. Consequently, the NRC staff concludes that application of the requirements of 10 CFR 50.82(a)(8)(i)(A) and 10 CFR 50.75(h)(1)(iv), that funds from the DTFs only be used for radiological decommissioning activities and not for spent fuel management and site restoration activities, is not necessary to achieve the underlying purpose of the rule. Thus, special circumstances are present supporting approval of the exemption request.

In its submittal, HDI also requested exemption from the requirement of 10 CFR 50.75(h)(1)(iv) concerning prior written notification to the NRC of withdrawals from the DTFs to fund activities other than radiological decommissioning. The underlying

purpose of notifying the NRC prior to withdrawal of funds from the DTFs is to provide opportunity for NRC intervention, when deemed necessary, if the withdrawals are for expenses other than those authorized by 10 CFR 50.75(h)(1)(iv) and 10 CFR 50.82(a)(8) that could result in there being insufficient funds in the DTFs to accomplish radiological decommissioning.

By granting the exemption to 10 CFR 50.75(h)(1)(iv) and 10 CFR 50.82(a)(8)(i)(A), the NRC staff considers that withdrawals consistent with HDI's submittal dated February 12, 2020, are authorized. As stated previously, the NRC staff determined that there are sufficient funds in the DTFs to complete radiological decommissioning activities, as well as to conduct spent fuel management and site restoration activities, consistent with HDI's PSDAR, SSCE, and February 12, 2020, exemption request. Pursuant to the requirements in 10 CFR 50.82(a)(8)(v) and (vii), licensees are required to monitor and annually report to the NRC the status of the DTFs and the licensee's funding for spent fuel management. These reports provide the NRC staff with awareness of, and the ability to take action on, any actual or potential funding deficiencies. Additionally, 10 CFR 50.82(a)(8)(vi) requires that the annual financial assurance status report must include additional financial assurance to cover the estimated cost of completion if the sum of the balance of any remaining decommissioning funds, plus earnings on such funds calculated at not greater than a 2-percent real rate of return, together with the amount provided by other financial assurance methods being relied upon, does not cover the estimated cost to complete the decommissioning. The requested exemption would not allow the withdrawal of funds from the DTFs for any other purpose that is not currently authorized in the regulations without prior notification to the NRC. Therefore, the granting of the exemption to 10 CFR 50.75(h)(1)(iv) to allow HDI to make withdrawals from the DTFs to cover authorized expenses for spent fuel management and site restoration activities without prior written notification to the NRC will still meet the underlying purpose of the regulation.

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(iii), are present whenever compliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated. HDI states that the DTFs contain funds in excess of the estimated costs of radiological decommissioning and that these excess funds are needed for spent fuel management and site restoration activities. The NRC does not preclude the use of funds from DTFs in excess of those needed for radiological decommissioning for other purposes, such as spent fuel management or site restoration activities.

The NRC has stated that funding for spent fuel management and site restoration activities may be commingled in DTFs, provided that the licensee is able to identify and account for the radiological decommissioning funds separately from the funds set aside for spent fuel management and site restoration activities (see NRC Regulatory Issue Summary 2001–07, Rev. 1, ''10 CFR 50.75 Reporting and Recordkeeping for Decommissioning Planning,'' dated January 8, 2009 (ADAMS Accession No. ML083440158), and Regulatory Guide 1.184, Revision 1, ''Decommissioning of Nuclear Power Reactors,'' dated October 2013 (ADAMS Accession No. ML13144A840)). Preventing access to those excess funds in DTFs because spent fuel management and site restoration activities are not associated with radiological decommissioning would create an unnecessary financial burden without any corresponding safety benefit. The adequacy of the IPEC DTFs to cover the cost of activities associated with spent fuel management and site restoration, in addition to radiological decommissioning, is supported by HDI's SSCE. If HDI cannot use its DTFs for spent fuel management and site restoration activities, it would need to obtain additional funding that would not be recoverable from the DTFs, or it would have to modify its decommissioning approach and methods. The NRC staff concludes that either outcome would impose an unnecessary and undue burden significantly in excess of that contemplated when 10 CFR 50.82(a)(8)(i)(A) and 10 CFR 50.75(h)(1)(iv) were adopted.

The underlying purposes of 10 CFR 50.82(a)(8)(i)(A) and 10 CFR 50.75(h)(1)(iv) would be achieved by allowing HDI to use a portion of the IPEC DTFs for spent fuel management and site restoration activities without prior NRC notification, and compliance with the regulations would result in an undue hardship or other costs that are significantly in excess of those contemplated when the regulations were adopted. Thus, the special circumstances required by 10 CFR 50.12(a)(2)(ii) and 10 CFR 50.12(a)(2)(iii) exist and support the approval of the requested exemption.

E. Environmental Considerations

In accordance with 10 CFR 51.31(a), the Commission has determined that granting the exemption will not have a significant effect on the quality of the human environment (see Environmental Assessment and Finding of No Significant Impact published in the **Federal Register** on November 10, 2020 (85 FR 71664)).

IV. Conclusions.

In consideration of the above, the NRC staff finds that the proposed exemption confirms the adequacy of funding in the IPEC DTFs, considering growth, to complete radiological decommissioning of the site and to terminate the licenses and also to cover estimated spent fuel management and site restoration activities.

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the exemption is authorized by law, will not present an undue risk to public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants HDI an exemption from the requirements of 10 CFR 50.82(a)(8)(i)(A) and 10 CFR 50.75(h)(1)(iv) to allow the use of a portion of the funds from the IPEC DTFs for spent fuel management and site restoration activities in accordance with HDI's PSDAR and SSCE, dated December 19, 2019. Additionally, the Commission hereby grants HDI an exemption from the requirement of 10 CFR 50.75(h)(1)(iv) to allow such withdrawals without prior NRC notification.

This exemption is effective upon issuance.

Dated: November 23, 2020.

For the Nuclear Regulatory Commission.

Craig G. Erlanger,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–26189 Filed 11–25–20; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Comment Request for Review of a Revised Information Collection: Leadership Assessment Surveys

AGENCY: Office of Personnel Management.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Office of Personnel Management (OPM) intends to submit to the Office of Management and Budget (OMB) a request for review of a currently approved collection, Leadership Assessment Surveys. OPM is requesting approval of the OPM Leadership 360™, Leadership Potential Assessment, and the Leadership Profiler as a part of this collection. Approval of these surveys is necessary to collect information on Federal agency performance and leadership effectiveness.

DATES: Comments are encouraged and will be accepted until January 26, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by the following method:

Federal Rulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

All submissions received must include the agency name and docket number for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting Human Resources Strategy and Evaluation Solutions, Office of Personnel Management, 1900 E Street, RM 2469, NW, Washington, DC 20415, Attention: Coty Hoover, C/O Henry Thibodeaux, or via email to *Organizational_Assessment@opm.gov.*

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. The previous collection (OMB No. 3206–0253, published in the **Federal Register** on December 27, 2017 at 82 FR 61339) has a clearance that expires September 30, 2021. Comments are particularly 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. Whether our estimate of the public burden of this collection is accurate, and based on valid assumptions and methodology; and

3. Ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of the appropriate technological collection techniques or other forms of information technology.

OPM's Human Resources Strategy and Evaluation Solutions performs assessment and related consultation activities for Federal agencies on a reimbursable basis. The assessments are authorized by various statutes and regulations: Section 4702 of Title 5, U.S.C; E.O. 12862; E.O. 13715; Section 1128 of the National Defense Authorization Act for Fiscal Year 2004, Public Law 108–136; 5 U.S.C. 1101 note, 1103(a)(5), 1104, 1302, 3301, 3302, 4702, 7701 note; E.O. 13197, 66 FR 7853, 3 CFR 748 (2002); E.O. 10577, 12 FR 1259, 3 CFR, 1954–1958 Comp., p. 218; and Section 4703 of Title 5, United States Code.

This collection request includes surveys we currently use and plan to use during the next three years to measure Federal leaders' effectiveness. These surveys all measure leadership characteristics. Non-Federal respondents will almost never receive more than one of these surveys. All of these surveys consist of Likert-type, mark-one, and mark-all-that-apply items, and may include a small number of open-ended comment items. OPM's Leadership 360™ assessment measures the 28 competencies that comprise the five Executive Core Qualifications and Fundamental Competencies in the OPM leadership model. The OPM Leadership 360™ consists of 116 items and is almost never customized, although customization to meet an agency's needs is possible. OPM's Leadership Potential Assessment consists of 104 items focused on identifying individuals ready to move into supervisory positions. OPM's Leadership Profiler consists of 245 items that measure leadership personality characteristics within a ''Big 5'' framework. These assessments are almost always administered electronically.

Analysis

Agency: Human Resources Strategy and Evaluation Solutions, Office of Personnel Management.

Title: Leadership Assessment Surveys.

OMB Number: 3206–0253.

Frequency: On occasion.

Affected Public: Individuals and Government contractors.

Number of Respondents: Approximately 24,000.

Estimated Time per Respondent: 15 minutes for the OPM Leadership 360™ and Leadership Potential Assessment; 45 minutes for the Leadership Profiler. The latter will almost never be administered to non-Federal employees, so the average time is approximately 15 minutes.

Total Burden Hours: 6,000 hours.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2020–26154 Filed 11–25–20; 8:45 am]

BILLING CODE 6325–43–P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: This notice identifies Schedule A, B, and C appointing authorities applicable to a single agency that were established or revoked from March 1, 2020 to March 31, 2020.

FOR FURTHER INFORMATION CONTACT: Julia Alford, Senior Executive Resources Services, Senior Executive Services and Performance Management, Employee Services, 202–606–2246.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 213.103, Schedule A, B, and C appointing authorities available for use by all agencies are codified in the Code of Federal Regulations (CFR). Schedule A, B, and C appointing authorities applicable to a single agency are not codified in the CFR, but the Office of Personnel Management (OPM) publishes a notice of agency-specific authorities established or revoked each month in the **Federal Register** at *www.gpo.gov/fdsys/.* OPM also publishes an annual notice of the consolidated listing of all Schedule A, B, and C appointing authorities, current as of June 30, in the **Federal Register**.

Schedule A

No Schedule A Authorities to report during March 2020.

Schedule B

No Schedule B Authorities to report during March 2020.

Schedule C

The following Schedule C appointing authorities were approved during March 2020.

Agency name	Organization name	Position title	Authorization No.	Effective date
DEPARTMENT OF AGRICULTURE	National Institute of Food and Agriculture.	Policy Advisor	DA200049	03/04/2020
	Natural Resources Conservation Service.	Chief of Staff	DA200065	03/23/2020
	Office of the Secretary	Advance Associate	DA200043	03/30/2020
		Legislative Correspondent	DA200051	03/30/2020
DEPARTMENT OF COMMERCE	Immediate Office	Special Advisor	DC200068	03/04/2020
	Office of International Trade Administration.	Special Advisor	DC200065	03/04/2020
	Office of National Telecommunications and Information Administration.	Senior Advisor	DC200034	03/06/2020
	Office of Policy and Strategic Planning.	Special Assistant	DC200067	03/04/2020
	Office of the White House Liaison	Deputy White House Liaison	DC200080	03/09/2020
		White House Liaison	DC200084	03/13/2020
DEPARTMENT OF DEFENSE	Office of the Assistant to the Secretary of Defense (Public Affairs).	Special Assistant (3)	DD200122	03/11/2020
			DD200136	03/27/2020
			DD200115	03/30/2020
	Office of the Under Secretary of Defense (Policy).	Special Assistant	DD200113	03/25/2020
DEPARTMENT OF THE ARMY	Office of the Assistant Secretary of the Army (Financial Management and Comptroller).	Special Assistant	DW200027	03/27/2020
DEPARTMENT OF EDUCATION	Office of the Secretary	Confidential Assistant	DB200042	03/05/2020
		Director, White House Liaison	DB200045	03/19/2020
	Office for Civil Rights	Confidential Assistant	DB200044	03/23/2020
		Attorney Advisor	DB200043	03/25/2020
DEPARTMENT OF ENERGY	Office of Science	Senior Advisor	DE200070	03/03/2020
	Office of Management	Operations Manager	DE200111	03/31/2020
ENVIRONMENTAL PROTECTION AGENCY.	Office of Public Affairs	Assistant Deputy Associate Administrator for Policy.	EP200048	03/05/2020
	Office of Public Engagement and Environmental Education.	Special Advisor	EP200060	03/19/2020
	Office of the Administrator	Principal Deputy Chief of Staff	EP200047	03/05/2020
		Deputy Director for Advance	EP200059	03/31/2020
	Office of the Assistant Administrator for International and Tribal Affairs.	Senior Advisor	EP200057	03/10/2020
	Office of the Associate Administrator for Congressional and Intergovernmental Relations.	Director of House Relations	EP200050	03/27/2020
		Special Advisor for Oversight	EP200033	03/31/2020
EXPORT-IMPORT BANK	Office of Communications	Speechwriter	EB200011	03/24/2020
	Office of the Chief Banking Officer	Senior Advisor	EB200012	03/30/2020
GENERAL SERVICES ADMINISTRATION.	Office of the Administrator	White House Liaison	GS200027	03/03/2020
		Deputy White House Liaison	GS200035	03/24/2020
DEPARTMENT OF HEALTH AND HUMAN SERVICES.	Office of Refugee Resettlement/Office of the Director.	Chief of Staff	DH200099	03/23/2020
DEPARTMENT OF HOMELAND SECURITY.	Office of the Secretary	White House Liaison	DM200188	03/10/2020
	Office of the Assistant Secretary for Policy.	Senior Advisor	DM200138	03/25/2020
		Special Assistant DM200164 03/27/2020.		
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT.	Office of Community Planning and Development.	Senior Advisor	DU200054	03/05/2020
	Office of Public Affairs	Digital Strategist	DU200080	03/17/2020
	Office of Field Policy and Management.	Advisor	DU200087	03/23/2020
DEPARTMENT OF JUSTICE	Office of Civil Division	Counsel (2)	DJ200049	03/06/2020
			DJ200066	03/06/2020
	Office of Justice Programs	Chief of Staff	DJ200081	03/03/2020
		Senior Advisor (2)	DJ190201	03/17/2020
			DJ200075	03/23/2020
	Office of Public Affairs	Press Assistant	DJ200045	03/06/2020
	Office of the Attorney General	Special Assistant	DJ200086	03/06/2020
DEPARTMENT OF LABOR	Office of the Secretary	Principal Travel Aide	DL200089	03/13/2020
	Office of Congressional and Intergovernmental Affairs.	Regional Representative	DL200074	03/15/2020

Agency name	Organization name	Position title	Authorization No.	Effective date
	Office of Veterans Employment and Training Service.	Special Assistant	DL200080	03/23/2020
	Office of Public Liaison	Deputy Director	DL200093	03/31/2020
NATIONAL TRANSPORTATION SAFETY BOARD.	National Transportation Safety Board.	Confidential Assistant	TB200004	03/23/2020
OFFICE OF MANAGEMENT AND BUDGET.	Office of Education, Income Maintenance and Labor Programs.	Special Assistant	BO200024	03/30/2020
	Office of the Director	Confidential Assistant	BO200025	03/31/2020
OFFICE OF PERSONNEL MANAGEMENT.	Office of the Director	Executive Secretariat and Resources Management Officer.	PM200038	03/27/2020
	Senior Advisor	Executive Secretariat and Resources Management Officer.	PM200043	03/31/2020
OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE.	Office of the Ambassador	Executive Secretary	TN200003	03/18/2020
OFFICIAL RESIDENCE OF THE VICE PRESIDENT.	Office of Official Residence of the Vice President.	Deputy Social Secretary	RV200001	03/10/2020
SMALL BUSINESS ADMINISTRATION.	Office of Congressional and Legislative Affairs.	Deputy Assistant Administrator	SB200020	03/27/2020
	Office of Capital Access	Special Assistant	SB200011	03/30/2020
	Office of the Administrator	White House Liaison	SB200019	03/30/2020
DEPARTMENT OF STATE	Bureau of Near Eastern Affairs	Deputy Assistant Secretary	DS200045	03/03/2020
DEPARTMENT OF TRANSPORTATION.	Office of the Administrator	Director of Governmental Affairs	DT200096	03/24/2020
	Office of the Assistant Secretary for Governmental Affairs.		DT200094	03/16/2020
	Senior Governmental Affairs Officer.			
	Office of the Assistant Secretary for Transportation Policy.	Special Assistant for Public Engagement and External Outreach.	DT200091	03/16/2020
		Public Liaison and Engagement Advisor.	DT200072	03/27/2020
	Immediate Office of the Administrator.	Governmental Affairs Officer	DT200088	03/27/2020
	Office of Public Affairs	Digital Communications Manager	DT200093	03/16/2020
		Special Assistant	DT200085	03/27/2020
	Office of the Secretary	Special Assistant (2)	DT200090	03/16/2020
			DT200092	03/19/2020
DEPARTMENT OF THE TREASURY.	Secretary of the Treasury	White House Liaison	DY200073	03/23/2020
DEPARTMENT OF VETERANS AFFAIRS.	Office of the Assistant Secretary for Congressional and Legislative Affairs.	Special Advisor	DV200048	03/18/2020

The following Schedule C appointing authorities were revoked during March 2020.

Agency name	Organization name	Position title	Request number	Date vacated
COMMODITY FUTURES TRADING COMMISSION.	Office of the Chairperson	Legislative Specialist	CT190001	03/31/2020
OFFICE OF THE SECRETARY OF DEFENSE.	Office of the General Counsel	Attorney-Advisor (General)	DD190022	03/07/2020
	Office of the Under Secretary of Defense (Acquisition, Technology, and Logistics).	Director, Congressional and Strategic Outreach.	DD180100	03/07/2020
	Office of the Secretary	Protocol Officer (2)	DD190179	03/14/2020
			DD200107	03/27/2020
	Washington Headquarters Services	AttorneyAdvisor (General)	DD190031	03/28/2020
DEPARTMENT OF THE NAVY	Department of the Navy	Special Assistant to the Chief of Staff.	DN180003	03/28/2020
DEPARTMENT OF EDUCATION	Office of Communications and Outreach.	Confidential Assistant	DB190086	03/28/2020
	Office of the Under Secretary	Executive Director, Center for Faith and Opportunity Initiatives.	DB190029	03/28/2020
	Office of the Secretary	Director, White House Liaison	DB190034	03/31/2020
DEPARTMENT OF HEALTH AND HUMAN SERVICES.	Office of the Secretary	Deputy Scheduler	DH200054	03/06/2020
	Office of Refugee Resettlement/Office of the Director.	Policy Advisor	DH190096	03/28/2020
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT.	Office of Community Planning and Development.	Deputy Assistant Secretary for Economic Development.	DU190001	03/14/2020
		Senior Advisor (2)	DU180035	03/06/2020

Agency name	Organization name	Position title	Request number	Date vacated
			DU190071	03/21/2020
		Special Assistant	DU190030	03/14/2020
	Office of Congressional and Intergovernmental Relations.	Congressional Relations Specialist	DU190107	03/04/2020
		Senior Advisor	DU170084	03/28/2020
	Office of Field Policy and Management.	Assistant Advisor	DU190078	03/14/2020
	Office of Policy Development and Research.	Special Policy Advisor	DU190038	03/28/2020
	Office of the Administration	Advance Coordinator	DU190062	03/28/2020
	Office of the Chief Financial Officer	Senior Advisor	DU190018	03/28/2020
	Office of the General Counsel	Paralegal Specialist	DU190013	03/28/2020
	Office of the Secretary	White House Liaison	DU200012	03/14/2020
		Special Assistant (2)	DU190050	03/28/2020
			DU190082	03/28/2020
DEPARTMENT OF JUSTICE	Office of Justice Programs	Senior Advisor	DJ180136	03/28/2020
	Office of the Attorney General	Special Assistant	DJ190066	03/30/2020
		Director of Scheduling	DJ190238	03/31/2020
DEPARTMENT OF LABOR	Office of the Assistant Secretary for Policy.	Counselor to the Assistant Secretary.	DL200005	03/18/2020
		Special Assistant	DL190058	03/19/2020
DEPARTMENT OF STATE	Bureau of Public Affairs	Senior Advisor	DS190060	03/20/2020
ENVIRONMENTAL PROTECTION AGENCY.	Office of Public Affairs	Senior Advisor for Strategic Communications and Policy.	EP190120	03/14/2020
	Office of the Administrator	Senior Advisor to the Administrator	EP190023	03/14/2020
FEDERAL COMMUNICATIONS COMMISSION.	Office of Media Relations	Director	FC170008	03/14/2020
GENERAL SERVICES ADMINISTRATION.	Office of the Administrator	Special Assistant to the Administrator and Chief Scheduler.	GS190037	03/14/2020
OFFICE OF PERSONNEL MANAGEMENT.	Office of the Director	Senior Advisor for Policy	PM200023	03/28/2020
SMALL BUSINESS ADMINISTRATION.	Office of the Administrator	Senior Advisor	SB180024	03/14/2020
		Director of External Affairs and Strategic Engagement.	SB190007	03/21/2020

(Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp., p. 218)

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2020–26155 Filed 11–25–20; 8:45 am]

BILLING CODE 6325–39–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2021–28 and CP2021–29]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 1, 2020.

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 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment

[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).

deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2021–28 and CP2021–29; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 178 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 20, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Gregory S. Stanton; *Comments Due:* December 1, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–26219 Filed 11–25–20; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34103; File No. 812–14979]

Main Street Capital Corporation, et al.

November 23, 2020.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

Summary of Application: Applicants request an order to permit certain business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other.

Applicants: Main Street Capital Corporation (''MSCC''), MSC Adviser I, LLC (''MSC Adviser I''), Main Street Mezzanine Fund, LP (''SBIC Fund I''), Main Street Capital II, LP (''SBIC Fund II''), Main Street Capital III, LP (''SBIC Fund III'' and together with SBIC Fund I and SBIC Fund II, the ''SBIC Funds''), Main Street Equity Interests, Inc., Main Street CA Lending, LLC, MS International Holdings, Inc., BIGTS Loan Servicing, LLC, Clad-Rex Investments, Inc., MS Equity Holdings, Inc. (collectively, the ''MSCC Subs''), HMS Income Fund, Inc. (''HMS Income''), HMS Adviser LP (''HMS Adviser''), HMS Equity Holding, LLC, HMS Equity Holding II, Inc., HMS Funding I LLC and HMS California Holdings LP (collectively, the ''HMS Income Subs'').

Filing Dates: The application was filed on November 26, 2018, and amended on February 10, 2020, June 8, 2020, and September 8, 2020.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on December 18, 2020, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: *JBeauvais@mainstcapital.com.*

FOR FURTHER INFORMATION CONTACT: Laura J. Riegel, Senior Counsel, at (202) 551–3038 or Lisa Reid Ragen, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Introduction

1. The applicants request an order of the Commission under sections 17(d) and 57(i) and rule 17d–1 thereunder (the ''Order'') to permit, subject to the terms and conditions set forth in the application (the ''Conditions''), one or more Regulated Funds [1] and/or one or more Affiliated Funds [2] to enter into Co-Investment Transactions with each other. ''Co-Investment Transaction'' means any transaction in which a Regulated Fund (or its Wholly-Owned Investment Sub (as defined below)) participated together with one or more Affiliated Funds and/or one or more other Regulated Funds in reliance on the Order. ''Potential Co-Investment Transaction'' means any investment opportunity in which a Regulated Fund (or its Wholly-Owned Investment Sub) could not participate together with one or more Affiliated Funds and/or one or more other Regulated Funds without obtaining and relying on the Order.[3]

2. The Order sought by the applicants would supersede the prior order [4] (''Prior Order'') with the result that no person will continue to rely on the Prior Order if the Order is granted.

Applicants

3. MSCC is a non-diversified, closed-end management investment company incorporated in Maryland that has elected to be regulated as a BDC under the Act.[5] MSCC is internally managed. The Board [6] of MSCC currently consists

[1] ''Regulated Funds'' means MSCC, HMS Income, the Future Regulated Funds, and the BDC Downstream Funds (defined below). ''Future Regulated Fund'' means a closed-end management investment company (a) that is registered under the Act or has elected to be regulated as a BDC, (b) (i) whose investment adviser (and sub-advisers, if any) are MSC Advisers or (ii) whose investment adviser is HMS Adviser and sub-adviser is an MSC Adviser, and (c) that intends to participate in the co-investment Program (the ''Co-Investment Program''). ''Adviser'' means (i) HMS Adviser, (ii) any MSC Adviser, and (iii) with respect to MSCC, MSCC. ''MSC Adviser'' means MSC Adviser I, together with any future investment adviser that (i) controls, is controlled by or is under common control with MSC Adviser I and (ii) is registered under the Advisers Act of 1940 (the ''Advisers Act'').

[2] ''Affiliated Fund'' means any entity (a) whose investment adviser (and sub-adviser(s), if any) are MSC Advisers, (b) that either (X) would be an investment company but for Section 3(c)(1), 3(c)(5)(C) or 3(c)(7) of the Act, or (Y) relies on the Rule 3a–7 exemption from investment company status, (c) that is not a BDC Downstream Fund, and (d) that intends to participate in the Co-Investment Program. There currently are no existing Affiliated Funds. ''BDC Downstream Fund'' means, with respect to any Regulated Fund that is a business development company (''BDC''), an entity (i) that the BDC directly or indirectly controls, (ii) that is not controlled by any person other than the BDC (except a person that indirectly controls the entity solely because it controls the BDC), (iii) that would be an investment company but for section 3(c)(1) or 3(c)(7) of the Act, (iv) whose investment adviser (and sub-adviser, if any) is an Adviser, (v) that is not a Wholly-Owned Investment Sub (defined below), and (vi) that intends to participate in the Co-Investment Program.

[3] All existing entities that currently intend to rely on the Order have been named as applicants and any existing or future entities that may rely on the Order in the future will comply with its terms and Conditions set forth in the application.

[4] HMS Income Fund, *et al.,* Investment Company Act Rel. Nos. 30984 (Mar. 18, 2014) (notice) and 31016 (Apr. 15, 2014) (order) (''Prior Order'').

[5] Section 2(a)(48) defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in section 55(a)(1) through 55(a)(3) and makes available significant managerial assistance with respect to the issuers of such securities.

[6] ''Board'' means (i) with respect to a Regulated Fund other than a BDC Downstream Fund, the

Continued

of eleven members, nine of whom are Independent Directors.[7]

4. HMS Income is a non-diversified, closed-end management investment company incorporated in Maryland that has elected to be regulated as a BCC under the Act. The Board of HMS Income currently consists of five members, three of whom are Independent Directors.

5. HMS Adviser, a limited partnership under the laws of Texas, is registered with the Commission as an investment adviser under the Advisers Act. HMS Adviser serves as the investment adviser to HMS Income. MSC Adviser I is a wholly-owned subsidiary of MSCC and is registered with the Commission as an investment adviser under the Advisers Act. MSC Adviser I serves as the sub-adviser to HMS Income.

6. Applicants state that a Regulated Fund may, from time to time, form one or more Wholly-Owned Investment Subs.[8] Such a subsidiary may be prohibited from investing in a Co-Investment Transaction with a Regulated Fund (other than its parent) or any Affiliated Fund because it would be a company controlled by its parent Regulated Fund for purposes of section 57(a)(4) and rule 17d–1. Applicants request that each Wholly-Owned Investment Sub be permitted to participate in Co-Investment Transactions in lieu of the Regulated Fund that owns it and that the Wholly-Owned Investment Sub's participation in any such transaction be treated, for purposes of the Order, as though the parent Regulated Fund were participating directly.

Applicants' Representations:

A. Allocation Process

7. Applicants represent that the Advisers have established rigorous processes for ensuring compliance with the Prior Order and for allocating initial investment opportunities, opportunities for subsequent investments in an issuer and dispositions of securities holdings reasonably designed to treat all clients fairly and equitably. Further, applicants represent that these processes will be extended and modified in a manner reasonably designed to ensure that the additional transactions permitted under the Order will both (i) be fair and equitable to the Regulated Funds and the Affiliated Funds and (ii) comply with the Conditions.

8. Opportunities for Potential Co-Investment Transactions may arise when investment advisory personnel of an Adviser becomes aware of investment opportunities that may be appropriate for a Regulated Fund and one or more other Regulated Funds and/or one or more Affiliated Funds. If the requested Order is granted, the Advisers will establish, maintain and implement policies and procedures reasonably designed to ensure that, when such opportunities arise, the relevant Advisers to the relevant Regulated Funds are promptly notified and receive the same information about the opportunity as any other Advisers considering the opportunity for their clients. In particular, consistent with Condition 1, if a Potential Co-Investment Transaction falls within the then-current Objectives and Strategies[9] and any Board-Established Criteria[10] of a Regulated Fund, the policies and procedures will require that the relevant portfolio managers, Investment Teams (defined below), and/or Investment Committees (defined below) responsible for that Regulated Fund receive sufficient information to allow the Regulated Fund's Adviser to make its independent determination and recommendations under the Conditions.[11] The Adviser to each applicable Regulated Fund working through the applicable portfolio manager, Investment Team or Investment Committee will then make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances. If the Adviser to a Regulated Fund deems the Regulated Fund's participation in such Potential Co-Investment Transaction to be appropriate, then it will formulate a recommendation regarding the proposed order amount for the Regulated Fund. If the Adviser to a Regulated Fund deems the Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate, it will, working through the applicable portfolio manager, Investment Team, or Investment Committee, formulate a

board of directors (or the equivalent) of the applicable Regulated Fund and (ii) with respect to a BDC Downstream Fund, the Independent Party of the BDC Downstream Fund. ''Independent Party'' means, with respect to a BDC Downstream Fund, (i) if the BDC Downstream Fund has a board of directors (or the equivalent), the board or (ii) if the BDC Downstream Fund does not have a board of directors (or the equivalent), a transaction committee or advisory committee of the BDC Downstream Fund.

[7] ''Independent Director'' means a member of the Board of any relevant entity who is not an ''interested person'' as defined in section 2(a)(19) of the Act. No Independent Director of a Regulated Fund (including any non-interested member of an Independent Party) will have a financial interest in any Co-Investment Transaction, other than indirectly through share ownership in one of the Regulated Funds.

[8] ''Wholly-Owned Investment Sub'' means an entity (i) that is wholly-owned by a Regulated Fund (with such Regulated Fund at all times holding, beneficially and of record, 95% or more of the voting and economic interests); (ii) whose sole business purpose is to hold one or more investments on behalf of such Regulated Fund (and in the case of an SBIC Subsidiary, maintain a license under the Small Business Investment Act of 1958 (''SBA Act'') and issue debentures guaranteed by the Small Business Administration (''SBA'')); (iii) with respect to which such Regulated Fund's Board has the sole authority to make all determinations with respect to the entity's participation under the Conditions; and (iv) that (A) would be an investment company but for section 3(c)(1), 3(c)(5)(C), or 3(c)(7) of the Act, or (B) that qualifies as a real estate investment trust within the meaning of section 856 of the Internal Revenue Code because substantially all of its assets would consist of real properties. ''SBIC Subsidiary'' means a Wholly-Owned Investment Sub that is licensed by the SBA to operate under the SBA Act as a small business investment company. Each of the SBIC Funds and the MSCC Subs is a Wholly-Owned Investment Sub of MSCC, and each of the HMS Income Subs is a Wholly-Owned Investment Sub of HMS Income.

[9] ''Objectives and Strategies'' means (i) with respect to any Regulated Fund other than a BDC Downstream Fund, its investment objectives and strategies, as described in its most current registration statement on Form N–2, other current filings with the Commission under the Securities Act of 1933 (''Securities Act'') or under the Securities Exchange Act of 1934, as amended, and its most current report to stockholders, and (ii) with respect to any BDC Downstream Fund, those investment objectives and strategies described in its disclosure documents (including private placement memoranda and reports to equity holders) and organizational documents (including operating agreements).

[10] ''Board-Established Criteria'' means criteria that the Board of a Regulated Fund may establish from time to time to describe the characteristics of Potential Co-Investment Transactions regarding which the Adviser to the Regulated Fund should be notified under Condition 1. The Board-Established Criteria will be consistent with the Regulated Fund's Objectives and Strategies. If no Board-Established Criteria are in effect, then the Regulated Fund's Adviser will be notified of all Potential Co-Investment Transactions that fall within the Regulated Fund's then-current Objectives and Strategies. Board-Established Criteria will be objective and testable, meaning that they will be based on observable information, such as industry/sector of the issuer, minimum EBITDA of the issuer, asset class of the investment opportunity or required commitment size, and not on characteristics that involve a discretionary assessment. The Adviser to the Regulated Fund may from time to time recommend criteria for the Board's consideration, but Board-Established Criteria will only become effective if approved by a majority of the Independent Directors. The Independent Directors of a Regulated Fund may at any time rescind, suspend or qualify their approval of any Board-Established Criteria, though applicants anticipate that, under normal circumstances, the Board would not modify these criteria more often than quarterly.

[11] The Advisers are organized and managed such that the individual portfolio managers, as well as the teams and committees of portfolio managers, analysts and senior management (''Investment Teams'' and ''Investment Committees'') responsible for evaluating investment opportunities and making investment decisions on behalf of clients are promptly notified of the opportunities. Investment Teams and Investment Committees responsible for an area of investment may include investment professionals and senior management from among one or more Advisers.

recommendation, which may be in the form of a percentage, regarding the proposed order amount for the Regulated Fund.

9. Applicants state that for each Regulated Fund and Affiliated Fund whose Adviser recommends participating in a Potential Co-Investment Transaction, the applicable portfolio manager, Investment Team or Investment Committee will approve the investment and the investment amount. Prior to the External Submission (defined below), each proposed order amount may be reviewed and adjusted, in accordance with the Advisers' written allocation policies and procedures.[12] The order of a Regulated Fund or Affiliated Fund resulting from this process is referred to as its ''Internal Order.'' The Internal Order will be submitted for approval by the Required Majority of any participating Regulated Funds in accordance with the Conditions.[13]

10. If the aggregate Internal Orders for a Potential Co-Investment Transaction do not exceed the size of the investment opportunity immediately prior to the submission of the orders to the underwriter, broker, dealer or issuer, as applicable (the ''External Submission''), then each Internal Order will be fulfilled as placed. If, on the other hand, the aggregate Internal Orders for a Potential Co-Investment Transaction exceed the size of the investment opportunity immediately prior to the External Submission, then the allocation of the opportunity will be made pro rata on the basis of the size of the Internal Orders.[14] If, subsequent to such External Submission, the size of the opportunity is increased or decreased, or if the terms of such opportunity, or the facts and circumstances applicable to the Regulated Funds' or the Affiliated Funds' consideration of the opportunity, change, the participants will be permitted to submit revised Internal Orders in accordance with written allocation policies and procedures that the Advisers will establish, implement, and maintain, provided that if the size of the opportunity is decreased such that the aggregate of the original Internal Orders would exceed the amount of the remaining investment opportunity, then upon submitting any revised order amount to the Board of a Regulated Fund for approval, the Adviser to the Regulated Fund will also notify the Board promptly of the amount that the Regulated Fund would receive if the remaining investment opportunity were allocated pro rata on the basis of the size of the original Internal Orders.[15]

B. Follow-On Investments

11. Applicants state that from time to time the Regulated Funds and Affiliated Funds may have opportunities to make Follow-On Investments [16] in an issuer in which a Regulated Fund and one or more other Regulated Funds and/or Affiliated Funds previously have invested.

12. Applicants propose that Follow-On Investments would be divided into two categories depending on whether the prior investment was a Co-Investment Transaction or a Pre-Boarding Investment.[17] If the Regulated Funds and Affiliated Funds had previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Follow-On Investment would be subject to the Standard Review Follow-Ons described in Condition 8. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Follow-On Investment would be subject to the Enhanced-Review Follow-Ons described in Condition 9. All Enhanced Review Follow-Ons require the approval of the Required Majority. For a given issuer, the participating Regulated Funds and Affiliated Funds would need to comply with the requirements of Enhanced-Review Follow-Ons only for the first Co-Investment Transaction. Subsequent Co-Investment Transactions with respect to the issuer would be governed by the requirements of Standard Review Follow-Ons.

13. A Regulated Fund would be permitted to invest in Standard Review Follow-Ons either with the approval of the Required Majority under Condition 8(c) or without Board approval under Condition 8(b) if it is (i) a Pro Rata Follow-On Investment [18] or (ii) a Non-Negotiated Follow-On Investment.[19] Applicants believe that these Pro Rata and Non-Negotiated Follow-On Investments do not present a significant opportunity for overreaching on the part of any Adviser and thus do not warrant the time or the attention of the Board. Pro Rata Follow-On Investments and Non-Negotiated Follow-On Investments remain subject to the Board's periodic review in accordance with Condition 10.

[12] The reason for any such adjustment to a proposed order amount will be documented in writing and preserved in the records of the Advisers.

[13] ''Required Majority'' means a required majority, as defined in section 57(o) of the Act. In the case of a Regulated Fund that is a registered closed-end fund, the Board members that make up the Required Majority will be determined as if the Regulated Fund were a BDC subject to section 57(o). In the case of a BDC Downstream Fund with a board of directors (or the equivalent), the members that make up the Required Majority will be determined as if the BDC Downstream Fund were a BDC subject to section 57(o). In the case of a BDC Downstream Fund with a transaction committee or advisory committee, the committee members that make up the Required Majority will be determined as if the BDC Downstream Fund were a BDC subject to section 57(o) and as if the committee members were directors of the fund.

[14] The Advisers will maintain records of all proposed order amounts, Internal Orders and External Submissions in conjunction with Potential Co-Investment Transactions. Each applicable Adviser will provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with the Conditions. ''Eligible Directors'' means, with respect to a Regulated Fund and a Potential Co-Investment Transaction, the members of the Regulated Fund's Board eligible to vote on that Potential Co-Investment Transaction under section 57(o) of the Act (treating any registered investment company or series thereof as a BDC for this purpose).

[15] The Board of the Regulated Fund will then either approve or disapprove of the investment opportunity in accordance with Condition 2, 6, 7, 8 or 9, as applicable.

[16] ''Follow-On Investment'' means an additional investment in the same issuer, including, but not limited to, through the exercise of warrants, conversion privileges or other rights to purchase securities of the issuer.

[17] ''Pre-Boarding Investments'' are investments in an issuer held by a Regulated Fund as well as one or more Affiliated Funds and/or one or more other Regulated Funds that were acquired prior to participating in any Co-Investment Transaction: (i) In transactions in which the only term negotiated by or on behalf of such funds was price in reliance on one of the JT No-Action Letters (defined below); or (ii) in transactions occurring at least 90 days apart and without coordination between the Regulated Fund and any Affiliated Fund or other Regulated Fund.

[18] A ''Pro Rata Follow-On Investment'' is a Follow-On Investment (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investments in the issuer or security, as appropriate, immediately preceding the Follow-On Investment, and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in the pro rata Follow-On Investments as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Follow-On Investments, in which case all subsequent Follow-On Investments will be submitted to the Regulated Fund's Eligible Directors in accordance with Condition 8(c).

[19] A ''Non-Negotiated Follow-On Investment'' is a Follow-On Investment in which a Regulated Fund participates together with one or more Affiliated Funds and/or one or more other Regulated Funds (i) in which the only term negotiated by or on behalf of the funds is price and (ii) with respect to which, if the transaction were considered on its own, the funds would be entitled to rely on one of the JT No-Action Letters. ''JT No-Action Letters'' means SMC Capital, Inc., SEC No-Action Letter (pub. avail. Sept. 5, 1995) and Massachusetts Mutual Life Insurance Company, SEC No-Action Letter (pub. avail. June 7, 2000).

C. Dispositions

14. Applicants propose that Dispositions [20] would be divided into two categories. If the Regulated Funds and Affiliated Funds holding investments in the issuer had previously participated in a Co-Investment Transaction with respect to the issuer, then the terms and approval of the Disposition would be subject to the Standard Review Dispositions described in Condition 6. If the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer but hold a Pre-Boarding Investment, then the terms and approval of the Disposition would be subject to the Enhanced Review Dispositions described in Condition 7. Subsequent Dispositions with respect to the same issuer would be governed by Condition 6 under the Standard Review Dispositions.[21]

15. A Regulated Fund may participate in a Standard Review Disposition either with the approval of the Required Majority under Condition 6(d) or without Board approval under Condition 6(c) if (i) the Disposition is a Pro Rata Disposition [22] or (ii) the securities are Tradable Securities [23] and the Disposition meets the other requirements of Condition 6(c)(ii). Pro Rata Dispositions and Dispositions of a Tradable Security remain subject to the Board's periodic review in accordance with Condition 10.

D. Delayed Settlement

16. Applicants represent that under the terms and Conditions of the application, all Regulated Funds and Affiliated Funds participating in a Co-Investment Transaction will invest at the same time, for the same price and with the same terms, conditions, class, registration rights and any other rights, so that none of them receives terms more favorable than any other. However, the settlement date for an Affiliated Fund in a Co-Investment Transaction may occur up to ten business days after the settlement date for the Regulated Fund, and vice versa. Nevertheless, in all cases, (i) the date on which the commitment of the Affiliated Funds and Regulated Funds is made will be the same even where the settlement date is not and (ii) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other.

E. Holders

17. Under Condition 15, if an Adviser, its principals, or any person controlling, controlled by, or under common control with the Adviser or its principals, and the Affiliated Funds (collectively, the ''Holders'') own in the aggregate more than 25 percent of the outstanding voting shares of a Regulated Fund (the ''Shares''), then the Holders will vote such Shares as required under the Condition.

Applicants' Legal Analysis

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit participation by a registered investment company and an affiliated person in any ''joint enterprise or other joint arrangement or profit-sharing plan,'' as defined in the rule, without prior approval by the Commission by order upon application. Section 17(d) of the Act and rule 17d–1 under the Act are applicable to Regulated Funds that are registered closed-end investment companies.

2. Similarly, with regard to BDCs, section 57(a)(4) of the Act generally prohibits certain persons specified in section 57(b) from participating in joint transactions with the BDC or a company controlled by the BDC in contravention of rules as prescribed by the Commission. Section 57(i) of the Act provides that, until the Commission prescribes rules under section 57(a)(4), the Commission's rules under section 17(d) of the Act applicable to registered closed-end investment companies will be deemed to apply to transactions subject to section 57(a)(4). Because the Commission has not adopted any rules under section 57(a)(4), rule 17d–1 also applies to joint transactions with Regulated Funds that are BDCs.

3. Co-Investment Transactions are prohibited by either or both of rule 17d–1 and section 57(a)(4) without a prior exemptive order of the Commission to the extent that the Affiliated Funds and the Regulated Funds participating in such transactions fall within the category of persons described by rule 17d–1 and/or section 57(b), as modified by rule 57b–1 thereunder, as applicable, vis-à-vis each participating Regulated Fund. With respect to HMS Income, section 57(b) applies to any investment adviser to a BDC, including a sub-adviser. Therefore, MSC Adviser I could be deemed to be related to HMS Income in a manner described by section 57(b). MSCC controls MSC Adviser I and therefore MSCC (or a Wholly-Owned Investment Subsidiary or BDC Downstream Fund of MSCC) could be deemed to be related to HMS Income in a manner described by section 57(b) and prohibited by section 57(a)(4) and rule 17d–1 from participating in Co-Investment Transactions with HMS Income. With respect to any other Regulated Funds or Affiliated Funds, each may be deemed to be affiliated persons vis-à-vis a Regulated Fund within the meaning of section 2(a)(3) by reason of common control because an MSC Adviser will advise or sub-advise, and may be deemed to control, each of the Affiliated Funds and Regulated Funds, except for MSCC, which will control any MSC Adviser. Thus, each of the Affiliated Funds and other Regulated Funds could be deemed to be a person related to the Regulated Funds that are BDCs in a manner described by section 57(b) and related to Regulated Funds that are not BDCs in a manner described by section 17(d); and therefore the prohibitions of rule 17d–1 and sections 17(d) and 57(a)(4) would apply respectively to prohibit the Affiliated Funds from participating in

[20] ''Disposition'' means the sale, exchange or other disposition of an interest in a security of an issuer.

[21] However, with respect to an issuer, if a Regulated Fund's first Co-Investment Transaction is an Enhanced Review Disposition, and the Regulated Fund does not dispose of its entire position in the Enhanced Review Disposition, then before such Regulated Fund may complete its first Standard Review Follow-On in such issuer, the Eligible Directors must review the proposed Follow-On Investment not only on a stand-alone basis but also in relation to the total economic exposure in such issuer (*i.e.,* in combination with the portion of the Pre-Boarding Investment not disposed of in the Enhanced Review Disposition), and the other terms of the investments. This additional review would be required because such findings would not have been required in connection with the prior Enhanced Review Disposition, but they would have been required had the first Co-Investment Transaction been an Enhanced Review Follow-On.

[22] A ''Pro Rata Disposition'' is a Disposition (i) in which the participation of each Affiliated Fund and each Regulated Fund is proportionate to its outstanding investment in the security subject to Disposition immediately preceding the Disposition; and (ii) in the case of a Regulated Fund, a majority of the Board has approved the Regulated Fund's participation in pro rata Dispositions as being in the best interests of the Regulated Fund. The Regulated Fund's Board may refuse to approve, or at any time rescind, suspend or qualify, its approval of Pro Rata Dispositions, in which case all subsequent Dispositions will be submitted to the Regulated Fund's Eligible Directors.

[23] ''Tradable Security'' means a security that meets the following criteria at the time of Disposition: (i) It trades on a national securities exchange or designated offshore securities market as defined in rule 902(b) under the Securities Act; (ii) it is not subject to restrictive agreements with the issuer or other security holders; and (iii) it trades with sufficient volume and liquidity (findings as to which are documented by the Advisers to any Regulated Funds holding investments in the issuer and retained for the life of the Regulated Fund) to allow each Regulated Fund to dispose of its entire position remaining after the proposed Disposition within a short period of time not exceeding 30 days at approximately the value (as defined by section 2(a)(41) of the Act) at which the Regulated Fund has valued the investment.

Co-Investment Transactions with the Regulated Funds and a Regulated Fund from participating in Co-Investment Transactions with the other Regulated Funds.

4. In passing upon applications under rule 17d–1, the Commission considers whether the company's participation in the joint transaction is consistent with the provisions, policies, and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

5. Applicants state that in the absence of the requested relief, in many circumstances the Regulated Funds would be limited in their ability to participate in attractive and appropriate investment opportunities. Applicants state that, as required by rule 17d–1(b), the Conditions ensure that the terms on which Co-Investment Transactions may be made will be consistent with the participation of the Regulated Funds being on a basis that it is neither different from nor less advantageous than other participants, thus protecting the equity holders of any participant from being disadvantaged. Applicants further state that the Conditions ensure that all Co-Investment Transactions are reasonable and fair to the Regulated Funds and their shareholders and do not involve overreaching by any person concerned, including the Advisers. Applicants state that the Regulated Funds' participation in the Co-Investment Transactions in accordance with the Conditions will be consistent with the provisions, policies, and purposes of the Act and would be done in a manner that is not different from, or less advantageous than, that of other participants.

Applicants' Conditions

Applicants agree that the Order will be subject to the following Conditions:

1. *Identification and Referral of Potential Co-Investment Transactions.*

(a) The Advisers will establish, maintain and implement policies and procedures reasonably designed to ensure that each Adviser is promptly notified of all Potential Co-Investment Transactions that fall within the then-current Objectives and Strategies and Board-Established Criteria of any Regulated Fund the Adviser manages.

(b) When an Adviser to a Regulated Fund is notified of a Potential Co-Investment Transaction under Condition 1(a), the Adviser will make an independent determination of the appropriateness of the investment for the Regulated Fund in light of the Regulated Fund's then-current circumstances.

2. *Board Approvals of Co-Investment Transactions.*

(a) If the Adviser deems a Regulated Fund's participation in any Potential Co-Investment Transaction to be appropriate for the Regulated Fund, it will then determine an appropriate level of investment for the Regulated Fund.

(b) If the aggregate amount recommended by the Advisers to be invested in the Potential Co-Investment Transaction by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, the investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application. Each Adviser to a participating Regulated Fund will promptly notify and provide the Eligible Directors with information concerning the Affiliated Funds' and Regulated Funds' order sizes to assist the Eligible Directors with their review of the applicable Regulated Fund's investments for compliance with these Conditions.

(c) After making the determinations required in Condition 1(b) above, each Adviser to a participating Regulated Fund will distribute written information concerning the Potential Co-Investment Transaction (including the amount proposed to be invested by each participating Regulated Fund and each participating Affiliated Fund) to the Eligible Directors of its participating Regulated Fund(s) for their consideration. A Regulated Fund will enter into a Co-Investment Transaction with one or more other Regulated Funds or Affiliated Funds only if, prior to the Regulated Fund's participation in the Potential Co-Investment Transaction, a Required Majority concludes that:

(i) The terms of the transaction, including the consideration to be paid, are reasonable and fair to the Regulated Fund and its equity holders and do not involve overreaching in respect of the Regulated Fund or its equity holders on the part of any person concerned;

(ii) the transaction is consistent with:

(A) The interests of the Regulated Fund's equity holders; and

(B) the Regulated Fund's then-current Objectives and Strategies;

(iii) the investment by any other Regulated Fund(s) or Affiliated Fund(s) would not disadvantage the Regulated Fund, and participation by the Regulated Fund would not be on a basis different from, or less advantageous than, that of any other Regulated Fund(s) or Affiliated Fund(s) participating in the transaction; provided that the Required Majority shall not be prohibited from reaching the conclusions required by this Condition 2(c)(iii) if:

(A) The settlement date for another Regulated Fund or an Affiliated Fund in a Co-Investment Transaction is later than the settlement date for the Regulated Fund by no more than ten business days or earlier than the settlement date for the Regulated Fund by no more than ten business days, in either case, so long as: (x) The date on which the commitment of the Affiliated Funds and Regulated Funds is made is the same; and (y) the earliest settlement date and the latest settlement date of any Affiliated Fund or Regulated Fund participating in the transaction will occur within ten business days of each other; or

(B) any other Regulated Fund or Affiliated Fund, but not the Regulated Fund itself, gains the right to nominate a director for election to a portfolio company's board of directors, the right to have a board observer or any similar right to participate in the governance or management of the portfolio company so long as: (x) The Eligible Directors will have the right to ratify the selection of such director or board observer, if any; (y) the Adviser agrees to, and does, provide periodic reports to the Regulated Fund's Board with respect to the actions of such director or the information received by such board observer or obtained through the exercise of any similar right to participate in the governance or management of the portfolio company; and (z) any fees or other compensation that any other Regulated Fund or Affiliated Fund or any affiliated person of any other Regulated Fund or Affiliated Fund receives in connection with the right of one or more Regulated Funds or Affiliated Funds to nominate a director or appoint a board observer or otherwise to participate in the governance or management of the portfolio company will be shared proportionately among any participating Affiliated Funds (who may, in turn, share their portion with their affiliated persons) and any participating Regulated Fund(s) in accordance with the amount of each such party's investment; and

(iv) the proposed investment by the Regulated Fund will not involve compensation, remuneration or a direct or indirect [24] financial benefit to the Advisers, any other Regulated Fund, the Affiliated Funds or any affiliated person

[24] For example, procuring the Regulated Fund's investment in a Potential Co-Investment Transaction to permit an affiliate to complete or obtain better terms in a separate transaction would constitute an indirect financial benefit.

of any of them (other than the parties to the Co-Investment Transaction), except (A) to the extent permitted by Condition 14, (B) to the extent permitted by section 17(e) or 57(k), as applicable, (C) indirectly, as a result of an interest *in the securities issued by one of the parties to the Co-Investment Transaction, or* (D) in the case of fees or other compensation described in Condition 2(c)(iii)(B)(z).

3. *Right to Decline.* Each Regulated Fund has the right to decline to participate in any Potential Co-Investment Transaction or to invest less than the amount proposed.

4. *General Limitation.* Except for Follow-On Investments made in accordance with Conditions 8 and 9 below,[25] a Regulated Fund will not invest in reliance on the Order in any issuer in which a Related Party has an investment.[26]

5. *Same Terms and Conditions.* A Regulated Fund will not participate in any Potential Co-Investment Transaction unless (i) the terms, conditions, price, class of securities to be purchased, date on which the commitment is entered into and registration rights (if any) will be the same for each participating Regulated Fund and Affiliated Fund and (ii) the earliest settlement date and the latest settlement date of any participating Regulated Fund or Affiliated Fund will occur as close in time as practicable and in no event more than ten business days apart. The grant to one or more Regulated Funds or Affiliated Funds, but not the respective Regulated Fund, of the right to nominate a director for election to a portfolio company's board of directors, the right to have an observer on the board of directors or similar rights to participate in the governance or management of the portfolio company will not be interpreted so as to violate this Condition 5, if Condition 2(c)(iii)(B) is met.

6. *Standard Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of an interest in a security and one or more Regulated Funds and Affiliated Funds have previously participated in a Co-Investment Transaction with respect to the issuer, then:

(i) The Adviser to such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition.

(b) *Same Terms and Conditions.* Each Regulated Fund will have the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and conditions as those applicable to the Affiliated Funds and any other Regulated Fund.

(c) *No Board Approval Required.* A Regulated Fund may participate in such a Disposition without obtaining prior approval of the Required Majority if:

(i) (A) The participation of each Regulated Fund and Affiliated Fund in such Disposition is proportionate to its then-current holding of the security (or securities) of the issuer that is (or are) the subject of the Disposition; [27] (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in such Dispositions on a pro rata basis (as described in greater detail in the application); and (C) the Board of the Regulated Fund is provided on a quarterly basis with a list of all Dispositions made in accordance with this Condition; or

(ii) each security is a Tradable Security and (A) the Disposition is not to the issuer or any affiliated person of the issuer; and (B) the security is sold for cash in a transaction in which the only term negotiated by or on behalf of the participating Regulated Funds and Affiliated Funds is price.

(d) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that it is in the Regulated Fund's best interests.

7. *Enhanced Review Dispositions.*

(a) *General.* If any Regulated Fund or Affiliated Fund elects to sell, exchange or otherwise dispose of a Pre-Boarding Investment in a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds an investment in the issuer of the proposed Disposition at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to participation by such Regulated Fund in the Disposition; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Disposition solely to the extent that a Required Majority determines that:

(i) The Disposition complies with Condition 2(c)(i), (ii), (iii)(A), and (iv); and

(ii) the making and holding of the Pre-Boarding Investments were not prohibited by section 57 or rule 17d–1, as applicable, and records the basis for the finding in the Board minutes.

(c) *Additional Requirements:* The Disposition may only be completed in reliance on the Order if:

(i) *Same Terms and Conditions.* Each Regulated Fund has the right to participate in such Disposition on a proportionate basis, at the same price and on the same terms and Conditions as those applicable to the Affiliated Funds and any other Regulated Fund;

(ii) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(iii) *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as

[25] This exception applies only to Follow-On Investments by a Regulated Fund in issuers in which that Regulated Fund already holds investments.

[26] ''Related Party'' means (i) any Close Affiliate and (ii) in respect of matters as to which any Adviser has knowledge, any Remote Affiliate. ''Close Affiliate'' means the Advisers, the Regulated Funds, the Affiliated Funds and any other person described in section 57(b) (after giving effect to rule 57b–1) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) except for limited partners included solely by reason of the reference in section 57(b) to section 2(a)(3)(D). ''Remote Affiliate'' means any person described in section 57(e) in respect of any Regulated Fund (treating any registered investment company or series thereof as a BDC for this purpose) and any limited partner holding 5% or more of the relevant limited partner interests that would be a Close Affiliate but for the exclusion in that definition.

[27] In the case of any Disposition, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Disposition.

modified by rule 57b–1) or rule 17d–1, as applicable;

(iv) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial [28] in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(v) *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

8. *Standard Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer and the Regulated Funds and Affiliated Funds holding investments in the issuer previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time; and

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund.

(b) *No Board Approval Required.* A Regulated Fund may participate in the Follow-On Investment without obtaining prior approval of the Required Majority if:

(i) (A) The proposed participation of each Regulated Fund and each Affiliated Fund in such investment is proportionate to its outstanding investments in the issuer or the security at issue, as appropriate,[29] immediately preceding the Follow-On Investment; and (B) the Board of the Regulated Fund has approved as being in the best interests of the Regulated Fund the ability to participate in Follow-On Investments on a pro rata basis (as described in greater detail in the application); or

(ii) it is a Non-Negotiated Follow-On Investment.

(c) *Standard Board Approval.* In all other cases, the Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority makes the determinations set forth in Condition 2(c). If the only previous Co-Investment Transaction with respect to the issuer was an Enhanced Review Disposition the Eligible Directors must complete this review of the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms of the investment.

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

9. *Enhanced Review Follow-Ons.*

(a) *General.* If any Regulated Fund or Affiliated Fund desires to make a Follow-On Investment in an issuer that is a Potential Co-Investment Transaction and the Regulated Funds and Affiliated Funds holding investments in the issuer have not previously participated in a Co-Investment Transaction with respect to the issuer:

(i) The Adviser to each such Regulated Fund or Affiliated Fund will notify each Regulated Fund that holds securities of the portfolio company of the proposed transaction at the earliest practical time;

(ii) the Adviser to each Regulated Fund that holds an investment in the issuer will formulate a recommendation as to the proposed participation, including the amount of the proposed investment, by such Regulated Fund; and

(iii) the Advisers will provide to the Board of each Regulated Fund that holds an investment in the issuer all information relating to the existing investments in the issuer of the Regulated Funds and Affiliated Funds, including the terms of such investments and how they were made, that is necessary for the Required Majority to make the findings required by this Condition.

(b) *Enhanced Board Approval.* The Adviser will provide its written recommendation as to the Regulated Fund's participation to the Eligible Directors, and the Regulated Fund will participate in such Follow-On Investment solely to the extent that a Required Majority reviews the proposed Follow-On Investment both on a stand-alone basis and together with the Pre-Boarding Investments in relation to the total economic exposure and other terms and makes the determinations set forth in Condition 2(c). In addition, the Follow-On Investment may only be completed in reliance on the Order if the Required Majority of each participating Regulated Fund determines that the making and holding of the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule17d–1,

[28] In determining whether a holding is ''immaterial'' for purposes of the Order, the Required Majority will consider whether the nature and extent of the interest in the transaction or arrangement is sufficiently small that a reasonable person would not believe that the interest affected the determination of whether to enter into the transaction or arrangement or the terms of the transaction or arrangement.

[29] To the extent that a Follow-On Investment opportunity is in a security or arises in respect of a security held by the participating Regulated Funds and Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the security in question immediately preceding the Follow-On Investment using the most recent available valuation thereof. To the extent that a Follow-On Investment opportunity relates to an opportunity to invest in a security that is not in respect of any security held by any of the participating Regulated Funds or Affiliated Funds, proportionality will be measured by each participating Regulated Fund's and Affiliated Fund's outstanding investment in the issuer immediately preceding the Follow-On Investment using the most recent available valuation thereof.

as applicable. The basis for the Board's findings will be recorded in its minutes.

(c) *Additional Requirements.* The Follow-On Investment may only be completed in reliance on the Order if:

(i) *Original Investments.* All of the Affiliated Funds' and Regulated Funds' investments in the issuer are Pre-Boarding Investments;

(ii) *Advice of counsel.* Independent counsel to the Board advises that the making and holding of the investments in the Pre-Boarding Investments were not prohibited by section 57 (as modified by rule 57b–1) or rule 17d–1, as applicable;

(iii) *Multiple Classes of Securities.* All Regulated Funds and Affiliated Funds that hold Pre-Boarding Investments in the issuer immediately before the time of completion of the Co-Investment Transaction hold the same security or securities of the issuer. For the purpose of determining whether the Regulated Funds and Affiliated Funds hold the same security or securities, they may disregard any security held by some but not all of them if, prior to relying on the Order, the Required Majority is presented with all information necessary to make a finding, and finds, that: (x) Any Regulated Fund's or Affiliated Fund's holding of a different class of securities (including for this purpose a security with a different maturity date) is immaterial in amount, including immaterial relative to the size of the issuer; and (y) the Board records the basis for any such finding in its minutes. In addition, securities that differ only in respect of issuance date, currency, or denominations may be treated as the same security; and

(iv) *No control.* The Affiliated Funds, the other Regulated Funds and their affiliated persons (within the meaning of section 2(a)(3)(C) of the Act), individually or in the aggregate, do not control the issuer of the securities (within the meaning of section 2(a)(9) of the Act).

(d) *Allocation.* If, with respect to any such Follow-On Investment:

(i) The amount of the opportunity proposed to be made available to any Regulated Fund is not based on the Regulated Funds' and the Affiliated Funds' outstanding investments in the issuer or the security at issue, as appropriate, immediately preceding the Follow-On Investment; and

(ii) the aggregate amount recommended by the Advisers to be invested in the Follow-On Investment by the participating Regulated Funds and any participating Affiliated Funds, collectively, exceeds the amount of the investment opportunity, then the Follow-On Investment opportunity will be allocated among them pro rata based on the size of the Internal Orders, as described in section III.A.1.b. of the application.

(e) *Other Conditions.* The acquisition of Follow-On Investments as permitted by this Condition will be considered a Co-Investment Transaction for all purposes and subject to the other Conditions set forth in the application.

10. *Board Reporting, Compliance and Annual Re-Approval.*

(a) Each Adviser to a Regulated Fund will present to the Board of each Regulated Fund, on a quarterly basis, and at such other times as the Board may request, (i) a record of all investments in Potential Co-Investment Transactions made by any of the other Regulated Funds or any of the Affiliated Funds during the preceding quarter that fell within the Regulated Fund's then-current Objectives and Strategies and Board-Established Criteria that were not made available to the Regulated Fund, and an explanation of why such investment opportunities were not made available to the Regulated Fund; (ii) a record of all Follow-On Investments in and Dispositions of investments in any issuer in which the Regulated Fund holds any investments by any Affiliated Fund or other Regulated Fund during the prior quarter; and (iii) all information concerning Potential Co-Investment Transactions and Co-Investment Transactions, including investments made by other Regulated Funds or Affiliated Funds that the Regulated Fund considered but declined to participate in, so that the Independent Directors, may determine whether all Potential Co-Investment Transactions and Co-Investment Transactions during the preceding quarter, including those investments that the Regulated Fund considered but declined to participate in, comply with the Conditions.

(b) All information presented to the Regulated Fund's Board pursuant to this Condition will be kept for the life of the Regulated Fund and at least two years thereafter, and will be subject to examination by the Commission and its staff.

(c) Each Regulated Fund's chief compliance officer, as defined in rule 38a–1(a)(4), will prepare an annual report for its Board each year that evaluates (and documents the basis of that evaluation) the Regulated Fund's compliance with the terms and Conditions of the application and the procedures established to achieve such compliance. In the case of a BDC Downstream Fund that does not have a chief compliance officer, the chief compliance officer of the BDC that controls the BDC Downstream Fund will prepare the report for the relevant Independent Party.

(d) The Independent Directors (including the non-interested members of each Independent Party) will consider at least annually whether continued participation in new and existing Co-Investment Transactions is in the Regulated Fund's best interests.

11. *Record Keeping.* Each Regulated Fund will maintain the records required by section 57(f)(3) as if each of the Regulated Funds were a BDC and each of the investments permitted under these Conditions were approved by the Required Majority under section 57(f).

12. *Director Independence.* No Independent Director (including the non-interested members of any Independent Party) of a Regulated Fund will also be a director, general partner, managing member or principal, or otherwise be an ''affiliated person'' (as defined in the Act) of any Affiliated Fund.

13. *Expenses.* The expenses, if any, associated with acquiring, holding or disposing of any securities acquired in a Co-Investment Transaction (including, without limitation, the expenses of the distribution of any such securities registered for sale under the Securities Act) will, to the extent not payable by the Advisers under their respective advisory agreements with the Regulated Funds and the Affiliated Funds, be shared by the Regulated Funds and the participating Affiliated Funds in proportion to the relative amounts of the securities held or being acquired or disposed of, as the case may be.

14. *Transaction Fees.*[30] Any transaction fee (including break-up, structuring, monitoring or commitment fees but excluding brokerage or underwriting compensation permitted by section 17(e) or 57(k)) received in connection with any Co-Investment Transaction will be distributed to the participants on a pro rata basis based on the amounts they invested or committed, as the case may be, in such Co-Investment Transaction. If any transaction fee is to be held by an Adviser pending consummation of the transaction, the fee will be deposited into an account maintained by the Adviser at a bank or banks having the qualifications prescribed in section 26(a)(1), and the account will earn a competitive rate of interest that will also be divided pro rata among the participants. None of the Advisers, the

[30] Applicants are not requesting and the Commission is not providing any relief for transaction fees received in connection with any Co-Investment Transaction.

Affiliated Funds, the other Regulated Funds or any affiliated person of the Affiliated Funds or the Regulated Funds will receive any additional compensation or remuneration of any kind as a result of or in connection with a Co-Investment Transaction other than (i) in the case of the Regulated Funds and the Affiliated Funds, the pro rata transaction fees described above and fees or other compensation described in Condition 2(c)(iii)(B)(z), (ii) brokerage or underwriting compensation permitted by section 17(e) or 57(k), or (iii) in the case of the Advisers, investment advisory compensation paid in accordance with investment advisory agreements between the applicable Regulated Fund(s) or Affiliated Fund(s) and its Adviser.

15. *Independence.* If the Holders own in the aggregate more than 25 percent of the Shares of a Regulated Fund, then the Holders will vote such Shares in the same percentages as the Regulated Fund's other shareholders (not including the Holders) when voting on (1) the election of directors; (2) the removal of one or more directors; or (3) any other matter under either the Act or applicable State law affecting the Board's composition, size or manner of election.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26227 Filed 11–25–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90466; File No. SR–NYSE–2020–94]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change To Amend Section 907.00 of the Manual To Extend the Period of Time for the Entitlement of Certain Eligible Issuers To Receive Complimentary Products and Services Under That Rule

November 20, 2020.

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 November 6, 2020, 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 907.00 of the Manual to modify the entitlement of eligible issuers to complimentary products and services under that rule. 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

Section 907.00 of the Manual sets forth complimentary products and services that issuers are entitled to receive in connection with their NYSE listing. The Exchange offers certain complimentary products and services and access to discounted third-party products and services through the NYSE Market Access Center to currently and newly listed issuers. The Exchange also provides complimentary market surveillance products and services (with a commercial value of approximately $55,000 annually), web-hosting products and services (with a commercial value of approximately $16,000 annually), web-casting services (with a commercial value of approximately $6,500 annually), market analytics products and services (with a commercial value of approximately $30,000 annually), and news distribution products and services (with a commercial value of approximately $20,000 annually) to Eligible New Listings [4] and Eligible Transfer Companies [5] based on the following tiers: [6]

Tier A: For Eligible New Listings and Eligible Transfer Companies with a global market value of $400 million or more, in each case calculated as of the date of listing on the Exchange, the Exchange offers market surveillance, market analytics, web-hosting, webcasting, and news distribution products and services for a period of 24 calendar months.

Tier B: For Eligible New Listings and Eligible Transfer Companies with a global market value of less than $400 million, in each case calculated as of the date of listing on the Exchange, the Exchange offers web-hosting, market analytics, web-casting, and news distribution products and services for a period of 24 calendar months.

Currently, the Exchange provides all of the additional complimentary products and services to Eligible New Listings and Eligible Transfer Companies for a period of 24 months. The Exchange now proposes to extend this period for the additional services provided to Eligible New Listings and Eligible Transfer Companies from 24 months to 48 months.[7] The proposed amendment would be applicable to Eligible New Listings and Eligible Transfer Companies that list on or after the date of SEC approval of the proposal. The Exchange believes that this amendment would assist it in the competition for new listings, as well as in attracting transfers of issuers from other exchanges. The market for new

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] For the purposes of Section 907.00, the term ''Eligible New Listing'' means (i) any U.S. company that lists common stock on the Exchange for the first time and any non-U.S. company that lists an equity security on the Exchange under Section 102.01 or 103.00 of the Manual for the first time, regardless of whether such U.S. or non-U.S. company conducts an offering and (ii) any U.S. or non-U.S. company emerging from a bankruptcy, spinoff (where a company lists new shares in the absence of a public offering), and carve-out (where a company carves out a business line or division, which then conducts a separate initial public offering).

[5] For purposes of Section 907.00, the term ''Eligible Transfer Company'' means any U.S. or non-U.S. company that transfers its listing of common stock or equity securities, respectively, to the Exchange from another national securities exchange. For purposes of Section 907.00, an ''equity security'' means common stock or common share equivalents such as ordinary shares, New York shares, global shares, American Depository Receipts, or Global Depository Receipts.

[6] Section 907.00 provides for separate service entitlements for Acquisition Companies listed under Section 102.06 and the issuers of Equity Investment Tracking Stocks listed under Section 102.07.

[7] Eligible New Listings and Eligible Transfer Companies will continue to be entitled to complimentary whistleblower services for 24 months, as is the case with all eligible listed companies.

listings and for the retention and transfer of listed companies is intensely competitive and the provision of attractive service offerings is a significant aspect of that competition. The Exchange notes that the Nasdaq Stock Market, Inc. (''Nasdaq'') already provides four years of complimentary services to companies transferring from the NYSE to Nasdaq Global Market that have a market capitalization of at least $750 million, while providing two years of services to other newly listed companies.[8]

The specific tools and services offered to Eligible New Listings and Eligible Transfer Companies as part of the complimentary offering limited to those categories of issuers under Section 907.00 are provided solely by third-party vendors. Issuers are not forced or required as a condition of listing to utilize the complimentary products and services available to them pursuant to Section 907.00 and some issuers have selected competing products and services. In deciding which complimentary products and services to provide, the NYSE considers the quality of competing products and services and the needs of its listed issuers in selecting the vendors. The NYSE may change vendors from time to time based on this ongoing review of the products and services provided by current vendors and its willingness to change vendors is consistent with competition for vendor services. The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard, NYSE notes that it may choose to use multiple vendors for the same type of product or service. The NYSE notes that, from time to time, issuers elect to purchase products and services from other vendors at their own expense instead of accepting the products and services described above offered by the Exchange.

The Exchange also proposes to delete two separate passages of rule text that no longer have any substantive effect as they relate to entitlements that have ceased to be relevant as the periods of time for which they existed have ended.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act'') generally.[9] Section 6(b)(4)[10] requires that exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using the facilities of an exchange. Section 6(b)(5)[11] requires, among other things, that exchange rules promote just and equitable principles of trade and that they are not designed to permit unfair discrimination between issuers, brokers or dealers. Section 6(b)(8)[12] prohibits any exchange rule from imposing any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The NYSE faces competition in the market for listing services, and competes, in part, by offering valuable services to companies. The Exchange believes that it is reasonable to offer complimentary services to attract and retain listings as part of this competition. Notably, Nasdaq currently provides four years of complimentary services to NYSE companies with a market capitalization of at least $750 million transferring to Nasdaq Global Market.

The Exchange does not believe that the proposal to extend the period for which it provides certain complimentary products and services to Eligible New Listings and Eligible Transfer Companies harms the market for the complimentary products and services in a way that constitutes a burden on competition or an inequitable allocation of fees, or fails to promote just and equitable principles of trade, in a manner inconsistent with the Act. The specific tools and services offered to Eligible New Listings and Eligible Transfer Companies as part of the complimentary offering limited to those categories of issuers under Section 907.00 are provided solely by third-party vendors. As noted above, issuers are not required to utilize the complimentary products and services and some issuers have selected competing products and services. The NYSE believes that its consideration of quality and the needs of its listed issuers in selecting the vendors and its willingness to change vendors is consistent with competition for vendor services. In this regard, the NYSE notes that it may choose to use multiple vendors for the same type of product or service. The NYSE notes that, from time to time, issuers elect to purchase products and services from other vendors at their own expense instead of accepting the products and services described above offered by the Exchange.

Further, the NYSE believes that it is appropriate to offer complimentary products and services for a longer period to Eligible New Listings and Eligible Transfer Companies that list after approval of this proposal than the period for which such products and services are provided to companies already listed on the NYSE. The purpose of the proposal is to attract future new listings and transfers and that this competitive purpose would not be served by providing the complimentary products and services for an extended period to companies that are already listed. In addition, the Exchange expects that companies that consider listing on the NYSE after the proposal is approved will take the enhanced offering into account when budgeting for their needs that are met by the complimentary products and services, while existing listed companies will have undertaken their financial planning on the basis of the current services offering and will not in any way be harmed by the proposed change. Based on the above, the Exchange believes that, upon approval of this proposal, the complimentary products and services will be equitably allocated among issuers as required by Section 6(b)(4) of the Act and the proposal does not unfairly discriminate among issuers as required by Section 6(b)(5) of the Act.

The non-substantive changes to eliminate non-applicable history from the rule text will improve the rule's readability and thereby remove an impediment to a free and open market and a national market system and help to better protect investors.

Finally, the Exchange also believes it is reasonable to balance its need to remain competitive with other listing venues, while at the same time ensuring adequate revenue to meet is regulatory responsibilities. The Exchange notes that no other company will be required to pay higher fees as a result of this proposal and it represents that providing the proposed services will have no impact on the resources available for its regulatory programs.

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. As noted above, the Exchange faces competition in the market for listing services, and competes, in part, by offering valuable services to companies. The proposed rule change reflects that competition, but it does not impose any burden on

[8] *See* Nasdaq Marketplace Rules IM–5900–7.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78f(b)(8).

the competition with other exchanges. Rather, the Exchange believes the proposed changes will enhance competition for listings, as it will increase the competition for new listings and the listing of companies that are currently listed on other exchanges. Other exchanges can also offer similar services to companies, thereby increasing competition to the benefit of those companies and their shareholders. Accordingly, the Exchange does not believe the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

In addition, the Exchange does not believe that the proposal to extend the period for which it provides certain complimentary products and services to Eligible New Listings and Eligible Transfer Companies will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard, the NYSE notes that the specific tools and services offered to Eligible New Listings and Eligible Transfer Companies as part of the complimentary offering limited to those categories of issuers under Section 907.00 are provided solely by third-party vendors. In addition, the NYSE may choose to use multiple vendors for the same type of product or service. The NYSE also notes that currently listed and newly listed companies would not be required to accept the offered products and services from the NYSE, and an issuer's receipt of an NYSE listing is not conditioned on the issuer's acceptance of such products and services. In addition, the NYSE notes that, from time to time, issuers elect to purchase products and services from other vendors at their own expense instead of accepting the products and services described above offered by the Exchange.

Moreover, the number of companies eligible for the complimentary products and services for a longer period of time (*i.e.,* companies newly listing on the NYSE) will be very small in comparison to the total number of companies that comprise the target market for the services (*i.e.,* all public companies), so that there can be no competitively meaningful foreclosure of similar services offered by third parties if the proposed rule is approved.

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 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–2020–94 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–2020–94. 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–2020–94 and should be submitted on or before December 18, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26143 Filed 11–25–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90473; File No. PCAOB–2020–01]

Public Company Accounting Oversight Board; Notice of Filing of Proposed Rules on Amendments to PCAOB Interim Independence Standards and PCAOB Rules To Align With Amendments to Rule 2–01 of Regulation S–X

November 20, 2020.

Pursuant to Section 107(b) of the Sarbanes-Oxley Act of 2002 (the ''Act'' or ''Sarbanes-Oxley Act''), notice is hereby given that on November 20, 2020, the Public Company Accounting Oversight Board (the ''Board'' or ''PCAOB'') filed with the Securities and Exchange Commission (the ''Commission'' or ''SEC'') the proposed rules described in Items I and II below, which items have been prepared by the Board. The Commission is publishing this notice to solicit comments on the proposed rules from interested persons.

I. Board's Statement of the Terms of Substance of the Proposed Rules

On November 19, 2020, the Board adopted amendments to the PCAOB's interim independence standards and PCAOB rules to align with amendments by the SEC to Rule 2–01 of Regulation S–X (collectively, the ''proposed rules''). The text of the proposed rules appears in Exhibit A to the SEC Filing Form 19b–4 and is available on the Board's website at *https://pcaobus.org/Rulemaking/Pages/Docket047.aspx* and at the Commission's Public Reference Room.

[13] 17 CFR 200.30–3(a)(12).

II. Board's Statement of the Purpose of, and Statutory Basis for, the Proposed Rules

In its filing with the Commission, the Board included statements concerning the purpose of, and basis for, the proposed rules. The text of these statements may be examined at the places specified in Item IV below. The Board has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements. In addition, the Board is requesting that, pursuant to Section 103(a)(3)(C) of the Sarbanes-Oxley Act, the Commission approve the proposed rules for application to audits of emerging growth companies (''EGCs'').[1] The Board's request is set forth in section D.

A. Board's Statement of the Purpose of, and Statutory Basis for, the Proposed Rules

(a) Purpose

Summary

The federal securities laws require, among other things, that issuers, brokers, and dealers file certain periodic reports with the SEC that contain financial statements audited by an independent public accountant. These laws recognize that audits conducted by objective and impartial professionals can protect investors and instill confidence in the public markets.

Congress has provided both the SEC and the PCAOB with jurisdiction to establish auditor independence standards for audits of issuers and broker-dealers. The Sarbanes-Oxley Act specifically authorizes the PCAOB to establish independence standards and rules to be used by registered public accounting firms in the preparation and issuance of audit reports, and as may be necessary or appropriate in the public interest or for the protection of investors.[2]

The Board first exercised its authority under the Act by adopting the independence standards of the American Institute of Certified Public Accountants (''AICPA''), as they existed as of April 16, 2003, as the Board's interim independence standards, and subsequently adopted independence rules set out in Section 3, Part 5 of the Rules of the Board. Although the PCAOB's standard-setting authority initially extended only to audits of issuers, as defined in the Act,[3] the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank'') extended that authority to include audits of brokers and dealers.

Because both the PCAOB and the SEC have jurisdiction with respect to auditor independence, it is important for the PCAOB to consider how its independence standards and rules relate to the SEC's requirements, including Rule 2–01 of Regulation S–X (''Rule 2–01'').[4] The PCAOB's interim independence standards, as adopted from the AICPA in 2003, cover many of the same topics as Rule 2–01. Recognizing the overlap, the Board directed audit firms in 2003 to comply with the more restrictive of the Board's interim independence standards and Rule 2–01. Subsequently, the PCAOB's permanent independence rules have imposed certain incremental independence obligations (*e.g.,* additional prohibitions on tax services for persons in financial reporting oversight roles at issuer audit clients [5]) on registered public accounting firms. The PCAOB's independence rules use definitions aligned with the definitions in the SEC's Rule 2–01(f).

From 2003 to 2018, the SEC's requirements and the PCAOB's interim independence standards and independence rules worked together to establish the independence compliance requirements for auditors subject to the Board's jurisdiction. In 2018, however, the SEC began the process of making certain amendments to Rule 2–01. Specifically, the Commission proposed in 2018, and then adopted in 2019, amendments to Rule 2–01(c)(1)(ii)(A) to refocus the analysis that must be conducted to determine whether an auditor is independent when the auditor has a lending relationship with certain shareholders of an audit client at any time during the audit and professional engagement period. The Commission next proposed in 2019, and then adopted in 2020, additional amendments to address certain arrangements and relationships that the SEC believed were less likely to threaten an auditor's objectivity or impartiality, so that auditors and audit committees could spend more time focusing on relationships that are more likely to pose such threats.[6] Several commenters on the latter proposal noted that the SEC's proposed amendments overlapped with the PCAOB's requirements relating to lending arrangements and further observed that the SEC's proposal to amend certain definitions in Rule 2–01(f) might give rise to differences with some of the Board's existing definitions in Rule 3501.

To avoid differences and duplicative requirements, and to provide greater regulatory certainty, the Board adopted targeted amendments to its interim independence standards applicable to lending arrangements between auditors and audit clients. In addition, the Board adopted targeted amendments to align certain terms defined in Rule 3501 with the Commission's recent amendments to its definitions of those terms in Rule 2–01(f).

Background

SEC Authority and Independence Requirements

The federal securities laws authorize the SEC to establish independence requirements for audits of financial statements filed with the Commission.[7] The SEC's rule on auditor independence is Rule 2–01, which the SEC has described as setting forth a ''comprehensive framework governing auditor independence.'' [8] Under the general standard in Rule 2–01(b), the SEC ''will not recognize an accountant as independent, with respect to an audit client, if the accountant is not, or a reasonable investor would conclude that the accountant is not, capable of exercising objective and impartial judgment on all issues encompassed within the accountant's engagement.''

In addition to the general standard in Rule 2–01(b), the rule includes a non-exclusive specification of circumstances that are inconsistent with Rule 2–01(b). Rule 2–01(c)(1)–(4) addresses financial, employment, and business relationships between accountants and their audit clients, as well as the performance of certain non-audit services. Other provisions of Rule 2–01(c)–(e) address contingent fees, partner rotation on audit engagements, audit committee administration of the audit engagement, partner compensation, independence quality controls, and grandfathering and transition provisions.[9] Rule 2–01(f)

[1] The term ''emerging growth company'' is defined in Section 3(a)(80) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(80)). *See also Inflation Adjustments and Other Technical Amendments Under Titles I and III of the JOBS Act,* Rel. 33–10332 (Mar. 31, 2017), 82 FR 17545 (Apr. 12, 2017).

[2] 15 U.S.C. 7213.

[3] *See* Section 2(a)(7) of the Act, 15 U.S.C. 7201(a)(7).

[4] *See* 17 CFR 210.2–01.

[5] PCAOB Rule 3523.

[6] *See Qualifications of Accountants,* Release No. 33–10876 (Oct. 16, 2020) (''2020 Adopting Release'').

[7] *See, e.g., Strengthening the Commission's Requirements Regarding Auditor Independence,* Release No. 33–8183 (Jan. 28, 2003), 68 FR 6006, 6044 (Feb. 5, 2003) (identifying the SEC's statutory bases to adopt independence requirements).

[8] *See Amendments to Rule 2–01, Qualifications of Accountants,* Release No. 33–10738 (Dec. 30, 2019), 85 FR 2332 (Jan. 15, 2020) (''2020 Proposing Release'').

[9] *See* Rule 2–01(c)(5)–(8) and Rule 2–01(d)–(e).

defines certain terms used in Rule 2–01. The Commission's interpretations on auditor independence are collected in the Codification of Financial Reporting Policies,[10] and the SEC staff has also issued ''Frequently Asked Questions'' on auditor independence.[11]

PCAOB Authority and Independence Requirements

Under the Act, the Board is authorized to establish ethics and independence standards to be used by registered public accounting firms in the preparation and issuance of audit reports, as required by the Act or SEC rules, or ''as may be necessary or appropriate in the public interest or for the protection of investors.'' [12] The Act also authorized the Board to adopt as its rules other professional standards that the Board determined satisfied the requirements of Section 103(a)(1) of the Act.[13]

When the PCAOB was established in 2003, the Board adopted the professional standards promulgated by other bodies, including the AIPCA, on an interim basis, as authorized under the Act,[14] which assured continuity and certainty in the standards that govern audits of public companies.[15] The Board further stated that it would determine whether to adopt its interim standards as permanent standards of the Board, or repeal or modify those standards, in the future.[16] Currently, Rule 3500T, *Interim Ethics and Independence Standards,* requires registered public accounting firms to comply with independence standards as described in Rule 101 of the AICPA's Code of Professional Conduct (''AICPA Code''), as well as the AICPA's interpretations and rulings thereunder that appear in ET §§ 101 and 191, as in existence on April 16, 2003, to the extent not superseded or amended by the Board.[17] A Note to Rule 3500T also states that the Board's interim independence standards do not supersede the Commission's auditor independence rules and that registered public accounting firms must comply with the ''more restrictive'' of the rules.[18]

The PCAOB began to adopt permanent independence rules in 2005.[19] These rules set forth the fundamental ethical obligation for a registered public accounting firm and its associated persons to be independent of the firm's audit clients throughout the audit and professional engagement period,[20] and include definitions of certain terms used in the Board's independence rules.[21] The rules also prohibit contingent fee arrangements for any service or product a registered public accounting firm provides to an audit client (Rule 3521), restrict certain types of tax services that may be provided to an audit client and to persons in a financial reporting oversight role at an issuer audit client (Rules 3522 and 3523), require audit committee pre-approval of certain tax services and services related to internal control over financial reporting to be performed for an issuer audit client (Rules 3524 and 3525), and require certain communications with an audit client's audit committee concerning auditor independence (Rule 3526). In 2013, after Dodd-Frank was enacted, the Board adopted amendments to certain of these rules to extend their application to audits of brokers and dealers.[22]

Recent SEC Amendments to Rule 2–01

From 2003 through 2019, there were no changes to Rule 2–01 by the Commission. In June 2019, the SEC adopted amendments to Rule 2–01(c)(1)(ii)(A) (the ''Loan Provision'') ''to refocus the analysis that must be conducted to determine whether an auditor is independent when the auditor has a lending relationship with certain shareholders of an audit client at any time during the audit and professional engagement period.'' [23] The Commission further stated that the amendments ''would more effectively identify those debtor-creditor relationships that could impair an auditor's objectivity and impartiality, yet would not include certain attenuated relationships that are unlikely to present threats to objectivity or impartiality.'' [24]

In December 2019, the SEC proposed further updates to Rule 2–01, including additional amendments to the provisions of Rule 2–01(c)(1) that address lending relationships. In proposing these amendments, the SEC stated that they were intended ''to more effectively focus the [independence] analysis on those relationships or services that are more likely to pose threats to an auditor's objectivity and impartiality.'' [25] After considering public comments on the proposal, the Commission amended Rule 2–01 again in October 2020.[26]

The final amendments added certain student and consumer loans to the Commission's categorical exclusions from independence-impairing lending relationships. The SEC also updated several of the definitions in Rule 2–01(f), including amendments to the definitions of the terms ''affiliate of the audit client'' and ''investment company complex'' in Rule 2–01(f)(4) and (f)(14) to address certain affiliate relationships, including entities under common control, and an amendment to the definition of ''audit and professional

[10] *See* Codification of Financial Reporting Policies, Section 600, *Matters Relating to Independent Accountants.*

[11] See Office of the Chief Accountant: Application of the Commission's Rules on Auditor Independence Frequently Asked Questions, available at *https://www.sec.gov/info/accountants/ocafaqaudind080607.htm.*

[12] *See* Sections 103(a)(1) and 103(b) of the Act, 15 U.S.C. 7213(a)(1) and (b).

[13] *See* Section 103(a)(3)(A) of the Act, 15 U.S.C. 7213(a)(3)(A).

[14] *See* Section 103(a)(3)(B) of the Act, 15 U.S.C. 7213(a)(3)(B).

[15] *See* PCAOB Rel. No. 2003–006, *Establishment of Interim Professional Auditing Standards* (Apr. 18, 2003) (''2003 Adopting Release'').

[16] *See id.* at 3.

[17] Rule 3500T also requires compliance with (1) certain independence standards and interpretations of the former Independence Standards Board, to the extent not superseded by the Board and (2) certain ethics standards described in Rule 102 of the AICPA Code and the related interpretations and rulings thereunder, as in existence on April 16, 2003, to the extent not superseded or amended by the Board.

[18] *See also* PCAOB Release No. 2013–010, *Amendments to Conform the Board's Rules and Forms to the Dodd-Frank Act and Make Certain Updates and Clarifications* (Dec. 4, 2013) at 20 fn. 60 (stating that the Note to Rule 3500T ''means that the less restrictive rule still applies but satisfying the more restrictive rule is deemed to satisfy the less restrictive rule'').

[19] In 2005, the Board adopted Rules 3501–3502 and Rules 3520–3524. *See* PCAOB Release No. 2005–014, *Ethics and Independence Rules Concerning Independence, Tax Services, and Contingent Fees* (July 26, 2005) (''2005 Adopting Release''). In 2007 and 2008, the Board adopted Rules 3525 and 3526, respectively. *See* PCAOB Release No. 2007–005, *Auditing Standard No. 5—An Audit of Internal Control Over Financial Reporting That Is Integrated with An Audit of Financial Statements and Related Independence Rule and Conforming Amendments* (May 24, 2007); PCAOB Release No. 2008–003, *Ethics and Independence Rule 3526, Communication with Audit Committees Concerning Independence, Amendment to Interim Independence Standards, Amendment to Rule 3523, Tax Services for Persons in Financial Reporting Oversight Roles, Implementation Schedule for Rule 3523* (Apr. 22, 2008).

[20] *See* PCAOB Rule 3520. Registered public accounting firms must satisfy not only the Board's independence requirements, but also all other independence criteria applicable to a firm's engagement, including Rule 2–01. *See* Note 1 to PCAOB Rule 3520.

[21] In adopting the definitions in Rule 3501, the Board stated that many of those definitions were based on the SEC's existing definitions of those terms in Rule 2–01. *See, e.g.,* 2005 Adopting Release at 19 n. 36 (the Board's definition of the term ''audit and professional engagement period'' in Rule 3501(a)(iii) ''adapts the definition of 'audit and professional engagement period' from the definition of that term in * * * Rule 2–01 of the Commission's Regulation S–X''); *id.* at 21 n. 43 (the Board's definitions of the terms ''affiliate of the audit client'' and ''investment company complex'' in Rules 3501(a)(i) and 3501(i)(ii) are ''verbatim the SEC's definitions of these same terms and should be understood to cover the same entities that would be covered by these terms in applying the SEC's independence rules'').

[22] *See* PCAOB Release No. 2013–010.

[23] *See Auditor Independence With Respect to Certain Loans or Debtor-Creditor Relationships,* Release No. 33–10648 (June 18, 2019), 84 FR 32040 (July 5, 2019) (''2019 Adopting Release'').

[24] *Id.* at 84 FR 32043.

[25] *See* 2020 Proposing Release at 85 FR 2350.

[26] *See* 2020 Adopting Release.

engagement period'' in Rule 2–01(f)(5) to shorten the ''look back period'' for domestic first-time filers in assessing compliance with the Commission's independence requirements.[27]

Amendments to the Board's Independence Requirements

Overview

The Board adopted amendments to the PCAOB's interim independence standards and independence rules to eliminate differences and duplicative requirements in its independence requirements following the SEC's amendments to Rule 2–01 in 2019 and 2020, respectively. Specifically, as discussed below, the Board amended ET § 101.02 and deleted ET § 101.07, both of which are interpretations of Rule 101 of the AICPA Code that are part of the Board's interim independence standards. In addition, the Board deleted ET §§ 191.150–.151, ET §§ 191.182–.183, ET §§ 191.196–.197, and ET §§ 191.220–.222, which are four Ethics Rulings under Rule 101 that also address lending arrangements and are part of the Board's interim independence standards. Finally, the Board amended Rule 3501, which defines certain terms used in Section 3, Part 5 of the Rules of the Board, to align the definitions of three terms used in the independence requirements of both the SEC and the PCAOB.[28]

As discussed further below, without amendments to the Board's interim independence standards, certain provisions that address lending relationships would overlap with and differ from Rule 2–01, as amended. Specifically, ET § 101.02 and ET § 101.07 would be inconsistent with the SEC's restrictions on lending relationships and the exceptions to those restrictions in Rule 2–01(c)(1)(ii), as amended. In addition, the four Ethics Rulings would also be inconsistent with the Commission's independence requirements.

Moreover, absent amendments to the Board's definitions of the terms ''affiliate of the audit client,'' ''audit and professional engagement period,'' and ''investment company complex'' in Rule 3501(a)(ii), (a)(iii), and (i)(ii), these definitions would differ from the SEC's definitions of those terms in Rule 2–01(f)(4), (f)(5), and (f)(14), as amended. Confusion might arise if certain terms used in both the PCAOB's and the SEC's independence rules were defined differently by the Board and the Commission.[29]

These targeted amendments to the Board's independence requirements apply to all audits conducted under PCAOB standards. The amendments should clarify the professional obligations of auditors and avoid regulatory uncertainty regarding the treatment of lending arrangements and the scope of the definitions in the independence requirements of the PCAOB and the SEC.

Amendments to Interim Independence Standards

The SEC's 2019 amendments to Rule 2–01(c)(1)(ii)(A)(*1*) replaced the category of owners of an audit client's equity securities whose lending relationships with an accountant may impair independence (''any individuals owning ten percent or more of the client's outstanding equity securities'') with ''beneficial owners (known through reasonable inquiry) of the audit client's equity securities where such beneficial owner has significant influence over the client.'' At that time, the Commission stated that it had become aware that ''in certain circumstances, the existing [requirement] may not be functioning as it was intended,'' and that the amendments ''would more effectively identify those debtor-creditor relationships that could impair an auditor's objectivity and impartiality,'' while excluding ''certain attenuated relationships that are unlikely to present threats to objectivity or impartiality.'' [30]

In addition, as amended in October 2020, Rule 2–01(c)(1)(ii)(A)(*1*) includes an exception from the scope of the Loan Provision for student loans obtained from a financial institution client under its normal lending procedures, terms, and requirements by a covered person in a firm or his or her immediate family members, provided the loans were not obtained while the covered person was a covered person. The amendments also replace a prior exception in Rule 2–01(c)(1)(ii)(E) for certain credit card balances and cash advances from a lender that is an audit client with an exception for consumer loans, provided that the aggregate outstanding balance is reduced to $10,000 or less on a current basis taking into consideration the payment due date and any available grace period.[31]

The amendments to Rule 2–01 in 2019 and 2020 created differences between Rule 2–01 and the Board's independence requirements. Under Rule 3500T, registered public accounting firms and their associated persons must comply with independence standards in Rule 101 of the AICPA Code and the interpretations and rulings thereunder, as in existence on April 16, 2003, to the extent not superseded or amended by the Board. These interpretations include ET § 101.02, which provides, among other things, that loans from owners of 10% or more of an audit client's equity securities to an accounting firm, other individuals who fall within the definition of a ''covered member'' of the firm,[32] and the immediate family of

[27] Other revisions to Rule 2–01 adopted by the SEC included an amendment to the Commission's restriction on business relationships in Rule 2–01(c)(3), an amendment to replace an existing transition and grandfathering provision in Rule 2–01(e) with a new transition provision addressing mergers or acquisitions involving an audit client, and certain miscellaneous updates.

[28] The Board also considered whether to amend the Board's independence rules to align with the SEC's new provision for addressing inadvertent violations described in Rule 2–01(e). Rule 2–01(e) provides that an accounting firm's independence will not be impaired because an audit client engages in a merger or acquisition that gives rise to a relationship or service that is inconsistent with Rule 2–01, provided that the firm satisfies certain conditions, which include having a quality control system in place as described in Rule 2–01(d)(3) with specified features. The PCAOB has an ongoing project to consider revisions to the Board's quality control standards, including an ethics and independence component that would address the fulfillment of firm and individual responsibilities under applicable ethics and independence requirements. *See* PCAOB Release No. 2019–003, *Potential Approach to Revisions to PCAOB Quality Control Standards* (Dec. 17, 2019). Accordingly, the Board believed it would be premature to amend its independence rules to conform to the SEC's exemption described in Rule 2–01(e). Pending further action, however, the Board generally would not expect to consider an accounting firm's independence impaired solely because an audit client engages in a merger or acquisition that gives rise to a relationship or service that is inconsistent with the Board's independence rules, provided that the firm has satisfied all the conditions in Rule 2–01(e). In such circumstances, firms should also consider their obligations under Rule 3526, *Communication with Audit Committees Concerning Independence.*

[29] *See* 2005 Adopting Release at 19–21. Several commenters on the 2020 Proposing Release identified a potential inconsistency between the Commission's proposed amendments to the definitions in Rule 2–01 and the existing definitions in Rule 3501 and urged the SEC and the PCAOB to preserve the alignment of the definitions in Rule 2–01 with the Board's definitions in Rule 3501.

[30] *See* 2019 Adopting Release at 84 FR 32042–43.

[31] *See* 2020 Adopting Release at 53–57 and 59–62. In proposing amendments to Rule 2–01(c)(1)(ii), the SEC reiterated that certain debtor-creditor relationships between an accounting firm, a covered person, or a covered person's immediate family members ''reasonably may be viewed as creating a self-interest that competes with the auditor's obligation to serve only investors' interests,'' but stated that ''not all creditor or debtor relationships threaten an auditor's objectivity and impartiality.'' *See* 2020 Proposing Release at 85 FR 2339, *citing Revision of the Commission's Auditor Independence Requirements,* Release No. 33–7870 (June 30, 2000), 65 FR 43148, 43161 (July 12, 2000).

[32] The definition of a ''covered member'' for purposes of ET § 101.02 and ET § 101.07 is similar to the definition of a ''covered person in the firm'' in Rule 2–01(f)(11) in certain respects, but differs in other respects. For example, the AICPA's definition of ''covered member,'' as of April 16, 2003, includes an accountant's firm, whereas the SEC's definition of ''covered persons in the firm'' in Rule 2–01(f)(11) only includes certain natural persons.

such covered members may impair the accounting firm's independence, unless permitted by ET § 101.07. ET § 101.02 also includes provisions relating to the collection and repayment of loans by covered members who were formerly employed by or otherwise associated with an audit client. In turn, ET § 101.07, which is also an interpretation of Rule 101 of the AICPA Code, reiterates the restrictions on certain loans in ET § 101.02, but provides exceptions for certain grandfathered and permitted loans that are not deemed to impair a covered member's independence. Following the SEC's amendments to Rule 2–01 in 2019 and 2020, the requirements under existing ET § 101.02 and ET § 101.07 with respect to lending arrangements are inconsistent with the Commission's requirements under Rule 2–01, as amended.

ET §§ 191.150–.151, ET §§ 191.182–.183, ET §§ 191.196–.197 and ET §§ 191.220–.221 are four Ethics Rulings under Rule 101 of the AICPA Code, as in existence on April 16, 2003. These rulings (Ethics Rulings 75, 91, 98, and 110) discuss the application of ET § 101.02 and ET § 101.07 regarding lending arrangements in specific circumstances and include references to ET § 101.02, ET § 101.07, or both:

- Ethics Ruling 75 addresses membership in a client credit union and conditions to be followed to preserve independence if loans are made to the auditor, including compliance with requirements with respect to lending arrangements under ET § 101.02 and ET § 101.07.
- Ethics Ruling 91 addresses the leasing by an auditor of property to or from a client and provides that certain capital leases would be considered a loan that impairs independence unless the arrangement complied with requirements with respect to lending arrangements under ET § 101.02 and ET § 101.07.
- Ethics Ruling 98 addresses an auditor's loan from a nonclient subsidiary or parent of an attest client and provides, among other things, that a loan from a nonclient subsidiary would impair the auditor's independence unless it was a grandfathered or permitted loan pursuant to ET § 101.07.
- Ethics Ruling 110 addresses, among other things, loans from an audit firm's client to or from an entity over which an auditor has control and provides that, in such situations, independence is impaired unless the loan is permitted under ET § 101.07.

Each of these rulings also includes other language that is inconsistent with the SEC's independence requirements. For example, ET §§ 191.150–.151 (Ethics Ruling 75) permits an auditor to have certain uninsured deposits at a credit union client that are not allowed under Rule 2–01(c)(1)(ii)(B), while ET §§ 191.196–.197 (Ethics Ruling 98) provides that certain loans from a nonclient parent of an audit client would not impair independence, even though such loans are not allowed under Rule 2–01(c)(1)(ii)(A) in some circumstances.[33]

The Board updated its requirements with respect to lending relationships to avoid such differences and duplicative requirements. Specifically, the Board amended ET § 101.02 to delete the language in that interpretation that addresses lending arrangements and deleting ET § 101.07 in its entirety. In addition, the Board deleted ET §§ 191.150–.151, ET § 191.182–.183, ET §§ 191.196–.197 and ET §§ 191.220–.221 (Ethics Rulings 75, 91, 98, and 110) to eliminate inconsistent requirements in these rulings relating to lending arrangements under the Board's interim independence standards and the SEC's independence rules and guidance.

The Board took this action in light of the SEC's amendments to Rule 2–01. Removing the provisions relating to lending arrangements from the Board's interim independence standards, rather than making specific amendments to conform them to the SEC's amendments to Rule 2–01, avoids duplicative Board and SEC independence requirements on lending arrangements and helps facilitate compliance with Rule 2–01, as amended, by clarifying a firm's professional obligations. The amendments should also facilitate cooperation and coordination between the Board and the SEC when monitoring compliance with the SEC's revised independence requirements in Rule 2–01.

In adopting the amendments to the interim independence standards, the Board also took notice of the regulatory process employed by the Commission to update its independence framework for lending arrangements in Rule 2–01. Specifically, before amending Rule 2–01 in both 2019 and 2020, the SEC issued a rulemaking proposal, identified the Commission's rationale for proposed amendments to Rule 2–01, solicited public comment on its proposals, and included an economic analysis that included a description of the problem, an analysis of potential benefits and costs, and a consideration of alternatives. After receiving public comments on the proposals, many of which broadly supported the objective of the proposed amendments or were generally in favor of the proposals, the Commission then adopted the amendments largely as proposed.[34] The Board has considered the SEC's rulemaking record on both proposals. The Board believed that this process—structured by the Commission to satisfy the requirements of the Administrative Procedure Act—is at least as robust as the Board's process would have been had the PCAOB considered amendments to the Board's independence requirements without the benefit of the SEC's analysis.

Accordingly, the Board did not perceive any reason or compelling basis in the SEC's rulemaking record to disregard the goal of the SEC's 2019 and 2020 amendments or to impede the benefits that the Commission sought to achieve through its revisions to Rule 2–01 by maintaining differences between the independence requirements of the Board and the SEC relating to lending arrangements. If the Board were to determine at a future date that diverging from the SEC's approach to lending arrangements is necessary or appropriate in the public interest or for the protection of investors, the Board retains the authority under the Act to do so.

Amendments to Rule 3501

The Board adopted Rule 3501 as part of a suite of independence rules in 2005. Although the Board's permanent independence rules, which now include Rules 3520 through 3526, impose additional substantive restrictions on auditors beyond those set forth in Rule 2–01, the scope of those rules has been consistent with the SEC's approach in Rule 2–01.

Specifically, when the Board adopted Rule 3501, it based the definitions of the terms ''affiliate of the audit client'' in Rule 3501(a)(ii), ''audit and professional

[33] In addition, ET §§ 191.–182–.183 (Ethics Ruling 91) and ET §§ 191.220–.221 (Ethics Ruling 110) are less restrictive in certain respects than Section 602.02.e of the Codification of Financial Reporting Policies. In particular, ET §§ 191.–182–.183 (Ethics Ruling 91) permits an auditor to enter into certain operating leases with an audit client without regard to the materiality of the lease, which is inconsistent with Section 602.02.e, while ET §§ 191.220–.221 (Ethics Ruling 110) differs from Section 602.02.e in describing the circumstances in which a loan to or from an audit client from an entity with which an auditor is connected as an officer, director, or shareholder may impair independence.

[34] A few commenters did not support the SEC's proposals, and one of these commenters expressed the view that the proposals could negatively affect investor protection and capital formation. This commenter suggested that, in lieu of the proposals, more should be done to strengthen auditor independence standards and the enforcement of such standards. *See* 2020 Adopting Release at 5–6.

engagement period'' in Rule 3501(a)(iii), and ''investment company complex'' in Rule 3501(i)(ii) on the SEC's definitions of the same terms in Rule 2–01.[35] The existing definitions of ''affiliate of the audit client,'' and ''investment company complex'' in Rule 3501 largely tracked the SEC's definitions of those terms verbatim, except for different formatting. The definition of ''audit and professional engagement period'' in Rule 3501 was adapted from the Commission's definition of that term in Rule 2–01, with the only difference being the replacement of references to an ''accountant'' in Rule 2–01(f)(5) with references to a ''registered public accounting firm'' in Rule 3501(a)(iii). This distinction reflects the use of the term ''accountant'' under Rule 1001(a)(ii) to refer to natural persons who are certified public accountants or authorized to engage in public accounting or participate in audits, whereas Rule 2–01(f)(5) defines the term more broadly to include accounting firms with which certified public accountants or public accountants are affiliated.

The Board's definitions in Rule 3501, in turn, determine the scope of the substantive requirements in Rules 3520 through 3526.[36] Rules 3520 through 3526 address independence matters in addition to those expressly addressed in Rule 2–01, including the impact of certain tax services on independence (Rules 3522 and 3523), audit committee pre-approval of certain tax services and services related to internal control over financial reporting (Rules 3524 and 3525), and communications with audit committees concerning independence (Rule 3526).[37]

The SEC's amendments to Rule 2–01 in 2020 included revisions to the definitions of each of the terms ''affiliate of the audit client,'' ''audit and professional engagement period,'' and ''investment company complex'' in Rule 2–01(f). These amendments resulted in differences between the SEC's definitions of those terms and the Board's definitions in Rule 3501. Discussed in more detail below are (1) the relevant SEC amendments and why the Commission changed these definitions; (2) the resulting differences between the SEC's amended definitions and the Board's existing definitions; and (3) why and how the Board amended the definitions of these three terms in Rule 3501 to avoid differences with the SEC's amended definitions.

As discussed above with respect to the amendments to the Board's interim independence standards, in amending the definitions of ''affiliate of the audit client,'' ''investment company complex,'' and ''audit and professional engagement period'' in Rule 3501, the Board took note of the SEC's rulemaking process when the Commission amended the definitions of those terms in Rule 2–01(f) in 2020. The SEC's robust process included a detailed rationale for the amendments to the definitions and was also informed by public comment on the Commission's proposals. The Board believed it was important to align the definitions of these terms in Rule 3501 with the SEC's amended definitions in Rule 2–01(f) to ensure they have the same meaning under the independence rules of the Board and the SEC and avoid the confusion that might arise if the same terms were used in the independence rules of the PCAOB and the Commission, but defined differently.

''Affiliate of the Audit Client'' and ''Investment Company Complex'' Definitions

Prior to the SEC's 2020 amendments to Rule 2–01, the term ''affiliate of the audit client'' was defined in Rule 2–01(f)(4) to include, in part, both ''[a]n entity that has control over the audit client, or over which the audit client has control, or which is under common control with the audit client, including the audit client's parents and subsidiaries'' and ''[e]ach entity in the *investment company complex* when the audit client is an entity that is part of an investment company complex'' (emphasis added). Rule 2–01(f)(14), in turn, had defined an ''investment company complex'' to include, in part, ''[a]ny entity controlled by or controlling an investment adviser or sponsor * * * or any entity under common control with an investment adviser or sponsor * * * if the entity: (1) Is an investment adviser or sponsor; or (2) Is engaged in the business of providing administrative, custodian, underwriting, or transfer agent services to any investment company, investment adviser, or sponsor * * *.''

In its 2020 amendments to Rule 2–01, the Commission amended these definitions to address challenges that had arisen in their application, including in the private equity and investment company contexts, and more effectively focus on those relationships and services that the SEC believed were more likely to threaten auditor objectivity and impartiality. The SEC's amendments also include dual materiality thresholds in the respective common control provisions and distinguish how the definition applies when an accountant is auditing a portfolio company, an investment company, or an investment adviser or sponsor.

The SEC's amendments created differences with certain definitions in Rule 3501. Accordingly, the Board aligned the definitions of the terms ''affiliate of the audit client'' and ''investment company complex'' in Rule 3501 to be consistent with the SEC's 2020 amendments to the definitions of these terms in Rule 2–01(f). The Board's amendments to these definitions avoid potential confusion by auditors when applying the independence rules of the SEC and PCAOB; without such amendments, auditors would be required to undertake a different analysis to determine which entities fall within or outside the scope of the ''affiliate of the audit client'' and ''investment company complex'' definitions (and, therefore, considered the ''audit client'') for purposes of Rule 2–01 and the Board's rules.

Accordingly, the Board amended Rule 3501(a)(ii) and Rule 3501(i)(ii) to conform to the SEC's amended definitions in Rule 2–01(f)(4) and 2–01(f)(14). Specifically, the Board amended these definitions to incorporate the SEC's amended definitions by cross-referencing the SEC's definitions in Rule 2–01(f). This approach is intended to facilitate the continued alignment of the Board's definitions in Rule 3501(a)(ii) and Rule 3501(i)(ii) with the SEC's definitions in Rule 2–01(f). In the event of later changes by the SEC to the scope of those definitions in Rule 2–01(f), the definitions of these terms in Rule 3501 would automatically update, without requiring further action by the Board.[38] The Board did not delete these definitions, as it did with respect to the provisions of the Board's interim independence standards that address lending arrangements and overlap with the SEC's independence criteria, because the definitions in Rule 3501 remain relevant for purposes of Rules

[35] *See* 2005 Adopting Release at 19–21.

[36] Specifically the term ''investment company complex'' appears in the definition of ''affiliate of the audit client.'' In turn, the term ''affiliate of the audit client'' appears in the definition of the term ''audit client,'' which is used in each of Rules 3520 through 3526.

[37] In addition, both the SEC and the PCAOB have adopted restrictions on the receipt of contingent fees by audit firms. The Commission's restrictions are set forth in Rule 2–01(c)(5), and the Board's restrictions are set forth in Rule 3521.

[38] The Board only amended through cross-references those definitions in Rule 3501 that were identical to the SEC's definitions in Rule 2–01(f) and also the subject of the Commission's 2020 amendments. Certain other defined terms in Rule 3501, such as the definitions of ''financial reporting oversight role'' and ''immediate family member'' in Rules 3501(f)(i) and 3501(i)(i), respectively, continue to track the text of the SEC's definitions of those terms in Rule 2–01(f).

3520 through 3526, which are part of the Board's permanent independence rules. The Board retains the authority to amend these definitions in the future, should the Board determine that such amendments are necessary or appropriate in the public interest or for the protection of investors.

''Audit and Professional Engagement Period'' Definition

Prior to its amendment by the SEC in 2020, the term ''audit and professional engagement period'' had been defined differently in Rule 2–01(f)(5) for domestic issuers and for foreign private issuers (''FPIs'') with respect to situations where a company first files, or is required to file, a registration statement or report with the Commission.[39] Specifically, Rule 2–01(f)(5)(i) and (ii) had defined the ''audit and professional engagement period'' to include both the ''period covered by the financial statements being audited or reviewed'' and the ''period of the engagement to audit or review the financial statements or to prepare a report filed with the Commission.'' For audits of the financial statements of FPIs, however, Rule 2–01(f)(5)(iii) narrowed the ''audit and professional engagement period'' to exclude periods prior to ''the first day of the last fiscal year before the [FPI] first filed, or was required to file, a registration statement or report with the Commission, provided there has been full compliance with home country independence standards in all prior periods covered by any registration statement or report filed with the Commission.''

Under the SEC's amendments to the definition of ''audit and professional engagement period'' in Rule 2–01(f)(5)(iii), the one-year ''look back'' provision for issuers filing or required to file a registration statement or report with the Commission for the first time (''first-time filers'') will apply to all such filers. As a result, an auditor for a first-time filer that is either a domestic issuer or an FPI would apply Rule 2–01 for the most recently completed fiscal year included in its first filing, provided there has been full compliance with applicable independence standards in all prior periods covered by any registration statement or report filed with the Commission. In amending Rule 2–01(f)(5)(iii), the SEC stated that the prior definition of ''audit and professional engagement period'' may have resulted in certain inefficiencies in the initial public offering (''IPO'') process for domestic filers, and that the narrower definition applicable to FPIs had created a disparate application of the independence requirements between domestic issuers and FPIs.[40]

The Commission's amendment to Rule 2–01(f)(5)(iii) created a difference between that definition and the definition of ''audit and professional engagement period'' in Rule 3501(a)(iii), specifically under paragraph (3) of this definition. Maintaining different definitions of this term under the independence rules of the SEC and PCAOB could lead to potential confusion among auditors, since the term ''audit and professional engagement period'' appears in numerous provisions of Rule 2–01, while Rules 3520 through 3523 also set forth certain circumstances that are deemed to impair an audit firm's independence if they occur during either the ''audit and professional engagement period'' or the ''professional engagement period.''

To avoid this potential confusion when applying the independence rules of the SEC and PCAOB, the Board amended the definition of ''audit and professional engagement period'' in Rule 3501(a)(iii)(3) to be consistent with the SEC's amendment to Rule 2–01(f)(5)(iii). As discussed above with respect to the amendments to the definitions of ''affiliate of the audit client'' and ''investment company complex,'' without an amendment to this definition, it would no longer be consistent with the SEC's definition in Rule 2–01(f)(5)(iii), as has been the case since the Board adopted its definition in 2005. Instead, the one-year look back period would apply to both domestic issuers and FPIs that were first-time filers under Rule 2–01, but only to FPIs that were first-time filers under Rule 3501(a)(iii)(3).

The Board did not replace the current definition of ''audit and professional engagement period,'' however, with a cross-reference to Rule 2–01(f)(5). Specifically, the Board continued to use the term ''registered public accounting firm'' in the definition of ''audit and professional engagement period,'' rather than the term ''accountant,'' which is used in Rule 2–01(f)(5). The term ''accountant'' has a different meaning under Rule 1001(a)(ii) than under Rule 2–01(f)(1), whereas the use of the term ''registered public accounting firm'' is consistent with the Act and other rules of the Board. As with the SEC's amendment to Rule 2–01(f)(5)(iii) in 2020, under Rule 3501(a)(iii)(3), as amended, the one-year look back period will apply to both domestic issuers and FPIs that are first-time filers.

Administrative Considerations

The Board took action to make targeted amendments to its interim independence standards and Rule 3501 in light of the SEC's recent amendments to Rule 2–01. Removing the provisions relating to lending arrangements from the Board's interim independence standards avoids differences and duplicative PCAOB and Commission requirements that would otherwise exist after the effective date of the SEC's amendments to the independence requirements in Rule 2–01(c)(1)(ii) on lending arrangements. The Board also amended the definitions of certain terms used in Rule 3501 to align these definitions with the SEC's amended definitions of the same terms in Rule 2–01(f) to ensure they have the same meaning under the independence rules of the Board and the SEC. The Board believed the regulatory process employed by the Commission to update its independence rules under Rule 2–01 was at least as robust as the Board's process would have been had the PCAOB considered amendments to the Board's independence requirements without the benefits of the SEC's analysis. Therefore, the Board believed that public notice and comment in advance of adopting these targeted amendments to the Board's independence requirements was not necessary.

Effective Date

The Board determined that the targeted amendments to its interim independence analysis and Rule 3501 take effect, subject to approval by the SEC, 180 days after the date of the publication of the SEC's October 16, 2020 amendments to Rule 2–01 in the **Federal Register**. The effective date is aligned with the effective date of the Commission's amendments to Rule 2–01.[41] Auditors may elect to comply before the effective date at any point after SEC approval of the Board's amendments, provided that the final amendments are applied in their entirety.

(b) Statutory Basis

The statutory basis for the proposed rules is Title I of the Act.

[39] A ''foreign private issuer'' is any foreign issuer other than a foreign government, except for an issuer that (1) has more than 50% of its outstanding voting securities held of record by U.S. residents; and (2) any of the following: (i) A majority of its executive officers or directors are citizens or residents of the United States; (ii) more than 50% of its assets are located in the United States; or (iii) its business is principally administered in the United States. *See* 17 CFR 240.3b–4(c).

[40] *See* 2020 Adopting Release at 101.

[41] *See* 2020 Adopting Release at 81.

B. Board's Statement on Burden on Competition

Not applicable. The Board's consideration of the economic impacts of the proposed rules is discussed in section D below.

C. Board's Statement on Comments on the Proposed Rules Received From Members, Participants or Others

The Board did not solicit written comments on the proposed rules. Therefore, there are no comments on the proposed rules received from stakeholders.

D. Economic Considerations and Application to Audits of Emerging Growth Companies

The Board is mindful of the economic impacts of its rulemaking. This section discusses economic considerations related to the amendments, including the need for the rulemaking; description of the baseline; consideration of benefits, costs, and unintended consequences; and alternatives considered. It also discusses considerations related to audits of EGCs.

Need for Rulemaking

The Board needed to amend its interim independence standards and independence rules to (1) eliminate differences and duplicative requirements between Rule 2–01 and the Board's independence requirements; and (2) avoid the confusion that might arise if certain terms were used in the independence rules of the PCAOB and the Commission, but defined differently. The Board also did not perceive any reason or compelling basis in the SEC's rulemaking record to impede the benefits that the Commission sought to achieve through its revisions to Rule 2–01 in 2019 and 2020 by maintaining differences between the independence requirements of the Board and the SEC relating to lending arrangements or by not addressing the differences in the definitions of certain terms that appear in the independence rules of both the Commission and the Board.

Specifically, because the PCAOB and the SEC both have jurisdiction with respect to auditor independence, it is important for the PCAOB to consider how its independence standards and rules relate to the SEC's requirements. The PCAOB's interim independence standards, as adopted from the AICPA in 2003, cover many of the same topics as Rule 2–01 and the SEC's regulations and the PCAOB's interim independence standards and independence rules have worked together to establish the independence obligations for auditors subject to the Board's jurisdiction. Amendments to Rule 2–01 adopted by the SEC, however, included amendments to the scope of Rule 2–01(c)(1)(ii) to exclude certain lending arrangements that the SEC did not believe posed a threat to an auditor's objectivity or impartiality. The Commission also adopted targeted amendments to the definitions of the terms ''affiliate of the audit client,'' ''audit and professional engagement period,'' and ''investment company complex,'' as used in Rule 2–01(f).

To avoid differences and duplicative requirements, the Board adopted targeted amendments to its interim independence standards applicable to lending arrangements between auditors and audit clients. These amendments deleted the independence criteria that relate to lending arrangements under ET §§ 101.02 and 101.07, as well as under ET §§ 191.150–.151, ET §§ 191.182–.183, ET §§ 191.196–.197 and ET §§ 191.220–.221, and thereby eliminated inconsistent requirements under the Board's interim independence standards and the SEC's independence rules and guidance. In addition, the Board adopted targeted amendments to its independence rules to align the definitions of ''affiliate of the audit client,'' ''audit and professional engagement period,'' and ''investment company complex'' with the SEC's amendments to the definitions of the same terms in Rule 2–01(f). These amendments avoid the potential confusion that might arise if these terms were used in both the SEC's and the PCAOB's independence rules, but defined differently in Rule 2–01(f) and Rule 3501.

Baseline

The Board evaluated potential benefits, costs, and unintended consequences of the Board's amendments relative to a baseline that includes the amendments to Rule 2–01 adopted by the SEC in 2019 and 2020. In other words, the baseline assumes that the amendments that the SEC adopted in 2020 to Rule 2–01 have become effective.

In identifying the baseline, the Board gave consideration to the existing framework of independence requirements as well as the parties that would be affected by the Board's amendments. The existing framework of independence requirements applicable to engagements performed by registered public accounting firms and their associated persons is described in section A and includes the Board's interim independence standards, the Board's permanent independence rules (including Rules 3501 and 3502 and Rules 3520 through 3526), and the SEC's independence rules and guidance. In addition, the Board's quality control standards require firms to establish policies and procedures to provide reasonable assurance that firm personnel maintain independence, both in fact and appearance, in all required circumstances.[42] This framework, including the amendments to Rule 2–01 adopted by the SEC in 2019 and 2020, provides the baseline against which the impacts of the Board's amendments can be considered.

With respect to the affected parties, the Board took note of the SEC's analysis of the parties that would be affected by the SEC's amendments to Rule 2–01 in the 2019 Adopting Release and the 2020 Adopting Release. The SEC observed that the amendments will affect auditors, audit clients, institutions engaging in financing transactions with audit firms and their partners and employees, current or potential affiliates of audit clients, and ''covered persons'' of accounting firms and their immediate family members, and will affect investors indirectly.[43] The Board's amendments are expected to affect the same parties.

Due to limitations on the data available, the SEC was unable to estimate precisely the number of audit engagements, the number of lenders, or the number of covered persons and their immediate family members that would be immediately affected by the SEC's amendments.[44] Instead, the SEC estimated the potential universe of auditors that might be impacted by the amendments, and reported that 1,729 audit firms were registered with the PCAOB as of August 3, 2020.[45] The SEC also estimated that approximately 6,792 issuers filing on domestic forms and 849 FPIs filing on foreign forms would be affected by the SEC's amendments.[46] In addition:

- For the SEC's amendments to the Loan Provision, the Commission focused mainly on the investment management industry and provided statistics on audited fund series and their investment company auditors.[47]
- For the SEC's amendment related to the ''look-back'' period for assessing independence compliance with respect to first-time filers, the Commission examined historical data for domestic IPOs and reported that there were

[42] *See* QC § 20.09, System of Quality Control for a CPA Firm's Accounting and Auditing Practice.

[43] *See* 2019 Adopting Release at 84 FR 32054; 2020 Adopting Release at 86.

[44] *See id.*

[45] *See* 2020 Adopting Release at 87.

[46] *See id.*

[47] *See* 2019 Adopting Release at 84 FR 32054–55.

approximately 543 domestic IPOs between January 1, 2017 and December 31, 2019.[48]

• For the SEC's amendments to the ''investment company complex'' definition, the Commission focused on registered investment companies and unregistered funds. The SEC reported that, as of September 2020, there were 2,763 registered investment companies that filed annual reports on Form N–CEN. It also reported the numbers and total net assets of mutual funds, exchange traded funds, closed-end funds, variable annuity separate accounts, money market funds, and business development companies as of July 2020.[49]

The above estimates and statistics regarding the parties immediately affected by the SEC's amendments are also relevant to the Board's related amendments. Specifically, the Board's amendments are intended to align the Board's interim independence standards relating to lending arrangements with the independence criteria presented in Rule 2–01 and to align the meaning of the definitions of certain terms used in the independence rules of the SEC and the PCAOB.

Consideration of Benefits, Costs, and Unintended Consequences

This section discusses the potential benefits, costs, and unintended consequences of the Board's amendments. The analysis is largely qualitative in nature because the Board is unable to quantify the economic effects due to a lack of information necessary to provide reasonable estimates. Similar to the SEC, the Board is not able to reasonably estimate the number of current audit engagements that will be immediately affected by the amendments as we lack relevant data about such engagements. The Board also similarly does not have precise data on audit clients' ownership and control structures.[50]

Benefits

The Board's amendments avoid differences between the independence requirements of the PCAOB and the SEC by deleting the portions of the interim independence standards relating to lending arrangements and aligning the meaning of certain definitions used in the independence rules of the SEC and the PCAOB. The amendments should thus clarify the professional obligations of auditors and avoid regulatory uncertainty regarding the treatment of lending arrangements and the meaning of certain terms used in the independence requirements of both the SEC and the PCAOB, leading to a potential reduction in overall compliance costs. In amending the Board's independence requirements, the Board also took note of certain of the potential benefits identified by the Commission when amending Rule 2–01 in 2019 and 2020.[51]

• For example, the SEC stated in the 2019 Adopting Release and the 2020 Adopting Release that its amendments to Rule 2–01 may reduce compliance costs for audit firms and audit clients by updating existing requirements that may be unduly burdensome. The SEC also observed that, under the amended rules, auditors and their clients will be able to focus their attention and resources on monitoring those relationships and services that pose the greatest risk to auditor independence, thus reducing overall compliance burdens without significantly diminishing investor protections.[52]

• The SEC observed that the amendments to Rule 2–01 may lead to a potentially larger pool of auditors eligible to perform audit engagements, which in turn could reduce the costs associated with searching for an independent auditor and reduce the costs resulting from switching from one audit firm to another. In this regard, the Commission further stated that an expanded pool of eligible auditors also might improve matching between auditor expertise and necessary audit procedures and considerations for a particular audit client, which could lead to improvements in audit quality and financial reporting quality, as well as improvements in the efficiency of auditing processes. If the amendments lead to improvements in financial reporting quality, investors might be positioned to make more efficient investment decisions.[53]

• The SEC stated that auditors also could benefit from potentially having a broader spectrum of audit clients and clients for non-audit services as a result of the SEC's amendments to Rule 2–01. For example, the Commission observed that if the amendments reduce certain burdensome constraints on auditors in complying with the independence requirements, auditors likely will incur fewer compliance costs. Another example was the Commission's observation that the amendments potentially could reduce auditor turnover due to changes in audit clients' organizational structure arising from certain merger and acquisition activities.[54]

• The Commission's 2019 Adopting Release and the 2020 Adopting Release also discuss the expected benefits of each of the specific amendments to Rule 2–01 adopted by the Commission. For example, the SEC stated that its amendments to Rule 2–01(c)(1)(ii) to permit some covered persons to be considered independent notwithstanding the existence of certain lending relationships, such as student and consumer loans satisfying the criteria set forth in Rule 2–01, might lead to improved matching between partner and staff experience and audit engagements and, therefore, to increases in audit efficiency and audit quality.[55] Another example was the Commission's observation that the amendment to the definition of ''audit and professional engagement period'' in Rule 2–01(f)(5), such that the one-year look back provision applies to all first-time filers, domestic and foreign, might avoid the need for a domestic first-time filer to delay an IPO or switch to a different auditor to comply with independence requirements.[56]

To the extent they eliminate potential conflicts with Rule 2–01, as amended, the Board's amendments to its interim independence standards regarding lending arrangements increase the likelihood that the benefits anticipated by the SEC will be realized. In addition, the Board's amendments to align the definitions of ''affiliate of the audit client,'' ''audit and professional engagement period,'' and ''investment company complex'' with the SEC's amendments avoid the potential compliance costs of having to apply different definitions of the same terms when complying with the independence rules of the SEC and the PCAOB.

Costs and Unintended Consequences

The Board also considered the potential costs and unintended consequences of the amendments to its interim independence standards and independence rules. Overall, the Board does not anticipate that the amendments are likely to impose significant incremental compliance costs on audit firms and audit clients, or give rise to unintended consequences, since the amendments are limited in nature and audit firms are expected to revise their independence policies and procedures

[48] *See* 2020 Adopting Release at 88.

[49] *See id*. at 88–89.

[50] *See id*. at 86.

[51] *See generally* 2019 Adopting Release at 84 FR 32055–56; 2020 Adopting Release at 89–92.

[52] *See* 2020 Adopting Release at 89.

[53] *See* 2019 Adopting Release at 84 FR 32055; 2020 Adopting Release at 95–96.

[54] *See* 2020 Adopting Release at 91.

[55] *See id*. at 103–04.

[56] *See id*. at 101.

to take into account the SEC's amendments to Rule 2–01 in 2019 and 2020.

In evaluating the potential costs and unintended consequences of the Board's amendments, the Board also took note of the SEC's analysis of the potential costs and other consequences associated with its amendments to Rule 2–01 in the 2019 Adopting Release and the 2020 Adopting Release. For example, in adopting amendments to Rule 2–01 in 2020, the SEC stated that, if the amendments to Rule 2–01 result in an increased risk to auditor objectivity and impartiality due to newly permissible relationships and services, then investors might have less confidence in the quality of financial reporting, which could lead to less efficient investment allocations and increased cost of capital.[57] The Commission also observed, however, that it did not anticipate significant costs to investors or other market participants associated with the amendments because they address relationships and services that are less likely to threaten auditors' objectivity and impartiality.[58]

The Commission further observed in the 2019 Adopting Release and the 2020 Adopting Release that its updates to Rule 2–01 might require more efforts from auditors and audit clients to familiarize themselves with the SEC's amended requirements. For example, the Commission observed in the 2019 Adopting Release that its revisions to the Loan Provision might require the exercise of more judgment in independence determinations, thus potentially contributing to increases in compliance costs in the short term.[59] However, the Commission also stated that it did not anticipate that its amendments to the Loan Provision in 2019 would impose significant compliance costs on auditors.[60] The Commission similarly observed in the 2020 Adopting Release that certain of its amendments to Rule 2–01 earlier this year, such as the inclusion of a dual materiality threshold in the ''affiliate of the audit client'' and ''investment company complex'' definitions in Rules 2–01(f)(4) and 2–01(f)(14), might require more efforts from audit firms and audit clients to familiarize themselves with and apply the amended requirements, but that it did not anticipate significant incremental compliance costs.[61]

The Board also took note of the Commission's observation in the 2019 Adopting Release and the 2020 Adopting Release that the SEC's updates to Rule 2–01 could result in some crowding-out effect in the audit industry. For example, the SEC stated in the 2019 Adopting Release that the potentially increased ability of larger firms to compete for audit clients under the amendments to Rule 2–01 adopted by the SEC in 2019 could potentially crowd out smaller audit firms, but also estimated that four audit firms already performed 86% of audits in the investment management industry.[62] In addition, the Commission observed in the 2020 Adopting Release that the larger accounting firms may be more likely to be positively affected by the amendments to Rule 2–01 as these firms may be able to compete for or retain a larger pool of audit clients, which could potentially crowd out the audit business of smaller audit firms.[63] The SEC estimated that the four largest accounting firms already performed 49.2% of audits for all registrants and more than 80% of audits in the registered investment company space and, as a result, it did not expect any potential change in the competitive dynamics among accounting firms to be significant.[64]

Alternatives Considered

The Board considered three alternatives to the amendments to its interim independence standards and independence rules described herein: (1) Making amendments to its interim independence standards and independence rules to track the language of the SEC's amendments to Rule 2–01 as closely as possible; (2) issuing guidance relating to compliance with the independence requirements of the PCAOB and the SEC following the Commission's amendments to Rule 2–01 in 2020; or (3) taking no action.

First, the Board considered making specific amendments to its interim independence standards to track the language of the SEC's amendments to Rule 2–01 as closely as possible. This alternative would have maintained duplicative and overlapping requirements relating to lending arrangements under ET § 101.02 and ET § 101.07, as well as under ET §§ 191.150–.151, ET §§ 191.182–.183, ET §§ 191.196–.197, and ET §§ 191.220–.221, in the Board's interim independence standards established by the AICPA. This approach also would have been more challenging from a drafting perspective, especially with respect to potential amendments to the provisions of the Board's interim independence standards relating to grandfathered and permitted loans, since the Board's interim independence standards use different terminology and have a different organizational structure than Rule 2–01. As a result, this alternative would have provided less clarification to auditors on their professional obligations with respect to lending arrangements than the approach adopted by the Board, which eliminates duplicative and overlapping requirements relating to lending arrangements under the Board's interim independence standards.

Under the first alternative, the Board also considered amending the definitions of ''affiliate of the audit client'' and ''investment company complex'' in Rules 3501(a)(ii) and (i)(ii), respectively, to track the language of the SEC's amendments to the definitions of the same terms in Rule 2–01 as closely as possible. The Board decided to amend the definitions of ''affiliate of the audit client'' and ''investment company complex'' by incorporating by reference the definition of these terms used in Rule 2–01. Amending the definitions to clarify that these terms have the same meaning as defined in Rule 2–01(f) avoids having to repeat the same definitions in the Board's rules. As discussed, however, the Board amended the definition of ''audit and professional engagement period'' in Rule 3501(a)(iii) to conform to the SEC's amendments to the definition of ''audit and professional engagement period'' in Rule 2–01(f)(5) by adapting the Commission's definition and using specific terms used in the Act and other rules of the Board (specifically, by replacing the term ''accountant'' with the term ''registered public accounting firm'').

Second, as an alternative to rulemaking, the Board considered the issuance of guidance to inform auditors that, after the effective date of the SEC's 2020 amendments to Rule 2–01, the Board would not object if auditors looked to the requirements of Rule 2–01, as amended, when complying with the independence requirements relating to lending arrangements under the Board's interim independence standards and applying the definitions set forth in Rule 3501(a)(ii), (a)(iii) and (i)(ii). This alternative could be accomplished relatively quickly and would avoid the need for the Board to amend the Board's interim independence standards or Rule 3501. This approach would leave in place, however, provisions of the Board's interim independence standards relating to lending arrangements and definitions of certain terms in Rule 3501

[57] *See id.* at 92.

[58] *See id.*

[59] *See* 2019 Adopting Release at 84 FR 32056–57.

[60] *See id.* at 84 FR 32056.

[61] *See* 2020 Adopting Release at 97, 99–100.

[62] *See* 2019 Adopting Release at 84 FR 32057.

[63] *See* 2020 Adopting Release at 108–09.

[64] *See id.* at 109.

that include differences with Rule 2–01, as amended, or otherwise overlap with the SEC's independence requirements relating to lending arrangements. This approach might also create regulatory uncertainty and additional costs by leaving auditors and audit clients, especially those who were not aware of the Board's guidance, uncertain as to their professional obligations.

Third, the Board considered taking no action at this time to amend its interim independence standards or independence rules. This alternative would require auditors to comply with two different sets of independence requirements relating to lending arrangements under Rule 2–01 and the Board's interim independence standards [65] and to look to two different definitions of ''affiliate of the audit client,'' ''audit and professional engagement period,'' and ''investment company complex'' when complying with the independence rules of the SEC and the PCAOB. While this approach might underscore the Board's authority to establish independence standards for registered public accounting firms, it would leave unaddressed certain differences between the independence requirements of the Board and the SEC that had not existed when the PCAOB adopted its interim independence standards in 2003 or began to adopt its permanent independence rules in 2005, including with respect to both lending arrangements and the scope of the entities considered part of the ''audit client'' for purposes of the Board's independence rules. This approach might also impede some of the benefits that the Commission sought to achieve through its revisions to Rule 2–01 and result in additional compliance costs when applying two different definitions of the same terms in Rule 2–01 and the Board's rules.

In comparison to these alternatives, the Board's decision to remove the provisions relating to lending arrangements from the Board's interim independence standards avoids duplicative requirements in the independence requirements of the Board and the SEC on lending arrangements and helps facilitate compliance with Rule 2–01, as amended, by clarifying the professional obligations of audit firms. The amendments should also facilitate cooperation and coordination between the Board and the SEC when monitoring compliance with the SEC's revised provisions in Rule 2–01(c)(1)(ii) relating to lending arrangements.

[65] *See supra* note 15 (discussing the Note to Rule 3500T).

Application to Audits of Emerging Growth Companies

Pursuant to Section 104 of the Jumpstart Our Business Startups Act (''JOBS Act''), rules adopted by the Board subsequent to April 5, 2012 generally do not apply to the audits of EGCs, as defined in Section 3(a)(8) of the Securities Exchange Act of 1934, unless the SEC ''determines that the application of such additional requirements is necessary or appropriate in the public interest, after considering the protection of investors, and whether the action will promote efficiency, competition, and capital formation.'' [66] As a result of the JOBS Act, the rules and related amendments to PCAOB standards the Board adopts are generally subject to a separate determination by the SEC regarding their applicability to audits of EGCs.

To inform consideration of the application of the Board's rules and standards to audits of EGCs, the Board's staff publishes a white paper that provides general information about characteristics of EGCs.[67] As of the November 15, 2019 measurement date, the PCAOB staff identified 1,761 companies that had identified themselves as EGCs and had filed audited financial statements with the SEC, including an audit report signed by a registered public accounting firm in the 18 months preceding the measurement date.

In amending Rule 2–01 in 2019 and 2020, the Commission conducted an economic analysis, which included an analysis of the effect of the amendments to Rule 2–01 on efficiency, competition, and capital formation. The SEC concluded that the amendments to Rule 2–01 likely would improve the practical application of Rule 2–01 and reduce compliance burdens, and might increase competition among auditors and lead to a potential reduction in audit costs. In addition, the Commission determined that the amendments to Rule 2–01 may also facilitate capital formation.[68] Additionally, the SEC's economic analysis regarding the amendments to the definition of ''audit and professional engagement period'' in Rule 2–01(f)(5) concluded that a shorter look-back period may facilitate additional IPOs and thereby promote efficiency and capital formation.

The economic considerations discussed above are generally applicable to audits of EGCs. Moreover, if the Board's amendments were determined not to apply to the audits of EGCs, auditors would be required to address the differing independence requirements in their independence policies and procedures and in their quality control systems, which would create the potential for confusion.

Accordingly, and for the reasons explained above, the Board requests that the Commission determine that it is necessary or appropriate in the public interest, after considering the protection of investors and whether the action will promote efficiency, competition, and capital formation, to apply the Board's targeted amendments to its interim independence standards and independence rules to audits of EGCs. The Board stands ready to assist the Commission in considering any comments the SEC receives on these matter during the Commission's public comment process.

[66] *See* Public Law 112–106 (Apr. 5, 2012). *See* Section 103(a)(3)(C) of the Act, as added by Section 104 of the JOBS Act. Section 104 of the JOBS Act also provides that any rules of the Board requiring (1) mandatory audit firm rotation or (2) a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer (auditor discussion and analysis) shall not apply to an audit of an EGC. The Board's amendments do not fall within either of these two categories.

[67] *See* PCAOB white paper, Characteristics of Emerging Growth Companies and Their Audit Firms as of November 15, 2019 (Nov. 9, 2020), available on the Board's website.

[68] *See* 2019 Adopting Release at 84 FR 32057; 2020 Adopting Release at 107.

III. Date of Effectiveness of the Proposed Rules and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period not more than an additional 45 days (i) if the Commission determines that such longer period is appropriate and publishes the reasons for such determination or (ii) as to which the Board consents, the Commission will:

(A) By order approve or disapprove such proposed rules; or

(B) institute proceedings to determine whether the proposed rules 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 rules are consistent with the requirements of Title I of 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/pcaob.shtml*); or

• Send an email to *rule-comments@sec.gov.* Please include File Number PCAOB–2020–01 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 PCAOB–2020–01. 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/pcaob.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rules that are filed with the Commission, and all written communications relating to the proposed rules between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the PCAOB. All comments received will be posted without charge. 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 PCAOB–2020–01 and should be submitted on or before December 18, 2020.

For the Commission by the Office of the Chief Accountant, by delegated authority.[69]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26145 Filed 11–25–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Wednesday, December 2, 2020.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topic:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Dated: November 24, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–26316 Filed 11–24–20; 11:15 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2020–0058]

Agency Information Collection Activities: Proposed Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA) Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2020–0058].

The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than January 26, 2021. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Partnership Questionnaire—20 CFR 404.1080–404.1082—0960–0025. SSA considers partnership income in determining entitlement to Social Security benefits. SSA uses information from Form SSA–7104 to determine several aspects of eligibility for benefits, including the accuracy of reported partnership earnings; the veracity of a retirement; and lag earnings where SSA needs this information to determine the status of the insured. The respondents are applicants for, and recipients of, Title II Social Security benefits who are reporting partnership earnings.

Type of Request: Revision of an OMB-approved information collection.

[69] 17 CFR 200.30–11(b)(1) and (3).

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–7104 (submission via mail)	6,175	1	30	3,088	* 25.72		*** 79,423
SSA–7104 (completed in or brought to a field office)	6,175	1	30	3,088	* 25.72	** 24	*** 142,952
Totals	12,350			6,176			*** 222,375

* We based this figure on the average U.S. citizen's hourly salary, as reported by the U.S. Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm*).

** We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. Statement of Marital Relationship (By one of the parties)—20 CFR 404.726—0960–0038. SSA must obtain a signed statement from a spousal applicant if the applicant claims a common-law marriage to the insured in a state in which such marriages are recognized, and no formal marriage documentation exists. SSA uses information we collect on Form SSA–754 to determine if an individual applying for spousal benefits meets the criteria of common-law marriage under state law. The respondents are applicants for spouse's Social Security benefits or Supplemental Security Income (SSI) payments.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–754	30,000	1	30	15,000	* $25.72	** 24	*** $694,440

* We based this figure on the average U.S. citizen's hourly salary, as reported by the U.S. Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm*).

** We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

3. Application for Search of Census Records for Proof of Age—20 CFR 404.716—0960–0097. When preferred evidence of age is not available, or the available evidence is not convincing, SSA may ask the U.S. Department of Commerce, Bureau of the Census, to search its records to establish a claimant's date of birth. SSA collects information from claimants using Form SSA–1535 to provide the Census Bureau with sufficient identification information to allow an accurate search of census records. Additionally, the Census Bureau uses a completed, signed SSA–1535 to bill SSA for the search. The respondents are applicants for Social Security benefits who need to establish their date of birth as a factor of entitlement.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–1535	18,030	1	12	3,606	* $25.72	** 24	*** $278,239

* We based this figure on the average U.S. citizen's hourly salary, as reported by the U.S. Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm*).

** We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

4. Workers' Compensation/Public Disability Questionnaire—20 CFR 404.408—0960–0247. Section 224 of the Social Security Act (Act) provides for the reduction of disability insurance benefits (DIB) when the combination of DIB and any workers' compensation (WC) or certain Federal, State or local public disability benefits (PDB) exceeds 80 percent of the worker's pre-disability earnings. SSA field office staff conduct in-person interviews with applicants using the electronic SSA–546 WC/PDB screens in the Modernized Claims System (MCS) to determine if the worker's receipt of WC or PDB payments will cause a reduction of DIB.

The respondents are applicants for the Title II DIB.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–546 (MCS Screens)	248,000	1	15	62,000	$10.73	**24	***$1,729,676

*We based this figure on average DI payments based on SSA's current FY 2020 data (*https://www.ssa.gov/legislation/2020Fact%20Sheet.pdf*).

**We based this figure on the average FY 2020 wait times for field offices, based on SSA's current management information data.

***This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

5. Supplemental Security Income (SSI) Claim Information Notice—20 CFR 416.210—0960–0324. Section 1611(e)(2) of the Act requires individuals to file for and obtain all payments (annuities, pensions, disability benefits, veteran's compensation, etc.) for which they are eligible before qualifying for SSI payments. Individuals do not qualify for SSI if they do not first apply for all other benefits. SSA uses the information on Form SSA–L8050 to verify and establish a claimant's or recipient's eligibility under the SSI program. Respondents are SSI applicants or recipients who may be eligible for other payments from public or private programs.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–L8050	17,044	1	10	2,841	*$10.73	**$30,484

*We based this figure on average DI payments based on SSA's current FY 2020 data (*https://www.ssa.gov/legislation/2020Fact%20Sheet.pdf*).

**This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

6. Medical Source Statement of Ability To Do Work Related Activities (Physical and Mental)—20 CFR 404.1512–404.1513, 416.912–416.913, 404.1517, and 416.917—0960–0662. When a claimant appeals a denied disability claim, SSA may ask the claimant to have a consultative examination at the agency's expense, if the claimant's medical sources cannot, or will not, give the agency sufficient evidence to determine whether the claimant is disabled. The medical providers who perform these consultative examinations provide a statement about the claimant's state of disability. Specifically, these medical source statements determine the work-related capabilities of these claimants. SSA collects the medical data on the HA–1151 and HA–1152 to assess the work-related physical and mental capabilities of claimants who appeal SSA's previous determination on their issue of disability. The respondents are medical sources who provide reports based either on existing medical evidence or on consultative examinations.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
HA–1151	5,000	30	15	37,500	*$40.21	**$1,507,875
HA–1152	5,000	30	15	37,500	*$40.21	**$1,507,875
Totals	10,000	.....	.....	75,000	.....	**$3,015,750

*We based this figure on average medical professionals' salaries, as reported by the U.S. Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes290000.htm*).

**This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

7. Objection to Appearing by Video Teleconferencing; Acknowledgement of Receipt (Notice of Hearing); Waiver of Written Notice of Hearing—20 CFR 404.935, 404.936; 404.938, 404.939, 416.1435, 416.1436, 416.1438, & 416.1439—0960–0671. SSA uses the information we obtain on Forms HA–55, HA–504, HA–504–OP1, HA–510, and HA–510–OP1 to manage the means by which we conduct hearings before an administrative law judge (ALJ), and the

scheduling of hearings with an ALJ. We use the HA–55, Objection to Appearing by Video Teleconferencing, and its accompanying cover letter, HA–L2, to allow claimants to opt-out of an appearance via video teleconferencing (VTC) for their hearing with an ALJ. The HA–L2 explains the good cause stipulation for opting out of VTC if the claimant misses their window to submit the HA–55, and for verifying a new residence address if the claimant moved since submitting their initial hearing request. SSA uses the HA–504 and HA–504–OP1, Acknowledgement of Receipt (Notice of Hearing), and accompanying cover letter, HA–L83, to: (1) Acknowledge the claimants will appear for their hearing with an ALJ; (2) establish the time and place of the hearing; and (3) remind claimants to gather evidence in support of their claims. The only difference between the two versions of the HA–504 is the language used for the selection check boxes as determined by the type of appearance for the hearing (in-person, phone teleconference, or VTC). In addition, the cover letter, HA–L83, explains: (1) The claimants' need to notify SSA of their wish to object to the time and place set for the hearing; (2) the good cause stipulation for missing the deadline for objecting to the time and place of the hearing; and (3) how the claimants can submit, in writing, any additional evidence they would like the ALJ to consider, or any objections they have on their claims. The HA–510, and HA–510–OP1, Waiver of Written Notice of Hearing, allows the claimants to waive their right to receive the Notice of Hearing as specified in the HA–L83. We typically use these forms when there is a last minute available opening on an ALJ's schedule, so the claimants can fill in the available time slot. If the claimants agree to fill the time slot, we ask them to waive their right to receive the Notice of Hearing. We use the HA–510–OP1 at the beginning of our process for representatives and claimants who wish to waive the 20-day (for amended or continued hearing notices) or 75-day (for all other hearing notices) requirement earlier in the process, and the HA–510 later in the process for those representatives and claimants who want the full 20 or 75 days prior to the scheduled hearing. The respondents are applicants for Social Security disability payments who request a hearing to appeal an unfavorable entitlement or eligibility determination or their representative payees.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
HA–504+ HA–504–OP1 HA–504–OP2	900,000	1	30	450,000	*$18.22	**$8,199,000
HA–L83—404.936(e); 416.1436(e)	900,000	1	30	450,000	*18.22	**8,199,000
HA–L83—Good cause for missing deadline—404.936(e)(1); 416.1436(e)(1)	5,000	1	5	417	*18.22	**7,598
HA–L83—Objection stating issues in notice are incorrect—sent 5 days prior to hearing 404.939; 416.1439	45,000	1	5	3,750	*18.22	**68,325
HA–55—404.936; 404.938; 416.1436; 416.1438	850,000	1	5	70,833	*18.22	**1,290,577
HA–L2—Verification of New Residence 404.936(c)(1); 416.1436(d)(1)	45,000	1	5	3,750	*18.22	**68,325
HA–L2—Notification of objection to video teleconference more than 30-days after receipt of notice showing good cause 404.936(c)(2); 416.1436(d)(2) ...	13,500	1	10	2,250	*18.22	**40,995
HA–510; HA–510–OP1—404.938(a); 416.1438(a)	4,000	1	2	133	*18.22	**2,423
Totals	2,762,500	.....	.....	981,133	.....	**17,876,243

+ Due to the COVID–19 pandemic, we are currently not conducting hearings in person with administrative law judges. We are holding all hearings with the administrative law judges by telephone and online video while offices remain closed. We are using different versions of the HA–504 depending on the format of the hearing (HA–504 is used for in-person/traditional VTC, HA–504–OP1 is used for phone, HA–504–OP2 is used for online video). At this time, we are unable to provide an accurate breakdown of their usages individually until offices reopen. The combined total for all of the versions is a good estimate.

Public Reporting Burdens for the Temporary COVID–19 Enhanced Outreach (CEO)

We estimate a total universe of approximately 560,000 respondents for the COVID–19 Enhanced Outreach (CEO) project. This number represents 280,000 cases in ''Ready to Schedule'' (RTS) and ''Scheduled'' (SCHD) statuses with attorney or non-attorney representatives, plus a courtesy copy to the claimant. We will also conduct a follow-up call for cases without a returned form. We expect 25% or less will be non-responsive. The numbers on this chart reflect our estimates for this outreach project:

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
CEO Letter and Form Mailed to Representative	280,000	1	10	46,667	*$25.72	**$1,200,275
Courtesy Copy of CEO Letter to Claimant	280,000	No response required	2	9,333	*25.72	**240,045

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
CEO Follow up Call with Representative—no form returned (non-responsive)	70,000	1	5	5,833	* 25.72	** 150,025
Totals	630,000			61,833		** 1,590,345
Grand Total	3,392,500			1,042,966		** $19,466,588

* We based these figures on average DI hourly wages for single students based on SSA's current FY 2020 data (*https://www.ssa.gov/legislation/2020Fact%20Sheet.pdf*), and on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes231011.htm*), as well as a combination of those two figures (for the paper form, as we do not collect data on whether the paper forms are filled out by individuals or representatives or both).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

8. Medicare Subsidy Quality Review Forms—20 CFR 418.3125(b)(5)—0960–0707. The Medicare Modernization Act of 2003 mandated the creation of the Medicare Part D prescription drug coverage program and provides certain subsidies for eligible Medicare beneficiaries to help pay for the cost of prescription drugs. As part of the stewardship duties of the Medicare Part D subsidy program, SSA conducts periodic quality reviews of the information Medicare beneficiaries report on their subsidy applications (Form SSA–1020). SSA uses the Medicare Quality Review program to conduct these checks. The respondents are applicants for the Medicare Part D subsidy whom SSA chose to undergo a quality review.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–9301 (Medicare Subsidy Quality Review Case Analysis Form	3,500	1	30	1,750	* $25.72	** $45,010
SSA–9302 (Notice of Quality Review Acknowledgment Form for those with Phones)	3,500	1	15	875	* $25.72	** $22,505
SSA–9303 (Notice of Quality Review Acknowledgment Form for those without Phones)	350	1	15	88	* $25.72	** $2,263
SSA–9308 (Request for Information)	7,000	1	15	1,750	* $25.72	** $45,010
SSA–9310 (Request for Documents)	3,500	1	5	292	* $25.72	** $7,510
SSA–9311 (Notice of Appointment- Denial -Reviewer Will Call)	450	1	15	113	* $25.72	** $2,906
SSA–9312 (Notice of Appointment-Denial-Please Call Reviewer)	50	1	15	13	* $25.72	** $334
SSA–9313 (Notice of Quality Review acknowledgment Form for those with Phones)	2,500	1	15	625	* $25.72	** $16,075
SSA–9314 (Notice of Quality Review acknowledgement Form for those without Phones)	500	1	15	125	* $25.72	** $3,215
Total	21,350			5,631		** $144,828

* We based this figures on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm*).

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

9. Application to Collect a Fee for Payee Services—20 CFR 404.2040a & 416.640a—0960–0719. Sections 205(j) and 1631(a) of the Act allow SSA to authorize certain organizational representative payees to collect a fee for providing payee services. Before an organization may collect this fee, they complete and submit Form SSA–445. SSA uses the information to determine whether to authorize or deny permission to collect fees for payee services. The respondents are private sector businesses, or State and local government offices, applying to become a fee-for-service organizational representative payee.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Private sector business	90	1	13	20	*$15.37	**$307
State/local government offices	10	1	10	2	*$15.07	**$30
Totals	100			22		**$337

*We based these figures on average Personal Care and Service Occupations hourly wages (*https://www.bls.gov/oes/current/oes390000.htm*), as reported by Bureau of Labor Statistics data.

**This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

10. Certification of Low Birth Weight for SSI Eligibility—20 CFR 416.924, 416.926, and 416.931—0960–0720. Hospitals and claimants use Form SSA–3380 to provide medical information to local field offices (FO) and the Disability Determination Services (DDS) on behalf of infants with low birth weight. FOs use the form as a protective filing statement and the medical information to make presumptive disability findings, which allow expedited payment to eligible claimants. DDSs use the medical information to determine disability and continuing disability. The respondents are hospitals and claimants who have information identifying low birth weight babies and their medical conditions.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
SSA–3380	28,125	1	15	7,031	*$61.97	$435,711

*We based this figure by averaging the average U.S. worker's (*https://www.bls.gov/oes/current/oes_nat.htm*) and General Medical Hospital employee's hourly wages (*https://www.bls.gov/oes/current/oes291215.htm*), as reported by Bureau of Labor Statistics data.

**This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

11. Electronic Records Express (Third Parties)—20 CFR 404.1700—404.1715—0960–0767. Electronic Records Express (ERE) is an online system which enables medical providers and various third party representatives to electronically access clients' disability files online and submit disability claimant information electronically to SSA as part of the disability application process. To ensure only authorized people access ERE, SSA requires third parties to complete a unique registration process if they wish to use this system. This information collection request (ICR) includes the third-party registration process and the burden for submitting evidence to SSA is part of other, various ICRs. The respondents are representatives of disability applicants who want to use ERE to electronically access clients' disability files online and submit information to SSA.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
ERE Third-Party	37,314	81	1	50,374	*$59.11	**$2,977,607

*We based this figures on average Lawyer's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm*).

**This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

Dated: November 23, 2020.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2020–26178 Filed 11–25–20; 8:45 am]

BILLING CODE 4191–02–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36459]

Great Basin and Northern Railroad—Change in Operators Exemption—City of Ely and Nevada Northern Railway Foundation

Great Basin and Northern Railroad (Great Basin), a Class III rail carrier, has filed a verified notice of exemption pursuant to 49 CFR 1150.41 to assume operations over approximately 0.9 miles of rail line between milepost 127.0 and milepost 127.9 at or near McGill Junction in White Pine County, Nev. (the Line). The Line is owned by the City of Ely (the City) and the Nevada Northern Railway Foundation (the Foundation), and is currently operated

by S&S Shortline Leasing, LLC (S&S). Great Basin states that it anticipates reaching an agreement with the City and the Foundation in the near future for rights to operate over the Line. According to Great Basin, it will replace S&S as the operator of the Line, and S&S has agreed to discontinue its service over the Line concurrent with its replacement by Great Basin.

Great Basin states that the Line is a segment of a longer rail line running from milepost 0.0 at or near Cobre, Nev., to and beyond McGill Junction. In addition to the Line, S&S currently operates the portion of the longer line from milepost 0.0 to milepost 127.0. *See S&S Shortline Leasing, LLC—Operation Exemption—City of Ely, Nev., et al.,* FD 35284 (STB served Aug. 14, 2009). Great Basin states that it operates the remaining portion of the line from milepost 127.9 to milepost 146.1 at or near Keystone, Nev., and two branch lines connecting to this line segment. *See Great Basin & N.R.R.—Change in Operators Exemption—City of Ely, et al.,* FD 34506 (STB served June 7, 2004) (addressing the portion of the line from milepost 127.9 to milepost 146.1).

Great Basin certifies that the proposed transaction does not involve a provision or agreement that may limit future interchange with a third-party connecting carrier. Great Basin also certifies that its projected revenues as a result of the transaction will not result in the creation of a Class II or Class I rail carrier and will not exceed $5 million.

Under 49 CFR 1150.42(b), a change in operator requires that notice be given to shippers. Great Basin states that no active rail shippers are on or served by the Line.

The transaction may be consummated on or after December 13, 2020, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 4, 2020 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36459, should be filed with the Surface Transportation Board via e-filing on the Board's website. In addition, a copy of each pleading must be served on Great Basin's representative, Jeffrey O. Moreno, Thompson Hine LLP, 1919 M Street NW, Suite 700, Washington, DC 20036.

According to Great Basin, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Decided: November 20, 2020.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2020–26201 Filed 11–25–20; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Action on Proposed Highway Project in Georgia, the I–285/I–20 East Interchange Project, DeKalb County, Georgia (Atlanta Metropolitan Area)

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitations on claims for judicial review of action by FHWA and other Federal agencies.

SUMMARY: This notice announces actions taken by FHWA and other Federal agencies that are final. This final agency action relates to the reconstruction of the I–285/I–20 east interchange and improvements along I–20 east of the interchange and I–285 north of the interchange in DeKalb County. The FHWA's Finding of No Significant Impact (FONSI) provides details on the Selected Alternative for the proposed improvements.

DATES: By this notice, FHWA is advising the public of the final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before April 26, 2021. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA: Mr. Aaron Hernandez, Environmental Coordinator, Federal Highway Administration Georgia Division, 61 Forsyth Street, Suite 17T100, Atlanta, Georgia 30303; telephone (404) 562–3584; email: *aaron.hernandez@dot.gov.* The FHWA Georgia Division Office's normal business hours are 8:00 a.m. to 5:00 p.m. (Eastern Time) Monday through Friday. For Georgia Department of Transportation (GDOT): Mr. Eric Duff, State Environmental Administrator, Georgia Department of Transportation, 600 West Peachtree Street NW, 16th Floor, Atlanta, Georgia 30308; telephone (404) 631–1100; email: *eduff@dot.ga.gov.* The GDOT Office of Environmental Service's normal business hours are 8 a.m. to 5 p.m. (Eastern Time) Monday through Friday.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA has taken a final agency action by issuing a FONSI for the following highway project in the State of Georgia: The I–285/I–20 East Interchange Project located in DeKalb County, Georgia. The proposed project will improve safety and operational efficiency at the I–285/I–20 east interchange through the reconstruction of two directional ramps that accommodate higher design speeds, and through geometric improvements at each of the other ramps within the interchange. This project also includes the extension and/or addition of auxiliary and collector-distributor lanes along the heavily travelled 6.3-mile stretch of I–20 between Lithonia Industrial Boulevard and the I–285/I–20 east interchange and along I–285 north of the interchange to Glenwood Road. The facility will include improvements to approximately 6.6 miles along I–20 and 2.8 miles along I–285. The purpose of the project is to reduce crashes and improve traffic flow within the I–285/I–20 east interchange and along portions of I–20 east of the interchange.

The FHWA's action, related actions by other Federal agencies, and the laws under which such actions were taken are described in the Environmental Assessment (EA) approved on July 29, 2020, in FHWA's FONSI issued on November 17, 2020, and other documents in the project file. The EA, FONSI, and other project records are available by contacting FHWA or the Georgia Department of Transportation at the addresses listed above. The EA and FONSI can also be reviewed and downloaded from the project website at *https://majormobilityga.com/projects/eastsideic/.*

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. Air: Clean Air Act [42 U.S.C. 7401–7671(q)].

3. Noise: Noise Control Act of 1972 [42 U.S.C. 4901–4918]; 23 CFR part 772.

4. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303].

5. Wildlife: Endangered Species Act (ESA) [16 U.S.C. 1531–1544 and Section 1536]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667d]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

6. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–470(ll)]; Archeological and Historic Preservation Act [16 U.S.C. 469–469c]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

7. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

8. Wetlands and Water Resources: Coastal Zone Management Act [16 U.S.C. 1451–1465]; Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601–4604]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)–300(j)(6)]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Flood Disaster Protection Act [42 U.S.C. 4001–4128].

9. Hazardous Materials: Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601–9675]; Superfund Amendments and Reauthorization Act of 1986 (SARA); Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].

10. Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13045 Protection of Children From Environmental Health Risks and Safety Risks; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Issued on: November 18, 2020.

Moises Marrero,

Division Administrator, Atlanta, Georgia.

[FR Doc. 2020–25851 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2020–0050]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt six individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to operate CMVs in interstate commerce.

DATES: The exemptions were applicable on October 16, 2020. The exemptions expire on October 16, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov/docket?D=FMCSA-2020-0050* and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

On September 16, 2020, FMCSA published a notice announcing receipt of applications from six individuals requesting an exemption from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8) and requested comments from the public (85 FR 57926). The public comment period ended on October 16, 2020, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting exemptions to these individuals would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in § 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria [1] to assist medical examiners (MEs) in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a

[1] These criteria may be found in Appendix A to Part 391—Medical Advisory Criteria, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at *https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.*

level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on the 2007 recommendations of the Agency's Medical Expert Panel. The Agency conducted an individualized assessment of each applicant's medical information, including the root cause of the respective seizure(s) and medical information about the applicant's seizure history, the length of time that has elapsed since the individual's last seizure, the stability of each individual's treatment regimen and the duration of time on or off of anti-seizure medication. In addition, the Agency reviewed the treating clinician's medical opinion related to the ability of the driver to safely operate a CMV with a history of seizure and each applicant's driving record found in the Commercial Driver's License Information System for commercial driver's license (CDL) holders, and interstate and intrastate inspections recorded in the Motor Carrier Management Information System. For non-CDL holders, the Agency reviewed the driving records from the State Driver's Licensing Agency. A summary of each applicant's seizure history was discussed in the September 16, 2020, **Federal Register** notice (85 FR 57926) and will not be repeated in this notice.

These six applicants have been seizure-free over a range of 12 to 38 years while taking anti-seizure medication and maintained a stable medication treatment regimen for the last 2 years. In each case, the applicant's treating physician verified his or her seizure history and supports the ability to drive commercially.

The Agency acknowledges the potential consequences of a driver experiencing a seizure while operating a CMV. However, the Agency believes the drivers granted this exemption have demonstrated that they are unlikely to have a seizure and their medical condition does not pose a risk to public safety.

Consequently, FMCSA finds that in each case exempting these applicants from the epilepsy and seizure disorder prohibition in § 391.41(b)(8) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and includes the following: (1) Each driver must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified ME, as defined by § 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the six exemption applications, FMCSA exempts the following drivers from the epilepsy and seizure disorder prohibition, § 391.41(b)(8), subject to the requirements cited above:

Robert S. Kessler (KS)

Thomas J. Kline (PA)

Jeffrey T. Lang (PA)

Ty Martin (WV)

Rick S. Morrison (NC)

Darrel Rinder (CA)

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–26160 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2013–0109; FMCSA–2013–0442; FMCSA–2013–0443; FMCSA–2018–0051]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for eight individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates provided below.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2013–0109, FMCSA–2013–0442, FMCSA–2013–0443, or FMCSA–2018–0051, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the

DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

On May 7, 2020, FMCSA published a notice announcing its decision to renew exemptions for eight individuals from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8) to operate a CMV in interstate commerce and requested comments from the public (85 FR 27262). The public comment period ended on September 24, 2020, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in § 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria [1] to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based on its evaluation of the eight renewal exemption applications, FMCSA announces its decision to exempt the following drivers from the epilepsy and seizure disorders prohibition in § 391.41(b)(8).

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of May and are discussed below.

As of May 19, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following six individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers (85 FR 27262):

Jeffrey Ballweg (WI)

Ronald Hartl (WI)

Craig Hoisington (NH)

Raymond Lobo (NJ)

Michael Miller (WI)

Peter Thompson (FL)

The drivers were included in docket numbers FMCSA–2013–0109, FMCSA–2013–0442, and FMCSA–2013–0443. Their exemptions were applicable as of May 19, 2020, and will expire on May 19, 2022.

As of May 30, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following two individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers (85 FR 27262):

Nathan Kanouff (GA) and

Joe L. King, Jr. (NC).

The drivers were included in docket number FMCSA–2018–0051. Their exemptions were applicable as of May 30, 2020, and will expire on May 30, 2022.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–26158 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–EX–P

[1] These criteria may be found in Appendix A to Part 391—Medical Advisory Criteria, section H. *Epilepsy:* § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at *https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.*

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0014]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of applications for exemption; request for comments.

SUMMARY: FMCSA announces receipt of applications from three individuals for an exemption from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. If granted, the exemptions will enable these individuals to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: Comments must be received on or before December 28, 2020.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA–2020–0014 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/docket?D=FMCSA-2020-0014.* Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2020–0014), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov/docket?D=FMCSA-2020-0014.* Click on the ''Comment Now!'' button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov/docket?D=FMCSA-2020-0014* and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The three individuals listed in this notice have requested an exemption from the vision requirement in 49 CFR 391.41(b)(10). Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

The physical qualification standard for drivers regarding vision found in § 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal Meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing standard red, green, and amber.

On July 16, 1992, the Agency first published the criteria for the Vision Waiver Program, which listed the conditions and reporting standards that CMV drivers approved for participation would need to meet (57 FR 31458). The current Vision Exemption Program was established in 1998, following the enactment of amendments to the statutes governing exemptions made by § 4007 of the Transportation Equity Act for the 21st Century, Public Law 105–178, 112 Stat. 107, 401 (June 9, 1998). Vision exemptions are considered under the procedures established in 49 CFR part 381 subpart C, on a case-by-case basis upon application by CMV drivers who do not meet the vision standards of § 391.41(b)(10).

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely in intrastate commerce with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at *https://www.regulations.gov/docket?D=FMCSA-1998-3637.*

FMCSA believes it can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrated the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively.[1] The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

[1] A thorough discussion of this issue may be found in a FHWA final rule published in the **Federal Register** on March 26, 1996 and available on the internet at *https://www.govinfo.gov/content/pkg/FR-1996-03-26/pdf/96-7226.pdf.*

III. Qualifications of Applicants

Terence L. Broadwater

Mr. Broadwater, 63, has a cataract in his right eye due to a traumatic incident in childhood. The visual acuity in his right eye is 20/200, and in his left eye, 20/20. Following an examination in 2020, his optometrist stated, ''Mr. Broadwater has sufficient vision to drive a commercial vehicle.'' Mr. Broadwater reported that he has driven straight trucks for 16 years, accumulating 672,000 miles, and tractor-trailer combinations for 24 years, accumulating 3.36 million miles. He holds a Class A CDL from West Virginia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Shannon L. Cagle

Mr. Cagle, 35, has had amblyopia in his right eye since birth. The visual acuity in his right eye is 20/200, and in his left eye, 20/20. Following an examination in 2020, his ophthalmologist stated, ''It is my opinion that he has compensated for his vision loss in the right eye giving him sufficient vision to operate a commercial vehicle.'' Mr. Cagle reported that he has driven straight trucks for 10 years, accumulating 50,000 miles. He holds a Class A CDL from Georgia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Frank L. Crenshaw

Mr. Crenshaw, 59, has a retinal detachment in his right eye due to a traumatic incident in 2000. The visual acuity in his right eye is 20/60, and in his left eye, 20/25. Following an examination in 2020, his optometrist stated, ''It is my medical opinion that his horizontal meridian visual fields and his visual acuity are sufficient to perform the driving tasks to safely operate a commercial vehicle.'' Mr. Crenshaw reported that he has driven straight trucks for 2 years, accumulating 20,000 miles, and tractor-trailer combinations for 5 years, accumulating 1 million miles. He holds a Class A CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

IV. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315(b), FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments and material received before the close of business on the closing date indicated under the **DATES** section of the notice.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–26159 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1998–3637; FMCSA–1999–6480; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2002–12294; FMCSA–2003–16564; FMCSA–2005–22194; FMCSA–2006–23773; FMCSA–2008–0266; FMCSA–2009–0206; FMCSA–2009–0291; FMCSA–2010–0201; FMCSA–2011–0379; FMCSA–2014–0002; FMCSA–2014–0004; FMCSA–2014–0006; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2014–0297; FMCSA–2016–0029; FMCSA–2016–0031; FMCSA–2016–0033; FMCSA–2016–0206; FMCSA–2016–0207; FMCSA–2016–0208; FMCSA–2016–0209; FMCSA–2016–0210; FMCSA–2017–0017; FMCSA–2018–0010; FMCSA–2018–0011; FMCSA–2018–0017; FMCSA–2018–0018]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 42 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates provided below.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–1998–3637; FMCSA–1999–6480; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2002–12294; FMCSA–2003–16564; FMCSA–2005–22194; FMCSA–2006–23773; FMCSA–2008–0266; FMCSA–2009–0206; FMCSA–2009–0291; FMCSA–2010–0201; FMCSA–2011–0379; FMCSA–2014–0002; FMCSA–2014–0004; FMCSA–2014–0006; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2014–0297; FMCSA–2016–0029; FMCSA–2016–0031; FMCSA–2016–0033; FMCSA–2016–0206; FMCSA–2016–0207; FMCSA–2016–0208; FMCSA–2016–0209; FMCSA–2016–0210; FMCSA–2017–0017; FMCSA–2018–0010; FMCSA–2018–0011; FMCSA–2018–0017; FMCSA–2018–0018, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

On October 5, 2020, FMCSA published a notice announcing its decision to renew exemptions for 42 individuals from the vision requirement in 49 CFR 391.41(b)(10) to operate a CMV in interstate commerce and requested comments from the public (85 FR 62793). The public comment period ended on November 4, 2020, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to,

or greater than, the level that would be achieved by complying with the current regulation § 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in § 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based on its evaluation of the 42 renewal exemption applications and comments received, FMCSA confirms its decision to exempt the following drivers from the vision requirement in § 391.41(b)(10).

As of November 9, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 30 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (63 FR 196; 63 FR 30285; 64 FR 68195; 65 FR 20251; 65 FR 33406; 65 FR 57234; 65 FR 66293; 67 FR 38311; 67 FR 46016; 67 FR 57266; 67 FR 57267; 67 FR 67234; 68 FR 74699; 69 FR 10503; 69 FR 26921; 69 FR 51346; 69 FR 52741; 69 FR 62741; 70 FR 57353; 70 FR 72689; 71 FR 6828; 71 FR 6829; 71 FR 19604; 71 FR 27033; 71 FR 50970; 71 FR 53489; 71 FR 62147; 73 FR 27018; 73 FR 36955; 73 FR 42403; 73 FR 48270; 73 FR 51336; 73 FR 51689; 73 FR 63047; 73 FR 74565; 74 FR 43217; 74 FR 57551; 74 FR 65842; 75 FR 9482; 75 FR 36779; 75 FR 38602; 75 FR 50799; 75 FR 52062; 75 FR 54958; 75 FR 64396; 75 FR 66423; 75 FR 70078; 76 FR 66123; 77 FR 10604; 77 FR 15184; 77 FR 27850; 77 FR 38384; 77 FR 40946; 77 FR 48590; 77 FR 52389; 77 FR 64582; 77 FR 68199; 77 FR 68200; 78 FR 77782; 79 FR 10608; 79 FR 10619; 79 FR 18392; 79 FR 2200379 FR 29498; 79 FR 35212; 79 FR 35218; 79 FR 38659; 79 FR 38661; 79 FR 45868; 79 FR 46300; 79 FR 47175; 79 FR 51643; 79 FR 53514; 79 FR 56104; 79 FR 59357; 79 FR 64001; 79 FR 68199; 81 FR 20435; 81 FR 28138; 81 FR 42054; 81 FR 52514; 81 FR 59266; 81 FR 60115; 81 FR 66722; 81 FR 68098; 81 FR 71173; 81 FR 72642; 81 FR 74494; 81 FR 80161; 81 FR 81230; 81 FR 90050; 81 FR 96196; 82 FR 20962; 82 FR 37499; 83 FR 18633; 83 FR 24585; 83 FR 28325; 83 FR 28332; 83 FR 28342; 83 FR 34661; 83 FR 34677; 83 FR 40638; 83 FR 45750; 83 FR 53724; 83 FR 56137; 83 FR 56902):

Rodney R. Anderson (PA)
Gary A. Brown (PA)
James W. Carter, Jr. (KS)
Jose D. Chavez (MD)
David M. Clark (MD)
David A. Coburn, Sr. (VT)
Thomas L. Corey (IN)
Herman A. Davis (AL)
Joseph A. Dunlap (OH)
Tyron O. Friese (MN)
Randy M. Garcia (NM)
Andeberhan O. Gidey (WA)
Rodney P. Hains (ND)
Ronnie L. Henry (KS)
William G. Hix (AR)
Daniel Hollins (KY)
Darryl D. Kelley (TX)
Timothy L. Klose (PA)
Aaron C. Lougher (OR)
Phillip E. Mason (MO)
Odilio Monterroso De Leon (TX)
Dennis E. Palmer, Jr. (CT)
Larry A. Priewe (ND)
Christopher W. Robinson (NY)
Scott D. Russell (WI)
Benjamin R. Sauder (PA)
Jimmy E. Settle (MO)
Mark A. Smith (IA)
Leon W. Tanksley (GA)
Brian C. Wittenburg (NC)

The drivers were included in docket numbers FMCSA–1998–3637; FMCSA–1999–6480; FMCSA–2000–7165; FMCSA–2000–8203; FMCSA–2002–12294; FMCSA–2003–16564; FMCSA–2005–22194; FMCSA–2006–23773; FMCSA–2008–0266; FMCSA–2009–0206; FMCSA–2009–0291; FMCSA–2010–0201; FMCSA–2011–0379; FMCSA–2014–0002; FMCSA–2014–0004; FMCSA–2014–0006; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2016–0029; FMCSA–2016–0031; FMCSA–2016–0033; FMCSA–2016–0206; FMCSA–2017–0017; FMCSA–2018–0010; FMCSA–2018–0011; FMCSA–2018–0017. Their exemptions were applicable as of November 9, 2020, and will expire on November 9, 2022.

As of November 11, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following eight individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (81 FR 70248; 81 FR 70251; 81 FR 70253; 81 FR 90046; 81 FR 96178; 81 FR 96191; 83 FR 53724):

Elijah A. Allen (AR)
Daniel L. Bawden (IL)
Timothy J. Dougherty (MN)
Josh Gallant (SC)
Dillon L. Hendren (SC)
George P. Mendiola (CA)
Alfred L. Robinson (AR)
Jerry L. Smith (VA)

The drivers were included in docket numbers FMCSA–2016–0207; FMCSA–2016–0208; FMCSA–2016–0209. Their exemptions were applicable as of November 11, 2020, and will expire on November 11, 2022.

As of November 22, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following three individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (79 FR 63211; 80 FR 2471; 81 FR 72664; 81 FR 94013; 83 FR 53724):

Peter J. Faber (NE);
James F. McLaughlin (MN); and
Michael J. Monroe (IA)

The drivers were included in docket numbers FMCSA–2014–0297; FMCSA–2016–0210. Their exemptions were applicable as of November 22, 2020, and will expire on November 22, 2022.

As of November 24, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual has satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (83 FR 53727; 84 FR 2328):

Marcel Spinu (WA)

The driver was included in docket number FMCSA–2018–0018. The exemption was applicable as of November 24, 2020, and will expire on November 24, 2022.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–26162 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2000–7165; FMCSA–2002–12294; FMCSA–2006–23773; FMCSA–2007–29019; FMCSA–2008–0106; FMCSA–2008–0231; FMCSA–2010–0082; FMCSA–2010–0114; FMCSA–2011–0365; FMCSA–2011–0366; FMCSA–2012–0104; FMCSA–2012–0160; FMCSA–2012–0161; FMCSA–2013–0028; FMCSA–2013–0169; FMCSA–2013–0170; FMCSA–2013–0174; FMCSA–2014–0003; FMCSA–2014–0004; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2015–0056; FMCSA–2015–0070; FMCSA–2015–0347; FMCSA–2016–0025; FMCSA–2016–0030; FMCSA–2016–0031; FMCSA–2016–0033; FMCSA–2017–0022; FMCSA–2017–0026; FMCSA–2018–0007; FMCSA–2018–0011; FMCSA–2018–0012; FMCSA–2018–0013; FMCSA–2018–0014]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 44 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates provided below.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2000–7165; FMCSA–2002–12294; FMCSA–2006–23773; FMCSA–2007–29019; FMCSA–2008–0106; FMCSA–2008–0231; FMCSA–2010–0082; FMCSA–2010–0114; FMCSA–2011–0365; FMCSA–2011–0366; FMCSA–2012–0104; FMCSA–2012–0160; FMCSA–2012–0161; FMCSA–2013–0028; FMCSA–2013–0169; FMCSA–2013–0170; FMCSA–2013–0174; FMCSA–2014–0003; FMCSA–2014–0004; FMCSA–2014–0007; FMCSA–2014–0010; FMCSA–2015–0056; FMCSA–2015–0070; FMCSA–2015–0347; FMCSA–2016–0025; FMCSA–2016–0030; FMCSA–2016–0031; FMCSA–2016–0033; FMCSA–2017–0022; FMCSA–2017–0026; FMCSA–2018–0007; FMCSA–2018–0011; FMCSA–2018–0012; FMCSA–2018–0013; FMCSA–2018–0014, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

On October 8, 2020, FMCSA published a notice announcing its decision to renew exemptions for 44 individuals from the vision requirement in 49 CFR 391.41(b)(10) to operate a CMV in interstate commerce and requested comments from the public (85 FR 63649). The public comment period ended on November 9, 2020, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with the current regulation § 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in § 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based on its evaluation of the 44 renewal exemption applications and comments received, FMCSA confirms its decision to exempt the following drivers from the vision requirement in § 391.41(b)(10).

As of September 8, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 32 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (71 FR 6826; 71 FR 19602; 72 FR 58362; 72 FR 67344; 73 FR 11989; 73 FR 35198; 73 FR 48275; 74 FR 57553; 75 FR 13653; 75 FR 25919; 75 FR 39729; 75 FR 44051; 76 FR 70212; 77 FR 3552; 77 FR 5874; 77 FR 13691; 77 FR 17117; 77 FR 23797; 77 FR 38381; 77 FR 41879; 77 FR 46153; 77 FR 51846; 77 FR 52391; 78 FR 27281; 78 FR 41188; 78 FR 64274; 78 FR 67454; 78 FR 77778; 79 FR 1908; 79 FR 4803; 79 FR 13085; 79 FR 14333; 79 FR 14571; 79 FR 18392; 79 FR 23797; 79 FR 28588; 79 FR 29498; 79 FR 38659; 79 FR 41735; 79 FR 41740; 79 FR 46153; 79 FR 53514; 80 FR 33007; 80 FR 59230; 80 FR 63839; 80 FR 67476; 81 FR 1284; 81 FR 1474; 81 FR 15401; 81 FR 15404; 81 FR 20433; 81 FR 20435; 81 FR 21647; 81 FR 28138; 81 FR 45214; 81 FR 48493; 81 FR 52514; 81 FR 66726; 81 FR 68098; 81 FR 90050; 81 FR 91239; 82 FR 15277; 82 FR 37504; 82 FR 47309; 83 FR 2306; 83 FR 2311; 83 FR 6925; 83 FR 15195; 83 FR 15214; 83 FR 18648; 83 FR 24146; 83 FR 24585; 83 FR 28320; 83 FR 28325; 83 FR 28328; 83 FR 28332; 83 FR 28335; 83 FR 33292; 83 FR 34661; 83 FR 34677; 83 FR 40648; 83 FR 45749; 83 FR 54644):

Daniel C. Berry (AR)
Christopher L. Binkley (NH)
John R. Bohman (OH)
Clifford L. Burruss (CA)
Ronald H. Carey (PA)
Darrin G. Davis (WI)
Vincent DeMedici (PA)
Jeffrey D. Duncan (IN)
Paul D. Evenhouse (IL)
John W. Forgy (ID)
Grant G. Gibson (MN)

Rickey W. Goins (TN)
Jorge Gonzalez (FL)
John E. Halcomb (GA)
Nenad Harnos (NJ)
Brian D. Hoover (IA)
Alvin H. Horgdal (IA)
Elvin M. Hursh (PA)
Michael A. Kafer (KS)
Jason W. King (MT)
Allen J. Kunze (ND)
Mickey D. McCoy (TN)
Earl L. Mokma (MI)
Terrence A. Odrick (DE)
James L. Okonek (WI)
James C. Paschal, Jr. (GA)
Riland O. Richardson (GA)
Jacob H. Riggle (OK)
Michael J. Schmelzle (KS)
Gregory S. Smith (AR)
Larry L. Stewart (NC)
William B. Van Drielen (NV)

The drivers were included in docket numbers FMCSA–2006–23773; FMCSA–2007–29019; FMCSA–2008–0106; FMCSA–2010–0082; FMCSA–2011–0365; FMCSA–2011–0366; FMCSA–2012–0160; FMCSA–2012–0161; FMCSA–2013–0028; FMCSA–2013–0169; FMCSA–2013–0170; FMCSA–2013–0174; FMCSA–2014–0003; FMCSA–2014–0004; FMCSA–2014–0007; FMCSA–2015–0056; FMCSA–2015–0070; FMCSA–2015–0347; FMCSA–2016–0025; FMCSA–2016–0030; FMCSA–2016–0031; FMCSA–2017–0022; FMCSA–2017–0026; FMCSA–2018–0007; FMCSA–2018–0011; FMCSA–2018–0012; FMCSA–2018–0013; and FMCSA–2018–0014. Their exemptions were applicable as of September 8, 2020, and will expire on September 8, 2022.

As of September 9, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following three individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (75 FR 34212; 75 FR 47888; 77 FR 27847; 77 FR 38386; 77 FR 40945; 77 FR 41879; 77 FR 52391; 79 FR 29495; 79 FR 41735; 81 FR 81230; 83 FR 40638):

Michael J. Hoffarth (WA);
Shane N. Maul (IN); and
Robert Smiley (NM)

The drivers were included in docket numbers FMCSA–2010–0114; FMCSA–2012–0104; FMCSA–2012–0161. Their exemptions were applicable as of September 9, 2020, and will expire on September 9, 2022.

As of September 21, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following four individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 33406; 65 FR 57234; 67 FR 46016; 67 FR 57266; 67 FR 57267; 69 FR 51346; 69 FR 52741; 71 FR 50970; 71 FR 53489; 73 FR 48270; 73 FR 51336; 75 FR 50799; 75 FR 52062; 77 FR 52389; 79 FR 46300; 81 FR 81230; 83 FR 40638):

Jack D. Clodfelter (NC)
Daniel K. Davis, III (MA)
Reginald I. Hall (TX)
Alfred C. Jewell, Jr. (WY)

The drivers were included in docket numbers FMCSA–2000–7165; and FMCSA–2002–12294. Their exemptions were applicable as of September 21, 2020, and will expire on September 21, 2022.

As of September 23, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following three individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (73 FR 46973; 73 FR 54888; 75 FR 52063; 77 FR 52388; 79 FR 52388; 81 FR 81230; 83 FR 40638):

Terrence L. Benning (WI);
Larry D. Curry (GA); and
Thomas P. Shank (NY)

The drivers were included in docket number FMCSA–2008–0231. Their exemptions were applicable as of September 23, 2020, and will expire on September 23, 2022.

As of September 29, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual has satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (81 FR 59266; 81 FR 74494; 83 FR 40638):

Gregory M. Anderson (NY)

The driver was included in docket number FMCSA–2016–0033. The exemption was applicable as of September 29, 2020, and will expire on September 29, 2022.

As of September 30, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual has satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (79 FR 51643; 79 FR 64001; 81 FR 81230; 83 FR 40638):

Loran J. Weiler (IA)

The driver was included in docket number FMCSA–2014–0010. The exemption was applicable as of September 30, 2020, and will expire on September 30, 2022.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–26163 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2020–0089]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System

Under part 235 of title 49 of the Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that on November 12, 2020, BNSF Railway (BNSF) petitioned the Federal Railroad Administration (FRA) seeking approval to discontinue or modify a signal system. FRA assigned the petition Docket Number FRA–2020–0089.

Applicant: BNSF Railway, Mr. Jerad W. Fritz, AVP Signals, 2600 Lou Menk Drive, Ft. Worth, TX 76131

Specifically, BNSF requests permission to discontinue automatic cab signals on the Chicago Division, Chicago Subdivision from Union Avenue to Intermediate 36.1, Line Segment 71, milepost (MP) 2.3 to MP 36.1, currently in use for suburban trains only.

BNSF states the reason for the proposed discontinuance is a positive train control system, compliant with 49 CFR part 236, subpart I, Positive Train Control Systems, and certified accordingly, has been placed in service within the limits described.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov*.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the

comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation (DOT), 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Ave. SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by January 11, 2021 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacyhttps://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2020–26161 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0093]

Deepwater Port License Application: Texas GulfLink LLC

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of availability; notice of virtual public meetings; request for comments.

SUMMARY: The Maritime Administration (MARAD) and the U.S. Coast Guard (USCG) announce the availability of the Draft Environmental Impact Statement (DEIS) for the Texas GulfLink LLC (GulfLink) deepwater port license application for the export of crude oil from the United States to nations abroad. Publication of this notice announces a 45-day comment period, requests public participation in the environmental impact review process, provides information on how to participate in the environmental impact review process, and announces the two virtual public meetings and an informational open house website for the DEIS.

DATES: To ensure comments on the DEIS will be considered, materials submitted in response to this request for comments must be submitted to the *www.regulations.gov* website or the Federal Docket Management Facility as detailed in the **ADDRESSES** section no later than 45 days after the Environmental Protection Agency publishes its notice of availability of the Draft Environmental Impact Statement for GulfLink Deepwater Port License Application MARAD–2019–0093 in the **Federal Register**.

MARAD and USCG will hold two virtual public meetings in connection with the GulfLink DEIS. The first virtual public meeting will be held via webinar/teleconference on December 16, 2020, from 6:00 p.m. to 8:00 p.m. Central Standard Time. The second virtual public meeting will be held via webinar/teleconference on December 17, 2020, from 6:00 p.m. to 8:00 p.m. Central Standard Time. The public meetings may end later than the stated time, depending on the number of persons who wish to make a comment on the record.

Anyone that is interested in attending and/or speaking at the virtual public meetings must register. Registration information is provided on both the Virtual Open House website, which is located at *TexasGulfLinkDWP-EIS.consultation.ai,* and the Registration part of this notice.

ADDRESSES: The informational open house and virtual public meetings will take place virtually (via webinar/teleconference) due to the nation-wide public health emergency.

The GulfLink deepwater port license application, comments, supporting information and the DEIS are available for viewing and electronic comment submission at *http://www.regulations.gov* under docket number MARAD–2019–0093. The Final EIS (FEIS), when published, will be announced and available at the site as well.

If you are unable to provide electronic comments using *www.regulations.gov,* you may submit hard copy comments to include the docket number ''MARAD–2019–0093'' by mail to U.S. Department of Transportation, Docket Management Facility, West Building, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Federal Docket Management Facility's telephone number is 202–366–9317 or 202–366–9826, the fax number is 202–493–2251.

We encourage you to submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* If you submit your comments electronically, it is not necessary to also submit a hard copy by mail. If you are unable to submit electronic comments using *http://www.regulations.gov,* but wish to submit comments electronically, please contact either Mr. Patrick W. Clark, USCG, or Mr. Linden Houston, MARAD, as listed in the following **FOR FURTHER INFORMATION CONTACT** section of this document. Additionally, if you go to the public docket and sign up for email alerts, you will be notified when comments are posted.

FOR FURTHER INFORMATION CONTACT: Mr. Patrick W. Clark, Project Manager, USCG, telephone: 202–372–1358, email: *Patrick.W.Clark@uscg.mil;* or Mr. Linden Houston, Transportation Specialist, Office of Deepwater Ports and Port Conveyance, MARAD, telephone: 202–366–4839, email: *Linden.Houston@dot.gov.*

SUPPLEMENTARY INFORMATION: A Notice of Application that summarized the GulfLink deepwater port license application for a project that would include pipelines and a crude oil storage terminal located onshore in Brazoria County, Texas, and an offshore pipeline leading to a deepwater port to be located 26.6 nautical miles off the coast of Brazoria County, Texas was published in the **Federal Register** on June 26, 2019 (84 FR 30298–30300). A Notice of Intent to Prepare an Environmental Impact Statement (EIS) and Notice of Public Meetings was published in the **Federal Register** on July 3, 2019 (84 FR 32008–32010).

Request for Comments

MARAD requests public comments or other relevant information related to the DEIS for the proposed GulfLink deepwater port. These comments will inform preparation of the FEIS. Attendance is encouraged at the virtual public meetings. If you are unable to submit electronic comments using *http://www.regulations.gov,* and wish to submit comments electronically, please

contact either Mr. Patrick W. Clark, USCG, or Mr. Linden Houston, MARAD, as listed in the following **FOR FURTHER INFORMATION CONTACT** section. All comments and/or material submitted will be posted, without change, to the Federal Docket Management Facility website (*http://www.regulations.gov*), and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Use Notice that is available on the *www.regulations.gov* website, and the Department of Transportation (DOT) Privacy Act Notice that appeared in the **Federal Register** on April 11, 2000 (65 FR 19477), see PRIVACY ACT. You may view docket submissions at the DOT Docket Management Facility or electronically at the *www.regulations.gov* website.

Virtual Public Meeting and Informational Open House

We encourage you to visit the informational open house website and attend one of the virtual public meetings to learn about, and to comment on the proposed action and the environmental impact analysis contained in the DEIS.

The informational open house website (*TexasGulfLinkDWP-EIS.consultation.ai*) will be available throughout the public comment period, which will end 45 days after the Environmental Protection Agency publishes its notice of availability of the DEIS for GulfLink Deepwater Port License Application MARAD–2019–0093 in the **Federal Register**. The website includes information about the project, including the DEIS presented in a virtual open house format. The project docket, located online at *www.regulations.gov* (docket number MARAD–2019–0093) will be available for viewing during the public comment period as well as after the end of the public comment period.

The public meetings will be hosted on the Zoom platform and will be accessible via webinar online and by phone. The virtual public meetings will be recorded and transcribed for placement in the public docket for the GulfLink project. The Zoom platform can be accessed online by visiting the Zoom website at *www.zoom.us.*

Registration

Interested parties wishing to speak during the virtual public meetings as well as to attend the meetings must register prior to the public meetings. You may register online at *TexasGulfLinkDWP-EIS.consultation.ai* or obtain help registering by contacting AECOM toll free at 833–588–1191.

Meeting Procedure

Registered speakers will be recognized in the following order: Elected officials, public agency representatives, then individuals or groups in the order in which they registered. In order to accommodate all speakers, speaker time may be limited, meeting hours may be extended, or both. Speakers' transcribed remarks will be included in the public docket. You may also submit written material for inclusion in the public docket throughout the 45-day comment period. Written material must include the author's name. Please respect the meeting procedures to ensure a constructive information-gathering session. The presiding officer will use their discretion to conduct the meetings in an orderly manner.

The virtual public meetings are intended to be accessible to all participants. Individuals who require special assistance such as sign language services, language interpreters or other reasonable accommodation, please indicate your special assistance need when registering either at *TexasGulfLinkDWP-EIS.consultation.ai* or contact AECOM toll free at 833–588–1191. Requests for special assistance must be made at least five business days in advance of the virtual public meeting. Please include contact information as well as information about your specific needs.

Background

On January 31, 2019, MARAD and USCG received a license application from GulfLink for all Federal authorizations required for a license to construct, own, and operate a deepwater port for the export of crude oil. The proposed deepwater port would be located in Federal waters approximately 26.6 nautical miles off the coast of Brazoria County, Texas. Texas was designated as the Adjacent Coastal State (ACS) for the GulfLink license application.

The Federal agencies involved held a public scoping meeting in connection with the GulfLink license application. The public scoping meeting was held in Lake Jackson, Texas on July 17, 2019. Transcripts of the scoping meetings are included in the public docket located at *www.regulations.gov* under docket number MARAD–2019–0093.

MARAD and USCG issued a regulatory ''stop-clock'' letter to GulfLink for its application on May 31, 2019, which remained in effect until October 23, 2019, when MARAD and USCG determined the agencies received sufficient information to continue the Federal review process. A second ''stop clock letter'' was issued to GulfLink on September 15, 2020 for additional information requests and remained in effect until November 10, 2020.

The purpose of the DEIS is to analyze reasonable alternatives to, and the direct, indirect, and cumulative environmental impacts of the proposed action. The DEIS is currently available for public review at the Federal docket website: *www.regulations.gov* under docket number MARAD–2019–0093.

Summary of the License Application

GulfLink is proposing to construct, own, and operate a deepwater port terminal in the Gulf of Mexico to export domestically produced crude oil. Use of the deepwater port would include the loading of various grades of crude oil at flow rates of up to 85,000 barrels per hour (bph). The GulfLink deepwater port would allow for up to two Very Large Crude Carriers (VLCCs) or other crude oil carriers to moor at single point mooring (SPM) buoys and connect with the deepwater port via floating connecting crude oil hoses. The maximum frequency of loading VLCCs or other crude oil carriers would be one million barrels per day, 365 days per year.

The overall project would consist of offshore and marine components as well as onshore components as described below.

The GulfLink deepwater port offshore and marine components would consist of the following:

- *An Offshore Platform:* One fixed offshore platform with piles in Outer Continental Shelf Galveston Area Lease Block GA–423, approximately 26.6 nautical miles off the coast of Brazoria County, Texas in a water depth of approximately 104 feet. The fixed offshore platform would have four decks comprising of personal living space, pipeline metering, a surge system, a pig receiving station, generators, lease automatic custody transfer unit, oil displacement prover loop, sample system, radar tower, electrical and instrumentation building, portal cranes, a hydraulic crane, an Operations/Traffic Room, and helicopter deck.
- One 42-inch outside diameter, 28.1-nautical-mile long crude oil pipeline would be constructed from the shoreline crossing in Brazoria County, Texas, to the GulfLink deepwater port for crude oil delivery. This pipeline would connect the proposed onshore GulfLink Jones Creek Terminal (described below) to the offshore GulfLink deepwater port.
- The fixed offshore platform is connected to VLCC tankers for loading by two separate 42-inch diameter

departing pipelines. Each pipeline will depart the fixed offshore platform, carrying the crude oil to a Pipeline End Manifold (PLEM) in approximately 104 feet water depth located 1.25 nautical miles from the fixed offshore platform. Each PLEM is then connected through two 24-inch hoses to a Single Point Mooring (SPM) Buoy. Two 24-inch floating loading hoses will connect the SPM Buoy to the VLCC or other crude oil carrier. SPM Buoy 1 is in Outer Continental Shelf Galveston Area Lease Block GA–423 and SPM Buoy 2 is in Outer Continental Shelf Galveston Area Lease Block GA A 36.

The GulfLink deepwater port onshore storage and supply components would consist of the following:

- *An Onshore Storage Terminal:* The proposed GulfLink Jones Creek Terminal would be located in Brazoria County, Texas, on approximately 262 acres of land, consisting of eight above ground storage tanks, each with a working storage capacity of 708,168 barrels, for a total onshore storage capacity of approximately 6 million barrels. The facility can accommodate four (4) additional tanks, bringing the total to twelve tanks or up to 8.0 million barrels of working capacity.
- *The GulfLink Jones Creek Terminal also would include:* Six electric-driven mainline crude oil pumps; three electric driven booster crude oil pumps; one crude oil pipeline pig launcher; one crude oil pipeline pig receiver; two measurement skids for measuring incoming crude oil—one skid located on the Department of Energy's Bryan Mound facility, and one skid installed for the outgoing crude oil barrels leaving the tank storage to be loaded on the VLCC; and ancillary facilities to include an operations control center, electrical substation, offices, and warehouse building.
- Two crude oil pipelines would be constructed onshore to support the GulfLink deepwater port and include the following items:

○ One proposed incoming 9.7 statute mile 36-inch outside diameter pipeline connected to a leased 40-inch ExxonMobil pipeline originating at the Department of Energy (DOE) facility in Bryan Mound with connectivity to the Houston market.

○ One proposed outgoing 12.7 statute mile 42-inch outside diameter connection from the GulfLink Jones Creek Terminal to the shore crossing where this becomes the pipeline supplying the proposed offshore GulfLink deepwater port.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov.*

(Authority: 33 U.S.C. 1501 *et seq.,* 49 CFR 1.93(h)).

* * * * *

Dated: November 18, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–25843 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0124; Notice of Agency Decision]

General Motors LLC, Denial of Consolidated Petition for Decision of Inconsequential Defect

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Denial of consolidated petition.

SUMMARY: TK Holdings Inc. (''Takata'') has filed defect information reports (DIRs), in which it determined that a defect exists in certain passenger-side frontal air bag inflators that it manufactured, including passenger-side inflators that it supplied to General Motors, LLC (GM) for use in certain GMT900 vehicles. GM petitioned NHTSA for a decision that, because of differences in inflator design and vehicle integration, the equipment defect determined to exist by Takata is inconsequential as it relates to motor vehicle safety in GM's GMT900 vehicles, and that GM should therefore be relieved of its notification and remedy obligations under the National Traffic and Motor Vehicle Safety Act of 1966 and its applicable regulations. After reviewing GM's consolidated petition, supporting materials, and public comments, NHTSA has concluded that GM has not met its burden of establishing that the defect is inconsequential to motor vehicle safety, and denies the petition.

ADDRESSES: For further information on this decision contact Stephen Hench, Office of Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, W41–326, Washington, DC 20590 (telephone: 202–366–5263).

For general information regarding NHTSA's investigation into Takata air bag inflator ruptures and the related recalls: *www.nhtsa.gov/takata.*

SUPPLEMENTARY INFORMATION:

I. Background

The Takata air bag inflator recalls (''Takata recalls'') are the largest and most complex vehicle recalls in U.S. history. These recalls currently involve 19 vehicle manufacturers and over 60 million Takata air bag inflators in tens of millions of vehicles in the United States alone.[1] The recalls are due to a design defect, whereby the propellant used in Takata's air bag inflators degrades after long-term exposure to high humidity and temperature cycling. During air bag deployment, this propellant degradation can cause the inflator to over-pressurize, causing sharp metal fragments (like shrapnel) to penetrate the air bag and enter the vehicle compartment. To date, these rupturing Takata inflators have resulted in the deaths of 18 people across the United States[2] and hundreds of injuries, including lacerations and other serious consequences to occupants' face, neck, and chest areas.

In May 2015, NHTSA issued, and Takata agreed to, a Consent Order,[3] and Takata filed four defect information reports (''DIRs'')[4] for inflators installed in vehicles manufactured by twelve[5] vehicle manufacturers. Recognizing that these unprecedented recalls would involve many challenges for vehicle manufacturers and consumers, NHTSA began an administrative proceeding in June 2015 providing public notice and seeking comment (Docket Number NHTSA–2015–0055) that culminated in NHTSA's establishment of a

[1] These numbers include the approximately 5.9 million GMT900 vehicles and associated passenger inflators addressed by this decision.

[2] Globally, including the United States, the deaths of at least 30 people are attributable to these rupturing Takata inflators.

[3] The May 2015 Consent Order is available at: *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/consent-order-takata-05182015_0.pdf.*

[4] Recall Nos. 15E–040, 15E–041, 15E–042, and 15E–043.

[5] The twelve vehicle manufacturers affected by the May 2015 recalls were: BMW of North America, LLC; FCA US, LLC (formerly Chrysler); Daimler Trucks North America, LLC; Daimler Vans USA, LLC; Ford Motor Company; General Motors, LLC; American Honda Motor Company; Mazda North American Operations; Mitsubishi Motors North America, Inc.; Nissan North America, Inc.; Subaru of America, Inc.; and Toyota Motor Engineering and Manufacturing.

Coordinated Remedy Program (''Coordinated Remedy'') in November 2015.[6] The Coordinated Remedy prioritizes and phases the various Takata recalls to not only accelerate the repairs, but also—given the large number of affected vehicles—to ensure that repair parts are available to fix the highest-risk vehicles first.[7]

Under the Coordinated Remedy, vehicles are prioritized for repair parts based on various factors relevant to the safety risk—primarily on vehicle model year (MY), as a proxy for inflator age, and geographic region. In the early stages of the Takata inflator recalls, affected vehicles were categorized as belonging to one of two regions: The High Absolute Humidity (''HAH'') region (largely inclusive of Gulf Coast states and tropical island states and territories), or the non-HAH region (inclusive of the remaining states and the District of Columbia). On May 4, 2016, NHTSA issued, and Takata agreed to, an amendment to the November 3, 2015 Consent Order (''ACO''), wherein these geographic regions were refined based on improved understanding of the risk, and were then categorized as Zones A, B, and C. Zone A encompasses the higher risk HAH region as well as certain other states,[8] Zone B includes states with more moderate climates (*i.e.,* lower heat and humidity than Zone A),[9] and Zone C includes the cooler-temperature states largely located in the northern part of the country.[10]

The ACO also required Takata to declare on a rolling basis a defect in all frontal driver and passenger-side air bag inflators that contain a phase-stabilized ammonium nitrate (''PSAN'')-based propellant without a moisture-absorbing desiccant. The first DIR was due on May 16, 2016; the second on December 31, 2016; the third on December 31, 2017; the fourth on December 31, 2018; and the fifth on December 31, 2019.[11]

GM's May 27, 2016 DIRs and First Petition

Takata timely submitted the first scheduled equipment DIRs on May 16, 2016.[12] Those DIRs included non-desiccated passenger inflators, designated as SPI YP (''YP'') and PSPI–L YD (''YD'') variants, that were installed as original equipment on certain GMT900 motor vehicles manufactured by GM, as well as other non-desiccated passenger inflators installed as original equipment on motor vehicles manufactured by GM that are not at issue here. The Takata filing triggered GM's obligation to file a DIR for the affected GM vehicles.[13] GM submitted two DIRs on May 27, 2016. On November 15, 2016, GM submitted a Petition for Inconsequentiality and Request for Deferral of Determination Regarding Certain GMT900 Vehicles Equipped with Takata ''SPI YP'' and ''PSPI–L YD'' Passenger Inflators (the ''First Petition for Inconsequentiality'' or ''First Petition''), pursuant to 49 U.S.C. 30118(d), 30120(h) and 49 CFR part 556. In the First Petition, GM requested that NHTSA defer its decision on inconsequentiality until GM was able to complete its testing and engineering analysis in August 2017.[14]

On November 28, 2016, the Agency published a notice of receipt of the First Petition in the **Federal Register** and granted two administrative requests.[15] First, as a matter of its enforcement discretion, NHTSA accepted the First Petition even though it was filed outside the regulatory thirty-day filing deadline.[16] Second, based on unique facts and circumstances, NHTSA granted GM's request for additional time to conduct research and submit information to the Agency, and allowed GM until August 31, 2017 to develop and present further evidence, data, and information before issuing a decision on the First Petition. NHTSA opened public docket no. NHTSA–2016–0124 as a repository for the Petition and supporting materials, and to receive public comments until September 14, 2017.

NHTSA further required that GM submit monthly testing updates. GM submitted such updates for December 2016 and January through July 2017, and a comprehensive submission in August 2017 that included testing, statistical analysis, and other information. GM also presented technical briefings to NHTSA on August 16, 2017 and August 23, 2017. On September 15, 2017, NHTSA sent follow-up questions to GM seeking clarification of information GM had provided, and GM submitted responses on September 29, 2017 (''GM's September 2017 Response''). GM continued providing additional updates to NHTSA at meetings on February 12, April 9, and June 8, 2018. NHTSA sent GM additional follow-up questions to the June 8 meeting on July 10, 2018, and GM submitted responses to those questions on July 20, 2018 (''GM's July 2018 Response'').

GM submitted voluminous materials to the Agency over the course of about two years, including materials from Orbital-ATK (''OATK'')[17] and Cornerstone Research (''Cornerstone'').[18] To apprise the public of this information—which the Agency was considering in rendering the instant decision—the Agency regularly posted GM's materials on public docket no. NHTSA–2016–0124.[19] The Agency

[6] *See* Notice of Coordinated Remedy Program Proceeding for the Replacement of Certain Takata Air Bag Inflators, 80 FR 32197 (June 5, 2015).

The Coordinated Remedy Order, which established the Coordinated Remedy, is available at: *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/nhtsa-coordinatedremedyorder-takata.pdf.* The Third Amendment to the Coordinated Remedy Order incorporated additional vehicle manufacturers, that were not affected by the recalls at the time NHTSA issued the CRO into the Coordinated Remedy, and is available at: *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/final_public_-_third_amendment_to_the_coordinated_remedy_order_with_annex_a-corrected_12.16.16.pdf.* The additional affected vehicle manufacturers are: Ferrari North America, Inc.; Jaguar Land Rover North America, LLC; McLaren Automotive, Ltd.; Mercedes-Benz US, LCC; Tesla Motors, Inc.; Volkswagen Group of America, Inc.; and, per Memorandum of Understanding dated September 16, 2016, Karma Automotive on behalf of certain Fisker vehicles.

[7] *See* Coordinated Remedy Order at 15–18, Annex A; Third Amendment to the Coordinated Remedy Order at 14–17. These documents, among other documents related to the Takata recalls discussed herein, are available on NHTSA's website at *http://www.nhtsa.gov/takata.*

[8] Zone A comprises the following U.S. states and jurisdictions: Alabama, California, Florida, Georgia, Hawaii, Louisiana, Mississippi, South Carolina, Texas, Puerto Rico, American Samoa, Guam, the Northern Mariana Islands (Saipan), and the U.S. Virgin Islands. Amendment to November 3, 2015 Consent Order at ¶ 7.a.

[9] Zone B comprises the following U.S. states and jurisdictions: Arizona, Arkansas, Delaware, District of Columbia, Illinois, Indiana, Kansas, Kentucky, Maryland, Missouri, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Pennsylvania, Tennessee, Virginia, and West Virginia. Amendment to November 3, 2015 Consent Order at ¶ 7.b.

[10] Zone C comprises the following U.S. states and jurisdictions: Alaska, Colorado, Connecticut, Idaho, Iowa, Maine, Massachusetts, Michigan, Minnesota, Montana, New Hampshire, New York, North Dakota, Oregon, Rhode Island, South Dakota, Utah, Vermont, Washington, Wisconsin, and Wyoming. Amendment to November 3, 2015 Consent Order at ¶ 7.c.

[11] NHTSA has permitted Takata to file within a few days of these deadlines to account for weekends and holidays.

[12] *See* Recall Nos. 16E–042, 16E–043, and 16E–044.

[13] *See* 49 CFR part 573; ACO at ¶ 16; Third Amendment to Coordinated Remedy Order at ¶ 32.

[14] First Petition at 18.

[15] 81 FR 85681 (Nov. 28, 2016).

[16] 49 CFR 556.4(c).

[17] OATK was subsequently purchased by Northrop Grumman. For simplicity and continuity across NHTSA's documents regarding the Takata inflator recalls and Coordinated Remedy, NHTSA will continue to refer to the company as OATK.

[18] GM also retained Professor Arnold Barnett, the George Eastman Professor of Management Science and Professor of Statistics at the Massachusetts Institute of Technology, who worked with Cornerstone Research, to provide GM's statistical assessment.

[19] Docket no. NHTSA–2016–0124 can be accessed at *https://www.regulations.gov/docket?D=NHTSA-2016-0124.* Note that limited materials, including

further offered the opportunity for public comment, and comments were both received and considered.

GM's January 10, 2017 DIRs and Second Petition

On January 3, 2017, Takata timely submitted the second scheduled equipment DIRs.[20] The Takata filing triggered GM's obligation to file a DIR for the affected GM vehicles,[21] and GM submitted DIRs on January 10, 2017 recalling additional GMT900 vehicles as well as other vehicles containing non-desiccated PSAN inflators supplied to GM that are not at issue here. GM notified NHTSA of its intention to file a petition for an exemption from its recall notification and remedy obligations as to the GMT900 vehicles only, and submitted a Petition for Inconsequentiality and Request for Deferral of Determination Regarding Certain GMT900 Vehicles Equipped with Takata ''SPI YP'' and ''PSPI–L YD'' Passenger Inflators Subject to January 2017 Takata Equipment DIR Filings (the ''Second Petition for Inconsequentiality'' or ''Second Petition''). On September 11, 2017, the Agency published a notice of receipt of the Second Petition and consolidated the First Petition with the Second Petition in Docket No. NHTSA–2016–0124.[22]

GM's January 9, 2018 DIRs and Third Petition

Takata timely submitted the third scheduled equipment DIRs on January 2, 2018.[23] The Takata filing triggered GM's obligation to file a DIR for the affected GM vehicles,[24] and GM submitted DIRs on January 9, 2018 recalling additional GMT900 vehicles as well as other vehicles containing non-desiccated PSAN inflators supplied to GM not at issue here. GM notified NHTSA of its intention to file a petition for an exemption from its recall notification and remedy obligations as to the GMT900 vehicles only, and submitted a Petition for Inconsequentiality Regarding Certain GMT900 Vehicles Equipped with Takata ''SPI YP'' and ''PSPI–L YD'' Passenger Inflators Subject to January 2018 Takata Equipment DIR Filings (the ''Third Petition for Inconsequentiality'' or ''Third Petition''). On April 9, 2018, the Agency published a notice of receipt of the Third Petition and consolidated the Third Petition with the previously consolidated First and Second Petitions.[25] NHTSA also reopened the public docket to take additional comment on GM's Petition and supporting materials. The closing date for the re-opened comment period was May 9, 2018.

GM's January 9, 2019 DIRs and Fourth Petition

Takata timely submitted the fourth scheduled equipment DIRs on January 2, 2019.[26] The Takata filing triggered GM's obligation to file a DIR for the affected GM vehicles,[27] and GM submitted DIRs on January 9, 2019 recalling additional GMT900 vehicles as well as other vehicles containing non-desiccated PSAN inflators supplied to GM that are not at issue here. GM notified NHTSA of its intention to file a petition for an exemption from its recall notification and remedy obligations as to the GMT900 vehicles only, and submitted a Petition for Inconsequentiality Regarding Certain GMT900 Vehicles Equipped with Takata ''SPI YP'' and ''PSPI–L YD'' Passenger Inflators Subject to January 2019 Takata Equipment DIR Filings (the ''Fourth Petition for Inconsequentiality'' or ''Fourth Petition''). On June 18, 2019, the Agency published notice of the Fourth Petition and consolidated it with the previously consolidated Petitions (collectively referred to as ''the Petition'' or ''GM's Petition'').[28] NHTSA also reopened the public docket to take additional comment on GM's Petition and supporting materials. The closing date for the re-opened comment period was July 18, 2019.

Public Comments on GM's Petition

NHTSA opened public docket number NHTSA–2016–0124 to provide the public an opportunity to review the data and information GM submitted in support of the Petition. NHTSA has taken into consideration all comments posted to the docket as of November 19, 2020.

As of that date, 302 comments have been posted to the docket. No comments were filed in support of granting the Petition, and few address technical aspects of GM's Petition or data. Many comments referred either to concerns with selling unrepaired vehicles, or to the economic hardship or disadvantage experienced as a result of diminished resale or trade-in value for vehicles with unrepaired inflators. Many commenters also expressed general concern about the air bags in their GMT900 vehicles. Since NHTSA concludes here that GM's Petition should be denied, those comments are not discussed here.

II. Motor Vehicles Involved

GM's Petition involves certain ''GMT900'' vehicles that contain ''SPI YP'' and ''PSPI–L YD'' inflator variants. GMT900 is a GM-specific vehicle platform that forms the structural foundation for a variety of GM light- and heavy-duty pickup trucks and sport utility vehicles, including: Chevrolet Silverado 1500, GMC Sierra 1500, Chevrolet Silverado 2500/3500, GMC Sierra 2500/3500, Chevrolet Tahoe, Chevrolet Suburban, Chevrolet Avalanche, GMC Yukon, GMC Yukon XL, Cadillac Escalade, Cadillac Escalade ESV, and Cadillac Escalade EXT. The Petition involves approximately 5.9 million MY 2007–2014 GMT900 vehicles in Zones A, B, and C.[29]

III. Summary of GM's Petition and Supporting Information

GM has petitioned the Agency for a decision that the Takata PSAN defect in the GMT900 vehicles is inconsequential as it relates to motor vehicle safety, and that GM should therefore be relieved of its notification and remedy obligations. GM asserts two primary arguments for why the defect should be deemed inconsequential in GMT900 vehicles. First, GM asserts that there are multiple ''unique'' design differences in the YD and YP variant inflators used in GMT900 vehicles that result in a reduced risk of rupture. Second, GM argues that the physical environment in GMT900 vehicles ''better protects the front-passenger inflator from the extreme temperature cycling that can cause inflator rupture.'' [30] GM's primary arguments and supporting information are summarized below.

A. Unique Inflator Design Differences and Vehicle Features

GM claims that the YD and YP variant inflators in GMT900 vehicles are not used by any other vehicle manufacturers and that these inflator variants have a

materials subject to requests for confidential treatment, are included in the docket via incorporation by memo.

[20] *See* Recall Nos. 17E–001, 17E–002, and 17E–003.

[21] *See* 49 CFR part 573; ACO at ¶ 16; Third Amendment to Coordinated Remedy Order at ¶ 32.

[22] 82 FR 42718 (Sept. 11, 2017). GM also filed a Supplemental Brief in Support of Petitions for Inconsequentiality Regarding Certain GMT900 Vehicles following submission of the Second Petition, which is also available in the public docket.

[23] *See* Recall Nos. 18E–001, 18E–002, and 18E–003.

[24] *See* 49 CFR part 573; ACO at ¶ 16; Third Amendment to Coordinated Remedy Order at ¶ 32.

[25] 83 FR 15233 (Apr. 9, 2018).

[26] Recall Nos. 19E–001, 19E–002, and 19E–003.

[27] *See* 49 CFR part 573; ACO at ¶ 16; Third Amendment to Coordinated Remedy Order at ¶ 32.

[28] 83 FR 15233 (June 18, 2019).

[29] Fourth Petition at 2. Based on information provided to NHTSA by GM, the precise number of vehicles under petition is 5,888,421.

[30] *See id.* at 11–12.

number of unique design features that result in a reduced risk of inflator rupture.[31] GM contends that these unique design features are ''crucially'' important factors that required Takata to ''heavily modify the characteristics'' of their inflators in order to meet GM's standards.[32] As noted in GM's petitions and information presented to NHTSA, these alleged design differences include the following:

Thinner Propellant Wafers. GM claims that the thinner (8mm) propellant wafers used in the GMT900 inflators have more predictable ballistic properties than thicker (11mm) wafers used in many other Takata PSAN inflator variants, which ''create less excess surface area as they degrade.'' [33] As a result, GM contends that the thinner propellant wafers used in the GMT900 vehicles age more slowly and burn more efficiently than thicker propellant wafers, resulting in a reduced risk of inflator rupture.[34]

Larger Vent Area. GM claims that a greater vent-area-to-propellant-mass ratio provides for more efficient burning and deployment of the GMT900 inflators, resulting in a reduced risk of inflator rupture.[35]

Steel Endcap. GM claims that the steel endcap used on the GMT900 inflators creates an improved hermetic seal compared to the aluminum endcaps used on other Takata PSAN inflators, and therefore better protects the propellant from moisture.[36] GM also claims that the use of steel endcaps improves the inflators' ''resistance to high-internal pressures.'' [37]

Other Design Differences. GM observed several other design differences in its presentations to NHTSA, including tablets in a cup (for YP variants), the incorporation of a ceramic cushion (also for YP variants), and the incorporation of a bulkhead disk with an anvil (for YD variants).[38] While noted and discussed during presentations, these design differences were not explicitly referenced or otherwise significantly expounded upon in GM's Petition documents.

GM also asserts that the physical environment in GMT900 vehicles better protects the front-passenger inflators from extreme temperature cycling that can cause inflator rupture. GM claims that the GMT900 vehicles have larger cabin volumes than other vehicles equipped with Takata PSAN inflators, and are all equipped with solar-absorbing glass windshields and side glass, which results in lower internal vehicle temperatures and thus a reduced risk of inflator rupture.[39]

B. Additional Supporting Data and Information

GM contends that the passenger inflators at issue are currently performing as designed, and will continue to function properly without risk of rupture for at least 30 to 35 years of service in the field.[40] In support of this argument, GM cites ballistic testing, aging studies, predictive modeling, and other analyses that it has conducted over the last several years.

1. Testing & Field Data Analyses

Testing by Takata. GM retrieved inflators from the field by removing parts from vehicles (a ''field return'' part or inflator) and sent them to Takata for ballistic testing and analysis. In total, Takata conducted ballistic tests of more than 4,200 field return inflators, with the majority (1,620 YD and 2,235 YP inflators) coming from Zone A.[41] GM states that none of the tested GMT900 inflators have ruptured.[42] Takata's testing further included CT scans of inflators to measure average and maximum wafer diameters of more than 5,000 YD and YP variant inflators, and GM also pointed to micro-CT and high-speed x-ray cinematography, which enabled researchers to view pores and fissures caused by PSAN propellant degradation.[43]

Stress-Strength Interference Analysis. GM conducted a stress-strength interference analysis of the GMT900 vehicle inflators based on CT scans of 1,578 YD and YP inflators.[44] GM explains stress-strength interference analysis as the plotting of curves on a graph related to the diameter of field-returned YP and YD inflators and the diameter of non-GM inflators that have ruptured during ballistic testing; the amount of overlap between the two curves ''represents the probability of rupture in a particular group of inflators.'' [45] GM provides plots of curves with no discernable overlap,[46] and concludes that ''even the oldest (MY 2007) Zone A Takata GMT 900 inflators are not at risk of rupture.'' [47]

Crash Deployment Estimates. GM estimates that its GMT900 vehicles equipped with YD and YP inflators have been involved in approximately 66,894 crashes where the passenger air bag has deployed, all allegedly without a field rupture.[48] GM asserts that this data demonstrates that the GMT900 inflators are ''currently performing as designed.'' [49]

2. Aging Studies

GM conducted a preliminary Aging Study (''GM Aging Study''), and later engaged a third party, OATK, to conduct a larger ''long-term'' Aging Study (''OATK Aging Study'') to simulate the propellant degradation process that occurs in Takata PSAN inflators.[50] It is the Agency's understanding that both studies were informed by vehicle temperature studies conducted by GM (the ''GM Temperature Study'') and Atlas Material Testing Solutions (the ''Atlas Cabin Temperature Study'').[51] For the GM Temperature Study, GM studied the Pontiac Vibe and two GMT900 vehicle models (Silverado and Suburban).[52] The Atlas Cabin

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[31] *See id.* at 12; Second Petition at 11–12; Third Petition at 5–8; Fourth Petition at 5–7.

[32] Fourth Petition at 6; *see* Third Petition at 6. GM's Third Petition asserts that strict adherence to the United States Council for Automotive Research (''USCAR'') air bag performance standards ''resulted in [GM] inflators with increased inflator-structural integrity, better ballistic performance, and greater resistance to moisture.'' Third Petition at 6. NHTSA notes that USCAR standards are utilized across the industry and adherence to those standards is not particular to the GMT900 inflators at issue.

In all events, for the reasons discussed here, GM has failed to meet its burden to show that the defect at issue here is inconsequential to motor vehicle safety.

[33] Fourth Petition at 6–7; *see* Third Petition at 6.

[34] *See* Third Petition at 6; Fourth Petition at 6–7.

[35] *See* Fourth Petition at 7.

[36] *See id.*

[37] *Id.*

[38] *See* GM's June 8, 2018 Presentation at 126; GM's August 23, 2017 Presentation at 111, 113; GM's April 5, 2017 Presentation at 84.

[39] Fourth Petition at 7; Second Petition at 11–12; First Petition at 12; Third Petition at 7.

[40] *See* GM's June 8, 2018 Presentation at 4, 32. This contention is based on 35 years of artificial aging (worst-case field exposure in Miami, Florida) of newly manufactured inflators, described *infra. Id.*

[41] Fourth Petition at 12–13; Third Petition at 13. GM's Third Petition cites 1,620 YD and 2,235 YP inflators and a ''vast majority'' coming from Zone A GMT900 vehicles, while GM's Fourth Petition cites 1,197 YD and 2,249 YP inflators and a ''majority'' coming from Zone A GMT900 vehicles.

[42] Fourth Petition at 12; Third Petition at 13.

[43] GM's June 8, 2018 Presentation at 37; GM's April 5, 2017 Presentation at 60–64, 70; *see* Exhibit A, Report of Dr. Harold Blomquist (''2020 Blomquist Report'') at paras. 88, 221 & n.120.

[44] Second Petition at 15–16; *see also* First Petition at 15–16.

[45] Second Petition at 16; First Petition at 16.

[46] *See* Second Petition, Exs. B & C; First Petition, Exs. B &C.

[47] First Petition at 3; *see* Second Petition at 15–17.

[48] Fourth Petition at 12; *see* GM's June 8, 2018 Presentation at 36. The 66,894 figure is referenced in GM's Fourth Petition, while GM's June 8, 2018 Presentation references 68,206 deployments.

[49] Fourth Petition at 12.

[50] *See* First Petition at 3, 14–15; Fourth Petition at 13–16; GM's August 23, 2017 Presentation at 94–97; GM's April 5, 2017 Presentation at 80–82.

[51] *See* GM's June 8, 2018 Presentation at 11, 14.

[52] *See* GM's August 23, 2017 Presentation at 171.

Temperature Study studied the Pontiac Vibe and 11 non-GM vehicles.[53] GM asserts these studies demonstrate that GMT900 vehicles normally achieve a relatively low peak vehicle temperature (below 60°C, or what GM refers to as the ''T1'' temperature range).[54] GM utilized these temperature studies in its aging studies as described below.

GM Aging Study. GM conducted a preliminary aging study of a small number of inflators, including field-return parts (both YP and YD variant inflators) to demonstrate the short-term safety of its inflators while the Petition was pending.[55] GM artificially aged the inflators by imposing four-hour cycles of temperature and humidity cycling per day for fifty-eight days, in closed-test laboratory chambers.[56] Though none of the inflators ruptured or demonstrated elevated pressure, all showed signs of wafer diameter growth.[57]

OATK Aging Study. GM retained OATK to conduct a long-term aging study to evaluate the future performance of GMT900 inflators through simulated laboratory aging.[58] Takata specially constructed YD, YP, and FD variant inflators for use in the OATK Aging Study.[59] The primary chambers in the inflators were loaded with three different levels of moisture: (1) No moisture added; (2) ''internal moisture approximately equal to 90th percentile moisture levels in Zone A''; and (3) ''moisture levels approximately two-times higher than the highest level ever measured in a GMT900 Inflator recovered from Zone A.'' [60] The OATK Aging Study employed four-hour temperature cycles; by June 2018, OATK had conducted 1,960 cycles of testing, which GM asserts simulated 35 years of field aging.[61] According to GM, ''all of the GMT900 Inflators in the study safely deployed without any ruptures,'' leading GM to the conclusion that the YP and YD inflators are safer and more resistant to rupture than other Takata PSAN inflators.[62] GM asserts that the study demonstrates the GMT900 inflators ''will continue to operate safely for decades, even in the highest temperature and humidity regions.'' [63]

3. Predictive Modeling

In 2018, GM presented results of a parametric mathematical model created by OATK (the ''OATK Model'' or ''the Model'') that was designed to predict the service-life expectancy of GMT900 inflators.[64] It is the Agency's understanding that this Model was informed by the GM Temperature Study and the Atlas Cabin Temperature Study, as well as the GM Aging Study and the OATK Aging Study.[65] The Model runs a Monte Carlo simulation 32,000 times simulating air bag deployments. Each trial combines variations of several different inputs, including usage profile (meaning how the vehicle is driven, where it is parked, how often and high the air conditioning is run, and any other factors that affect the moisture and temperature environment of the inflator),[66] peak vehicle temperature, the environmental conditions of the city in which the inflator resides, and the age of the inflator.[67] The final output of the Model is the ''probability of ED'' for a deployed inflator with these inputs, *i.e.,* the probability that an inflator will rupture under various circumstances.[68] From these Model-predicted outputs, GM concludes that the GMT900 inflators ''will not reach a threshold risk level within 30 years of worst case environmental field exposure in Miami [Florida].'' [69]

4. Risk Assessments

GM also presented statistical risk assessments from third parties Cornerstone and Professor Arnold Barnett, and OATK, which attempted to quantify the future risk of rupture for the GMT900 inflator variants.[70] These risk assessments were based upon data and inputs from the OATK Model, the OATK Aging Study, Takata's Master Engineering Analysis File (''MEAF'') file,[71] and GM's crash-data estimates.[72] Cornerstone concluded that the rupture risk for GMT900 inflators is ''significantly lower'' than that for ''typical 'benchmark' Takata inflators in other vehicles,'' and that the OATK model ''offers strong evidence that a GMT900's absolute risk'' of a rupture ''is extremely small.'' [73]

GM presented several assessments regarding the per-deployment risk, or the probability that a specific air bag will rupture in a given deployment.[74] Based upon the outputs of the OATK Model, GM predicts the following probabilities of future inflator rupture for inflators aged 30 years under the Model:[75]

Vehicle temperature band	YD	YP
For vehicles with cabin temperature less than 60°C (referred to by GM as ''T1'').	0% (*i.e.,* no risk of rupture)	0% (*i.e.,* no risk of rupture).
For vehicles with a cabin temperature between 60 and 65°C (referred to by GM as ''T2'').	0.87% (*i.e.,* 1 rupture per 115 deployments).	12% (*i.e.,*1 rupture per 8 deployments).
For vehicles with a cabin temperature above 65°C (referred to by GM as ''T3'').	66% (*i.e.,* 2 ruptures per 3 deployments).	99% (*i.e.,* 99 ruptures per 100 deployments).

[53] *See id.*

[54] *See* GM's June 8, 2018 Presentation at 11, 14.

[55] *See* First Petition at 3, 14–15; GM's August 23, 2017 presentation at 94–97; GM's April 5, 2017 Presentation to NHTSA at 80–82.

[56] First Petition at 14–15.

[57] *Id.; see* GM's August 23, 2017 Presentation at 94–97.

[58] Fourth Petition at 7–8; Third Petition at 8 & Ex.C.

[59] Fourth Petition at 8; Third Petition at 9 & Ex.C.

[60] Fourth Petition at 8; Third Petition at 9.

[61] *See* GM's August 23, 2017 Presentation at 12, 15; GM's June 8, 2018 Presentation at 4, 81; Fourth Petition at 13; Second Petition at 32–33 (Ex.D).

[62] Fourth Petition at 3; Third Petition at 3, 11.

[63] *Id.* at 3; *see* Fourth Petition at 3–4.

[64] Fourth Petition at 16.

[65] *See* GM's June 8, 2018 Presentation at 11, 14, 48.

[66] 2020 Blomquist Report at para. 189.

[67] *See* GM's June 8, 2018 Presentation at 6–14.

[68] *Id.* at 10, 145.

[69] Fourth Petition at 4; GM's June 8, 2018 Presentation at 4, 8 (defining threshold risk level as 1% chance of failure upon initiation in the 1% vehicle (most severe exposure)).

[70] June 8, 2018 Presentation at 4; *see* Fourth Petition at 14. These assessments were presented at briefings to the Agency in August 2017, February 2018, and June 2018. Cornerstone attended all three briefings, while Professor Barnett only attended the August 2017 and June 2018 meetings.

[71] For several years, Takata has inspected, tested, and analyzed inflators returned from the field. The compiled and summarized test results for more than 387,000 inflator tests or inspections (as of July 3, 2018), including GMT900 inflators, are contained in the Takata MEAF. Takata's MEAF file was available to the Agency in making its determination, and it is from this file that some of the information considered by the Agency was derived, and discussed herein.

[72] *See* GM's June 8, 2018 Presentation at 17.

[73] *Id.* at 18.

[74] *See, e.g.,* GM's July 20, 2018 Response, Ex.C. GM sometimes refers to this as the ''POF'' (probability of failure), ''probability of ED'' (probability of energetic deployment), or ''IR risk'' (inflator rupture risk).

GM also asserted that the probability of rupture in a given deployment is ''zero'' for the YD and YP inflators in the ''long-term,'' but did not provide supporting information. *See* GM's September 29, 2017 Response at 2. GM referred the Agency to GM's Supplemental Brief, but NHTSA found no information that supported this assertion, and therefore it is not addressed in NHTSA's analysis.

[75] GM provided hundreds of per-deployment risk estimates based on various combinations of inputs. *See* GM's July 2018 Response, Ex.C. The estimates in this table reflect estimates for inflators exposed to the most extreme conditions for which GM/OATK calculated risk.

GM asserts that all GMT900 vehicles fall within the lowest ''T1'' vehicle temperature range and therefore have a zero percent risk of rupture through age 30.[76] For vehicles that fall within the higher ''T2'' and ''T3'' vehicle temperature ranges, GM provided an estimate for the number of years until the inflator will have a 1-in-100 chance of rupturing if deployed: for the YD inflator, between 17.6 and 30-plus years; for the YP inflator, between 14.6 and 30-plus years.[77] GM further provided a lifetime risk estimate—namely, the probability that an individual inflator will experience at least one rupture over its lifetime when a person is seated in the front passenger seat, of not more than 1 in 50 million for the YD inflator variant, and not more than 1 in 3.4 million for the YP inflator variant.[78]

GM also provided ''comparative risk'' assessments for the GMT900 inflators.[79] GM contends that the comparator FD inflators—used in the Pontiac Vibe and other vehicles—were ''ideal'' because (1) they are from the same inflator family as the GMT900 light-duty inflator with certain design and construction similarities, but ''lack the critical design elements that, in GM's view, distinguish the GMT900 inflators from other Takata non-desiccated PSAN inflators and make the GMT900 Inflators resistant to the risk of energetic deployment,'' and (2) the FD inflators ''have consistently experienced ruptures during ballistic testing'' and have also experienced field ruptures.'' [80] Based upon the assertion that there have been no GMT900 ruptures in the OATK Aging Study, field returned samples (based upon MEAF data), or in the field, GM concludes that if the GMT900 inflators posed the same risk as other inflators, the probability of observing zero ruptures for GMT900 inflators given the sample size and when compared to other inflators is as follows: [81]

When compared to	YD & YP (pooled)	YD	YP
FD inflators, when each variant is artificially aged *(OATK Aging Study)*	1 in 499 billion	1 in 767,815	1 in 649,530.
Other inflators (excluding the Vibe),[82] when weighted according to certain conditions *(Field Return, MEAF data)*.	1 in 1.5 million	1 in 1,551	1 in 347.
Other 8- to 12-year old inflators in Zone A (excluding the Vibe) [83] *(Field Data Applying Crash Deployment Estimates)*.	1 in 10^{22}	1 in 41 trillion	1 in 174,267.

5. Dealer Replacements as Risk Creation

Finally, GM contends that because the GMT900 inflators are ''not at risk of rupture,'' dealers conducting repairs for the inflators under petition could ''unnecessarily expose'' occupants ''to the risk of an improper repair'' [84] by ''disrupting critical, sensitive, fully operational safety systems in millions of customer vehicles.'' [85]

IV. NHTSA's Analysis

A. Background

The National Traffic and Motor Vehicle Safety Act (the ''Safety Act''), 49 U.S.C. Chapter 301, defines ''motor vehicle safety'' as ''the performance of a motor vehicle or motor vehicle equipment in a way that protects the public against unreasonable risk of accidents occurring because of the design, construction, or performance of a motor vehicle, and against unreasonable risk of death or injury in an accident, and includes nonoperational safety of a motor vehicle.'' [86] Under the Safety Act, a manufacturer must notify NHTSA when it ''learns the vehicle or equipment contains a defect and decides in good faith that the defect is related to motor vehicle safety,'' or ''decides in good faith that the vehicle or equipment does not comply with an applicable motor vehicle safety standard.'' [87] The act of filing a notification with NHTSA is the first step in a manufacturer's statutory recall obligations of notification and remedy.[88] However, Congress has recognized that, under some limited circumstances, a manufacturer may petition NHTSA for an exemption from the requirements to notify owners, purchasers, and dealers and to remedy the vehicles or equipment on the basis that the defect or noncompliance is inconsequential to motor vehicle safety.[89]

''Inconsequential'' is not defined either in the statute or in NHTSA's regulations, and so must be interpreted based on its ''ordinary, contemporary, common meaning.'' [90] The inconsequentiality provision was added to the statute in 1974, and there is no indication that the plain meaning of the term has changed since 1961—meaning definitions used today are substantially the same as those used in 1974.[91] The Cambridge Dictionary defines ''inconsequential'' to mean ''not important'' or ''able to be ignored.'' [92] Other dictionaries similarly define the term as ''lacking importance'' [93] and ''unimportant.'' [94]

[76] *See* GM's June 8, 2018 Presentation at 14; *see also* GM's July 20, 2018 Response, Ex.C.

[77] *See* GM's July 20, 2018 Response, Ex. C.

[78] GM's June 8, 2018 Presentation at 26.

[79] *Id.* at 21–23, 39; GM's July 20, 2018 Response at 16.

[80] Third Petition at 10.

[81] GM's June 8, 2018 Presentation at 21–22; *see* GM's July 20, 2018 Response at 16. GM provided estimates for crash deployments that have occurred in GMT900 vehicles, and based its risk analyses on the assumption that there were no ruptures in those crash deployments. *See infra.*

[82] More specifically, 8–12-year-old SPI and PSPI–L inflators from non-GM vehicles (excluding the Vibe). GM's June 8, 2018 Presentation at 39.

[83] More specifically, 8–12-year-old SPI and PSPI–L inflators from non-GM vehicles (excluding the Vibe) in Alabama, Georgia, Hawaii, Louisiana, Mississippi, South Carolina, and Texas. *Id.* at 39, 46.

[84] Fourth Petition at 16.

[85] Third Petition at 17; *see also* Fourth Petition at 16; GM's June 8, 2018 Presentation at 5. Based on information provided to NHTSA by GM, the total number of vehicles under petition is 5,888,421.

[86] 49 U.S.C. 30102(a)(9).

[87] *Id.* 30118(c)(1). ''[A] defect in original equipment, or noncompliance of original equipment with a motor vehicle safety standard prescribed under this chapter, is deemed to be a defect or noncompliance of the motor vehicle in or on which the equipment was installed at the time of delivery to the first purchaser.'' 49 U.S.C. 30102(b)(1)(F).

[88] *Id.* 30118–20.

[89] *Id.* 30118(d), 30120(h); 49 CFR part 556.

[90] *See, e.g., Food Mktg. Institute* v. *Argus Leader Media,* 139 S. Ct. 2356, 2363 (2019) (quoting *Perrin* v. *United States,* 444 U.S. 37, 42 (1979)).

[91] *See* Pub. L. 93–492, Title I, § 102(a), 88 Stat. 1475 (Oct. 27, 1974); Webster's Third New Int'l Dictionary (principal copyright 1961) (defining ''inconsequential'' as ''inconsequent;' defining ''inconsequent'' as ''of no consequence,'' ''lacking worth, significance, or importance'').

The House Conference Report indicates that the Department of Transportation planned to define ''inconsequentiality'' through a regulation; however, it did not do so. *See* H.R. Rep. 93–1191, 1974 U.S.C.C.A.N. 6046, 6066 (July 11, 1974). Instead, NHTSA issued a procedural regulation governing the filing and disposition of petitions for inconsequentiality, but which did not address the meaning of the term ''inconsequential.'' 42 FR 7145 (Feb. 7, 1977). The procedural regulation, 49 CFR part 556, has remained largely unchanged since that time, and the changes that have been made have no effect on the meaning of inconsequentiality.

[92] *https://dictionary.cambridge.org/us/dictionary/english/inconsequential.*

[93] *https://ahdictionary.com/word/search.html?q=inconsequential.*

[94] *https://www.merriam-webster.com/dictionary/inconsequential.*

The statutory context is also relevant to the meaning of ''inconsequential.'' [95] The full text of the inconsequentiality provision is:

> On application of a manufacturer, the Secretary shall exempt the manufacturer from this section if the Secretary decides a defect or noncompliance is inconsequential to motor vehicle safety. The Secretary may take action under this subsection only after notice in the **Federal Register** and an opportunity for any interested person to present information, views, and arguments.[96]

As described above, the statute defines ''motor vehicle safety'' to mean ''the performance of a motor vehicle or motor vehicle equipment in a way that protects the public against unreasonable risk of accidents . . . and *against unreasonable risk of death or injury in an accident . . . .*'' [97] This is also consistent with the overall statutory purpose: ''to reduce traffic accidents and deaths and injuries resulting from traffic accidents.'' [98]

The statute explicitly allows a manufacturer to seek an exemption from carrying out a recall on the basis that either a defect or a noncompliance is inconsequential to motor vehicle safety.[99] However, in practice, substantially all inconsequentiality petitions have related to noncompliances, and it has been extremely rare for a manufacturer to seek an exemption in the case of a defect. This is because a manufacturer does not have a statutory obligation to conduct a recall for a defect unless and until it ''learns the vehicle or equipment contains a defect and decides in good faith that the defect is related to motor vehicle safety,'' or NHTSA orders a recall by making a ''final decision that a motor vehicle or replacement equipment contains a defect related to motor vehicle safety.'' [100] Until that threshold determination has been made by either the manufacturer or the Agency, there is no need for a statutory exception on the basis that a defect is inconsequential to motor vehicle safety. And since a defect determination involves a finding that the defect poses an unreasonable risk to safety, asking the agency to make a determination that a defect posing an unreasonable risk to safety is inconsequential has heretofore been almost unexplored.[101]

Given this statutory context, a manufacturer bears a heavy burden in petitioning NHTSA to determine that a defect related to motor vehicle safety (which necessarily involves an unreasonable risk of an accident, or death or injury in an accident) is nevertheless inconsequential to motor vehicle safety. In accordance with the plain meaning of ''inconsequential,'' the manufacturer must show that a risk posed by a defect is not important or capable of being ignored. This appropriately describes the actual consequence of granting a petition as well. The manufacturer would be relieved of its statutory obligations to notify vehicle owners and remedy the defect, and effectively ignore the defect as unimportant from a safety perspective. Accordingly, the threshold of evidence necessary for a manufacturer to carry its burden of persuasion that a defect is inconsequential to motor vehicle safety is difficult to satisfy. This is particularly true where the defect involves a potential failure of safety-critical equipment, as is the case here.

The Agency necessarily determines whether a defect or noncompliance is inconsequential to motor vehicle safety based on the specific facts before it. The scarcity of defect-related inconsequentiality petitions over the course of the Agency's history reflects the heavy burden of persuasion as well as the general understanding among regulated entities that the grant of such relief would be quite rare. The Agency has recognized this explicitly in the past. For example, in 2002, NHTSA stated that ''[a]lthough NHTSA's empowering statute alludes to the possibility of an inconsequentiality determination with regard to a defect, the granting of such a petition would be highly unusual.'' [102]

Of the three known occasions in which the Agency has previously considered petitions contending that a defect is inconsequential to motor vehicle safety, the Agency has granted only one of the petitions, nearly three decades ago, in a vastly different set of circumstances.[103] In that case, the defect was a typographical error in the vehicle's gross vehicle weight rating (GVWR) that had no impact on the actual ability of the vehicle to carry an appropriate load. NHTSA granted a motorcycle manufacturer's petition, finding that a defect was inconsequential to motor vehicle safety where the GVWR was erroneously described as only 60 lbs., which error was readily apparent to the motorcycle operator based upon both common sense and the fact that the 330 lbs. front axle rating and 540 lbs. rear axle rating were listed directly below the GVWR on the same label.[104] Moreover, the error did not actually impact the ability of the motorcycle to carry the weight for which it was designed.[105]

On the other hand, NHTSA denied another petition concerning a vehicle's weight label where there was a potential safety impact. NHTSA denied that petition from National Coach Corporation on the basis that the rear gross axle weight rating (RGAWR) for its buses was too low and could lead to overloading of the rear axle if the buses were fully loaded with passengers.[106] NHTSA rejected arguments that most of the buses were not used in situations where they were fully loaded with passengers and that there were no complaints.[107] NHTSA noted that its Office of Defects Investigation had conducted numerous investigations concerning overloading of suspensions that resulted in recalls, that other manufacturers had conducted recalls for similar issues in the past, and that, even if current owners were aware of the issue, subsequent owners were unlikely to be aware absent a recall.[108]

NHTSA also denied a petition asserting that a defect was inconsequential to motor vehicle safety where the defect involved premature corrosion of critical structure components (the vehicle's undercarriage), which could result in a crash or loss of vehicle control.[109] Fiat filed the petition preemptively, following NHTSA's initial decision that

[95] *See, e.g., Taniguchi* v. *Kan Pac. Saipan, Ltd.,* 566 U.S. 560, 569–72 (2012) (considering ordinary and technical meanings, as well as statutory context, in determining meaning of a ''interpreter'' under 28 U.S.C. 1920(6)).

[96] 49 U.S.C. 30118(d), 30120(h).

[97] *Id.* 30102(a)(9) (emphasis added).

[98] *Id.* 30101.

[99] *Id.* 30118(d), 30120(h).

[100] *Id.* 30118(c)(1).

[101] NHTSA notes that the current petition is different in that the inflators were declared defective by the supplier of the airbag, and that GM's defect notice was filed in response to the supplier's notice.

[102] Letter from J. Glassman, NHTSA, to V. Kroll, Adaptive Driving Alliance (Sept. 23, 2002), *https://www.nhtsa.gov/interpretations/ada3.*

[103] *See id.*

[104] *Suzuki Motor Co., Ltd.; Grant of Petition for Inconsequential Defect,* 47 FR 41458, 41459 (Sept. 20,1982) and 48 FR 27635, 27635 (June 16, 1983).

[105] *Id.*

[106] *Nat'l Coach Corp.; Denial of Petition for Inconsequential [Defect],* 47 FR 49517, 49517 (Nov. 1, 1982). NHTSA's denial was erroneously titled ''Denial of Petition for Inconsequential Noncompliance;'' the discussion actually addressed the issue as a defect. *See id.; see also Nat'l Coach Corp.; Receipt of Petition for Inconsequential Defect,* 47 FR 4190 (Jan. 28, 1982).

[107] *Id.* at 49517–18.

[108] *Id.* at 49518.

[109] *Final Determination & Order Regarding Safety Related Defects in the 1971 Fiat Model 850 and the 1970–74 Fiat Model 124 Automobiles Imported and Distributed by Fiat Motors of N. Am., Inc.; Ruling on Petition of Inconsequentiality,* 45 FR 2134, 2137, 41 (Jan. 10, 1980).

certain Fiat vehicles contained a safety-related defect.[110] In support of its petition, Fiat argued that no crashes or injuries resulted from components that failed due to corrosion, and that owners exercising due diligence had adequate warning of the existence of the defect.[111] NHTSA rejected those arguments and both finalized its determination that certain vehicles contained a safety-related defect (*i.e.,* ordered a recall) and found that the defect was not inconsequential to motor vehicle safety.[112] NHTSA explained that the absence of crashes or injuries was not dispositive: ''the possibility of an injury or accident can reasonably be inferred from the nature of the component involved.'' [113] NHTSA also noted that the failure mode was identical to another population of vehicles for which Fiat was carrying out a recall.[114] The Agency rejected the argument that there was adequate warning to vehicle owners, explaining that the average owner does not inspect the underbody of a car and interior corrosion may not be visible.[115]

Agency practice over several decades therefore shows that inconsequentiality petitions are rarely filed in the defect context, and virtually never granted. Nonetheless, in light of the importance of the issues here, and the fact that GM's defect notification was filed in response to the notification provided by their supplier, the Agency also considered the potential usefulness of the Agency's precedent on noncompliance. The same legal standard—''inconsequential to motor vehicle safety''—applies to both defects and noncompliances.[116]

In the noncompliance context, in some instances, NHTSA has determined that a manufacturer met its burden of demonstrating that a noncompliance was inconsequential to safety. For example, labels intended to provide safety advice to an occupant that may have a misspelled word, or may be printed in the wrong format or the wrong type size, have been deemed inconsequential where they should not cause any misunderstanding, especially where other sources of correct information are available.[117] These decisions are similar in nature to the lone instance where NHTSA granted a petition for an inconsequential defect, as discussed above.

However, the burden of establishing the inconsequentiality of a failure to comply with a *performance requirement* in a standard—as opposed to a *labeling requirement*—is more substantial and difficult to meet. Accordingly, the Agency has not found many such noncompliances inconsequential.[118] Potential performance failures of safety-critical equipment, like seat belts or air bags, are rarely deemed inconsequential.

An important issue to consider in determining inconsequentiality based upon NHTSA's prior decisions on noncompliance issues was the safety risk to individuals who experience the type of event against which the recall would otherwise protect.[119] NHTSA also does not consider the absence of complaints or injuries to show that the issue is inconsequential to safety.[120] ''Most importantly, the absence of a complaint does not mean there have not been any safety issues, nor does it mean that there will not be safety issues in the future.'' [121] ''[T]he fact that in past reported cases good luck and swift reaction have prevented many serious injuries does not mean that good luck will continue to work.'' [122]

Arguments that only a small number of vehicles or items of motor vehicle equipment are affected have also not justified granting an inconsequentiality petition.[123] Similarly, NHTSA has rejected petitions based on the assertion that only a small percentage of vehicles or items of equipment are likely to actually exhibit a noncompliance. The percentage of potential occupants that could be adversely affected by a noncompliance does not determine the question of inconsequentiality. Rather, the issue to consider is the consequence to an occupant who is exposed to the consequence of that noncompliance.[124] These considerations are also relevant when considering whether a defect is inconsequential to motor vehicle safety.

B. Information Before the Agency

In support of its Petition, GM submitted thousands of pages of information and data, including work by OATK and Cornerstone on GM's behalf, which is summarized above and further discussed below. In addition, the Agency retained Harold R. Blomquist, Ph.D. to consult on scientific issues related to NHTSA's ongoing investigation into Takata PSAN air bag inflators. As part of the Agency's review of GM's Petition, Dr. Blomquist attended presentations by GM made to the Agency and provided a technical assessment of the information provided by GM.

Dr. Blomquist is a highly-regarded and well-qualified expert in the automotive engineering field, who has spent most of his career focused on

[110] *Fiat Motors of N. Am., Inc.; Receipt of Petition for Determination of Inconsequential Defect,* 44 FR 60193, 60193 (Oct. 18, 1979); *Fiat Motors Corp. of N. Am.; Receipt of Petition for Determination of Inconsequential Defect,* 44 FR 12793, 12793 (Mar. 8, 1979).

[111] *See, e.g.,* 45 FR 2134, 2141 (Jan. 10, 1980).

[112] *Final Determination & Order Regarding Safety Related Defects in the 1971 Fiat Model 850 and the 1970–74 Fiat Model 124 Automobiles Imported and Distributed by Fiat Motors of N. Am., Inc.; Ruling on Petition of Inconsequentiality,* 45 FR 2137–41 (Jan. 10, 1980). Fiat also agreed to a recall of certain of the vehicles, and NHTSA found that Fiat did not reasonably meet the statutory recall remedy requirements. *Id.* at 2134–37.

[113] *Id.* at 2139.

[114] *Id.*

[115] *Id.* at 2140.

[116] 49 U.S.C. 30118(d), 30120(h).

[117] *See, e.g., Gen. Motors, LLC.; cf. Grant of Petition for Decision of Inconsequential Noncompliance,* 81 FR 92963 (Dec. 20, 2016). By contrast, in *Michelin,* we reached the opposite conclusion under different facts. There, the defect was a failure to mark the maximum load and corresponding inflation pressure in both Metric and English units on the sidewall of the tires. *Michelin N. America, Inc.; Denial of Petition for Decision of Inconsequential Noncompliance,* 82 FR 41678 (Sept. 1, 2017).

[118] *Cf. Gen. Motors Corporation; Ruling on Petition for Determination of Inconsequential Noncompliance,* 69 FR 19897, 19899 (Apr. 14, 2004) (citing prior cases where noncompliance was expected to be imperceptible, or nearly so, to vehicle occupants or approaching drivers).

[119] *See Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

[120] *See Combi USA Inc., Denial of Petition for Decision of Inconsequential Noncompliance,* 78 FR 71028, 71030 (Nov. 27, 2013).

[121] *Morgan 3 Wheeler Ltd.; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21666 (Apr. 12, 2016).

[122] *United States* v. *Gen. Motors Corp.,* 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it ''results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future'').

[123] *See Mercedes-Benz, U.S.A., L.L.C.; Denial of Application for Decision of Inconsequential Noncompliance,* 66 FR 38342 (July 23, 2001) (rejecting argument that noncompliance was inconsequential because of the small number of vehicles affected); *Aston Martin Lagonda Ltd.; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 41370 (June 24, 2016) (noting that situations involving individuals trapped in motor vehicles—while infrequent—are consequential to safety); *Morgan 3 Wheeler Ltd.; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21664 (Apr. 12, 2016) (rejecting argument that petition should be granted because the vehicle was produced in very low numbers and likely to be operated on a limited basis).

[124] *See Gen. Motors Corp.; Ruling on Petition for Determination of Inconsequential Noncompliance,* 69 FR 19897, 19900 (Apr. 14, 2004); *Cosco Inc.; Denial of Application for Decision of Inconsequential Noncompliance,* 64 FR 29408, 29409 (June 1, 1999).

issues related to ''the design of energetic solid materials such as propellants, pyrotechnics, explosives and gas generants (propellants) for missile systems and automotive air bag applications.'' [125] After earning his Ph.D. from Duke University in 1980, Dr. Blomquist began working in the rocket industry for Aerojet Strategic Propulsion Corporation and Olin Rocket Research Corporation, where he led propulsion research and development (''R&D'') activities.[126]

After ten years in the rocket industry, Dr. Blomquist transitioned to TRW Automotive in 1990, where the focus of his work was automotive air bag technologies.[127] For the next twenty years, Dr. Blomquist's work at TRW included inflator design research and energetic materials (propellant, booster, and autoignitiation) formulation R&D. Notably, during the 1990s, Dr. Blomquist worked on replacing TRW's azide-based propellant technology, through which he worked with inflators with PSAN oxidizers, like the Takata inflators at issue with this petition.[128]

Because of his work at TRW, Dr. Blomquist holds twenty-five air-bag related patents and was honored twice with product innovation awards related to airbag systems.[129] Further, Dr. Blomquist has published on the subject of airbags and propellants, including ''a technical paper describing PSAN-based propellant and corresponding inflator [which was] presented at the national meeting of the American Institute of Chemical Engineers.'' [130] Dr. Blomquist's experience is more fully set forth in his Report, along with his assessments and findings concerning GM's petition. Dr. Blomquist's report is available in docket no. NHTSA–2016–0124.

Dr. Blomquist reviewed the technical data provided by GM in support of its Petition, as well as information available to the Agency through its ongoing investigation in EA15–001, including presentations and information submitted by TK Global.[131] Ultimately, Dr. Blomquist concluded that GM's claim that design and environmental features render the GMT900 inflators less likely to rupture is unfounded.[132] Many of GM's enumerated features that allegedly make the GMT900 inflators uniquely resilient to rupture are, in fact, not unique to the GMT900 inflators, and other inflators that possess those characteristics have experienced field and testing ruptures, as well as abnormally high-pressure events indicative of propellant degradation.[133] Further, ballistic testing results for the GMT900 inflators that are subject to this petition include abnormally high-pressure events indicative of potential future rupture risk.[134] These findings illustrate that GM's inflators have a similar, if not identical, degradation continuum to that of the other Takata non-desiccated PSAN inflators, and test results from field-aged inflators are consistent with gradual propellant degradation and expected increasing high-pressure deployments.[135]

In addition, Dr. Blomquist found that the OATK Aging Study—which forms the basis for most of GM's supporting arguments—did not replicate real-world conditions.[136] ''Similarly, OATK's predictive model is anchored in key ways to the data derived from OATK's Aging Study, so any weaknesses observed in the Aging Study may explain the Model's inability to predict observed high pressure events and ruptures of field aged inflators.'' [137] Dr. Blomquist concluded, *inter alia,* that the inflators used in GM's vehicles under Petition here—like other Takata non-desiccated PSAN inflators—are susceptible to propellant degradation as built, and to risk of rupture.[138]

The Agency has independently reviewed all of the information submitted by GM and TK Global on this matter, as well as Dr. Blomquist's Report. Based upon this information, and applying its expert judgment as the Agency charged with overseeing motor vehicle safety, NHTSA has determined that GM has not demonstrated that the defect is inconsequential to safety in the GMT900 vehicles. The Petition is therefore denied, for the reasons set forth in more detail below.

C. Response to GM's Supporting Information & Analyses

Rather than focusing on the consequence to an occupant in the event of an inflator rupture,[139] GM instead seeks to show that the GMT900 inflators are not at risk of rupture, contending that GMT900 inflators are ''more resilient'' to rupture than other Takata PSAN inflators.[140] As discussed above, in support of this argument, GM points to unique inflator design differences and unique vehicle features, as well as testing and field data, aging studies, predictive modeling, risk assessments, and the notion that dealer repairs create a potential risk. GM does not discuss the consequence to an occupant in the event of an inflator rupture, and the information provided by GM does not persuasively demonstrate any specific or unique resiliency to propellant degradation or inflator rupture in GMT900 inflators. And, as discussed previously, field-return testing of GMT900 inflators show elevated deployment pressures indicative of propellant degradation and future rupture risk.

1. Unique Inflator Design Differences and Vehicle Features

GM has not demonstrated that any of the features described above—either alone or in conjunction with other features or factors—prevents propellant degradation or renders the defect in GMT900 inflators inconsequential to safety.[141] In fact, as outlined below, other Takata inflators with similar design features have experienced ruptures and high-pressure deployments. Similarly, vehicles with lower or similar peak temperatures have also experienced ruptures and high-pressure deployments. Thus, there is no persuasive evidence that GM's claimed ''unique'' design advantages lead to a reduced risk of inflator rupture.[142]

Thinner Propellant Wafers. GM claims that the thinner (8mm) propellant wafers used in the GMT900 inflators have more predictable ballistic properties than thicker (11mm) wafers used in many other Takata PSAN inflator variants, which ''create less

[125] 2020 Blomquist Report at para. 8.

[126] *Id.* at para. 9.

[127] *Id.*

[128] *Id.* at paras. 13–15.

[129] *Id.* at para. 10.

[130] *Id.* at para. 20.

[131] Some information reviewed by Dr. Blomquist—including certain information submitted by GM—is subject to a request for confidential treatment, and is not publicly available.

[132] 2020 Blomquist Report at paras. 253–56; *see generally id.* at 253–74 (Conclusions).

[133] *See id.* at paras. 259, 263.

[134] *Id.* at paras. 262, 263a.

[135] *Id.* at paras. 262, 269.

[136] *Id.* at para. 271.

[137] *Id.* at para. 272.

[138] *Id.* at paras. 273.

[139] In fact, as GM has never observed or induced a rupture of a GMT900 inflator, GM affirmatively stated it could not determine the safety consequence of an inflator rupture in a GMT900 vehicle. *See* GM's September 2017 Response at 7.

[140] *See, e.g.,* Fourth Petition at 16; GM's August 23, 2017 Presentation at 33.

[141] GM's assertion that strict adherence to the USCAR air bag performance standards ''resulted in [GM] inflators with increased inflator-structural integrity, better ballistic performance, and greater resistance to moisture'' does not change this conclusion. *See* Third Petition at 6. As noted above, USCAR standards are utilized across the industry, and adherence to those standards is not particular to the GMT900 inflators at issue. Moreover, gradual density reduction in both the YD and YP inflator variants demonstrate the GMT900 inflators are drafting out of conformance to SAE/USCAR 24–2 safety requirements. 2020 Blomquist Report at para. 265.

[142] *See id.* at para. 233.

excess surface area as they degrade.'' [143] As a result, GM contends that the thinner propellant wafers used in the GMT900 vehicles age more slowly and burn more efficiently than thicker propellant wafers, resulting in a reduced risk of inflator rupture.[144] In support of its argument, GM relies on two comparison inflator variants—the SPI AJ and the PSPI–L FD.[145] Both variants use primarily 11mm wafers, are commonly installed in vehicle platforms with higher peak temperatures, and have been shown in Takata test and field data to age faster and/or show ruptures and abnormal pressures more often than many other variants.[146]

GM's claim that 8 mm wafers age more slowly than 11 mm wafers is not supported by the results of the OATK Aging Study or by testing data obtained on field aged inflators. There was no significant difference in wafer growth between 8 mm wafers and 11 mm wafers for the inflators in the OATK Aging Study with as-built moisture levels; accordingly, at comparable moisture and temperature conditions, the growth rates of the two sized wafers are essentially the same.[147] At most, the evidence tends to show that the GMT900 inflators age more slowly than the worst performing inflator variants.[148]

Moreover, the use of thinner wafers is not unique to the GMT900 inflator variants, as 8 mm wafers are used in at least twenty-one other Takata PSPI inflator variants.[149] Those non-GM variants using 8 mm wafers—including certain variants that share many of the attributes of the GMT900 inflators—are also susceptible to propellant degradation, and have experienced ruptures and abnormally high pressures during ballistic testing.[150] Furthermore, GM's contention is undermined by ballistic testing conducted on the YP and YD inflator variants used in the GMT900 vehicles. Thus far, four YD and YP inflators have experienced abnormally high peak pressures consistent with propellant degradation, including one field-returned YP inflator that recorded a 91 MPa peak internal pressure—a near rupture.[151] As more time passes, it is reasonable to anticipate that this trend will continue—as has been seen with non-desiccated PSAN inflators generally.

Larger Vent Area. GM claims that a greater vent-area-to-propellant-mass ratio provides for more efficient burning and deployment of the GMT900 inflators, resulting in a reduced risk of inflator rupture.[152] The vent area is not variable in any Takata inflator; that is, the vent area does not change during air bag deployment.[153] While the larger vent size of a GMT900 inflator might provide for more efficient burning during *normal* air bag deployment, the same cannot be said during an abnormal deployment of a defective PSAN inflator.[154] Given the sudden increase in burning surface-area that may occur during an abnormal deployment of a defective PSAN inflator, the vent area may still be overwhelmed causing steep internal pressure increases.[155] Because the vent area of the GMT900 inflators does not, and cannot, change to address the steep internal pressure increases that occur when a defective PSAN inflator abnormally deploys, it does not render the inflators resistant to rupture.[156]

Steel Endcaps. GM claims that use of a steel endcap on the GMT900 inflators better protects the PSAN propellant from moisture by creating an improved hermetic seal compared to the aluminum endcaps used on other Takata PSAN inflators.[157] However, GM provided no evidence to support this argument or its statement that steel endcaps improved the inflators ''resistance to high-internal pressures'' [158] beyond an OATK investigation that pre-dated the petition—which, in any event, only illustrated that steel endcaps provide no measurable advantage over other variants with respect to moisture intrusion.[159]

Other Design Differences. As noted above, GM observed several other design differences in its presentations to NHTSA, but did not reference or elaborate on these differences in their Petition documents. In any event, the mere mention of these differences—tablets in a cup (for YP variants), the incorporation of a ceramic cushion (also for YP variants), and the incorporation of a bulkhead disk with an anvil (for YD variants)—are unpersuasive.

GM provided no data demonstrating that the behavior of tablets during deployment is a major or secondary factor in the root cause of ruptures arising from degradation, and density data in the OATK aging study ''is nearly flat for all three variants at as-built and flat at mid-level moisture levels at all peak temperatures.'' [160] GM also did not provide any information supporting the relevance of a ceramic cushion to mitigating inflator rupture or abnormally high-pressure deployments.[161] And data provided by GM showed that, for inflator variants with a bulkhead anvil, the moisture gain in the booster propellant did not significantly change the main propellant moisture levels in inflators, which varied in the same small range across all inflator variants tested in the OATK Aging Study.[162] Since the bulkhead-anvil feature had no effect on the main propellant moisture levels—which would be relevant to propellant degradation, the cause of inflator rupture—GM has not demonstrated that this design characteristic results in a reduced risk of rupture.[163]

Larger Cabin Volume & Solar Absorbing Glass. GM claims that the GMT900 vehicles have larger cabin volumes than other vehicles equipped with Takata PSAN inflators, and are all equipped with solar-absorbing glass windshields and side glass, which results in lower internal vehicle temperatures and thus a reduced risk of inflator rupture.[164] However, GM did not provide any data demonstrating the influence of larger cabin volume on peak temperatures independent of temperature band, or any data specific to how solar absorbing glass affects interior vehicle temperatures.[165] In fact, at least one non-GM vehicle has a much smaller cabin, yet has a temperature profile lower than that claimed for the GMT900 vehicles; nonetheless, that vehicle—a mid-sized pick-up truck—experienced an inflator rupture.[166] Further, GM did not demonstrate that these alleged lower internal vehicle temperatures rendered the GMT900

[143] Fourth Petition at 6–7; *see* Third Petition at 6.

[144] *See* Third Petition at 6; Fourth Petition at 6–7.

[145] *See* GM's August 23, 2017 Presentation at 44–45.

[146] 2020 Blomquist Report at paras. 60–63, 196.

[147] *Id.* at para. 212.

[148] *See id.* at paras. 195, 209–13.

[149] *See id.* at para. 263a.

[150] *See id.* at paras. 194, 263a, 273; GM's August 23, 2017 Presentation at 43–45, 171–178.

[151] GM's February 12, 2018 Presentation at 5–18; GM's April 9, 2018 Presentation at 14–15; GM's June 8, 2018 Presentation at 115; 2020 Blomquist Report at paras. 96–99, 173, 246–49, 263a.

[152] Fourth Petition at 7. While mass (density) is relevant to propellant degradation, it is the vent-area-to-burning-surface-area ratio that is most relevant to GM's claims here. *See* 2020 Blomquist Report at para. 65.

[153] *See* 2020 Blomquist Report at para. 65.

[154] *See id.* at paras. 65, 215–22.

[155] *See id.* at paras. 218–20, 263c.

[156] *See id.* at para. 218, 263c.

[157] Fourth Petition at 7.

[158] *Id.*

[159] *See* 2020 Blomquist Report at paras. 213–214, 263b.

[160] *Id.* at paras. 70, 223, 263d.

[161] *See id.* at paras. 71, 224, 263e.

[162] *Id.* at paras. 225–26, 263f.

[163] *See id.*

[164] First Petition at 12; Second Petition at 11–12; Third Petition at 7–8; Fourth Petition at 7.

[165] *See* 2020 Blomquist Report at paras. 73–74, 228, 230.

[166] *See id.* at para. 74.

inflators more resilient to rupture. Vehicles with similar, if not lower, peak vehicle temperatures have experienced inflator rupture and abnormally high-pressure deployments—including that of an inflator variant that is nearly identical to the GMT900 YP inflator variant.[167] Additionally, as explained below, at least four inflators from GMT900 vehicles have experienced abnormally high internal pressure deployments indicative of propellant degradation and increased risk of rupture. Given the evidence of degradation in GMT900 inflators and inflator variants that possess the same design features, the evidence does not demonstrate that the GMT900 vehicle environment characteristics appreciably reduce the risk of inflator rupture for defective Takata non-desiccated PSAN inflators.

GM further provided data from ballistic testing, field data, and temperature and aging studies, as well as outputs from a predictive model purporting to show that the GMT900 inflators pose a lower risk of rupture. As outlined below there are a number of compounding concerns with the information and analyses presented that render GM's arguments unpersuasive.

2. Testing & Field Inflator Analyses

Testing by Takata. In its Third Petition, GM claims that none of the GMT900 field return inflators collected and sent to Takata for ballistic testing and analysis ruptured or demonstrated elevated deployment pressure or other signs of abnormal deployment.[168] In its Fourth Petition, GM amended this claim to only assert that none of the field return inflators had ruptured.[169] This change may be in response to MEAF data indicating that at least four inflators recovered from GMT900 vehicles in Zone A experienced abnormally high pressure during ballistic testing: Three YP variant inflators and one YD inflator returned from MY 2007 GMT900 vehicles experienced high-pressure deployments. One of these even reached a pressure of 91 MPa: A near rupture.[170] It is true that, at present, there is no known incident of a rupture of a GMT900 inflator during ballistic testing having occurred during the pendency of GM's petition. However, this does not show that the defect here is inconsequential to safety. Instead, the testing results indicate that these inflators—even encompassing all of the design ''advantages'' claimed by GM—have and will continue to suffer propellant degradation in a manner similar to the other non-desiccated PSAN inflators.[171]

GM sought to distinguish the YP inflator that experienced the near-rupture ballistic result by categorizing it as a ''Gen1'' YP inflator that differs from ''Gen2'' YP inflators based on a shift from propellant tablets to granules, a minor decrease in the amount of tablet propellant weight, the use of a cup instead of a sleeve to hold the propellant tablets, and the addition of the ceramic cushions.[172] As discussed above, GM has not shown that these particular features prevent propellant degradation or provide special resiliency against inflator rupture.[173] Both Gen1 and Gen2 use the same number of 8 mm wafers, have the same vent area, and experience the same in-vehicle environmental conditions; yet, the 91 MPa deployment is clear evidence that the YP variant is experiencing propellant degradation that leads to ruptures and/or abnormally high internal inflator pressures.[174] In addition, the nearly identical SPI DH/MG inflator variant—which shares most design attributes, the same diameter growth rate, and the same peak vehicle temperature band—exhibited a rupture rate of 1 per 6,771 during ballistic testing.[175] GM has not explained how these ballistic test results can be reconciled with its position that the GMT900 inflators will not rupture ''within even unrealistically conservative vehicle-service life estimates.'' [176] Given the severity of a rupture outcome, the observed propellant degradation in the GMT900 inflators and inflator variants with similar (if not identical) characteristics cannot be ignored; these test results are consistent with the notion that the GMT900 inflators have and will continue to suffer propellant degradation in a manner similar to other non-desiccated PSAN inflators.

Further, NHTSA has concerns about the size of the ballistic-testing population. GM asserts that in deploying over 4,200 inflators taken from GMT900 vehicles, none have ruptured.[177] By comparison, the total GMT900 population under consideration is nearly 5.9 million vehicles. Thus, the number of ballistic tests conducted is approximately 0.07% of the total GMT900 population. Even when only comparing the number of inflators tested to the approximately 2 million 2007 and 2008 MY GMT900 vehicles under Petition (the oldest GMT900 vehicles covered by the Petition), the number of ballistic tests conducted is approximately 0.21% of that total population. By comparison, for example, that percentage of the GMT900 population tested is smaller than the percentage of inflators tested, as of November 2019, in a population of a non-GM mid-sized pick-up vehicle—1.81%—with one observed test rupture. Rupture risk in non-desiccated PSAN inflators increases with age/exposure; although testing may not yet have resulted in a rupture, that does not mean that ruptures will not occur in the future.

Stress-Strength Interference Analysis. In the First and Second Petitions, GM includes a ''stress-strength interference analysis'' that, it contended, suggests that propellant in MY 2007 and 2008 GMT900 inflators had not degraded to a sufficient degree to create a rupture risk.[178] GM explains stress-strength interference analysis as the plotting of curves on a graph related to the diameter of field-returned YP and YD inflators and the diameter of non-GM inflators that have ruptured during ballistic testing; the amount of overlap between the two curves ''represents the probability of rupture in a particular group of inflators.'' [179] GM did not discuss this assessment in its Third or Fourth Petitions, appearing to have largely abandoned it in favor of the OATK Aging Study and OATK Model discussed below. In any event, NHTSA does not find it persuasive or determinative on the question of inconsequentiality.

First, this analysis only measures the outside diameter of propellant wafers. While wafer growth and diameter are an indicator of propellant degradation, they are not the only indicator that degradation has occurred. As seen in inflators returned from the field, degradation is evidenced by the formation of pores or fissures in the propellant wafers, as well as changes in the propellant wafer density and diameter.[180] Therefore, reliance on wafer growth alone is of limited utility.

[167] *See id.* at paras. 74, 200, 263g; GM's August 23, 2017 Presentation at 45.

[168] Third Petition at 13.

[169] Fourth Petition at 12.

[170] *See* 2020 Blomquist Report at paras. 246–49.

[171] *See id.* at paras. 246–49, 267–69, 250–52, 273–74.

[172] *See* GM Presentation to NHTSA February 12, 2018, 5–18; 2020 Blomquist Report at paras. 97, 247.

[173] *See also* 2020 Blomquist Report at paras. 97, 247, 267.

[174] *See id.* at paras. 247–48.

[175] *See id.* at paras. 200, 248–49.

[176] *See* Fourth Petition at 4.

[177] *Id.* at 12.

[178] First Petition at 15–17; Second Petition at 15–17.

[179] Second Petition at 16.

[180] *See* 2020 Blomquist Report at paras. 42, 44–45, 53.

And second, this analysis focused on propellant with an average age of eight to nine years. As the vast majority of inflators take longer than that time period to experience propellant degradation sufficient for rupture, looking at inflators of this age is also of limited value.[181]

Crash Deployment Estimates. In the Fourth Petition, GM estimates that 66,894 Takata passenger air bag inflators have deployed in GMT900 vehicles without a reported rupture.[182] It is true that during the pendency of GM's petition, there is no known incident of a rupture of a GMT900 inflator in the field. However, that a rupture has not yet occurred or been reported does not mean that a rupture will not occur in the future. This is particularly relevant in the case of Takata non-desiccated PSAN inflators, where the risk of rupture increases as inflators age and have more exposure to heat and humidity, and in the HAH and Zone A geographic areas described above, first becomes manifest after more than ten years in service.

Moreover, GM's assertions based on ''rupture-free'' crash deployment estimates provide no support for the notion that, in the event of a GMT900 inflator rupture, the result will be inconsequential to safety. As noted above, when taking into consideration the Agency's noncompliance precedent, the likelihood of a rupture is not the only relevant factor here. Indeed, an important factor is also the severity of the consequence of the defect were it to occur—*i.e.,* the safety risk to an occupant who is exposed to an inflator rupture. The known consequence of a rupturing Takata non-desiccated PSAN air bag inflators is quite severe: The spraying of metal shrapnel toward vehicle occupants. GM does not provide any information to suggest that result would be any different were such an inflator to rupture in a GMT900 vehicle.

Even if GM's crash deployment estimates were informative, GM's estimate does not prove a helpful comparison, as it includes both air bag deployments in vehicles when they were new and unlikely to have experienced propellant degradation, as well as deployments in vehicles that were older and exposed to more temperature fluctuation and environmental moisture (*i.e.,* degradation). This estimate therefore fails to account for the differences in the risk of rupture for new vehicles and older vehicles. Additionally, in estimating the number of past GMT900 air bag deployments GM utilized its own attrition model, which resulted in a higher estimated number of deployments when compared to estimates based on NHTSA's attrition models.[183]

GM's estimate also is based only on reported ruptures, and passenger air bag ruptures in the field may not always be reported (and as such)—particularly if no passenger was present in the seat at the time of rupture.

3. Aging Studies [184]

The parameters of the OATK Aging Study are discussed above, and while the Agency appreciates the work that went into the Study, the Agency does not find the results of the Study persuasive for making an inconsequentiality determination, for several reasons. As an initial matter, certain inputs into the OATK Study are not sufficiently reliable. Temperature data from the GM Temperature Study and the Atlas Cabin Temperature Study informed the OATK Study's temperature cycles and temperature bands.[185] However, the GM Temperature Study included only two of the twelve vehicle models covered by the Petition, and was limited to only a handful of vehicles.[186] The Atlas Cabin Temperature Study also only utilized eleven non-GM vehicles and the Pontiac Vibe—no GMT900 vehicles.[187] In addition, for the GM Temperature Study, GM reported on one, two, or three vehicles subjected to testing for lengths of time that, at most, were only vaguely described—information that is critical to determining the reliability of the study.[188] Furthermore, the OATK Aging Study was based on analysis of fewer than 1,000 artificially aged inflators.[189] As outlined above, such low sample sizes (both in input from the temperature studies, and in the number of inflators tested) limits confidence in the Aging Study results, as well as any further study or model that relies on the results of that Aging Study.

Second, importantly, the OATK Aging Study did not appear to accurately replicate the real-world degradation process observed to occur in field-aged inflators.[190] The underlying defect in the GMT900 inflators is a consequence of inflator propellant degradation. As seen in inflators returned from the field, degradation is evidenced by the formation of pores or fissures in the propellant wafers, as well as changes in the propellant wafer density and diameter. While the Aging Study did show changes in inflator wafer density and diameter, the density changes observed during the Study did not replicate field aging in inflators of very-high moisture content, nor did it replicate the formation of pores or fissures seen in field-aged inflators.[191] Additionally, the lab-aged inflators in the OATK Aging Study showed no tendency to increase in pressure when wafers were above the diameter were accelerated burning is expected,[192] despite this result being well-documented in most Takata inflator variants.[193]

A third concern is the Aging Study's presumption that fifty-six four hour cycles of laboratory accelerated aging is equivalent to one year of aging in the field. It is the Agency's understanding that this ''equivalent year'' is derived from the number of days in Miami, FL that GM presented as reaching

[181] *See id.* at paras. 234, 266 (noting also the ''wide variation of vehicle utilization by consumers'' that ''makes the analysis difficult to use with confidence''). Indeed, GM's analysis did not address the rupture of an inflator variant with a wafer-growth rate similar to the YP variant, which ruptured at a field age of 11.6 years in Florida. *Id.* at para. 235.

[182] Fourth Petition at 12.

[183] *See* GM's June 18, 2018 Presentation at 36. Had GM used either the NHTSA 1995 or NHTSA–EPA 2016 attrition models when the estimating the number of GMT900 air bag deployments that have occurred in the past, GM would have estimated there to have been fewer rupture-free deployments of its inflators in the field. *See* NHTSA 1995 attrition model: *Updated Vehicle Survivability and Travel Mileage Schedules,* NHTSA (Report Number: DOT HS 808 339) (Nov. 1995); NHTSA–EPA 2016 attrition model: EPA, CARB, & NHTSA, Draft Technical Assessment Report: Midterm Evaluation of Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards for Model Years 2022–2025, EPA–420–D–16–900 July 2016, *available at https://www.nhtsa.gov/staticfiles/rulemaking/pdf/cafe/Draft-TAR-Final.pdf.*

[184] As noted above, the GM Aging Study was intended to demonstrate the short-term safety of GM's inflators while the longer-term OATK Aging Study was conducted. In previously granting GM additional time to provide evidence in support of its Petition, the Agency found GM's reliance on, *inter alia,* GM's Aging Study, as ''probative evidence'' to support its claim of inconsequentiality. 81 FR 85681, 85684 (Nov. 28, 2016). The Agency only found this information tended to support GM's petition ''at least with respect to the short-term safety'' of the GMT900 inflators—it was not sufficient to prove inconsequentiality. It does not appear that GM directly relies on the results of the GM Aging Study in reaching its conclusions, and therefore we do not analyze it here.

[185] 2020 Blomquist Report at para. 112.

[186] *See* GM's August 23, 2017 Presentation at 171.

[187] *See id.; supra* note 51 and accompanying text; 2020 Blomquist Report at para. 108.

[188] *See* 2020 Blomquist Report at para. 106.

[189] *See* First Petition, Ex.D (reflecting 891 inflators in Statement of Work); GM's August 23, 2017 Presentation at 24 (''700+ Inflators'').

[190] *See* 2020 Blomquist Report at paras. 236–45, 271.

[191] *See id.*

[192] GM August 23, 2017 Presentation at 17–18.

[193] 2020 Blomquist Report at para. 239.

temperatures above 90° F.[194] However, this presumes that propellant degradation only occurs on days or times that reach peak temperatures of 90° F, which is not correct as demonstrated by the many inflators—both in the field and in testing—that have been exposed to lower temperatures and still experienced propellant degradation and inflator rupture.[195] This test scheme also presumes that the temperature cycle can be condensed from a twenty-four hour day to four hours without compromising or altering the type of degradation caused to the propellant.[196] Based upon the information presented to NHTSA, it does not appear that this was the case.

It is also appropriate to note here that GM's reliance on the use of ''comparison inflators'' throughout its research (the SPI AJ and PSPI–L FD—the latter of which was, for example, included in the OATK Aging Study) to demonstrate the safety of the GMT900 inflators is misplaced. First, arguing that the GMT900 inflators are ''safer'' than other inflators with the same defect does not answer the question of whether that defect is inconsequential to safety. Second, the selected comparison inflators have been shown in Takata test and field data to age faster and show ruptures and abnormal pressures more often than many other variants.[197] Additionally, unlike the GMT900 inflator variants, the comparison variants use primarily 11mm wafers (as opposed to 8mm wafers) and are installed on vehicles with higher peak temperatures than what GM claims as the GMT900 peak temperature.[198] Comparing GMT900 inflators to such disparate non-GM inflators does little to quantify the risk posed by GM's inflators, and does not demonstrate that the defect is inconsequential to safety.

And finally, analysis of other inflator variants that possess the same attributes as the GMT900 inflators also weakens GM's claim that the unique inflator design differences and vehicle environment of the GMT900 vehicles render the GMT900 inflators more resilient to rupture. The non-GM SPI DH/MG inflator variant is nearly identical to GM's YP inflator in that it also uses 8mm wafers and enjoys a low peak inflator surface temperature. Data showed that diameter measurements for the (GM) YP inflators and (non-GM) DH/MG inflators were essentially the same after field aging, reinforcing the similarity of the two variants.[199] Notably, the DH/MG inflator variant has exhibited a rupture rate of 1 per of 6,771 ballistic tests. GM has not provided any further, persuasive information that would explain how these ballistic results can be reconciled with GM's position that its YP inflators will not rupture ''within even unrealistically conservative vehicle-service life estimates.'' [200]

Similarly, the non-GM PSPI–6 YB and PSPI–6 XG inflator variants, which both use primarily 8mm wafers, can provide insight into GM's YD inflators.[201] The YB variant is used on two non-GM vehicle platforms, one of which provides peak vehicle temperatures slightly lower than the GMT900, and one of which provides peak vehicle temperatures slightly higher than the GMT900. The non-GM platform using the YB variant that experiences higher peak vehicle temperature conditions has experienced at least one field rupture, three inflator ruptures during field-return ballistic testing, and one abnormally high-pressure result during ballistic testing.[202] ''These results indicate that an 8mm wafer inflator variant experiencing high peak inflator temperature in Zone A can rupture at a similar age to the Vibe PSPI–L FD (with an 11mm wafer) that GM used for comparison.'' [203] Another non-GM vehicle platform using 8mm wafers in the PSPI–6 XG variant has demonstrated ruptures or abnormally high pressures during ballistic testing at a rate of 1.06% of inflators tested, with all ruptures occurring in inflators field aged 9.4 to 10.3 years.[204] Even assuming this vehicle platform had a higher peak vehicle temperature than that alleged for the GMT900 vehicles, analysis of these similar inflator variants contradicts GM's claims that thinner propellant wafers render the GMT900 inflators less susceptible to rupture and degradation.

Given the severity of a rupture outcome, the observed propellant degradation in the GMT900 inflators and inflator variants with similar (if not identical) characteristics cannot be ignored; these test results are consistent with the notion that the GMT900 inflators have and will continue to suffer propellant degradation in a manner similar to other non-desiccated PSAN inflators—and, in all events, that the risk is not inconsequential to safety.

4. Predictive Modeling

As noted above, it is the Agency's understanding that this Model was informed by the GM Temperature Study and the Atlas Cabin Temperature Study, as well as the GM Aging Study and the OATK Aging Study.[205] Accordingly, the concerns the Agency has with those inputs (also described above) also adversely affect the reliability of the Model as it applies to GM's arguments here. The implications of this are even more pronounced when the number of trials in the underlying simulation are too small to detect certain rupture rates: If the risk of rupture is 1 in 100,000, then based on a Monte Carlo simulation with 32,000 trials, the OATK Model output would likely predict a zero risk of rupture, clearly understating the potential risk. Even setting aside concerns regarding the inputs, given the relative rarity of high pressure and rupture events across the non-desiccated PSAN inflator population, it is difficult to place much reliability on the OATK Model outputs when evaluating the likelihood of a rupture of a YP or YD inflator variant.[206]

Additionally, the OATK Model outputs underestimate the risk for consumers with YP or YD inflators exposed to the most extreme conditions. The OATK Model selects 32,000 random scenarios that combine different inputs of density and pressure; some of the 32,000 selected scenarios will pose a higher risk (*i.e.,* have a combination of density and pressure that is more rupture-prone) and some will pose a lower risk (*i.e.,* be less rupture-prone).[207] As a result, the output will tend to reflect the risk posed by an average inflator, thereby underestimating the risk posed by inflators subjected to the most extreme conditions. These shortcomings also reflect an underestimation of how quickly an inflator degrades—undermining GM's claim that GMT900 inflators will not reach a ''threshold risk

[194] *Id.* at para. 241; *see generally* GM's August 23, 2017 Presentation at 12.

[195] 2020 Blomquist Report at para. 241.

[196] *Id.* at para. 242; *see id.* at para.270.

[197] *See id.* at paras. 196–205.

[198] *Id.* at para. 196.

[199] GM's August 23, 2017 presentation at 45; 2020 Blomquist Report at para. 199 & n.13.

[200] *See* Fourth Petition at 4.

[201] *See* 2020 Blomquist Report at paras. 201–05.

[202] *Id.;* information received by NHTSA pursuant to Standing General Order 2015–01A.

[203] 2020 Blomquist Report at para. 204.

[204] *Id.* at para. 205.

[205] *See also id.* at paras. 250, 272.

[206] *See id.* at para. 252 (observing high-pressure and rupture events in the Takata non-desiccated PSAN population ''are relatively rare . . . for all vehicle platforms, with rupture rates for most variants well under 1%. Modeling at sufficient fidelity to predict low frequency events is challenging''). The Model's reliability for the purpose of advancing GM's arguments here is further called into question by its inability to produce similar probabilities for GM's YP inflators and the non-GM DH/MG inflators, which are nearly identical. *See id.*

[207] *See* GM's June 8, 2018 Presentation at 10–14.

level'' within 30 years of worst case environmental field exposure in Miami.

5. Risk Assessments

GM also presented statistical risk assessments from third parties Cornerstone and Professor Barnett, and OATK, which attempted to quantify the future risk of rupture for the GMT900 inflator variants, as described above. NHTSA does not find GM's statistical analysis persuasive, as there are multiple foundational concerns with GM's risk estimates.

First, GM's risk assessments depend upon the inputs and outputs from the OATK Model, the OATK Aging Study, and GM's crash data estimates, as well as information from the MEAF file.[208] Given the extent to which GM's various analyses and assessments inform one another, it is critical that the studies that fall earlier in the chain and the associated results and conclusions are sound. As described above, GM has not demonstrated the reliability and persuasiveness of those studies or the associated results and conclusions.

Second, it is a basic principle of statistics that to demonstrate an outcome with higher confidence, all other things being equal, larger sample sizes are necessary.[209] Given the low number of inflators tested and utilized in the earlier studies [210]—particularly when combined with the challenge posed by using models to predict low-frequency events—it is difficult to have confidence in GM's risk estimates, especially in the context of a decision on inconsequentiality. Moreover, GM did not provide any margins of error on their risk estimates—particularly important when evaluating the risk of a catastrophic event like an inflator rupture.[211]

Third, GM's comparative risk assessments (comparing the rupture rate of GMT900 inflators to those of other inflators through the OATK Aging Study, Takata MEAF data, and GM's crash estimates) [212] simply assert that GMT900 inflators are safer than other inflators—not that the defect is inconsequential.

And fourth, even to the extent GM's per-deployment or lifetime risk estimates inform the question of inconsequentiality, they do not reflect the compounding risk that arises from having millions of affected vehicles. The per-deployment risk is the risk that one specific air bag will rupture; the fleet-level risk is the probability that at least one air bag will rupture among the thousands of air bag deployments expected to occur in the nearly 5.9 million affected GMT900 vehicles over the coming years. GM did not provide any risk assessments that acknowledge the risk presented by the GMT900 inflator population as a whole, even though the fleet-level risk would be much larger than the per-deployment risk.

NHTSA also has additional, specific concerns about GM's various risk estimates. GM's comparative risk assessments—to the extent they inform the question of inconsequentiality—are undercut by the ballistic results showing elevated pressures discussed above. That a rupture has not yet been observed does not mean that ruptures will never occur—nor that the risk to safety is inconsequential—and estimates that ignore evidence that GM's inflators are experiencing a similar manner of degradation do not provide meaningful comparison.

In addition, GM's comparative risk estimates pool the risk posed by inflators across ages and/or Zones, even though the risk of rupture varies greatly between Zones A, B, and C and as the inflators age.[213] This pooling typically dilutes the risk that exists in the higher risk Zone A by combining it with the lower risk Zones.[214] Similarly, pooling younger inflators with older inflators dilutes the estimated risk of rupture for those older inflators, particularly as inflator age plays a vital role in the underlying defect. GM's comparative assessment of estimated field crash rupture rates also assumes both that GM's crash deployment estimates are accurate and that passenger air bag ruptures are reported (as such). As discussed above, these assumptions are not supported.[215]

Similarly concerning is that GM's per-deployment risk estimate of zero percent for the GMT900 vehicles relies on the assumption that GM's vehicles have a low vehicle cabin temperature,[216] but data provided by GM suggested that at least one GMT900 variant fell within a higher temperature range during testing—undermining both its risk estimates and GM's argument that all GMT900 vehicles have a lower cabin temperature due to a unique vehicle environment.[217] GM's ''lifetime risk'' estimate similarly suffers from questionable temperature range assumptions.[218] Moreover, the YP inflators will deploy any time sensors determine a crash of sufficient force is in progress—whether a passenger is present or not.[219] It is therefore not accurate to assume that occupants would not be harmed by the rupture of a passenger air bag when no passenger is present; indeed, occupants have suffered injuries from Takata inflator ruptures that did not occur directly in front of them.[220] And just like the assessments comparing GMT900 inflator rupture rates to the OATK Aging Study and MEAF data, GM's prediction of future rupture rates implies that because ruptures have (reportedly) not yet occurred they are unlikely to occur in the future. As this assumption is not accurate, these estimates are not persuasive in supporting GM's position that the Takata PSAN defect in the GMT900 vehicles is inconsequential to safety.

6. Dealer Replacements as Risk Creation

Finally, GM's claim that dealers conducting repairs for these vehicles could ''create risk'' to consumers [221] has no bearing on the question of whether the defect is inconsequential to safety. Even if the Agency were to consider any potential risk posed by potential improper repair in analyzing the consequentiality of a rupturing inflator, GM provided no information to corroborate or support this broad,

[208] *See* Third Petition at 15; GM's August 23, 2017 Presentation at 22, 24–30; GM's June 8, 2018 Presentation at 11–17, 24–26.

[209] *See generally* NIST/SEMATECH e-Handbook of Statistical Methods at 6.2.3.2, *available at http://www.itl.nist.gov/div898/handbook* (choosing a sampling plan with a given Operating Characteristic (''OC'') Curve; *id.* at 7.2.2.2 (providing example calculation of sample-size estimate for limiting error); *id.* at 3.1.3.4 (Populations and Sampling).

[210] *See generally supra.*

[211] While GM's upper bounds on the lifetime risk could be construed as a type of margin of error, it does not take into account important sources of variation, such as the Monte Carlo simulation.

[212] *See* GM's June 8, 2018 Presentation at 20–22.

[213] *See* GM's June 8, 2018 Presentation at 21–22, 39.

[214] GM's July 2018 Response (Ex.A) did provide estimates specific to Zone A; however, the response pooled the risk for the two inflator variants (YD and YP).

[215] There were also significant inconsistencies between the production numbers GM relied upon in arriving at these estimates and comparative registration data. *See* GM's July 2018 Response at 6–8. Additionally, GM's future deployment risk estimates assume that a passenger will be present in 25% of future GMT900 crashes, which is not consistent with National Automotive Sampling System General Estimates System (NASS GES) estimates.

[216] *Id.* Ex.C (providing, *inter alia,* temperature bands and probability).

[217] *See* GM's August 23, 2017 Presentation 8 (reflecting average peak and maximum peak temperatures in Michigan, Florida, and Arizona).

[218] *See* GM's June 8, 2018 Presentation at 26 (utilizing an average probability of failure for T1 and T2 as an upper bound).

[219] *See id.* at 36 (reflecting 25% passenger air bag activation rate for YD, and 100% activation rate for YP in front deployment level crashes).

[220] Information received by NHTSA pursuant to Standing General Order 2015–01A.

[221] Third Petition at 17; *see also* Fourth Petition at 16; GM's June 8, 2018 Presentation at 5.

speculative statement. GM can and does ensure quality recall repairs by specifying technician qualifications and repair techniques for its franchised dealer network.

V. Decision

The relief sought here is extraordinary, and GM's Petition goes far beyond the scope and complexity of any inconsequentiality petition that the Agency has considered, let alone granted. This is with respect not only to the volume of information and analyses bearing on the issue, but also the nature of the defect and associated safety risk. Indeed, the Petition concerning GMT900 inflators is quite distinct from the previous petitions discussed above, for example, relating to defective labels that may (or may not) mislead the user of the vehicle to create an unsafe condition.[222] Nor is the risk here comparable to a deteriorating exterior component of vehicle that—even if an average owner is unlikely to inspect the component—might (or might not) be visibly discerned.[223]

Rather, the defect here poses an unsafe condition caused by the degradation of an important component of a safety device that is designed to protect vehicle occupants in crashes. Instead of protecting occupants, this propellant degradation can lead to an uncontrolled explosion of the inflator and propel sharp metal fragments toward occupants in a manner that can cause serious injury, including lacerations to the face, neck and chest, and even death.[224] This unsafe condition—hidden in an air bag module—is not discernible even by a diligent vehicle owner, let alone an average owner.[225]

Moreover, nineteen manufacturers (including GM for other populations of their vehicles) have conducted similar recalls of other non-desiccated PSAN inflators. NHTSA has been offered no persuasive reason to think that without a recall, even if current owners are aware of the defect and instant petition, subsequent owners of vehicles equipped with GMT900 air bag inflators would be made aware of the issue.[226] This is not the type of defect for which notice alone enables an owner to avoid the safety risk. A remedy is required.

The threshold of evidence necessary to prove the inconsequentiality of a defect such as this one—involving the potential performance failure of safety-critical equipment—is very difficult to overcome. GM bears a heavy burden, and the evidence and argument GM provides suffers from numerous, significant deficiencies, as previously described in detail.

The ''unique'' inflator design differences and vehicle features to which GM points are unpersuasive. The use of thinner wafers is not unique to GMT900 inflators—other Takata inflator variants with 8mm wafers have experienced ruptures and abnormally high pressures during ballistic testing—and the results of the OATK Aging Study and testing data obtained on field aged inflators, at most, show that GMT900 inflators age more slowly than the worst performing inflator variants. Moreover, four GMT900 inflators have experienced abnormally high peak pressures consistent with propellant degradation. Larger vent areas in GMT900 inflators do not render those inflators more resistant to rupture, as the vent area does not change to address steep internal pressure increases that occur when a defective PSAN inflator abnormally deploys. GM did not demonstrate that steel endcaps provide any measurable advantage over other variants with respect to moisture intrusion. GM did not provide data demonstrating a correlation between lower peak temperatures and either solar absorbing glass or larger cabin volume, or demonstrate that alleged internal vehicle temperatures rendered the GMT900 inflators more resilient to rupture. And other design differences to which GM points—tablets in a cup, the incorporation of a ceramic cushion, and the incorporation of a bulkhead disk with an anvil—were not discussed in detail in its Petition, and in any event, either lack supporting data, or the data that GM did provide does not demonstrate that the design difference results in a reduced risk of rupture.

GM's stress-strength interference analysis ignores other indicators of propellant degradation, and relies heavily on relatively young inflators. And GM's crash deployment estimates also raise concerns for the Agency. That a rupture has not yet occurred or been reported does not mean that a rupture will not occur in the future, and it provides no support for the notion that in the event of a rupture, the result will be inconsequential to safety. Moreover, GM's estimates incorrectly imply that older vehicles have the same risk of rupture as newer vehicles, use GM's own attrition model instead of NHTSA's, and assume consistent reporting of ruptures and injuries despite GM having done no testing or analysis to determine the impact of a rupture.

The aging studies on which GM relies are similarly deficient and unpersuasive. These studies are adversely affected by inputs from two other studies that were not specific to GMT900 vehicles (in one of which certain information was vaguely described) and were limited in sample size. The OATK Aging Study also does not appear to replicate real-world propellant degradation, including degradation that might occur on days or times that do not reach peak temperatures of 90 °F, even though degraded and ruptured inflators in the field and in testing show that degradation occurs at lower temperatures. In addition, in its research, GM used certain comparison inflators despite key differences between the GMT900 inflators in wafer diameter and peak-temperature exposure. The comparison inflators have also been shown in testing and field data to age faster and show ruptures and abnormal pressures more often than many other variants, and there are other comparator candidates that have ruptured in ballistic testing—and one such inflator ruptured at least once in the field. And in any event, contending that the GMT900 inflators are ''safer'' does not answer the question of whether the defect is inconsequential to safety.

GM's predictive modeling and risk assessments are also adversely affected by unreliable inputs, with the former also understating the potential risk and the latter further limited by sample size, the pooling of risk across inflator age

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[222] *See Nat'l Coach Corp.; Denial of Petition for Inconsequential [Defect],* 47 FR 49517 (Nov. 1, 1982); *Suzuki Motor Co., Ltd.; Grant of Petition for Inconsequential Defect,* 48 FR 27635 (June 16, 1983).

[223] *See Final Determination & Order Regarding Safety Related Defects in the 1971 Fiat Model 850 and the 1970–74 Fiat Model 124 Automobiles Imported and Distributed by Fiat Motors of N. Am., Inc.; Ruling on Petition of Inconsequentiality,* 45 FR 2134 (Jan. 10, 1980).

[224] *Cf. Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 35355–01, 2013 WL 2489784 (June 12, 2013) (finding noncompliance inconsequential where ''occupant classification system will continue to operate as designed and will enable or disable the air bag as intended'').

[225] *See Final Determination & Order Regarding Safety Related Defects in the 1971 Fiat Model 850 and the 1970–74 Fiat Model 124 Automobiles Imported and Distributed by Fiat Motors of N. Am., Inc.; Ruling on Petition of Inconsequentiality,* 45 FR 2134 (Jan. 10, 1980) (rejecting argument there was adequate warning to vehicle owners of underbody corrosion, as the average owner does not undertake an inspection of the underbody of a vehicle, and interior corrosion of the underbody may not be visible).

[226] *See Nat'l Coach Corp.; Denial of Petition for Inconsequential [Defect],* 47 FR 49517 (Nov. 1, 1982) (observing, *inter alia,* that other manufacturers had conducted recalls for similar issues in the past, and that, even if current owners were aware of the issue, subsequent owners were unlikely to be aware absent a recall).

and zone in comparative risk assessments (which only assert that GMT900 inflators are safer than other inflators, not that the risk to safety is inconsequential), a failure to address fleet-level risk, and assumptions about vehicle cabin temperature, potential harm to occupants, and the future occurrence and reporting of ruptures in the field. GM also did not provide any margins of error on their estimates. GM's speculative claim that dealers conducting repairs could ''create risk'' to consumers is also unsupported—even if the Agency were to consider such a risk in analyzing the consequentiality of a rupturing inflator—and GM has the ability to ensure quality repairs.

Perhaps most importantly, the testing done by Takata, even with a small sample size, reflects abnormally high pressure during ballistic testing—indicative of the type of propellant degradation that leads to ruptures. Given the severity of the consequence of propellant degradation in these air bag inflators—the rupture of the inflator and metal shrapnel sprayed at vehicle occupants—a finding of inconsequentiality to safety demands extraordinarily robust and persuasive evidence. What GM presents here, while valuable and informative in certain respects, suffers from far too many shortcomings, both when the evidence is assessed individually and in its totality, to demonstrate that the defect in GMT900 inflators is not important or can otherwise be ignored as a matter of safety.

GM has not demonstrated that the defect is inconsequential to motor vehicle safety. Accordingly, GM's Petition is hereby denied and GM is obligated to provide notification of, and a remedy for, the defect pursuant to 49 U.S.C. 30118 and 30120. Within 30 days of the date of this decision, GM shall submit to NHTSA a proposed schedule for the notification of GMT900 vehicle owners and the launch of a remedy required to fulfill those obligations.

Authority: 49 U.S.C. 30101, *et seq.,* 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Associate Administrator, Enforcement.

[FR Doc. 2020–26148 Filed 11–25–20; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Notice of Funding Opportunity for Letters of Interest for the RRIF Express Pilot Program Under the Railroad Rehabilitation & Improvement Financing Program

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

ACTION: Notice of funding opportunity.

SUMMARY: This Notice of Funding Opportunity (NOFO) for the RRIF Express Pilot Program expands eligibility criteria and extends the deadline for submission of Letters of Interest. The eligibility criteria in section IV. are revised to: Increase the total project size limit to $150 million, broaden project scope consistent with the RRIF statute, and expand the proportion of refinancing allowed to 75%. Prospective RRIF borrowers who have been accepted into the RRIF Express program may amend their Letters of Interest to reflect the changed criteria. Prospective RRIF borrowers who received advice from DOT on issues to address in revising and resubmitting Letters of Interest may also take advantage of the expanded criteria while also following the advice provided. All projects that were previously eligible for RRIF Express financing remain eligible under this NOFO.

DATES: Letters of Interest from prospective RRIF borrowers for the RRIF Express Program will be accepted on rolling basis until available funding is expended or this notice is superseded by another notice.

Prospective RRIF borrowers that have previously submitted a Letter of Interest but that also seek acceptance into the RRIF Express Program should resubmit a Letter of Interest following the instructions below. *Prospective RRIF borrowers who previously submitted Letters of Interest under a previous RRIF Express Notice of Funding Opportunity (published on December 13, 2019, March 16, 2020, or June 19, 2020), and whose Letters of Interest have not been returned as ineligible, do not have to re-apply, and may amend their Letter of Interest to take advantage of the revised eligibility criteria. Prospective RRIF borrowers whose Letter of Interest for RRIF Express was returned by the Bureau with advice on issues to address in resubmitting a Letter of Interest may also take advantage of the revised eligibility criteria while also following the advice provided.*

Irrespective of the above, the Bureau continues to accept Letters of Interest on a rolling basis from *any* prospective RRIF borrower interested in receiving RRIF credit assistance *only* (*i.e.,* without participation in the RRIF Express Program).

ADDRESSES: Applicants to the RRIF Express Program must use the latest version of the Letter of Interest form available on the Build America Bureau website: *https://www.transportation.gov/content/build-america-bureau* (including applicants who have previously submitted Letters of Interest and who are now seeking participation in the RRIF Express Program). Letters of Interest must be submitted to the Build America Bureau via email at: *RRIFexpress@dot.gov* using the following subject line: ''Letter of Interest for RRIF Express Program.'' Submitters should receive a confirmation email, but are advised to request a return receipt to confirm transmission. Only Letters of Interest received via email at the above email address with the subject line listed above shall be deemed properly filed.

FOR FURTHER INFORMATION CONTACT: For further information regarding this notice please contact William Resch via email at *william.resch@dot.gov* or via telephone at 202–366–2300. A TDD is available at 202–366–3993.

SUPPLEMENTARY INFORMATION: The original NOFO with modifications follows.

The RRIF Express Program is administered by the DOT's National Surface Transportation and Innovative Finance Bureau (the ''Build America Bureau'' or ''Bureau''). The overall RRIF program finances development of railroad infrastructure, and is authorized to have up to $35 billion in outstanding principal amounts from direct loans and loan guarantees at any one time.

The 2018 Consolidated Appropriations Act [1] appropriated $25 million in budget authority to the DOT to cover the cost to the Federal Government (''the Government'') of RRIF credit assistance (Credit Risk Premium (''CRP'') Assistance or ''CRP Assistance''). Additionally, the 2016 Consolidated Appropriations Act [2] and the 2018 Consolidated Appropriations Act [3] provided $1.96 million and $350,000, respectively (of which approximately $1 million remains available), to the DOT to fund certain expenses incurred by prospective RRIF borrowers in preparation of their

[1] Public Law 115–141, div. L, tit. I, H.R. 1625 at 646 (as enrolled Mar. 23, 2018).

[2] Public Law 114–113, div. L, tit. I, § 152, 129 Stat. 2242, 2856.

[3] Public Law 115–141, div. L, tit. I, H.R. 1625 at 646 (as enrolled Mar. 23, 2018).

applications for RRIF credit assistance (this approximately $1 million assistance, collectively, ''Cost Assistance''). Using existing authorities and these new budget authorities, the DOT has established the RRIF Express Program.

Subject to the availability of funds, applicants accepted into the RRIF Express Program may benefit from two types of financial assistance: (a) Cost Assistance up to $100,000 per application to pay for a portion of the Bureau's advisor expenses borne by applicants; and (b) for those applicants that ultimately receive RRIF credit assistance, CRP Assistance up to 10% of the final RRIF loan amount, not to exceed $5 million, to offset the CRP paid by the borrower. Any costs beyond $100,000 and any CRP beyond the lower of 10% and $5 million would be paid by the prospective RRIF borrower. These funds will be made available to benefit applicants accepted into the RRIF Express Program on a first come, first served basis until each source of funding is expended or this notice is superseded by a new Notice of Funding Opportunity. Letters of Interest will be accepted in the order received and will be allocated cost assistance based on the date of acceptance into the pilot program. CRP assistance will be allocated in the order of financial close. For more information about potential financial assistance for RRIF Express applicants, see Supplementary Information: Section II. Funding of CRP and Cost Assistance.

This notice solicits Letters of Interest from prospective RRIF borrowers seeking acceptance into the RRIF Express Program, establishes eligibility criteria and describes the process that prospective borrowers must follow when submitting Letters of Interest.

RRIF Express pilot program information, including any additional resources, terms, conditions and requirements when they become available, can be found on the Build America Bureau website at: *https://www.transportation.gov/buildamerica/rrif-express.* For further information about the overall RRIF program in general, including details about the types of credit assistance available, eligibility requirements and the creditworthiness review process, please refer to the *Build America Bureau Credit Programs Guide* (''*Programs Guide*),'' available on the Build America Bureau website: *https://www.transportation.gov/buildamerica/programs-services/tifia/program-guide.*

Table of Contents

I. Background

The Transportation Equity Act for the 21st Century,[4] established the RRIF program, authorizing the DOT to provide credit assistance in the form of direct loans and loan guarantees to public and private applicants for eligible railroad projects. The RRIF program is a DOT program and final approval of credit assistance is reserved for the Secretary of the DOT. The 2005 Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users; [5] the Rail Safety Improvement Act of 2008; [6] and the 2015 Fixing America's Surface Transportation Act [7] (the ''FAST Act'') each made a number of changes to the RRIF program. In addition, the FAST Act authorized the creation of the Bureau to consolidate administration of certain DOT credit and grant programs, including the RRIF program.

II. Funding of CRP Assistance and Cost Assistance

Through the RRIF program, the DOT is authorized to have, at any one time, up to $35 billion in unpaid principal amounts of obligations under direct loans and loan guarantees to finance development of railroad infrastructure.

CRP Assistance

Prior to the 2018 Consolidated Appropriations Act, the RRIF program did not have an appropriation of budget authority to pay the cost to the Government of providing RRIF credit assistance. As a result, the RRIF borrower or a third party was required to bear this cost through the payment of a CRP. The 2018 Consolidated Appropriations Act [8] provided $25 million to the DOT to cover the cost to the Government of RRIF credit assistance. The DOT will use this funding to pay or offset the CRP (up to 10% of the RRIF loan amount, not to exceed $5 million) payable by participants in the RRIF Express Program, until this funding is expended or this notice is superseded by a new Notice of Funding Opportunity.

Cost Assistance

As described in the *Programs Guide,* RRIF borrowers are required to pay (or reimburse the DOT) for costs incurred by the Bureau in connection with the review of Letters of Interest and applications for RRIF credit assistance. The 2016 Consolidated Appropriations Act [9] and the 2018 Consolidated Appropriations Act [10] collectively provided $2.31 million to the DOT to be used to fund expenses incurred by prospective RRIF borrowers in preparation to apply for RRIF credit assistance. A portion of these funds have already been allocated for prior RRIF projects. The DOT is reserving approximately $1 million of remaining funds from these appropriations to offset the cost of DOT advisors (up to $100,000 per application) that would be payable by participants in the RRIF Express Program, until this funding is expended or this notice is superseded by a new Notice of Funding Opportunity.

III. Eligibility Requirements for RRIF Credit Assistance

The RRIF statute and implementing rules set forth eligibility requirements for applicants and projects. These requirements as well as other applicable federal requirements are described in detail in the *Programs Guide* and apply to all applicants and projects, including those seeking acceptance into the RRIF Express Program. In addition, for prospective borrowers seeking RRIF Express Program benefits, the requirements set forth in section IV (Eligibility Criteria for the RRIF Express Program) of this notice also apply.

IV. Eligibility Criteria for the RRIF Express Program

The DOT has identified the following strategic objectives for the RRIF Express Program: Encouraging increased utilization of RRIF credit assistance by Class II and Class III railroads; reducing transaction costs for Class II and Class III railroads; and streamlining the underwriting process for Class II and Class III railroads. These priorities are reflected in the eligibility criteria below. Generally, projects most suitable for the RRIF Express Program are rail line modernization projects where the borrower has a well-documented financial history and easily identified revenue stream(s) for loan repayment.

[4] Public Law 105–178, 7203, 112 Stat. 107, 471.

[5] Public Law 109–59, 9003, 119 Stat. 1144, 1921.

[6] Public Law 110–432, 701(e), 122 Stat. 4848, 4906.

[7] Public Law 114–94, Subtitle F, 129 Stat. 1312, 1693.

[8] Public Law 115–141, div. L, tit. I, H.R. 1625 at 646 (as enrolled Mar. 23, 2018).

[9] Public Law 114–113, div. L, tit. I, § 152, 129 Stat. 2242, 2856.

[10] Public Law 115–141, div. L, tit. I, H.R. 1625 at 646 (as enrolled Mar. 23, 2018).

To differentiate among Letters of Interest received for projects under this notice of funding opportunity, the DOT will consider whether the project satisfies the following eligibility criteria as demonstrated by the Letter of Interest:

(i) *Applicant:* The applicant must be a Class II railroad, a Class III railroad, a commuter railroad or a joint venture with a Class II, III, or commuter railroad.

(ii) *Project Size:* The project must have eligible project costs of $150 million or less with no minimum amount.

(iii) *Project Scope:* The project scope, as described in Section B4 of the Letter of Interest, *must be limited to the support of railroad activities that are otherwise eligible for RRIF financing and as outlined below:*

(a) Acquire, improve, or rehabilitate intermodal or rail equipment or facilities, including track, components of track, bridges, yards, buildings, and shops, and costs related to these activities, including pre-construction costs. Note that this category of eligible activities includes the installation of positive train control systems;

(b) Develop or establish new intermodal or railroad facilities;

(c) Reimburse planning and design expenses relating to activities listed above;

(d) Refinancing of non-federal debt (incurred at least three years prior to November 27, 2020) and for the purpose of one or more of the activities listed in 45 U.S.C. 822(b)(1)(A) or (C). Refinancing is limited to up to 75% of the final RRIF loan amount. Letters of Interest including refinancing must demonstrate with specificity in Section D5 how the refinancing would improve the creditworthiness of the applicant and document how such improvement would facilitate the activities referenced in items (a) and (b) above and would increase the applicant's ability to repay a RRIF loan and the overall financial health of the applicant.

(iv) *Applicant Financial History and Projections:* Attachment D–1 of the Letter of Interest must include audited financial statements (by a qualified third party, *e.g.,* a certified public accountant) for the two (2) most recent consecutive years preceding the year of application and that have no significant unresolved findings (*e.g.,* fiscal years 2018 and 2019). Interim unaudited financial statements may be submitted with a letter pledging to provide these audited statements within 60 days of submitting of the LOI and supporting materials. Failure to provide the audited financial statements within 60 days will disqualify the LOI. Applicants choosing this option must still provide unaudited financial statements for the previous five years and prospective financial projections (pro-forma) for the term of the loan.

(v) *Collateral:* If collateral will be pledged for the RRIF loan, Section D9 of the Letter of Interest must be supported with an independent appraisal of the collateral that must have been completed within the past 12 months preceding submission of an LOI. Section D9 of the Letter of Interest must demonstrate that the collateral will be unencumbered at time of closing, including a description of any lien release process that would occur prior to closing on the RRIF loan to render currently pledged collateral unencumbered.

(vi) *Environmental Documentation:* Section B6 and Attachment B–6 of the Letter of Interest must demonstrate that either NEPA review is complete or the project is likely to qualify for a Categorical Exclusion (CE) or Finding of No Significant Impact (FONSI) under NEPA. If a NEPA review has not been completed, Attachment B–6 must include a Federal Railroad Administration (FRA) CE worksheet with its Letter of Interest. Where appropriate, the CE worksheet must include substantive analysis of potential impacts to environmental resources and indicate the sources of the information or data used to reach conclusions. For some project types, the CE worksheet will satisfy NEPA review and documentation requirements; however, for other project types, the CE worksheet will inform FRA with sufficient details about the project scope and potential environmental impacts to determine if an Environmental Assessment (EA) is required. The Applicant would be responsible for providing sufficient information and funding for the preparation of an EA, which would also extend the duration of project development activities. FRA may require the use of a third-party contractor consistent with 23 CFR 771.109 (e) for the preparation of an EA. In the event that an EA is necessary, eligible projects must receive a FONSI to qualify for RRIF Express.

To help address compliance with Section 106 of the National Historic Preservation Act, supporting documentation must be submitted for projects involving reconstruction or replacement of existing railroad bridges, tunnels, culverts, stations, or depots that assesses the eligibility of these architectural properties for listing in the National Register of Historic Places. Supporting documentation must also be provided for projects involving ground-disturbing site preparation and construction activities in areas that have not been previously disturbed (such as by prior land development, agricultural activities, or the placement of fill), that assesses the archaeological sensitivity of the project area.

(vii) *Domestic Preference:* Section B4(a) of the Letter of Interest must demonstrate that the steel, iron, and manufactured goods used in the project will be produced in the United States in accordance with the Federal Railroad Administration RRIF Buy America policy, which follows 49 U.S.C. 24405(a). Projects that require a waiver are not eligible for the RRIF Express Program, however, prospective borrowers can seek a loan from the overall RRIF program for projects that require a waiver.

(viii) *Project Readiness:* Section B4(c) of the Letter of Interest must demonstrate the prospective borrower's ability to commence the contracting process for construction of the project (*e.g.,* issuance of a final RFP) by not later than 90 days after the date on which a RRIF credit instrument is obligated for the project.

V. Letter of Interest Process and Review and Next Steps

A. Submission of Letters of Interest

All prospective borrowers seeking acceptance into the RRIF Express Program should submit a Letter of Interest following the instructions described in this notice of funding opportunity. The Letter of Interest should be annotated with ''RRIF EXPRESS'' immediately following the Applicant Name in the Summary Information section on page one of the Letter of Interest. The Letter of Interest must, among other things:

(i) Describe the project and its components, location, and purpose in Section B, and include as Attachment B–2 the project budget organized according to construction elements from preliminary engineering estimates, and including costs as appropriate for property, vehicles, professional services, allocated and unallocated contingency, and finance charges;

(ii) Outline the proposed financial plan in Section C, and include the financial model, that addresses such aspects as model assumptions, annual cash flows, balance sheets, income statements and repayment schedules for the duration of the loan, as well as coverage ratios and debt metrics. The model should allow reviewers the flexibility to evaluate scenarios in the native spreadsheet (Microsoft Excel, or

equivalent) format and be included in the application as Attachment C–1;

(iii) Provide information regarding satisfaction of other statutory eligibility requirements of the RRIF credit program; and

(iv) Provide information regarding satisfaction of the RRIF Express Program eligibility criteria (as described in Section IV above).

Prospective RRIF Express borrowers should describe in Letter of Interest Section D8 if the project will (1) decrease transportation costs and improve access, especially for rural communities or communities in Opportunity Zones,[11] through reliable and timely access to employment centers and job opportunities; (2) improve long-term efficiency, reliability or costs in the movement of workers or goods; (3) increase the economic productivity of land, capital, or labor, including assets in Opportunity Zones; (4) result in long-term job creation and other economic opportunities; or (5) help the United States compete in a global economy by facilitating efficient and reliable freight movement. Projects that bridge gaps in service in rural areas, and projects that attract private economic development, all support local or regional economic competitiveness.

Letters of Interest must be submitted using the latest form on the Build America Bureau website: *https://www.transportation.gov/content/build-america-bureau.* Other RRIF Express pilot program information including any additional terms, conditions, and requirements can be found on the Build America Bureau website at: *https://www.transportation.gov/buildamerica/rrif-express.* The Bureau may contact a prospective borrower for clarification of specific information included in the Letter of Interest. The Bureau will review all Letters of Interest properly filed and received in the submission time window provided herein.

B. Review and Evaluation

Each Letter of Interest that is properly filed and received will be evaluated for completeness and eligibility for the RRIF Express Program using the criteria in this notice. This initial step of the review process will include (1) an evaluation as to whether the proposed project and applicant satisfy RRIF statutory eligibility requirements, and (2) an evaluation as to whether the proposed project and applicant satisfy the RRIF Express Program eligibility criteria. In addition, the Bureau will conduct a high-level feasibility assessment of the proposed project and the applicant's plan of finance before a Letter of Interest is accepted into the RRIF Express Program and before a Letter of Interest enters the creditworthiness process. With respect to the project, factors that will be considered include, but are not limited to, (1) the completion of the project being financed is not necessary to repay the proposed RRIF loan; (2) the project budget is in year of expenditure and includes contingencies to account for potential project risks; and (3) the maturity of the proposed RRIF loan does not extend beyond the project's anticipated useful life. With respect to the applicant's plan of finance, factors that will be considered include, but are not limited to, (1) a maximum loan size that, when added to the proposed borrower's existing outstanding and undrawn available debt, does not substantially exceed an earnings before interest, taxes, depreciation, and amortization multiple that would be market appropriate in a similar circumstance, for the most recent trailing twelve month period and for any period of the applicant's forecast; and (2) consistent levels of revenue and operating profitability demonstrated by the proposed borrower over the most recent fiscal year.

The Letters of Interest determined to be eligible for the RRIF Express Program will then be advanced to the Bureau's creditworthiness review process, which is an in-depth creditworthiness review of the project sponsor and the revenue stream proposed to repay the RRIF credit assistance as described in the *Programs Guide.* The Secretary reserves the right to limit the number of applications from a single entity or subordinates of a single parent or holding company. Prospective RRIF borrowers whose RRIF Express Program Letters of Interest are determined to be ineligible, but whose projects are otherwise statutorily eligible for standard RRIF credit assistance, have the option to be considered under the overall RRIF program.

Issued in Washington, DC, on October 22, 2020.

Elaine L. Chao,

Secretary of Transportation.

[FR Doc. 2020–25274 Filed 11–25–20; 8:45 am]

BILLING CODE 4910–9X–P

[11] See *https://www.cdfifund.gov/Pages/Opportunity-Zones.aspx* for more information on Opportunity Zones.

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Internal Revenue Service Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

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 December 28, 2020 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Molly Stasko by emailing *PRA@treasury.gov,* calling (202) 622–8922, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 1545–2208.

Type of Review: Extension of a currently approved collection.

Description: Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously to ensure that our programs are effective and meet our customers' needs, The Internal Revenue Service (hereafter ''the Agency'') seeks to obtain OMB approval of a generic clearance to collect qualitative feedback on our service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions but are not statistical surveys that yield quantitative results that can be generalized to the population of study.

Form: None.

Affected Public: Individuals or Households; and Businesses or other for-profit organizations.

Estimated Number of Respondents: 150,000.

Frequency of Response: On Occasion.

Estimated Total Number of Annual Responses: 150,000.

Estimated Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 15,000 hours.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: November 20, 2020.

Molly Stasko,

Treasury PRA Clearance Officer.

[FR Doc. 2020–26157 Filed 11–25–20; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services
42 CFR Part 513

Most Favored Nation (MFN) Model; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 513

[CMS–5528–IFC]

RIN 0938–AT91

Most Favored Nation (MFN) Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) implements the Most Favored Nation (MFN) Model, a new Medicare payment model under section 1115A of the Social Security Act (the Act). The MFN Model will test whether more closely aligning payment for Medicare Part B drugs and biologicals (hereafter, referred to as ''drugs'') with international prices and removing incentives to use higher-cost drugs can control unsustainable growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries.

DATES: *Effective date:* These regulations are effective on November 27, 2020.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 26, 2021.

ADDRESSES: In commenting, please refer to file code CMS–5528–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5528–IFC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5528–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Andrew York, 410–786–7400.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Executive Summary

A. Purpose

High drug prices are impacting the wallets of Medicare beneficiaries, especially during the Coronavirus disease 2019 Public Health Emergency (PHE). Increases in drug prices are accelerating at a rate that significantly outpaces the growth in spending on other Medicare Part B services, and prices in the United States (U.S.) for most Medicare Part B drugs with the highest Medicare spending far exceed prices in other countries. Specifically, drugs have consistently been a major contributor to the overall Medicare Part B spending trend. Medicare Part B Fee-For-Service (FFS) spending for separately payable physician-administered drugs and drugs furnished in a hospital outpatient department represented about 11 percent of Medicare Part B FFS benefit spending in 2015, but accounted for about 37 percent of the change in Medicare Part B FFS benefit spending from 2015 to 2020, and spending on these Medicare Part B FFS drugs increased to represent roughly 14 percent of Medicare Part B FFS benefit spending in 2019.[1] In addition to the continued growth in spending, the U.S. already pays almost twice as much on average as other developed countries pay. In one analysis of 27 drugs, acquisition costs in the U.S. were 1.8 times higher than in comparator countries.[2] A more recent analysis using the prescription drugs and countries in the MFN Model suggests Medicare Part B paid at least 2.05 times as much as other higher-income countries in 2018.[3] The Centers for Medicare & Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) is taking action on President Trump's goal to lower drug costs and seeking to realign financial incentives by implementing the Most Favored Nation (MFN) Model as described in this IFC.

Medicare pays substantially more than other countries for many of the highest-cost Medicare Part B drugs that beneficiaries receive in an outpatient setting for which Medicare Part B allows separate payment.[4] In many instances, Medicare pays more than twice as much for certain drugs as other countries do.[5, 6] This is because Medicare generally establishes the payment for separately payable Medicare Part B drugs using the methodology in section 1847A of the Act. In most cases, this means payment is based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on. Under this methodology, the Medicare program does not get the benefit of the substantial discounts provided in other

[1] 2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Accessed via: *https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf.*

[2] ''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures.*

[3] El-Kilani Z, Finegold K, Mulcahy A, and Bosworth A. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices).

[4] ''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures;* El-Kilani Z, Finegold K, Mulcahy A, and Bosworth A. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (*https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices*).

[5] ''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures;* El-Kilani Z, Finegold K, Mulcahy A, Bosworth A. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (*https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices*).

[6] Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug prices in the MFN Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

countries, because ASP is calculated using only the prices that manufacturers charge to certain U.S.-based purchasers. ASP-based payments may encourage the use of more expensive drugs because the dollar amount of the 6 percent add-on portion is larger for drugs with higher ASPs.[7] As MedPAC noted in its June 2017 Report, ''Although, in some cases, drugs with patent protection may face competition from other brand drugs in the same therapeutic class, price competition between such products may be limited because the [Medicare] Part B drug payment system is not structured to facilitate competition among brand products with similar health effects.'' [8] Thus, the ASP-based payment approach currently used in Medicare Part B may not promote price competition or provide sufficient incentive to minimize avoidable costs.

The MFN Model aims to take a global approach to calculating Medicare Part B drug payment amounts, by testing a new payment methodology that takes into account the discounts that other countries enjoy, and pays providers and suppliers with a fixed add-on amount that does not reward the use of higher-cost drugs. We expect that this model will reduce Medicare program expenditures while preserving or enhancing quality of care furnished to Medicare beneficiaries, and will lower beneficiary cost-sharing through lower drug payment amounts. The MFN Model will be tested in all states and U.S. territories by the CMS Innovation Center for 7 performance years, from January 1, 2021 to December 30, 2027.

B. Summary of the Major Provisions

The MFN Model will focus on a select cohort of separately payable Medicare Part B drugs. This cohort will initially include 50 single source drugs and biologicals (including biosimilar biological products) that encompass a high percentage of Medicare Part B drug spending. The MFN Model will require mandatory participation. Participants in the MFN Model will include all providers and suppliers that participate in the Medicare program and submit a separately payable claim for an MFN Model drug with limited exceptions, such as providers and suppliers that are paid for separately payable Medicare Part B drugs based on reasonable costs. The vast majority of providers and suppliers that furnish separately payable Medicare Part B drugs are physicians and non-physician practitioners, supplier groups (such as a group of physicians or other practitioners), hospital outpatient departments (HOPDs), including on- or off-campus provider-based departments (PBDs), whether paid under the outpatient prospective payment system (OPPS) or the physician fee schedule (PFS), and ambulatory surgical centers (ASCs) paid under the ASC Payment System. Claims from these providers and suppliers will encompass approximately 88 percent of the annual Medicare Part B spending on the drugs we selected for inclusion in the MFN Model beginning in performance year 1. Other types of providers and suppliers that furnish separately payable selected drugs will also be required to participate in the MFN Model, but they may not often furnish the selected drugs or may not typically receive separate payment for Medicare Part B drugs.

The MFN Model will—

- Calculate the payment amount for MFN Model drugs based on a price that reflects the lowest per capita Gross Domestic Product-adjusted (GDP-adjusted) price of any non-U.S. member country of the Organisation for Economic Co-operation and Development (OECD) with a GDP per capita [9] that is at least sixty percent of the U.S. GDP per capita, based on available data;
- Make an alternative add-on payment for MFN Model drugs that will remove or reduce the financial incentive to prescribe higher-cost drugs more frequently; and
- Reduce beneficiary cost sharing on MFN Model drugs.

C. Summary of Costs and Benefits

We believe the MFN Model will substantially lower drug payment amounts for the most costly Medicare Part B drugs, thereby lowering program expenditures and out-of-pocket costs for beneficiaries. As discussed in more detail in section VI. of this IFC, we estimate that the MFN Model will result in substantial overall Medicare savings during the 7-year model performance period (that is, 28 calendar quarters). In the CMS Office of the Actuary (OACT) estimate, OACT estimates savings of roughly $64.4 billion in Medicare FFS benefits, $49.6 billion in Medicare Advantage (MA) payments, and $9.9 billion in Medicaid [10] spending ($5.7 billion in federal payments and $4.3 billion in state payments). Overall, OACT estimates that the MFN Model will result in savings of $85.5 billion, net of the associated change in the Part B premium, in Medicare Part B spending. In addition, OACT estimates that all beneficiaries will save a total of $28.5 billion from a reduction in the Medicare Part B premium as a result of the MFN Model, and will also see their coinsurance reduced. In the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimate, ASPE estimates roughly a net reduction of $87.8 billion in spending on MFN Model drugs by the federal government, state governments, and beneficiaries over the 7 years of the model. We note that there is much uncertainty around the assumptions for both the OACT and ASPE estimates and refer readers to section VI. of this IFC for a more complete discussion of potential impacts of the MFN Model.

II. Background on Need for Regulatory Action

On May 11, 2018, President Trump released his Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,[11] which outlined the steps his administration is taking to combat high drug prices, end foreign freeloading, and spur biomedical innovation.[12]

On October 25, 2018, CMS released an advance notice of proposed rulemaking (ANPRM) (83 FR 54546) [13] (hereafter called the October 2018 ANPRM) describing a potential model, referred to in the October 2018 ANPRM as the International Pricing Index Model (IPI), that would test whether changing the payment amount for selected Medicare Part B drugs would reduce Medicare expenditures and preserve or enhance quality of care. In the October 2018 ANPRM, we sought comment on a model test that would—

- Calculate the Medicare payment amount for selected Medicare Part B

[7] MedPAC, June 2017, ''Medicare Part B Drug Payment Policy Issues,'' accessed via *http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf.*

[8] MedPAC, June 2017, ''Medicare Part B Drug Payment Policy Issues,'' accessed via: *http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf.*

[9] For the purposes of this IFC, GDP means GDP based on purchasing power parity (PPP), rather than nominal GDP. A nation's GDP at purchasing power parity (PPP) exchange rate is the sum value of all goods and services produced in the country valued at prices prevailing in the U. S.

[10] Medicaid savings estimates do not include impacts of changes in Average Manufacturer Price (AMP) and Best Price on manufacturer rebates under the Medicaid Drug Rebate Program.

[11] American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, Available at: *https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf?language=es.*

[12] ''President Donald J. Trump's Blueprint To Lower Drug Prices,'' accessed via: *https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/.*

[13] International Pricing Index Model for Medicare Part B Drugs; Medicare Program, 83 Fed. Reg (210) 54246 (Oct 30, 2018) available at: *https://www.govinfo.gov/content/pkg/FR-2018-10-30/pdf/2018-23688.pdf.*

drugs to be phased down to more closely align with international prices;

- Allow private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business;
- Increase the drug add-on payment to reflect 6 percent of historical drug costs; and
- Pay physicians and hospitals the add-on based on a set payment amount structure.

We considered the comments that we received in response to the October 2018 ANPRM in developing the MFN Model described in this IFC. In addition to considering these comments, we considered feedback and suggestions from a broad set of stakeholders gathered through comments on the President's Blueprint and through numerous meetings with stakeholders.

President Trump discussed an Executive Order (E.O.) regarding an MFN payment model for Medicare Part B drugs on July 24, 2020, and subsequently published a superseding Executive Order on Lowering Drug Prices by Putting America First on September 13, 2020.[14] In response to the September 13, 2020 Executive Order, we will implement the MFN Model described in this IFC.

A. Medicare Part B Drug Benefit and ASP Payment Methodology

Medicare Part B includes a limited drug benefit for drugs and biologicals described in section 1861(t) of the Act. The majority of drugs paid under Medicare Part B generally fall into three categories: Drugs furnished incident to a physician's service in the physician office, HOPD, or other outpatient setting; drugs administered via a covered item of durable medical equipment (DME); and other categories of drugs specified by statute (generally in section 1861(s)(2) of the Act).

Many drugs covered under Medicare Part B are administered via injection or infusion in a physician's office, an HOPD, and certain other outpatient settings, such as ASCs, and, when Medicare allows separate payment for these drugs, the payment limit is typically based on the methodology described in section 1847A of the Act. The payment amount for these drugs does not include payment for administering the drug to a beneficiary; payment for drug administration services is made in accordance with the applicable payment policy for the setting in which the drug was furnished, such as the Physician Fee Schedule (PFS) (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*), the Hospital Outpatient Prospective Payment System (OPPS) (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*), or the Ambulatory Surgical Center Payment System (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html*). Medicare Part B also allows separate payment for drugs in less common situations such as osteoporosis drugs furnished by a home health agency, and when a beneficiary does not have benefits available under the Part A program.

The payment methodology for drugs described in section 1847A of the Act is generally based on the volume-weighted ASP for all National Drug Codes (NDCs) that are assigned to a Healthcare Common Procedure Coding System (HCPCS) code for the drug plus a 6 percent add-on. The volume-weighted ASP for a HCPCS code is calculated quarterly using manufacturer-submitted data [15] on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act, such as sales at nominal charge and sales exempt from Medicaid best price [16]) with manufacturers' rebates, discounts, and price concessions included in the ASP calculation (that is, the sales price is net of these rebates, discounts, and price concessions). The ASP+6 percent payment amount that Medicare pays for an individual Medicare Part B drug claim generally does not vary based on the exact price an individual provider or supplier pays to acquire the drug. In the case of multiple source drugs, the price of a brand name drug and its generic equivalent(s) included in the same billing code are averaged together to determine the payment allowance.[17] As noted earlier, this payment methodology may create an incentive for the use of more expensive drugs, but, as noted in the MedPAC report (and by sources cited in the report; pages 68 and 79), an add-on may be needed to account for handling and overhead costs and additional mark-up in distribution channels that are not captured in the manufacturer-reported ASP.

Currently, under Medicare Part B, beneficiaries' cost-sharing [18] is generally 20 percent of the Medicare-allowed amount. The term ''Medicare-allowed amount'' means the maximum amount that a provider or supplier will be paid for a covered health care service or drug. However, for items and services paid under the OPPS, beneficiaries are only financially responsible for a copayment amount up to the amount of the inpatient hospital deductible.[19] Medicare pays for the remaining portion of the Medicare-allowed amount.[20]

B. Medicare and Beneficiary Spending

Medicare Part B spending for separately payable physician-administered drugs and drugs furnished in hospital outpatient departments represented about 11 percent of Medicare Part B FFS spending in 2015 but increased to represent roughly 14 percent of Medicare Part B FFS spending in 2019; spending on these Medicare Part B separately payable drugs accounted for about 37 percent of the change in Medicare Part B FFS spending from 2015 to 2019. Furthermore, Medicare Part B FFS spending per capita for separately payable drugs has increased at an average annual rate of 11.5 percent over this same period while Medicare Part B FFS spending per capita has increased by 3.8 percent. From 2015 to 2019, Medicare Part B spending for separately payable drugs increased from $19.4 billion to $29.8 billion (a nearly 55-percent increase) with per capita spending increasing from $583 to $900. This increase in Medicare Part B FFS spending for separately payable drugs during this period reflects increases in the prices of drugs, introduction of new drugs, changes in utilization of these drugs, changes in Medicare Part B FFS enrollment, and changes in the mix of drugs for those beneficiaries who received them.[21] Since beneficiaries

[14] Executive Order 13948, *https://www.govinfo.gov/content/pkg/FR-2020-09-23/pdf/2020-21129.pdf.*

[15] OMB Control Number 0938–0921.

[16] Best price is defined in section 1927(c)(1)(C) of the Act.

[17] Under section 3139 of the Affordable Care Act (Pub. L. 111–148) the add-on amount for a biosimilar is based on the ASP of the reference product. Biosimilars are not grouped together with one another or the reference product for payment purposes.

[18] Not including the annual deductible.

[19] Section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year. This limit is $1,408 in 2020.

[20] 2020 Medicare Parts A & B Premiums and Deductibles: Fact Sheet, available at: *https://www.cms.gov/newsroom/fact-sheets/2020-medicare-parts-b-premiums-and-deductibles.*

[21] The average annual growth in number of Medicare Part B FFS beneficiaries was less than 0 percent from 2015 to 2019, so the change in Medicare Part B beneficiaries does not fully account for the average annual growth (11.4 percent) in Medicare Part B spending for physician-administeredpayable drugs. Instead, the increase during this period is more fully explained by increases in the prices of drugs, introduction of new

without supplemental insurance typically pay 20 percent of the Medicare-allowed amount, as described in section II.A. of this IFC, they have faced similar increases in spending on Medicare Part B drugs as has Medicare.[22]

A new Issue Brief from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) provides additional evidence of the need for the rule. Between 2006 and 2017, Medicare Part B FFS drug spending per enrollee grew at 8.1 percent, more than twice as high as per capita spending on Medicare Part D (3.4 percent) and nearly three times as high as overall retail prescription per capita drug spending (2.9 percent). Spending and enrollment projections by OACT for the 2021 President's Budget suggest that per capita spending on Medicare Part B physician-administered drugs and separately payable hospital outpatient drugs will grow at a very similar annual rate of 8 percent between 2020 and 2027, before consideration of any COVID–19 pandemic impacts.[23] Because biologics account for about 77 percent of Medicare Part B FFS prescription drug spending, there has been little opportunity to reduce Medicare Part B spending growth through generic substitution, as has occurred in Medicare Part D and in retail pharmacy overall.[24]

C. Relative High Price of Medicare Part B Drugs

Drug acquisition costs in the U.S. exceed those in Europe, Canada, and Japan, according to an October 2018 ASPE analysis [25] of Medicare Part B physician-administered drugs. This finding was generally consistent with the existing evidence base as described in the HHS analysis's background section, which found peer-reviewed literature on this topic to be relatively limited and dated, but with similar findings of higher drug prices in the U.S. compared to other countries.[26] The HHS analysis compared U.S. drug acquisition costs for a set of Medicare Part B physician-administered drugs to acquisition costs in 16 other developed economies—Austria, Belgium, Canada, Czechia, Finland, France, Germany, Greece, Ireland, Italy, Japan, Portugal, Slovakia, Spain, Sweden, and the United Kingdom (UK).[27] The main analysis in the HHS report focused on 27 drugs accounting for 64 percent of total Medicare Part B drug spending in 2016.[28] Among the 27 drugs included in the analysis, acquisition costs in the U.S. were 1.8 times higher than in comparator countries. Acquisition cost ratios ranged from U.S. prices being on par with international prices for one of the 27 drugs, to U.S. prices being up to 7 times higher than the international prices for others. There was variability across the 16 countries in the study as well, with no one country consistently acquiring drugs at the lowest prices. The U.S. had the highest drug prices for 19 of the 27 products.[29]

A new ASPE Issue Brief updates the earlier analysis for the set of Medicare Part B drugs and the set of countries in the MFN Model. In 2018, based on available data, ASP rates were at least 2.05 times the value-weighted average price for these drugs in OECD countries with per capita GDP at least 60 percent of that in the U.S.[30]

The results of these reports demonstrate that, save for a few outlier cases, the U.S. prices used to calculate ASP rates are significantly higher than the prices in international comparator countries.[31] Based on this significant difference, which aligns with the analysis we present in this IFC, we will test the impact of more closely aligning payment for Medicare Part B drugs and biologicals with international prices in the MFN Model.

III. Provisions of the Interim Final Rule With Comment Period

A. Model Performance Period

In part 513, we codify the MFN Model that will be tested for 7 performance years. We define ''model performance period'' to mean January 1, 2021, the date the model will begin, through December 31, 2027. We are testing a 7-year performance period because it will allow a smooth transition to the MFN Price (described in section III.E.5. of this IFC) by performance year 4 and adequate duration to understand the impact of the MFN Model. As discussed in section III.N. of this IFC, we will assess for potential impacts of the MFN Model across quarterly time periods throughout the performance period. Further, we will assess initial impacts of the MFN Model on quality of care, including access to drugs, prior to beginning performance year 5.

B. Defined Population

Our goal is to include all beneficiaries who are furnished an MFN Model drug by an MFN participant and who, on the date of service, are enrolled in Medicare Part B, have Medicare as the primary payer, and are not covered under Medicare Advantage or any other group health plan, including a United Mine Workers of America health plan, hereafter called MFN beneficiaries. Thus, the defined population for the MFN Model will be Medicare FFS beneficiaries who receive an MFN Model drug from an MFN participant where payment for such drug is allowed under the MFN Model. We define the term ''MFN beneficiary'' in § 513.2.

Testing the model in the population of beneficiaries who receive drugs with high annual Medicare Part B spending allows the MFN Model payment to apply to a broad set of conditions, drugs, medical specialties, clinical settings, and localities rather than having MFN Model payment focused on a particular clinical presentation, course of treatment or single type of care setting. Defining the population in this

drugs, changes in drug utilization, and changes in the mix of drugs than by increases in Medicare enrollment.

[22] In 2016, 8 in 10 beneficiaries in traditional Medicare (81 percent) had some type of supplemental insurance (which typically covers some or all of Medicare Part A and Medicare Part B cost-sharing), including employer-sponsored insurance (30 percent), Medigap (29 percent), and Medicaid (22 percent). Nearly 1 in 5 beneficiaries in traditional Medicare (19 percent)—6.1 million beneficiaries overall—had no source of supplemental coverage in 2016. *https://www.kff.org/medicare/issue-brief/sources-of-supplemental-coverage-among-medicare-beneficiaries-in-2016/*.

[23] ASPE analysis of OACT spending and enrollment projections.

[24] Nguyen X. Nguyen and Steve Sheingold. Medicare Part B Drugs: Trends in Spending and Utilization, 2006–2017. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (*https://aspe.hhs.gov/pdf-report/medicare-part-b-drugs-spending-and-utilization*).

[25] Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures.*

[26] ''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures.*

[27] Please refer to the HHS report (''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures*) for more information on the countries selected for analysis.

[28] ''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures.*

[29] The ASPE report utilized ex-manufacturer prices (sometimes called the ex-factory price) stated in U.S. currency on the transaction date. The report defines ex-manufacturer prices as the price received by manufacturers of a product, including discounts applied at the point of sale.

[30] El-Kilani Z, Finegold K, Mulcahy A, and Bosworth A. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (*https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices*).

[31] ASP is defined in statute, and based on sales in the U.S.

manner allows CMS to observe the implications of a global approach to calculating Medicare Part B drug payment amounts and an alternative add-on approach across a broad set of providers and suppliers and beneficiaries, as well as a large set of manufacturers. Learnings from the MFN Model will inform CMS and other stakeholders about the effect of applying the innovative payment model to a broad set of drugs on a diverse set of beneficiaries and to the Medicare program.

C. MFN Participants

1. Eligible Providers and Suppliers

A majority of Medicare spending on separately payable Medicare Part B drugs is for drugs that are furnished incident to a physician's service (see section 1861(s)(2)(A) of the Act), in a HOPD (see section 1861(s)(2)(B) of the Act), including in an on- or off-campus PBD (regardless of whether those PBDs are excepted or nonexcepted),[32] or in an ASC (see section 1832(a)(2)(F)(i) of the Act). Depending upon the circumstances, Medicare Part B allows separate payment for drugs to other providers and suppliers, such as pharmacies, home health agencies, hospices, radiation therapy centers, independent diagnostic testing facilities, ambulance suppliers, durable medical equipment (DME) suppliers, mass immunization suppliers, inpatient hospitals (when Part A payment is not permitted), and other types of providers and suppliers. Our goal is to broadly include providers and suppliers that receive separate payment for MFN Model drugs as MFN participants, with limited exceptions. MFN participants will consist of Medicare participating providers and suppliers that submit a claim for a separately payable drug that is an MFN Model drug furnished to an MFN beneficiary, unless otherwise excluded.[33] Because separately payable Medicare Part B drugs (that is, potential MFN Model drugs) are most often furnished by physicians, non-physician practitioners, supplier groups (such as group practices), hospitals that are paid under the OPPS as defined in 42 CFR 419.20 (including off-campus PBDs paid under the PFS), and ASCs, these providers and suppliers will represent the vast majority of MFN participants. Other types of providers and suppliers (that are not excluded) also will be MFN participants to the extent that they submit a claim for an MFN Model drug furnished to an MFN beneficiary. For example, a home health agency that receives separate payment for an osteoporosis drug (defined in section 1861(kk) of the Act) will be an MFN participant if such drug is an MFN Model drug and the home health agency furnishes such drug to an included beneficiary and a claim is submitted.

We will exclude certain types of providers and suppliers that are ultimately not paid for drugs based on ASP as well as those who are subject to the hold harmless provision in section 1833(t)(7)(D)(ii) of the Act. Thus, in § 513.100(c), we exclude from the MFN Model the following providers and suppliers: Children's hospitals (defined under section 1886(d)(1)(B)(iii) of the Act); PPS-exempt cancer hospitals (defined under section 1886(d)(1)(B)(v) of the Act); critical access hospitals (CAHs) (defined under section 1820 of the Act); Indian Health Service (IHS) facilities (described in section 1880 of the Act), except when MFN Model drugs are furnished and such service is described in section 1880(e)(2)(B) of the Act; Rural Health Clinics (RHCs) (defined under section 1861(aa)(2) of the Act); Federally Qualified Health Centers (FQHCs) (defined under section 1861(aa)(4) of the Act); hospitals that are not subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act) and are paid on the basis of reasonable costs subject to a ceiling under section 1886(b) of the Act; and extended neoplastic disease care hospitals (defined in section 1886(d)(1)(B)(vi) of the Act). In addition, for the first quarter and second quarter of performance year 1, we will exclude acute care hospitals that participate in a CMS Innovation Center model under which they are paid for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, on a fully capitated or global budget basis in accordance with a waiver under such model of section 1833(t) of the Act. This exclusion, codified at § 513.100(c)(9), will apply during the first quarter and second quarter of performance year 1, and only if the hospital participates in a CMS Innovation Center model under which it is paid on a fully capitated or global budget basis. As codified at § 513.100(c)(10), for the third quarter of performance year 1 (that is, beginning July 1, 2021) and beyond, acute care hospitals that participate in a CMS Innovation Center model under which they are paid for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, on a fully capitated or global budget basis in accordance with a waiver under such model of section 1833(t) of the Act will be excluded from the MFN Model if the parameters of the other CMS Innovation Center model adjust for the difference in payment for MFN Model drugs between the MFN Model and non-MFN Model drug payments such that savings under the MFN Model are incorporated into the other CMS Innovation Center model's parameters (for example, the annual global budget) for the duration of the MFN Model. Thus, acute care hospitals that are participating in the Maryland Total Cost of Care Model will not be MFN participants during the first two calendar quarters of 2021 while they are paid on a fully capitated or global budget basis. Further, if the parameters of the Maryland Total Cost of Care Model have been updated to adjust for the difference in payment for MFN Model drugs between the MFN Model and non-MFN Model drug payments such that savings under the MFN Model are incorporated into the parameters for the Maryland Total Cost of Care Model (for example, the annual global budget) for the duration of the MFN Model, then these acute care hospitals will remain excluded from the MFN Model beginning with the third quarter of performance year 1 and beyond. However, if the parameters of the Maryland Total Cost of Care Model change such that the participating acute care hospitals are no longer paid on a fully capitated or global budget basis or if a participating acute care hospital leaves the Maryland Total Cost of Care Model such that they are paid under section 1833(t) of the Act, then such hospitals would no longer fall under this exclusion. This exclusion also applies on the same terms to acute care hospitals participating in the Pennsylvania Rural Health Model that otherwise meet the definition of MFN participant, unless the parameters of the Pennsylvania Rural Health Model change such that the participating acute care hospitals are no longer paid on a fully capitated or global budget basis or if a participating acute care hospital leaves the Pennsylvania Rural Health Model such that they are paid under section 1833(t) of the Act. We expect that the CMS Innovation Center will adjust the parameters of the Maryland Total Cost of Care Model and the Pennsylvania Rural Health Model such

[32] That is, regardless of whether those PBDs are excepted or nonexcepted under section 1833(t)(21)(B)(ii) of the Act, as added by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74).

[33] These providers and suppliers will be included as participants in the MFN Model only if they participate in Medicare; this means that nonparticipating physicians and non-physician practitioners will not be MFN participants and will continue to be paid in accordance with current program policies.

that the participants in these CMS Innovation Center models will remain excluded from the MFN Model for the duration of the MFN Model. Further, as discussed in section III.J.1. of this IFC, the CMS Innovation Center intends to address model overlaps with other CMS Innovation Center models whether or not the participants in other models are MFN participants, for example we will account for changes in Medicare Part B drug payments that impact other models' financial calculations.

We note that community mental health centers, comprehensive outpatient rehabilitation facilities (CORF), outpatient rehabilitation facilities (ORF), and certain other providers and suppliers do not submit claims for Medicare Part B drugs or are not paid separately for Medicare Part B drugs; thus, an express exclusion for these providers and suppliers is not necessary. We also note that including these providers and suppliers in the MFN Model would complicate the model design and make it challenging to test the impact of the MFN Model on these types of providers and suppliers because of the varied payment structures among these providers and suppliers.

Table 1 shows the distribution of 2019 Medicare Part B allowed charges for separately payable Medicare Part B drugs by provider and supplier type using available final action claims where Medicare was the primary payer, with limited exclusions as noted. This table shows the distribution of Part B drug claims among provider and supplier types. To assign claims to a provider or supplier type, we considered the type of Medicare Administrative Contractor (MAC) that processed the claim, type of bill, provider number, revenue center, line place of service code, and specialty of the health care practitioner associated with the drug claim line.

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TABLE 1 – DISTRIBUTION OF 2019 MEDICARE PART B ALLOWED CHARGES FOR SEPARATELY PAYABLE DRUGS* BY PROVIDER AND SUPPLIER TYPE

Provider/Supplier Type	Number of Entities (CCNs/TINs)	2019 Total Allowed Charges for Medicare Part B Drugs (All Part B drugs)	Percent of 2019 Total Allowed Charges for Medicare Part B Drugs	2019 Average Allowed Charges for Medicare Part B Drugs Per Entity	90th Percentile	75th Percentile	50th Percentile (Median)	25th Percentile	10th Percentile
OFFICE**	74,479	$20,847,712,641	51.10%	$279,914	$122,388	$16,581	$2,291	$225	$23
OPPS HOSPITAL	3,230	$13,896,570,373	34.06%	$4,302,344	$12,152,596	$4,422,271	$660,230	$52,065	$5,371
DME MAC CLAIMS***†	8,523	$1,999,151,286	4.90%	$234,560	$44,066	$10,363	$2,477	$525	$91
CANCER HOSPITAL†	11	$1,143,173,710	2.80%	$103,924,883	$191,145,257	$154,558,561	$78,485,411	$41,929,846	$40,509,378
CRITICAL ACCESS HOSPITAL†	1,339	$1,038,650,020	2.55%	$775,691	$2,026,327	$934,738	$312,662	$94,975	$23,730
MASS IMMUNIZATION (ROSTER BILLER)	5,616	$588,486,793	1.44%	$104,788	$21,038	$9,843	$4,099	$1,569	$467
PHARMACY	1,273	$587,394,274	1.44%	$461,425	$113,876	$10,264	$3,021	$829	$216
MARYLAND TCOC MODEL ****††	45	$414,242,305	1.02%	$9,205,385	$27,620,924	$10,748,035	$2,418,260	$973,704	$439,801
AMBULATORY SURGICAL CENTER	1,984	$111,196,719	0.27%	$56,047	$140,658	$20,601	$2,780	$325	$13
ESRD FACILITY†	15,175	$67,981,421	0.17%	$4,480	$10,413	$6,064	$2,656	$887	$308
CHILDRENS HOSPITAL†	56	$51,989,815	0.13%	$928,390	$1,230,460	$405,272	$78,414	$23,304	$3,492
INPATIENT HOSPITAL PART B ONLY†	3,725	$37,108,693	0.09%	$9,962	$26,399	$8,573	$1,905	$353	$90
HOME HEALTH AGENCIES	609	$6,437,758	0.02%	$10,571	$8,232	$2,732	$745	$171	$49
PENNSYLVANIA RURAL HEALTH MODEL††	5	$4,083,536	0.01%	$816,707	$3,148,242	$388,659	$326,307	$214,758	$5,570
PUBLIC HEALTH OR WELFARE AGENCY	215	$1,783,090	0.00%	$8,293	$19,683	$8,792	$2,786	$275	$56
SKILLED NURSING FACILITY	1,078	$1,593,255	0.00%	$1,478	$3,642	$1,629	$615	$202	$65
INDEPENDENT CLINICAL LABORATORY	5	$1,495,285	0.00%	$299,057	$1,492,110	$1,897	$1,128	$112	$38
INDEPENDENT DIAGNOSTIC TESTING FACILITY	184	$1,480,862	0.00%	$8,048	$20,711	$7,246	$1,929	$388	$49
FQHC/RHC*****†	26	$6,580	0.00%	$253	$291	$153	$108	$80	$69
TOTAL	117,578	$40,800,538,415	100.00%	$121,432,274	$239,347,312	$171,562,275	$82,307,825	$43,294,594	$40,988,875

*Claims where Medicare was not the primary payer and claims for radiopharmaceuticals were excluded for this analysis.
**Office includes suppliers such as physicians, non-physician practitioners, and supplier groups, such as group practices. Note that we exclude claims submitted by non-participating physicians from the MFN Model.
***DME Supplier includes all claims processed by the DME MAC, which include claims for drugs furnished by DME suppliers and other suppliers.
****Maryland Total Cost of Care (MD TCOC) Model Participants, acute care hospitals located in Maryland.
*****FQHC means federally qualified health center; RHC means rural health clinic.
† Indicates provider and supplier types that we exclude from the MFN Model or indicates that we exclude claims of this type from the MFN Model. Note that claims billed by ESRD Facilities that are not paid under the ESRD PPS will be subject to the MFN Model payment.
††CMS Innovation Center models that we are excluding for the first two calendar quarters of performance year 1 and then thereafter if conditions are met.

To minimize the complexity of the MFN Model, we are not including in the MFN Model Medicare Part B drugs that are furnished in the inpatient setting,

administered through covered DME, orally administered, or paid under the End-Stage Renal Disease Prospective Payment System (ESRD PPS). Therefore, in § 513.100(d), we provide an exception for claims submitted by acute care hospitals for separately payable Medicare Part B drugs that were administered during an inpatient stay or included on an inpatient claim, such as when a beneficiary has exhausted their Part A benefit days, claims administered by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) as described in 42 CFR 421.404(c)(2), and claims paid under the ESRD PPS, including claims for drugs that are paid using the transitional drug add-on payment adjustment.

Under the approach set forth in § 513.100(b), all Medicare participating providers and suppliers that submit a claim for an MFN Model drug (excluding claims specified in § 513.100(d)) furnished to an MFN beneficiary will be included as MFN participants unless otherwise excluded (as specified in § 513.100(c)), regardless of the volume of MFN Model drugs for which they submit claims. As Table 1 shows, a significant proportion of suppliers bill for a relatively lower volume of MFN Model drugs, such as less than $2,000 in total annual allowed charges, and will likely have limited claims paid under the MFN Model. We considered whether to make specific payment adjustments under the MFN Model for MFN participants that bill for a low volume of MFN Model drugs during a historical period or whether low-volume providers and suppliers could have the option to opt into or out of the MFN Model. However, we believe that requiring participation in the model only of providers and suppliers that bill for a higher volume of MFN Model drugs would not allow us to observe the impact of the MFN Model on a full range of providers and suppliers and would create opportunities for shifting sites of care and gaming. As such, we are including a broad set of providers and suppliers as MFN participants, regardless of their volume of billing for MFN Model drugs. As described in section III.I.2. of this IFC, the MFN Model includes a financial hardship exemption in the form of a potential reconciliation amount for MFN participants that are significantly affected by their participation in the MFN Model.

We note that MFN Model drugs could be furnished to a beneficiary in an HOPD who is subsequently admitted to an inpatient hospital stay. When a beneficiary receives outpatient hospital services, including MFN Model drugs, during the 3 days immediately preceding admission to a hospital defined under section 1886(d) of the Act, the outpatient hospital services are treated as inpatient services if the beneficiary has Medicare Part A coverage and such services are not separately payable under Medicare Part B. We will apply this policy consistently under the MFN Model such that if a beneficiary receives an MFN Model drug in an HOPD that is an MFN participant and is admitted to this hospital within 3 days, then those services, including drugs, will be treated as inpatient services (in accordance with Medicare inpatient payment policies) and will not be separately payable under the MFN Model. We note that when a beneficiary receives outpatient hospital services during the day immediately preceding a hospital admission to a hospital not paid under the Inpatient Prospective Payment System (IPPS), such as psychiatric hospitals and units, inpatient rehabilitation hospitals and units, long-term care hospitals, children's hospitals, and cancer hospitals, the statutory payment window is one day preceding the date of the patient's admission; but because these categories of hospitals will be excluded from the MFN Model, as discussed previously, the payment window policy will not be applicable for this model.

We are codifying these provisions in §§ 513.100(a) through (d).

We note that we include a limitation on the MFN Drug Payment Amount in § 513.210(d)(5) that will apply to certain claims submitted by 340B covered entities as described in section III.E.10. of this IFC to ensure that beneficiaries who are furnished MFN Model drugs by a 340B covered entity do not face increased cost-sharing under the MFN Model than would otherwise apply.

2. Mandatory Participation and Requirements

Model participation will be mandatory for Medicare participating providers and suppliers that satisfy the MFN participant definition. There will be no specific enrollment activities for MFN participants; rather, their participation will be effectuated by the submission of a claim for an MFN Model drug furnished to an MFN beneficiary, and we will apply the MFN Model payment to such a claim.

As we have described in previous rules implementing models with required provider or supplier participation, such as the Comprehensive Care for Joint Replacement (CJR) Model, mandatory participation can enhance the generalizability of model results, as mandatory model participants may be more broadly representative of all entity types that could be affected by a model. Requiring participation in the MFN Model will allow us to observe the experiences of providers and suppliers with diverse characteristics, such as geographies, patient populations, and specialty mixes. Mandatory participation (with specified exceptions) by providers and suppliers submitting claims for MFN Model drugs in a nationwide model, as further discussed in section III.C.3. of this IFC, will minimize administrative complexity and risk to the integrity of the MFN Model.

In § 513.100(e) and § 513.100(f), we are codifying MFN participant requirements during and after the MFN Model. During the MFN Model performance period described in § 513.1(c), MFN participants must—

- Adhere to the beneficiary protections requirements in § 513.410 to ensure beneficiaries' access to care is not adversely impacted;
- Adhere to the MFN Model-specific billing instructions established by CMS and the MAC responsible for processing the MFN participant's claims, including without limitation those described in § 513.200, to ensure appropriate and accurate Medicare payments; and
- Participate in MFN Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of information as the Secretary of Health and Human Services (the Secretary) determines is necessary to monitor and evaluate the MFN Model, including without limitation ''protected health information'' as that term is defined at 45 CFR 160.103.

For 2 years after termination of the MFN Model, MFN participants must participate in MFN monitoring activities as described in § 513.420.

MFN participants will continue to bill Medicare for separately payable MFN Model drugs furnished to MFN beneficiaries and be responsible for collecting beneficiary cost sharing amounts for MFN Drug Payment Amounts. As such, we anticipate MFN participants will have the same administrative requirements for collection of beneficiary cost-sharing amounts under the MFN Model as apply to collection of beneficiary cost-sharing outside the MFN Model.

As discussed in section III.L. of this IFC, manufacturers will exclude from their calculation of ASP all units of MFN Model drugs that are furnished to MFN beneficiaries and for which payment under § 513.210 is allowed.

Manufacturers will need to determine the number of units to exclude and may adjust purchasing arrangements with MFN participants in order to obtain information about such units. While MFN participants are not required to provide data to manufacturers related to the number of units of MFN Model drugs that were furnished to MFN beneficiaries and for which payment under § 513.210 was allowed, we anticipate that manufacturers may establish mechanisms to obtain such information, which also may create administrative burden for MFN participants related to the MFN Model. For example, manufacturers could require use of separate purchasing accounts, or reporting of information about units of MFN Model drugs that were furnished to MFN beneficiaries and for which payment under § 513.210 was allowed in order to receive a more favorable purchase price.

3. Model Geographic Area

In the October 2018 ANPRM, CMS anticipated the geographic area included in a potential IPI Model would encompass 50 percent of Medicare Part B drug spending. Several commenters expressed concern that having model participants subjected to multiple payment methodologies for included drugs based on having some but not all of their locations within the model's geographic area would be administratively burdensome. Additionally, some commenters expressed concern at the idea of requiring participation in some geographic areas but not others, noting that this approach would disproportionately affect some providers and suppliers and not others. Multiple commenters noted that reduced cost-sharing for patients in the model compared to those outside of the model would create potential differences in access for beneficiaries. One commenter noted that there would be a risk of patient steering if the model created a financial incentive for providers and suppliers to provide care at sites outside of the model geographic area rather than at sites in the model geographic area.

Due to the administrative complexity and risk to model integrity associated with a limited scope, CMS believes that the MFN Model cannot realize its full potential in spending reductions for Medicare and its beneficiaries and improvement in quality of care without broad participation of Medicare participating providers and suppliers through a nationwide scope. Section 1115A(b) of the Act gives the Secretary discretion in the design of models, including the scope of models. Section 1115A(a)(5) of the Act states that the Secretary may elect to limit testing of a model to certain geographic areas. It follows that the Secretary could similarly elect not to limit testing to certain geographic areas, and instead test a nationwide model.

The MFN Model requires mandatory, nationwide participation of Medicare participating providers and suppliers (with limited exclusions) to be able to successfully test the model for the reasons described later in this section. First, a nationwide scope avoids additional administrative burden on MFN participants with some service locations inside the MFN Model geographic area and others outside of the MFN Model geographic area, which could lead to such MFN participants needing to track and follow separate requirements for how drugs are acquired, furnished, and billed, depending on the service location. Second, a nationwide model geographic area eliminates the potential for MFN participants with service locations both inside and outside the MFN Model's geographic area to seek to influence beneficiaries' choice of treatment location in response to the differences between non-model payments and the MFN Model payments. This potential issue is of particular concern for the MFN Model given the broad use of MFN Model drugs and the ambulatory settings in which these drugs may be furnished, which can be geographically distributed over wide areas. Third, CMS also believes that a nationwide model geographic area maintains continuity with current treatment patterns by limiting disruption to beneficiary and health care provider treatment plans that may arise due to potential changes in the site of care. Fourth, a nationwide model geographic area allows all eligible beneficiaries who receive an MFN Model drug from an MFN participant where separate payment is allowed to benefit from the cost-sharing reductions under the MFN Model. Finally, CMS believes that a nationwide model geographic area along with mandatory participation creates the necessary market participation to increase the likelihood of MFN participants being able to acquire MFN Model drugs at lower prices as discussed in section VI. of this IFC. CMS notes that several of these points were commented on by several respondents to the October 2018 ANPRM. These points highlight the challenges that accompany a limited scope (non-nationwide) model geographic area. CMS therefore believes a nationwide scope is the most appropriate for the MFN Model. Thus, we are codifying in § 513.120 that the MFN Model geographic area includes all states and U.S. territories.

As described in section VI. of this IFC, we anticipate that there could be potential challenges associated with a mandatory, nationwide model, namely greater impacts on manufacturers, a greater number of MFN participants that potentially receive lower payments for drugs under the model, and fewer non-participants who potentially increase their patient volume should beneficiaries need to locate alternative sites of care. We have designed the model to mitigate these potential challenges where possible.

D. MFN Model Drugs

We will begin the MFN Model with 50 Medicare Part B drugs, identified by Healthcare Common Procedure Coding System (HCPCS) codes with high annual spending during 2019 (based on dates of service and after applying certain exclusions), that will be included on the MFN Model Drug HCPCS Codes List (described later in this section), and maintain approximately 50 Medicare Part B drugs on the MFN Model Drug HCPCS Codes List during the 7-year model performance period. We will focus the model on the separately payable, physician-administered Medicare Part B drugs with the highest annual spending which make up a portion of the roughly 550 HCPCS codes listed on the quarterly ASP pricing files, but encompass approximately three-quarters of annual Medicare Part B drug spending, [34] and are furnished by the types of providers and suppliers that frequently bill under Medicare Part B. The MFN Model payments will apply only to MFN Model drugs when these drugs are administered by MFN participants to MFN beneficiaries and Medicare Part B allows separate payment as the primary payer.

In § 513.130(b), we exclude some categories of Medicare Part B drugs from the model, such as certain vaccines, radiopharmaceuticals, oral drugs, compounded drugs, and intravenous immune globulin products. We also exclude drugs that are billed with HCPCS codes to which any generic drugs are assigned, including in applicable instances where single

[34] CMS publishes a Medicare Part B Drug Dashboard which can be used to view annual spending on drugs by HCPCS code. The downloadable file can be used to examine the proportion of annual spending for the included drugs. See: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB.*

source drugs or biologicals were within the same billing and payment code as of October 1, 2003. For purposes of the MFN Model, we consider a drug to be a generic drug if it is approved under an abbreviated new drug application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act. In accordance with President Trump's Blueprint to Lower Drug Prices, we are excluding such drugs because these drugs are already subject to competitive market forces and because the Medicare Part B payment allowances for these drugs already reflect price competition from generic products. In addition, we are excluding drugs for which there is an Emergency Use Authorization (EUA) or approval by the Food and Drug Administration (FDA) to treat patients with suspected or confirmed coronavirus disease 2019 (COVID–19). Since there may likely be urgent, high demand for such drugs and available supply may be targeted to certain populations, this exclusion allows maximum flexibility for potential changes in drug distribution for such drugs.

To encourage introduction and use of biosimilars, the Trump Administration has taken several actions, including establishing separate HCPCS codes for Medicare Part B biosimilar biological products. We are not excluding biosimilar biological products from the MFN Model, however, given the relative lower annual Medicare Part B spending for HCPCS codes for separately payable biosimilar biological products through 2019, only one biosimilar biological product is included among the performance year 1 MFN Model Drug HCPCS Codes List in Table 2.

We further discuss the drugs that will be included in or excluded from the MFN Model in the following four subsections.

1. MFN Model Drug HCPCS Codes List

We will use an approach for including drugs in the MFN Model that is similar to what we described in the October 2018 ANPRM. However, rather than beginning with approximately 27 drugs, as discussed in the October 2018 ANPRM, and adding drugs annually, we will include approximately 50 Medicare Part B drugs in the MFN Model for each performance year. We will identify the top 50 Medicare Part B separately payable drugs with the highest aggregated Medicare Part B total allowed charges in the baseline period, after excluding certain claims, to result in an initial set of drugs that will be included in the model beginning in performance year 1. Thereafter, annual additions will follow a similar process using claims data for the subsequent year.

Compared to beginning with a smaller number of drugs and phasing in additional drugs in each subsequent performance year, beginning with 50 Medicare Part B drugs simplifies the model design and reduces complexity for MFN participants. Based on spending patterns over time for high spend Medicare Part B drugs,[35] we expect the set of included Medicare Part B drugs to remain relatively stable over the model's 7-year performance period, and we believe that a generally stable set of MFN Model drugs will help MFN participants plan their drug acquisition strategies. We believe the benefits of this stability outweigh the incremental challenge of beginning the MFN Model with a longer drug list than envisioned in the October 2018 ANPRM, and allows Medicare and its beneficiaries to benefit from the model payment methodology sooner for more of the highest spend Medicare Part B drugs, if anticipated savings are realized.

By focusing the MFN Model on separately payable Medicare Part B drugs, payments for products that are bundled or otherwise included in payment for a procedure or other services will not be affected by the MFN Model and payments for such bundled services will not have to be separated or adjusted. This approach does not exclude drugs that are packaged under a Medicare payment system in certain settings and separately payable in other settings. However, the MFN Model payment only applies to such drugs in settings where separate payment is allowed.

In § 513.130, we describe the creation and periodic updates of an MFN Model Drug HCPCS Codes List, which designates the MFN Model drugs that are subject to the MFN Model payments specified in § 513 subpart C. Specifically, to select the list of drugs included in the MFN Model for the beginning of performance year 1 (that is, beginning January 1, 2021), the regulation text at § 513.130(a)(1) codifies that, after making the exclusions specified in § 513.130(b)(1) and (b)(2), CMS identifies the top 50 drugs by HCPCS code with the highest aggregate 2019 Medicare Part B total allowed charges, and adds those HCPCS codes to the MFN Model Drug HCPCS Codes List, after updating such HCPCS codes for any applicable changes. We will use HCPCS codes to identify drugs because they are an established way to identify, bill, and pay for separately payable Medicare Part B drugs in the Medicare claims processing system, and they are commonly used in other Medicare Part B drug payment resources like the ASP drug pricing files. For this process, we will use final action Medicare Part B claims for separately paid drugs with dates of service within calendar year 2019 and allowed charges greater than $0 where Medicare was the primary payer from all Medicare providers and suppliers as the baseline period. This period is the most recent full calendar year of claims data that was sufficiently available prior to the model performance period start on January 1, 2021. Accordingly, we arrayed drugs, using HCPCS codes, in descending order based on the aggregate Medicare Part B total allowed charges in the 2019 baseline period, after making the exclusions specified in § 513.130(b)(1) and (b)(2), and identified the 50 Medicare Part B drugs (identified by HCPCS codes) with the highest total Medicare Part B allowed charges. These HCPCS codes are included on the MFN Model Drug HCPCS Codes List for the beginning of performance year 1 as shown in Table 2 of this IFC.

The MFN Model uses an annual calendar year baseline period for purposes of identifying the drugs that will be added to the MFN Model Drug HCPCS Codes List for performance year 1 (and annually thereafter, using the next subsequent calendar year as the baseline) because: The vast majority of HCPCS Code updates occur annually in the January HCPCS update; the model will use an annual baseline period to calculate the alternative add-on payment amount described in section III.F. of this IFC; and these baseline periods will be aligned for consistency in the model design.

This approach for identifying the drugs that are included in the MFN Model at the beginning of performance year 1 captures most of the drugs listed in the October 2018 ASPE report,[36] which used the Medicare Part B National Summary Drug file from 2016 to identify approximately 27 HCPCS codes associated with high amounts of spending, and nearly all the drugs listed in the November 20, 2020 ASPE report, which applied the criteria in the MFN Model to Medicare Part B claims data

[35] CMS publishes a Medicare Part B Drug Dashboard, which can be used to view annual spending on drugs by HCPCS code. See: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB.html.*

[36] ''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures.*

for 2018.[37] This approach also results in the inclusion of a variety of drugs and biologicals (including biosimilar biological products) that are used to treat common conditions in the Medicare Part B beneficiary population. These drugs and biologicals with high annual Medicare allowed charges are frequently prescribed and administered by various physician specialties to beneficiaries with various medical conditions. Examples of uses of the drugs included in the MFN Model are: Drugs and biologicals used to treat cancer and related conditions, biologicals used for the treatment of rheumatoid arthritis and other immune mediated conditions, and biologicals used to treat macular degeneration. Beneficiaries who receive such drugs, often on a recurring basis, face substantial cost-sharing liability directly or through their supplemental insurance, and such costs may be partly avoidable (that is, reduced) if Medicare payment for these drugs were not based on the current ASP methodology.

Beginning with 50 of the highest spend HCPCS codes based on annual Medicare Part B allowed charges during 2019, after taking into account certain exclusions, focuses the MFN Model on a wide variety of frequently utilized Medicare Part B drugs and specialties that administer such drugs to Medicare FFS beneficiaries, and allows CMS to test the MFN Model payment on a broad set of drugs and biologicals that are furnished to many beneficiaries. We believe that including single source drugs and biologicals (including biosimilar biological products) that move into the top 50 HCPCS codes on an annual basis will capture potential shifts in utilization to drugs that had not yet been included in the MFN Model, if such shifting were to occur, and will mitigate the potential for medically unnecessary shifts in utilization.

In developing this approach, we also considered comments we received in response to the October 2018 ANPRM on using drug classes to help inform which drugs to include in the MFN Model, as well as requests to consider how access to Medicare Part B drugs (as a whole and for specific subsets of drugs) might be affected by inclusion in the model. We considered these suggestions and believe that using annual Medicare Part B allowed charges as a primary factor is a more transparent, consistent, and clear approach because attempting to identify drugs for inclusion in the MFN Model based on groups or classes of drugs could become complicated and confusing for MFN participants. There are numerous drug classification approaches available; for example, drug classification can be based on a chemical class, site of action, mechanism of action, as well as other factors. These approaches can become difficult to apply consistently when drugs from different chemical classes are used to treat the same condition, when a drug has more than one mechanism of action, or when conditions are treated with drugs having more than one mechanism of action. For example, the Medicare Part B biological products commonly used to treat rheumatoid arthritis include a variety of monoclonal antibodies. Using broad terms such as monoclonal antibodies to identify a ''group'' of MFN Model drugs would include a variety of biologicals that are commonly also used in treating other conditions, such as Crohn's disease, ulcerative colitis, cancer, and multiple sclerosis. Attempting to select MFN Model drugs using more narrow terms, for example by specifying agents that exert effects on more specific inflammatory pathways, such as tumor necrosis factor and interleukins, would miss biologicals that affect other pathways, like T cell stimulation. These approaches may also miss products that are primarily used to treat other diseases, but may be used less frequently in rheumatoid arthritis, and these approaches may not be readily adaptable for novel products that may be introduced over the 7-year performance period of the model.

In § 513.130(a)(2), we are codifying the process for annual updates of the MFN Model Drug HCPCS Codes List to update the list of drugs that will be included in the MFN Model for the subsequent performance year, as further described in section III.D.3. of this IFC.

2. Exclusion of Certain HCPCS Codes and Claims

In the October 2018 ANPRM, we discussed the potential exclusion of several groups of drugs from the potential IPI Model (83 FR 54555). Commenters generally agreed that these drugs should be excluded. As codified in § 513.130(b)(1), the MFN Model excludes the following types of drugs, by excluding claims at the HCPCS code level, before identifying the top 50 drugs with the highest aggregate annual Medicare Part B total allowed charges:

- Medicare Part B vaccines specified in section 1861(s)(10) of the Act (that is, influenza, pneumococcal pneumonia, and Hepatitis B vaccines, and any future vaccine for COVID–19). These preventive products are paid under section 1842(o)(1)(A)(iv) based on average wholesale price (AWP), a price that does not include discounts or rebates. Including such drugs in the MFN Model also would not comport with our test of an alternative add-on payment amount (described in section III.F. of this IFC) because the statutory add-on percentage under section 1847A of the Act does not apply to these drugs.
- Radiopharmaceuticals. Many radiopharmaceuticals are typically acquired outside of the traditional drug supply chain. Nuclear pharmacies are frequently involved in the preparation of patient-ready doses of these drugs, and Medicare Part B payment is frequently based on contractor pricing. We are excluding radiopharmaceuticals from the MFN Model because it is unlikely that we will be able to obtain reliable international drug pricing information for radiopharmaceuticals.
- Oral Medicare Part B drugs, including oral anticancer drugs described in section 1861(s)(2)(Q) of the Act, oral antiemetic drugs described in section 1861(s)(2)(T) of the Act and immunosuppressive drugs described in section 1861(s)(2)(J) of the Act. Oral anticancer, antiemetic, and many immunosuppressive drugs are often used outside of the provider and supplier settings (for example, these drugs are often used at home); therefore, we are excluding these oral drugs from the MFN Model.
- Compounded drugs including products prepared by outsourcing facilities.[38] Although subject to certain FDA requirements, these products are not approved by FDA per se, and with one exception under the OPPS [39] are not billed under drug-specific HCPCS codes; they are typically billed using under ''not otherwise classified'' (NOC) codes. Also, compounded drugs are typically acquired outside of the traditional drug supply chain, and Medicare Part B payment for compounded drugs is generally based on contractor pricing, such as invoice pricing. We are excluding these drugs because it is unlikely that we will be able to obtain reliable international drug pricing information for compounded drugs.

[37] El-Kilani Z, Finegold K, Mulcahy A, and Bosworth A. Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 20, 2020 (*https://aspe.hhs.gov/pdf-report/medicare-ffs-part-b-and-international-drug-prices*).

[38] See section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353b) with respect to the definition of outsourcing facilities and their regulation by FDA.

[39] C9257 Injection, bevacizumab, 0.25 mg.

• Intravenous immune globulin products. In response to the October 2018 ANPRM, a commenter suggested that CMS exclude plasma-derived products and stated such products have potential unique sourcing and distribution, and past supply shortages. We note that FDA has identified a current shortage related to one of the HCPCS codes that is among the top drugs with high aggregate 2019 Medicare Part B total allowed charges (J1569, Gammagard liquid infusion). Three other immune globulin products are also among the top drugs in 2019, J1459 (Inj ivig privigen 500 mg), J1561 (Gamunex-c/gammaked), and J1568 (Octagam injection). After considering this concern, we are excluding intravenous immune globulin products from the MFN Model because these products are at higher risk of shortage based on their complex sourcing and production, and we are aware of the ongoing exploration of the potential benefit of plasma in the treatment of patients with COVID–19.

• Drugs that are subject to an EUA or receive FDA approval to treat patients with suspected or confirmed COVID–19. The exclusion of these drugs will minimize any potential for the MFN Model to impact rapid, widespread availability of such drugs in the U.S. to treat patients with suspected or confirmed COVID–19.

• Drugs without drug-specific HCPCS codes, that is, those billed under ''not otherwise classified'' (NOC) codes, such as J3490. NOC codes are used to bill for drugs not assigned to a particular HCPCS code. NOC codes typically include a variety of unrelated drugs that cannot be easily separated for the purpose of ranking allowed charges of the individual drugs. Also, significantly greater claims processing complexity for Medicare and MFN participants would result if we had to identify whether an MFN Model drug was billed under a NOC code during MFN Model operations. By excluding HCPCS codes for these types of drugs, these drugs will be fully excluded from the MFN Model.

While we intend that the MFN Model drugs will encompass a wide variety of frequently utilized Medicare Part B drugs, we also intend that drugs will not be included on the basis of substantial use at home. Thus, in § 513.130(b)(2), we codify the exclusion of claims that were processed and paid by the DME MACs as described in 42 CFR 421.404(c)(2), and professional claims with a place of service code that indicates the drug was used in a home, including home-like settings, prior to identifying the top 50 drugs (by HCPCS code).[40] The place of service exclusion applies only to professional claims because place of service codes are not used on institutional claims to identify home use. Specifically, professional claims with place of service codes 04—homeless shelter, 12—home, 13—assisted living facility, 14—group home, 16—temporary lodging, and 33—custodial care facility will be excluded prior to identifying the top 50 drugs (by HCPCS code).

For future years of model implementation, we seek comment on whether all blood related, plasma derived, and human tissue products should be included in or excluded from the MFN Model. We also seek comment on how CMS should define such products and what would be the supporting rationale for such an exclusion and how to address such considerations in the future. We note that we are also considering as a potential addition to the model design whether certain drugs, such as certain gene and cell therapies (for example, chimeric antigen receptor T-cell (CAR–T) products) and drugs approved by FDA after the start of the MFN Model that are indicated for and used to treat rare diseases or conditions, should be excluded from the MFN Model for all performance years, or for several years after the drug is first sold in the U.S. We note that under the MFN Model, annual Medicare Part B allowed charges would have to exceed tens of millions of dollars for such drugs to reach the top 50 and be added to the MFN Model. We also note that many of the top 50 drugs in 2019 are used to treat conditions with limited populations and were first approved within the last 5 years. In addition, we note that while drugs may initially be approved for one or a few very narrow indications, subsequently approved indications can quickly expand the use of the drug to a much larger patient population. We are considering whether we should exclude certain gene and cell therapies based on supply chain criteria, similar to our policy to exclude vaccines and compounded drugs. For future years, we seek comment on whether we should exclude certain gene and cell therapies or new drugs for the treatment of rare diseases and conditions from the MFN Model, and how CMS would identify such drugs for exclusion, particularly how we would define such drugs, identify rare diseases and conditions for purposes of the MFN Model, and determine the appropriate length of such exclusion (for example, all performance years or several years after the drug is first sold in the U.S.).

Some commenters have suggested that drugs in short supply (based on inclusion on the FDA drug shortages list) should be excluded from drug payment models. As discussed previously, we are excluding intravenous immune globulin products from inclusion on the MFN Model Drug HCPCS Codes List, because these products are at higher risk of shortage based on their complex sourcing and production. Otherwise, based on our experience with ASP pricing, shortages of high cost single source drugs and biologicals are uncommon, of short duration, and generally apply to some but not all package sizes of a drug. As described in section III.E.12. of this IFC and codified in § 513.210(d)(2), we include a quarterly payment exception for MFN drugs that are in short supply (based on inclusion on the FDA drug shortages list). We believe it will be less disruptive to the MFN Model to include a quarterly payment exception for MFN Model drugs during the time they are in short supply than to exclude such drugs from the MFN Model altogether because a quarterly payment exception approach will avoid changing the inclusion status of drugs should a shortage occur and again when the shortage is resolved, eliminate the need to consider developing a process to add and remove replacement drugs to maintain the number of MFN Model drugs, and avoid manufacturers having to change processes for capturing sales of such drugs in their ASP calculations as discussed in section III.L. of this IFC (under this policy, manufacturers will not include in their calculation of the manufacturer's ASP any units of MFN Model drugs billed by MFN participants where the MFN Drug Payment Amount is paid by Medicare as the primary payer).

Finally, we considered whether an exception to inclusion on the MFN Model Drug HCPCS Codes List might be appropriate for MFN Model drugs in cases where pharmaceutical manufacturers that distribute the drug in the U.S. do not own the rights to the drug product for distribution outside the U.S. and therefore do not control ex-U.S. pricing for the drug product. To avoid a gaming opportunity whereby manufacturers' new or recent business arrangements create such cases, this type of exception could be defined such that only ownership rights that were transferred prior to the October 2018 ANPRM, when CMS announced a new

[40] The DME MACs process Medicare Durable Medical Equipment, Orthotics, and Prosthetics (DMEPOS) claims for a defined geographic area or ''jurisdiction,'' servicing suppliers of DMEPOS. Professional claims must comply with the ASC X12 837 Professional guide (005010X222A1).

Medicare Part B drug payment model was being developed, would qualify. To avoid an exception being too broad, we are concerned that additional criteria should be required to qualify for it, such as whether the increase in the MFN Model drug's applicable ASP (a measure of U.S. prices) based on sales since October 2018 has been slower than inflation (that is, the change in the CPI–U from the end of October 2018 through the ASP calendar quarter for the first calendar quarter of the model), and whether the U.S. manufacturer makes a legally enforceable commitment to future U.S. price increases being slower than inflation moving forward, if such an exception were to be granted. In addition, to maintain the exception for the remainder of the model, the increase in the MFN Model drug's applicable ASP since October 2018 would need to be assessed quarterly to determine whether it continues to be slower than inflation. Given the complex and numerous relationships that manufacturers may have across U.S. and international markets, we are not including such an exception for the MFN Model.

We seek comments for future years on our approach to identifying and maintaining the MFN Model Drug HCPCS Codes List and whether there is a need for an exception relating to manufacturers' ownership of drug products internationally, and if so, how such an exception might be defined and operated transparently.

3. Annual Updates to the MFN Model Drug HCPCS Codes List

As discussed in section III.D.1. of this IFC, the MFN Model will begin with 50 drugs and biologicals by HCPCS code on the MFN Model Drug HCPCS Codes List for performance year 1. We will keep approximately 50 drugs by HCPCS code in the MFN Model during the 7-year performance period so that drugs that continue to account for a large portion of Medicare Part B drug spending will continue to be included in the model. However, we believe that some adjustments to the MFN Model Drug HCPCS Codes List will likely be required from time to time as drugs enter and exit the market and as utilization of Medicare Part B drugs (measured by annual total allowed charges) changes. Thus, we will update the MFN Model Drug HCPCS Codes List annually. The annual update process will occur prior to the beginning of each performance year rather than more frequently, such as a quarterly process, because less frequent changes to the MFN Model Drug HCPCS Codes List will decrease the burden associated with participating in the model. We believe that making fewer changes to the MFN Model Drug HCPCS Codes List will result in MFN participants having to make fewer changes to acquisition arrangements, and this in turn will lessen any potential for disruption in workflow and care delivery compared to a quarterly update process. Additionally, as specified in § 513.130(a)(4), some quarterly changes may be necessary to comport with HCPCS coding updates that are applicable to the HCPCS codes on the MFN Model Drug HCPCS Codes List, such as when a code is terminated and a successor code is established.

For each annual update for performance years 2 through 7, as described in § 513.130(a)(2), we will array in descending order all separately payable Medicare Part B drugs, using HCPCS codes, based on total allowed charges after applying the exclusions codified in § 513.130(b)(1) and (b)(2), using the most recent full calendar year's Medicare Part B claims from all providers and suppliers. Those drugs (as identified by HCPCS codes) that have total allowed charges that fall in the top 50 drugs by spending for that calendar year that are not already on the MFN Model Drug HCPCS Codes List will be added to the MFN Model Drug HCPCS Codes List to take effect on the first day of the next performance year and the MFN Drug Payment Amount that will apply will be based on the applicable MFN Price phase-in for that performance year and will follow the annual payment updates thereafter. This process will be used only to add HCPCS codes that are new to the top 50—to maintain consistency, we will not remove any codes from the MFN Model Drug HCPCS Codes List on the grounds that the HCPCS code dropped out of the top 50. We will keep all HCPCS codes that were included on the MFN Model Drug HCPCS Codes List for the prior performance year on the MFN Model Drug HCPCS Codes List, except in certain circumstances as noted in section III.D.4. of this IFC, in order to have greater stability in the set of drugs that are included in the MFN Model across the performance years. As a result, in performance years 2 through 7, the number of HCPCS codes on the MFN Model Drug HCPCS Codes List may be greater than 50. We believe this approach has the potential to identify drugs that are alternative therapies to MFN Model drugs, such as competitor products, where MFN participants may shift utilization to avoid using drugs subject to the MFN Model payment, and will provide a mechanism for adding such drugs to the MFN Model. In addition, this approach will serve as a mechanism to identify newer drugs with high annual Medicare Part B spending for inclusion in the MFN Model.

To maintain transparency, when we add HCPCS codes that are new to the top 50 or are replacement codes for HCPCS codes that are listed on the MFN Model Drug HCPCS Codes List, we will list the code's start date for inclusion in the MFN Model. In addition, we will revise HCPCS codes on the MFN Model Drug HCPCS Codes List as necessary to reflect quarterly HCPCS code updates that are applicable to the HCPCS codes on the MFN Model Drug HCPCS Codes List, for example when a permanent code replaces a temporary code, a HCPCS code is terminated and a replacement code is established, or a HCPCS code is established for Medicare use. In such case, we will include an end date on the MFN Model Drug HCPCS Codes List for the terminated code. We will notify MFN participants of updates to the MFN Model Drug HCPCS Codes List no less frequently than quarterly by adding the updated MFN Model Drug HCPCS Codes List to the MFN Model website (*https://innovation.cms.gov/initiatives/most-favored-nation-model*).

4. Approach for Removing Drugs From the MFN Model Drug HCPCS Codes List

We do not anticipate that drugs will be removed from the MFN Model frequently. In accordance with § 513.130(a)(3), we will remove drugs from the MFN Model Drug HCPCS Codes List only under the following limited circumstances, but no more frequent than quarterly, to align with quarterly MFN Model payment updates:

- If they are permanently withdrawn from the U.S. market;
- If a specific HCPCS code included on the MFN Model Drug HCPCS Codes List is terminated with no replacement code available or planned; or
- The drug is excluded from the MFN Model pursuant to the exclusions in § 513.130(b)(1), for example a HCPCS code describes a generic drug approved under an ANDA or a drug with an EUA or FDA approval to treat patients with suspected or confirmed COVID–19.

To maintain transparency, we will remove HCPCS codes by setting an end date on the MFN Model Drug HCPCS Codes List at the next quarterly update after CMS becomes aware, through environmental scanning activities, that all of the NDCs assigned to a HCPCS code have been withdrawn from the U.S. market and the drug is permanently withdrawn from the U.S. market, or the HCPCS code has been terminated with

no replacement code available or planned, or the exclusion in § 513.130(b) applies. HCPCS codes that are removed from the MFN Model Drug HCPCS Codes List will no longer be subject to the MFN Model payment, but rather will be subject to current Medicare payment policies. If the conditions for removal no longer exist, the HCPCS code could again qualify for inclusion on the MFN Model Drug HCPCS Codes List at the next annual update.

5. Performance Year 1 MFN Model Drug HCPCS Codes List

To create the MFN Model Drug HCPCS Codes List for performance year 1, we arrayed drug HCPCS codes by aggregate 2019 Medicare Part B total allowed charges [41] after applying the exclusions in § 513.130(b)(1) and (b)(2). We then identified the top 50 drugs by HCPCS code with the highest aggregate 2019 Medicare Part B total allowed charges. This process excluded HCPCS codes for two influenza vaccines (90662 (Iiv no prsv increased ag im) and 90653 (Iiv adjuvant vaccine im)), two pneumococcal pneumonia vaccines (90732 (Ppsv23 vacc 2 yrs+ subq/im) and 90670 (Pcv13 vaccine im)), and a radiopharmaceutical (A9606 (Radium ra223 dichloride ther)) from the MFN Model Drug HCPCS Codes List. The exclusion of intravenous immune globulin products excluded four HCPCS codes: J1459, Inj ivig privigen 500 mg; J1561, Gamunex-c/gammake; J1568, Octagam injection; and J1569, Gammagard liquid injection. Additionally, one HCPCS code that describes a generic drug (J9395, Injection, fulvestrant) was excluded. Excluding claims that were processed and paid by the DME MACs resulted in the following HCPCS codes no longer falling within the top 50 drugs in 2019: J7605 (Arformoterol non-comp unit); J7686 (Treprostinil, non-comp unit); and J3285 (Treprostinil injection). Excluding claims based on the place of service exclusion resulted in one HCPCS code, J7192 (Factor viii recombinant nos), no longer falling within the top 50 drugs in 2019.

Using this approach for selecting MFN Model drugs, the resulting performance year 1 MFN Model Drug HCPCS Codes List includes single source drugs and biologicals that accounted for approximately 75 percent of annual Medicare Part B drug allowed charges for separately payable drugs during 2019. Table 2 displays the list of MFN Model drugs (by HCPCS code) that are included on the MFN Model Drug HCPCS Codes List for the beginning of performance year 1, along with the top billing specialties.

CMS will publish the MFN Model Drug HCPCS Codes List quarterly on the MFN Model website (*https://innovation.cms.gov/initiatives/most-favored-nation-model*), in advance of the calendar quarter, along with MFN Model Payment amounts and other MFN Model information and materials.

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[41] We used 2019 final action claims data that were available in the CMS Chronic Conditions Data Warehouse in September 2020 where Medicare was the primary payer.

TABLE 2: PERFORMANCE YEAR 1 MFN MODEL DRUG HCPCS CODES LIST WITH TOP BILLING SPECIALTIES

Rank	List of HCPCS Codes	Short Description*	2019 Total Allowed Charges, after exclusions (in dollars)	1st Top Specialty	2nd Top Specialty	3rd Top Specialty
1	J0178	Aflibercept injection	$2,982,942,674	Ophthalmology	Ambulatory Surgical Center	Internal Medicine
2	J9271	Inj pembrolizumab	$2,815,337,226	Hematology/Oncology	Internal Medicine	Medical Oncology
3	J9299	Injection, nivolumab	$1,878,981,569	Hematology/Oncology	Internal Medicine	Medical Oncology
4	J9312	Inj., rituximab, 10 mg	$1,865,991,330	Hematology/Oncology	Internal Medicine	Rheumatology
5	J0897	Denosumab injection	$1,721,580,561	Hematology/Oncology	Internal Medicine	Rheumatology
6	J2778	Ranibizumab injection	$1,295,341,479	Ophthalmology	Ambulatory Surgical Center	Internal Medicine
7	J2505	Injection, pegfilgrastim 6mg	$1,242,697,080	Hematology/Oncology	Internal Medicine	Medical Oncology
8	J9035	Bevacizumab injection	$1,099,476,084	Hematology/Oncology	Internal Medicine	Medical Oncology
9	J1745	Infliximab not biosimil 10mg	$1,010,328,165	Rheumatology	Gastroenterology	Internal Medicine
10	J0129	Abatacept injection	$968,556,135	Rheumatology	Internal Medicine	Hematology/Oncology
11	J9355	Inj trastuzumab excl biosimi	$851,042,669	Hematology/Oncology	Internal Medicine	Medical Oncology
12	J9145	Injection, daratumumab 10 mg	$843,712,153	Hematology/Oncology	Internal Medicine	Medical Oncology
13	J2350	Injection, ocrelizumab, 1 mg	$703,104,359	Neurology	Hematology/Oncology	Internal Medicine
14	J1300	Eculizumab injection	$562,413,430	Neurology	Hematology/Oncology	Internal Medicine
15	J9305	Pemetrexed injection	$539,680,121	Hematology/Oncology	Internal Medicine	Medical Oncology
16	J9022	Inj, atezolizumab,10 mg	$486,551,001	Hematology/Oncology	Internal Medicine	Medical Oncology
17	J9173	Inj., durvalumab, 10 mg	$476,638,073	Hematology/Oncology	Internal Medicine	Medical Oncology
18	J2353	Octreotide injection, depot	$466,969,222	Hematology/Oncology	Internal Medicine	Medical Oncology
19	J0717	Certolizumab pegol inj 1mg	$458,757,878	Rheumatology	Internal Medicine	Nurse Practitioner
20	J9041	Inj., velcade 0.1 mg	$436,302,629	Hematology/Oncology	Internal Medicine	Medical Oncology
21	J2357	Omalizumab injection	$423,947,996	Allergy/Immunology	Internal Medicine	Pulmonary Disease
22	J0585	Injection,onabotulinumtoxina	$389,236,097	Neurology	Physical Medicine and Rehabilitation	Ophthalmology
23	J1602	Golimumab for iv use 1mg	$368,492,761	Rheumatology	Internal Medicine	Nurse Practitioner
24	J3380	Injection, vedolizumab	$362,050,123	Gastroenterology	Hematology/Oncology	Internal Medicine
25	J9264	Paclitaxel protein bound	$333,264,824	Hematology/Oncology	Internal Medicine	Medical Oncology
26	J9228	Ipilimumab injection	$331,065,114	Hematology/Oncology	Internal Medicine	Medical Oncology
27	J9217	Leuprolide acetate suspnsion	$331,012,840	Urology	Hematology/Oncology	Internal Medicine
28	J9306	Injection, pertuzumab, 1 mg	$318,023,592	Hematology/Oncology	Internal Medicine	Medical Oncology
29	J9047	Injection, carfilzomib, 1 mg	$296,821,394	Hematology/Oncology	Internal Medicine	Medical Oncology
30	J3262	Tocilizumab injection	$279,068,051	Rheumatology	Internal Medicine	Hematology/Oncology
31	J1930	Lanreotide injection	$278,600,806	Hematology/Oncology	Internal Medicine	Medical Oncology
32	J3357	Ustekinumab sub cu inj, 1 mg	$264,386,412	Rheumatology	Gastroenterology	Dermatology
33	J0881	Darbepoetin alfa, non-esrd	$258,409,215	Hematology/Oncology	Internal Medicine	Medical Oncology
34	J2323	Natalizumab injection	$255,449,074	Neurology	Hematology/Oncology	Internal Medicine
35	J2796	Romiplostim injection	$248,212,119	Hematology/Oncology	Internal Medicine	Medical Oncology
36	J9034	Inj., bendeka 1 mg	$219,156,831	Hematology/Oncology	Internal Medicine	Medical Oncology
37	J0885	Epoetin alfa, non-esrd	$187,518,352	Hematology/Oncology	Internal Medicine	Nephrology
38	Q2043	Sipuleucel-t auto cd54+	$182,158,187	Urology	Hematology/Oncology	Internal Medicine
39	J2182	Injection, mepolizumab, 1mg	$177,640,239	Allergy/Immunology	Internal Medicine	Pulmonary Disease
40	J1439	Inj ferric carboxymaltos 1mg	$173,008,338	Hematology/Oncology	Internal Medicine	Medical Oncology
41	J9042	Brentuximab vedotin inj	$162,519,904	Hematology/Oncology	Internal Medicine	Medical Oncology
42	J9055	Cetuximab injection	$162,477,948	Hematology/Oncology	Internal Medicine	Medical Oncology
43	J9354	Inj, ado-trastuzumab emt 1mg	$157,438,453	Hematology/Oncology	Internal Medicine	Medical Oncology
44	Q5111	Injection, udenyca 0.5 mg	$155,483,502	Hematology/Oncology	Internal Medicine	Medical Oncology
45	J7324	Orthovisc inj per dose	$152,408,630	Orthopedic Surgery	Physician Assistant	Sports Medicine
46	J2785	Regadenoson injection	$150,339,213	Cardiology	Interventional Cardiology	Internal Medicine
47	J0517	Inj., benralizumab, 1 mg	$136,977,827	Allergy/Immunology	Internal Medicine	Pulmonary Disease
48	J2507	Pegloticase injection	$123,947,596	Rheumatology	Internal Medicine	Hematology/Oncology
49	J9176	Injection, elotuzumab, 1mg	$123,725,659	Hematology/Oncology	Internal Medicine	Medical Oncology
50	J9311	Inj rituximab, hyaluronidase	$121,583,613	Hematology/Oncology	Internal Medicine	Medical Oncology

Note: Ambulatory Surgical Center is included as a specialty to show drug utilization in this setting.
*The short description effective as of January 1, 2021.

TABLE 3 – DISTRIBUTION OF 2019 MEDICARE PART B ALLOWED CHARGES* FOR PERFORMANCE YEAR 1 MFN MODEL DRUGS BY PROVIDER AND SUPPLIER TYPE

Provider/Supplier Type	Number of Entities (CCNs/TINs)	2019 Total Allowed Charges for MFN Model Drugs	Percent of 2019 Total Allowed Charges for MFN Model Drugs	2019 Average Allowed Charges for MFN Model Drugs Per Entity	90th Percentile	75th Percentile	50th Percentile (Median)	25th Percentile	10th Percentile
OFFICE**	18,783	$16,896,364,008	56.64%	$899,556	$1,387,304	$173,219	$24,958	$3,355	$406
OPPS HOSPITAL	2,579	$10,970,275,972	36.77%	$4,253,694	$11,602,122	$4,771,715	$1,147,107	$79,683	$3,064
CANCER HOSPITAL†	11	$954,666,587	3.20%	$86,787,872	$157,901,464	$129,520,505	$63,472,661	$37,493,103	$34,352,282
CRITICAL ACCESS HOSPITAL†	1,146	$641,638,057	2.15%	$559,894	$1,515,002	$654,881	$200,902	$52,168	$11,697
MARYLAND TCOC MODEL***††	44	$307,057,157	1.03%	$6,978,572	$23,025,921	$8,433,607	$1,245,538	$191,929	$43,618
CHILDRENS HOSPITAL†	50	$36,455,923	0.12%	$729,118	$462,763	$172,467	$31,188	$4,860	$904
AMBULATORY SURGICAL CENTER	540	$17,318,224	0.06%	$32,071	$42,570	$14,649	$3,675	$726	$102
PENNSYLVANIA RURAL HEALTH MODEL††	4	$2,684,657	0.01%	$671,164	$2,306,421	$1,244,263	$160,364	$98,065	$57,508
INPATIENT HOSPITAL PART B ONLY†	506	$2,321,456	0.01%	$4,588	$11,454	$4,794	$804	$226	$109
PHARMACY	16	$1,382,119	0.00%	$86,382	$231,186	$106,502	$13,640	$5,489	$2,278
ESRD FACILITY†	5	$583,943	0.00%	$116,789	$576,224	$4,529	$2,443	$509	$237
INDEPENDENT DIAGNOSTIC TESTING FACILITY	4	$78,296	0.00%	$19,574	$65,538	$38,040	$6,319	$1,108	$118
FQHC/RHC****†	1	$2,151	0.00%	$2,151	$2,151	$2,151	$2,151	$2,151	$2,151
TOTAL	**23,689**	**$29,830,828,548**	**100.00%**	**$101,141,424**	**$199,130,121**	**$145,141,324**	**$66,311,750**	**$37,933,371**	**$34,474,473**

*Claims where Medicare was not the primary payer and claims for radiopharmaceuticals were excluded for this analysis.
**Office includes suppliers such as physicians, non-physician practitioners, and supplier groups, such as group practices. Note that we are excluding claims submitted by non-participating physicians from the MFN Model.
***Maryland Total Cost of Care (MD TCOC) Model Participants, acute care hospitals located in Maryland.
****FQHC means federally qualified health center; RHC means rural health clinic.
† Indicates provider and supplier types that we are excluding from the MFN Model or indicates that we are excluding claims of this type from the MFN Model. Note that claims billed by ESRD Facilities that are not paid under the ESRD PPS will be subject to the MFN Model payment.
††CMS Innovation Center models that we are excluding for the first two calendar quarters of performance year 1 and then thereafter if conditions are met.

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E. Model Payment Methodology for MFN Model Drugs

The MFN Model will test an innovative approach to calculating drug payment through use of a more comprehensive set of drug pricing data to calculate an alternative payment amount for MFN Model drugs, along with an alternative add-on payment, which is described in section III.F. of this IFC. Payment for drug administration services, when applicable, will continue to be separately billed by model participants to Medicare; there will be no change in the payment for drug administration services under the MFN Model. Providers and suppliers will continue to purchase MFN Model drugs, furnish such drugs to beneficiaries, submit claims to Medicare, and collect applicable beneficiary cost-sharing. Under the MFN Model, payments for separately payable Medicare Part B drugs will include the alternative drug payment amount and the alternative add-on payment amount, both subject to sequestration, as applicable.

Similar to the current approach under section 1847A of the Act, the MFN Model alternative payment limit for the ''drug portion'' of payment for MFN Model drugs (that is, not including the add-on amount) will be calculated by CMS quarterly. This amount is called the MFN Drug Payment Amount. The calculation of the MFN Drug Payment Amounts is codified in § 513.210(b). Beneficiary cost-sharing will apply to the MFN Drug Payment Amount for included drugs.

We will calculate an MFN Drug Payment Amount for each drug on the MFN Model Drug HCPCS Codes List based on an MFN Price, which will be derived from the lowest GDP-adjusted country-level price, based on non-U.S. OECD member countries with a GDP per capita that is at least 60 percent of the U.S. GDP per capita.[42] We will use GDP per capita information that is based on purchasing power parity. We are also establishing limits such that the MFN Drug Payment Amount will not exceed non-model payment for the drug (excluding any non-model add-on payment amount), will not apply to drugs that are not separately payable, and certain other limitations discussed later in this section.

Section III.E.1. of this IFC identifies the data sources for the MFN Model drugs' international drug pricing information that we will use to calculate the MFN Price for each drug. Section III.E.2. of this IFC outlines the international drug pricing information we will include in these calculations and the included countries. Section III.E.3. of this IFC defines the MFN Drug Payment Amount. Section III.E.4. of this IFC outlines our approach to calculating each drug's MFN Drug Payment Amount. Section III.E.5. of this IFC describes the phase-in of the MFN Price. Section III.E.6. of this IFC describes the alternative calculation for the MFN Drug Payment Amount for situations where no international drug pricing information is available for an MFN Model drug. Section III.E.7. of this IFC provides illustrative MFN Drug Payment Amounts for each drug on the performance year 1 MFN Model Drug HCPCS Codes List in Table 2 using historical data. Section III.E.8. of this IFC describes the timing of data and MFN Drug Payment Amount updates. Section III.E.9. of this IFC describes adjustments to the phase-in formula and incentives for manufacturers to address rising U.S. drug prices. Section III.E.10. of this IFC describes the limitation on the MFN Drug Payment Amount. Section III.E.11. of this IFC describes the method for establishing MFN Drug Payment Amounts for MFN Model drugs added to the model for performance year 2 and subsequent performance years. Section III.E.12. of this IFC describes the quarterly payment exception for MFN Model drugs in short supply. Section III.E.13. of this IFC describes continued payment of the blood clotting factor furnishing fee under the MFN Model.

1. Data Sources on International Drug Pricing Information

We will rely on existing data sources to obtain data that we will use to calculate and update the MFN Drug Payment Amounts. We will use existing data sources that contain international drug pricing information, including list prices, sales and/or volume data (for example, package size and number of packages sold), as available, in order to optimize operational efficiency. Sales may be based on ex-manufacturer prices (sometimes called the ex-factory price), that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, retail prices, prices for other distribution channels, or a combination thereof. Confidential manufacturer rebates will not likely be accounted for within these data; therefore, existing sources for international drug sales data may overstate actual prices realized by manufacturers.

In the October 2018 ANPRM, we considered establishing a data collection system for manufacturers to report to CMS their international drug sales data for prices and units sold to support the calculation of the model payment for each drug. In response to the October 2018 ANPRM, we received comments stating that CMS should use existing data sources for international drug pricing information in order not to place burden on manufacturers. Some commenters expressed concerns that new data reporting would greatly increase burdens and costs for manufacturers, further limiting their ability to invest in research and development for innovative therapies, and would be impractical because defining price reporting for foreign markets would be too complex and could not adequately capture fluid pricing policy changes. We appreciate these concerns, and as such, we will rely on existing data sources for purposes of calculating MFN Drug Payment Amounts. We believe that existing data sources are adequate for purposes of calculating country-level prices, GDP-adjusted country-level prices, and the MFN Prices, as described in this IFC, that will be used to calculate the MFN Drug Payment Amount.

Commenters also noted that one potential adverse reaction to the model described in the October 2018 ANPRM may be a shift internationally to a high price and high rebate pricing strategy. Specifically, commenters expressed concern that if the international drug pricing information used to establish payment under a model relied on the list prices in the included countries, then manufacturers would restructure their pricing arrangements to increase the list prices of the model's drugs in those countries, and offer higher rebates to offset the increased list price. CMS appreciates this concern, and we will prioritize use of available international drug pricing information that incorporate discounts and rebates to the extent possible, rather than just the list prices.

We have assessed several existing data sources to determine the availability and sufficiency of international drug pricing information. In § 513.140(c), we are codifying the use of one or more international drug pricing data sources. Specifically, we will use one or more data sources, available to CMS at least 20 business days prior to the start of a calendar

[42] Individual countries differ in the regulatory processes and standards governing approval of drugs and biologicals. Use of international drug pricing information in the MFN Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

quarter, that utilize a standardized method for identifying drugs across countries within that data source, such as using an internationally recognized method for identifying scientific and nonproprietary names (for example, active ingredient name) and a standard method for identifying drug forms that at a minimum distinguishes among injectable, oral, and other forms of a drug. For example, the data source might use the International Nonproprietary Names (INN), as applicable.[43] This process requires mapping between the data source's standardized method for identifying scientific and nonproprietary names and HCPCS codes, as discussed and illustrated in section III.E.7. of this IFC. Further, we will use one or more data sources that contain international drug pricing information stated in U.S. currency, such as list prices, ex-manufacturer prices (sometimes called the ex-factory price) that represents actual or calculated prices paid to the manufacturer by wholesalers and other distributors, actual or calculated sales for retail and other distribution channels, or volume data (for example, number of units sold).

If more than one data source is available for an MFN Model drug, as noted previously, we will prioritize the data sources using a hierarchy that we describe later in this section. Thus, for each MFN Model drug, we will identify and use the most comprehensive data source available, using the hierarchy codified in § 513.140(c)(3). We will use only one data source for an MFN Model drug for a quarter, meaning we will not combine data from different data sources or time periods to calculate the MFN Drug Payment Amount for an MFN Model drug for a quarter.

Whenever possible, we will use international drug pricing information from two calendar quarters prior to the calendar quarter to which the MFN Drug Payment Amount will apply since the ASP payment limits that apply to that calendar quarter are based on manufacturers' U.S. sales from two calendar quarters prior such that the U.S. and international drug pricing data will be based on information from the same calendar quarter. We use the term applicable ASP calendar quarter to mean the period that is two calendar quarters prior to the calendar quarter to which the MFN Drug Payment Amount will apply.

The hierarchy of data sources we will use is as follows:

- A data source with sales and volume data for the applicable ASP calendar quarter from at least one included country, that is, a non-U.S. OECD member country at the end of the applicable ASP calendar quarter with a GDP per capita that is at least 60 percent of the U.S. GDP per capita.
- A data source that does not have sales and volume data for the applicable ASP calendar quarter, but contains sales and volume data for any prior calendar quarter beginning on or after October 1, 2019 from at least one included country.
- The extracted data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website.
- A data source with ex-manufacturer price data for the applicable ASP calendar quarter from at least one included country.
- A data source with list price data for the applicable ASP calendar from at least one included country.

In each of these cases, if there is more than one data source meeting the requirements in § 510.140(c), we will use the data source at the highest level of the hierarchy that contains information from the highest number of included countries, and, if available, incorporates discounts and rebates into its drug pricing information. It is possible that we will use different data sources for different drugs over different quarters. We will use the data as available from the data source, and we will not make adjustments to account for differences between the data sources or for confidential rebates. We note that, based on the performance year 1 MFN Model Drug HCPCS Codes List shown in Table 2, levels 4 and 5 of the hierarchy will only apply to MFN Model drugs that are added to the MFN Model Drug HCPCS Codes List after performance year 1 and perhaps for Q2043 (Sipuleucel-t auto cd54+)[44] and J2507 (Pegloticase injection), because for other MFN Model drugs in performance year 1, the first three levels of the hierarchy will always result in an available data source as we consider the data used by CMS to create the illustrative MFN Prices and MFN Drug Payment Amounts in Table 6 of this IFC to satisfy level 3 of our hierarchy. To illustrate: Suppose we identified four data sources meeting the requirements of § 510.140(c), where Data Source 1 contains sales and volume data for MFN Model drug X for the applicable ASP calendar quarter from 10 included countries, Data Source 2 contains sales and volume data for MFN Model drug X for the applicable ASP calendar quarter from 15 included countries, Data Source 3 contains sales and volume data from the third calendar quarter of 2020 for MFN Model drug X from 16 included countries, and Data Source 4 contains list price information for the applicable ASP calendar quarter from all included countries. In this scenario, we would use information solely from Data Source 2 to determine the MFN Price for MFN Model drug X by calculating unadjusted country-level prices for each of the 15 countries for which Data Source 2 contains information, and we would not use Data Sources 1, 3, or 4 to calculate the MFN Price for MFN Model drug X for that quarter. For further illustration of how we will apply the hierarchy in calculating MFN Drug Payment Amounts, see section III.E.4.a. of this IFC.

We will use international sales and volume information from as early as the third calendar quarter in 2020 to minimize the possibility of having no international sales and volume information with which to calculate the MFN Price and to mitigate the potential effect of manufacturers' limiting the reporting of international drug pricing information during the model performance period.

In addition, the one or more data sources we will use will have mechanisms in place to maintain, update, and correct, if necessary, the data source on at least a quarterly basis. Further, the data sources we will use will be maintained by organizations that seek to limit the lag inherent in data to no more than 180 days from the end of the calendar quarter for which drug pricing information is compiled to the time that the organization makes such updates available to users of the data source.

We plan to monitor the implementation of a World Health Assembly (WHA) resolution to ''improve the transparency of markets for medicines, vaccines, and other health products.'' This resolution aims to help Member States make more informed decisions when purchasing health products, negotiate more affordable prices, and ultimately expand access to health products for their populations. In particular, the WHA resolution[45]—

- Urges Member States to publicly share information on net prices paid for

[43] World Health Organization, International Nonproprietary Names accessed via *https://www.who.int/medicines/services/inn/en/*.

[44] No data on international pricing or sales of Sipuleucel-t auto cd54+ were available in the data source used for Table 6, but international drug pricing information for this drug could be available in other sources.

[45] World Health Assembly Update, 28 May 2019, accessed via: *https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf*.

health products, to promote greater transparency on pharmaceutical patents and clinical trial results and to improve suppliers' reporting of information such as sales revenues and units sold; and,

• Requests the WHO secretariat to support the development and implementation of national policies relevant to transparency and to monitor the impact of transparency on affordability and availability of health products, including the effect of differential pricing.

We will monitor developments related to this WHA resolution and assess its impact on the availability of data we will use to calculate and update MFN Drug Payment Amounts.

As discussed previously, we will use a hierarchy when selecting from available data sources and start by using data sources that incorporate discounts and rebates to the extent possible in order to address commenters' concerns about a shift internationally to a high price and high rebate pricing strategy. We believe that using one or more data sources will help to ensure that we will capture sufficient information to monitor the international drug pricing landscape and to calculate and update MFN Drug Payment Amounts. Data sources that include the information described previously, as determined by CMS, will be considered sufficient, and as such, we will calculate MFN Drug Payment Amounts for MFN Model drugs using information extracted from such data sources. Specifically, as necessary, for each MFN Model drug, we will extract and use data that align with the data sources' standardized method for identifying scientific and nonproprietary names and dosage forms (for example, injectable forms), and with the HCPCS code's long descriptor, including dosage form, for the HCPCS codes on the MFN Model Drug HCPCS Codes List, as applicable. Further, we will only use the extracted data for dosage formulations that could be described by the MFN Model drug's HCPCS code descriptor as determined by CMS when such limitation is not feasible prior to extracting the data. For example, for a drug, one HCPCS code may include drug products that are a certain type of formulation, such as short-acting, intravenously administered drug products, and another HCPCS code may include drug products with the same scientific and nonproprietary name but a different formulation (such as a long-acting suspension for intramuscular injection), and the extracted data contains international drug pricing information for both formulations. In such case, we will align the extracted data in accordance with the HCPCS code descriptor for the MFN Model drug. In order to align with our existing policies for how we utilize manufacturer-reported ASP data to calculate payment limits, we may find it necessary to make adjustments to the data that we extract from international drug pricing information data sources. For example, in calculating payment amounts based on ASP we do not adjust the volume or units of a drug (that is, the amount of a drug in a package) for intentional overfill (see 75 FR 73466). If we find that a data source from which we obtain international drug pricing information makes adjustments for overfill, we will make adjustments to the data that we extract from such source so that the extracted data is comparable to ASP data. There could be other cases where we will have to examine the extracted data and make adjustments to align the data with a HCPCS code descriptor for an MFN Model drug. Specifically, we will adjust the extracted international drug pricing information for MFN Model drugs when the data source shows the package size of a drug product that is inconsistent with the manufacturer's information about that product as determined by CMS. In such cases where we confirm a difference, we will make adjustments to the pricing, sales and volume data as necessary before calculating the unadjusted country-level price for the drug at the HCPCS code level. We believe that such cases will be rare. However, we identified the need to make such adjustment to the international drug pricing information we used to illustrate the MFN Drug Payment Amounts for J9311 (Inj rituximab, hyaluronidase) shown in Table 6 to align the package size volume with manufacturer labeling and the HCPCS code dosage descriptor. We note that there could be additional cases if international drug pricing data sources that we will select show prices, sales or volume data that are adjusted for intentional overfill, include multiple ingredients for a single drug product, or are in error (for example, the package size represents the maximum volume of a vial instead of the volume of drug in a package).

We will only use the extracted data that have complete package size information. As discussed previously, we will use a hierarchy to determine which data source to use for each MFN Model drug for a quarter, in which we will select a data source that includes sales and volume data first. Data without both sales and volume data will not be able to be combined with other data, therefore we will exclude such observations. For data sources with international sales and volume data for a given MFN Model drug, we will exclude from the calculation of the unadjusted country-level price data that fall below a minimum threshold or are incomplete, that is, international pricing data with less than $1,000 in quarterly sales, with less than 1,000 units in quarterly volume, or where both sales and volume data are not present. We believe that $1,000 in quarterly sales and 1,000 units in quarterly volume for a package size is an appropriate minimum necessary to establish sufficient sales and volume for data to be included in the calculation of a meaningful and reliable unadjusted country-level price for an MFN Model drug and will minimize inclusion of potential outlier data. We will exclude presentations with low volume or low sales to prevent outlier presentations from exerting undue influence.

In developing the illustrative MFN Prices shown in Table 6, we applied these exclusions. Minimal sales and volume across all countries were excluded because of the low volume or sales exclusion criteria. We explored the impact of different volume and expenditure thresholds, and determined that $1,000 in quarterly sales and 1,000 units are a reasonable threshold to reduce risk associated with extremely low values. We found that data with potential outlier sales remained relatively common with lower thresholds (that is, below $1,000 in quarterly sales). While using higher thresholds may further reduce potential inclusion of outlier sales data, doing so would result in having less data to calculate unadjusted country-level prices.

The exclusion of international pricing data with less than $1,000 in quarterly sales or with less than 1,000 units in quarterly volume from the calculation of the unadjusted country-level price will greatly minimize the potential risk for including possible outlier or errant data. To better understand this potential issue, we considered the impact of including or excluding data with less than $1,000 in quarterly sales or less than 1,000 units in quarterly volume in the calculation of the unadjusted country-level price. There was little impact from including these data but, as a potential safeguard to prevent inclusion of inappropriately low or high international drug pricing information in our calculations for the MFN Model, we will exclude such data from the calculation of the unadjusted country-level price. Overall, where this approach had more than a 1 percent

impact, there tended to be an increase in the MFN Prices.

We also considered whether pricing information that is greater than or less than 95 percent of the mean across all data for the drug at the equivalent of the HCPCS code billing unit level should be considered a possible outlier or error and whether trimming such data or removing such data would be warranted. In our experience with international drug pricing information data sources, outlier or potentially erroneous data appear only in isolated instances and are often suggestive of unintended differences in the unit at which data is shown. For example, the pricing data for a product with a standard unit of one gram in one country could appear to be 1,000 times lower than the pricing data for that same product from other countries in the data source; in such a case, it seems likely that the data for the one country with a very low relative price represents the price per milligram not per gram and such data would likely be corrected over time by the data source. We believe international drug pricing data sources have mechanisms to correct such discrepancies based on market research of currently available international drug pricing information data sources. Further, as codified in § 513.140(c), the international drug pricing information data sources that we will obtain will have mechanisms in place to maintain, update, and correct, if necessary, the information on international drug pricing in the database on at least a quarterly basis. As such, because we will revise the MFN Drug Payment Amounts quarterly, we will recalculate the MFN Drug Payment Amounts for up to four prior quarters when revised international drug pricing information is available in the data source that we used to calculate the MFN Model drug's MFN Price for the relevant quarter or ASP updates for the relevant quarter are available.[46] In cases where an MFN Drug Payment Amount for a prior quarter is recalculated by CMS, CMS will prospectively apply the recalculations in the quarterly update following the availability of revised international drug pricing information and ASP updates, and will not automatically reprocess claims to apply the recalculation, but reserves the right to do so. To the extent that MFN Model claims are reprocessed due to revisions to the international drug pricing information, the Medicare payment amount and beneficiary cost sharing will be recalculated to reflect the revised prices. If prior to calculating the unadjusted-country level prices for a quarter, the data source confirms that there is an error that they plan to correct in a future version of the dataset and we have the corrected information, we will make the correction to avoid the need to reprocess claims later. Therefore, we do not believe it is necessary to take further steps to trim or remove potential outlier or erroneous international drug pricing information before calculating the unadjusted country-level prices. We note that CMS does not make outlier adjustments to ASP data.

In addition, for future years, we seek comment on whether a threshold should be applied to determine whether the MFN Drug Payment Amount should be recalculated for a prior quarter. Specifically, we are interested in comments on whether recalculations should only occur when the international drug pricing information data source used corrects its data and the impact on the MFN Price is more than a nominal amount. We seek comment on the appropriate amount of such threshold and how a nominal amount should be defined. Finally, in the event that the international drug pricing information data source that we used to calculate the MFN Drug Payment Amount for an MFN Model drug for a quarter identifies an error in their data and does not correct such error within 180 days after the applicable ASP calendar quarter, we seek comment on whether CMS should recalculate the MFN Drug Payment Amount for such MFN Model drug and quarter using international drug pricing information in accordance with the hierarchy in § 513.140(c)(3) after excluding the data source we initially used. We also seek comment on whether CMS should adopt an alternative approach to remediating such data errors.

2. International Data Included in the MFN Model

In the October 2018 ANPRM, for purposes of a potential IPI Model, we stated that we were considering using pricing data from the following countries: Austria, Belgium, Canada, Czechia, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom. We considered including these countries' data as they are either economies comparable to the U.S. or they are included in Germany's market basket for reference pricing for their drug prices, and existing data sources contain pricing information for these countries. We received wide-ranging and helpful feedback in response to the October 2018 ANPRM regarding which countries' data to include in a model. In addition to comments received to the October 2018 ANPRM, we also conducted significant outreach to stakeholders, such as stakeholder meetings and conference calls, to gather targeted feedback. There was also a substantial number of media and press reports surrounding which countries' data to include in the MFN Model.

Generally, we received a significant number of comments that expressed opposition to including data from countries that have health care systems that are substantially dissimilar to the U.S.'s health care system. Specifically, many commenters stated that data from countries utilizing government-run health care systems or imposing strict drug price controls should be excluded. Alternatively, other commenters noted that CMS should consider broadening the scope to include more countries, because the more countries that are included in the index, the harder it would be for pharmaceutical companies to manipulate or game the pricing changes. Commenters also recommended utilizing various criteria for selecting the countries that would be included, such as the launching speed of new drugs, the presence of rigorous health technology assessment, the proportions of public and private markets, the economies of those countries, and Human Development Index (HDI).[47]

Based on the comments received, we believe the most appropriate criteria for considering a country for MFN pricing is membership in the OECD and GDP per capita relative to the U.S. The current list of OECD countries includes all countries included in the October 2018 ANPRM as well as Australia, Chile, Colombia, Estonia, Hungary, Iceland, Israel, Latvia, Lithuania, Luxembourg, New Zealand, Norway, Poland, Portugal, Republic of Korea, Slovakia, Slovenia, Spain, Switzerland, and Turkey. OECD countries comprise a set of countries that share with the U.S. democratic principles and commitment to market-based economies, and these countries' GDP per capita (based on purchasing power parity) range from

[46] We will apply the recalculations in the quarterly update following the availability of revised international drug pricing information and ASP updates.

[47] The Human Development Index is utilized by the United Nations and is ''is a summary measure of average achievement in key dimensions of human development: a long and healthy life, being knowledgeable and have a decent standard of living. The HDI is the geometric mean of normalized indices for each of the three dimensions.'' Please see the United Nations Development Programme's Human Development Reports for more information: *http://hdr.undp.org/en/content/human-development-index-hdi.*

approximately 25 percent of the U.S. GDP per capita to over 175 percent of the U.S. GDP per capita. Based on this wide range of GDP per capita data, we believe it is most appropriate to include available international drug pricing information for countries with a GDP per capita of at least 60 percent of the U.S. GDP per capita, as codified in § 513.140(b). We believe that applying a minimum of 60 percent of the U.S. GDP per capita strikes a balance between—(1) having too low a GDP per capita threshold and including data from countries with economies that are substantially different from the U.S., while; (2) also not having such a high GDP per capita threshold that the list of countries would be very short, which commenters suggested we should avoid. To avoid creating a potential incentive for countries to discontinue their membership in the OECD, we will include available international drug pricing information for countries that were OECD members as of October 1, 2020, regardless of whether they remain OECD members after October 1, 2020, unless the country's GDP per capita, as determined by CMS quarterly, falls below the threshold of 60 percent of the U.S. GDP per capita. Based on available data, this means that we will calculate the MFN Price for the first quarter of performance year 1 based on available international drug pricing information from Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the United Kingdom.[48] These 22 OECD countries are among the countries with the highest GDP per capita worldwide.[49]

We considered alternative approaches to including data from countries for the MFN Model. Specifically, we considered including all non-U.S. OECD countries or selecting countries based on factors such as World Health Organization (WHO) recognition as a Stringent Regulatory Authority (SRA) and intellectual property protections. We also considered including data from only countries that may represent large markets for drug manufacturers such as the European Union, Canada, Japan, and United Kingdom. Additionally, the Foundation for Research on Equal Opportunity (FREOPP) recommended an alternative approach called the Market-Based International Index (MBII) as a benchmark for evaluating other countries' prescription drug pricing systems;[50] this approach would include data from the following countries that FREOPP identified as having market-based health care systems: Austria, Belgium, Czechia, Denmark, France, Germany, Ireland, Japan, Netherlands, Portugal, Singapore, Slovakia, and Switzerland.

Based on analyses examining potential alternatives, we believe that none of these alternative approaches would be as objective and predictable for purposes of calculating MFN Prices as our approach. Our approach will result in a large set of countries that are economically similar, have reasonably comparable purchasing power to the U.S., and generally have existing international drug pricing information that is available. We considered an alternative that would phase-in countries over time based on a defined set of characteristics, such GDP per capita or average drug prices. We believe that phasing in countries over time would create instability in the MFN Price. Thus we are adopting a set of included countries that meet the requirements in § 513.140(b), which allows for the inclusion of data from countries that were non-U.S. OECD member countries as of October 1, 2020, when CMS calculates the MFN Drug Payment Amounts for a calendar quarter. That means that at the end of each applicable ASP calendar quarter, CMS will assess the non-U.S. OECD member countries as of October 1, 2020, that have a GDP per capita that is at least 60 percent of the U.S. GDP per capita. Because available GDP data are updated infrequently, we believe this approach will result in a highly stable process for developing the MFN Prices.

We will include available international drug pricing information from the included countries when such data are contained in the data sources that we have described in § 513.140(c), as described in section III.E.1. of this IFC.

There are several existing sources for GDP data, including the Central Intelligence Agency (CIA) World Factbook,[51] the World Bank,[52] and the International Monetary Fund.[53] Upon examining these sources, we noted that the GDP data across these sources are highly associated with one another. We will use the CIA World Factbook as our source for GDP data as it is issued by a U.S. government agency and includes estimates for all OECD member countries. We will use the following process to determine the countries that were non-U.S. OECD member countries as of October 1, 2020, with a GDP per capita that is at least 60 percent of the U.S. GDP per capita. For each country, we will assess the GDP per capita based on purchasing power parity that is available in the CIA World Factbook at the end of the applicable ASP calendar quarter. The CIA World Factbook contains the most recent estimate of GDP per capita based on purchasing power parity for a country as well as historical data. We will identify whether a country has a GDP per capita that is at least 60 percent of the U.S. GDP per capita by dividing the most recent estimate of GDP per capita based on purchasing power parity for a country by the U.S. GDP per capita, using data for the same year, and assessing the results. We will use the GDP per capita from the same year as the international drug pricing information that is used to calculate the unadjusted country-level price, if available, or the most recent prior year.

3. Definition of the MFN Drug Payment Amount

As described later in this section, we will calculate the MFN Drug Payment Amount for a calendar quarter for the MFN Model drug based on a phased-in blend of the applicable ASP and the MFN Price, which we will determine by selecting the lowest GDP-adjusted country-level price from the included countries for the applicable ASP calendar quarter.

4. Calculation of the MFN Drug Payment Amounts

We will calculate an MFN Drug Payment Amount for each MFN Model drug for which there is international drug pricing information from at least one data source that meets our criteria for at least one included country. Section III.E.6. of this IFC describes an alternative approach for calculating the MFN Drug Payment Amount for situations where no international drug

[48] The non-U.S. OECD countries that will not be an included country for purposes of calculating the MFN Price for MFN Model drugs for the first quarter of performance year 1 will be Chile, Colombia, Czechia, Estonia, Greece, Hungary, Latvia, Lithuania, Mexico, Poland, Portugal, Slovakia, Slovenia, and Turkey.

[49] *https://www.cia.gov/library/publications/the-world-factbook/fields/211rank.html.*

[50] Roy, A. (2018) The Foundation for Research on Equal Opportunity, ''What Medicare Can Learn From Other Countries on Drug Pricing,'' accessed via *https://freopp.org/what-medicare-can-learn-from-other-countries-on-drug-pricing-bf298d390bc5.*

[51] *https://www.cia.gov/library/publications/the-world-factbook/fields/211rank.html.*

[52] *https://data.worldbank.org/indicator/ny.gdp.mktp.cd.*

[53] *https://www.imf.org/external/pubs/ft/weo/2019/01/weodata/weoselgr.aspx.*

pricing information is available for an MFN Model drug, for example, because the MFN Model drug is not approved for marketing by any included country.

When using international drug pricing information to calculate the MFN Drug Payment Amounts, we want to account for the relative economic resources of non-U.S. countries to be able to fairly compare country-level prices. We will address relative economic resources in two ways: (1) We will only use available international drug pricing information from non-U.S. OECD member countries with a GDP per capita that is at least 60 percent of the U.S. GDP per capita; and (2) we will adjust the extracted country-level prices using a GDP adjuster that adjusts for a country's GDP per capita if it is lower than that of the U.S.

Specifically, to calculate the MFN Drug Payment Amounts for a calendar quarter in a performance year, we will follow a multi-step process using the corresponding quarterly ASP pricing file, as well as the available international drug pricing information for included countries for the applicable ASP calendar quarter, where available. The key steps to calculate the MFN Drug Payment Amount for each MFN Model drug will be—

- Identify the available international drug pricing information for the MFN Model drug (by applying the hierarchy of data sources obtained by CMS and extracting the relevant data); [54]
- Remove incomplete and low sales and volume data, as applicable;
- Convert extracted volume data to the HCPCS code unit level and adjust for volume issues such as intentional overfill, as applicable;
- Calculate [55] the unadjusted country-level price (representing the average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit) for the MFN Model drug for each included country with available data in the selected data source for that drug;
- Calculate the GDP adjuster for each included country;
- Apply the GDP adjuster to the unadjusted country-level price;
- Select the lowest GDP-adjusted country-level price for each MFN Model drug, which, if available, will be the MFN Price;
- Identify the applicable ASP (which we define as the payment amount determined in accordance with 1847A of the Act, less the applicable add-on percentage, for the MFN Model drug's HCPCS code); [56]
- Compare the MFN Price to the applicable ASP (to apply limit, if applicable);
- Identify the applicable phase-in formula and adjustments; and
- Apply the applicable phase-in formula and adjustments, if applicable, to calculate the MFN Drug Payment Amount.

The following paragraphs further describe how we will calculate the MFN Model Drug Payment Amounts for each MFN Model drug for each calendar quarter during the model:

a. Identify the Available International Drug Pricing Information for the MFN Model Drug

Using the data sources that we obtain and applying the hierarchy described previously in this IFC, we will extract the available international drug pricing information for an MFN Model drug for the applicable time period (that is, the applicable ASP calendar quarter) by aligning the MFN Model drug's HCPCS code long description (in terms of name and dosage form) with the data sources' standard method for identifying scientific names or nonproprietary names (such as the International Nonproprietary Names). That is, for an MFN Model drug, we will identify the data sources' standardized scientific name or nonproprietary name for that drug, and then use that naming to identify data for all products within that data source with an applicable formulation. We will extract the applicable data (for example, data for all package sizes for injectable forms of the drug aligned with the identified scientific or nonproprietary name and formulations, for the included countries) from the data source for the applicable ASP calendar quarter, and in accordance with our hierarchy, select the data source for the MFN Model drug for that quarter.

As previously discussed in this IFC, we will only use extracted data from the selected data source that appears complete and represent dosage formulations that could be described by the MFN Model drug's HCPCS code descriptor, as determined by CMS. For example, J0178, Aflibercept injection, represents injectable ophthalmic formulations whereas a data source may contain data for aflibercept for both ophthalmic and systemic formulations; only data for ophthalmic formulations will be used to calculate the MFN Price for such drug. The international drug pricing data used to calculate the MFN Price will not be limited to distinguish between products with different inactive ingredients (for example, different excipients) or whether or not the product is protein bound. However, we will limit the international drug pricing data for combination drugs that contain multiple active ingredients or biological products to the extent feasible, as determined by CMS. This approach is particularly relevant for four of the MFN Model drugs for performance year 1, aflibercept injection (J0178), which represents ophthalmic formulations compared to systemic formulations; paclitaxel protein bound (J9264), which represents protein bound formulations compared to formulations of paclitaxel that are not protein bound; ferric carboxymaltos (J1439), which represents injected formulations compared to oral formulations; and rituximab, hyaluronidase (J9311), which represents formulations for subcutaneous administration compared to formulations of rituximab for intravenous administration.

In accordance with the hierarchy for selecting international drug pricing information data sources, we will prioritize use of international drug pricing information that includes sales and volume data for the applicable ASP calendar quarter if such information is available for a drug for one or more included countries. If more than one such data source is available, we will select the data source with international drug pricing information for the applicable ASP calendar quarter, even if another data source includes a higher number of included countries. For example, if the applicable ASP calendar quarter is the third quarter of 2021 and an available data source has sales and volume data for a drug for 20 of the included countries for the second quarter of 2021 and for 15 included countries for the third quarter of 2021, we would extract and then calculate unadjusted country-level prices for that drug based on sales and volume data

[54] Applicable subsequent steps depend upon the level of the hierarchy for the selected data source. For example, when there are no international sales and volume data available for the drug for an applicable ASP calendar quarter or from any quarter beginning on or after October 1, 2019, in accordance with level 3 of the hierarchy, we will use the extracted data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website, including the data used by CMS to create the illustrative MFN Prices and MFN Drug Payment Amounts in Table 6 of this IFC. In such case, it will not be necessary to redo steps to extract data from the data source; however, CMS will follow the remaining steps in the MFN Drug Payment Amount calculation.

[55] The calculation used depends upon whether volume data is available.

[56] In general, the ASP Pricing File contains payment limits based on 106 percent of the volume weighted average of manufacturers' ASP for a given HCPCS code. To identify the applicable ASP, we will divide the payment limit by 1.06 after removing the blood clotting factor furnishing fee, if applicable. For a biosimilar, we will remove the amount that represents 6 percent of the reference biological product's ASP.

from the third quarter of 2021 only for the 15 included countries for which data from that quarter are available.

If there are available data from a data source at the second level of our hierarchy (that is, no international sales and volume data for the applicable ASP calendar quarter, but sales and volume data from any quarter beginning on or after October 1, 2019), for a drug, we will use available international sales and volume data from that data source for the most recent prior quarter that begins on or after October 1, 2019 for that drug for included countries.

If there are no international sales and volume data available for the drug, we will use the extracted data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website, in accordance with the third level of the hierarchy.

If no MFN Drug Payment Amount has been publicly posted for the drug, we will use a data source at the fourth level of our hierarchy if available (the data source contains ex-manufacturer price data but does not include volume data for the applicable ASP calendar quarter).

If ex-manufacturer price data for the applicable ASP calendar quarter are not available, we will use a data source at the fifth level of our hierarchy (the data source contains list price data for the applicable ASP calendar quarter).

b. Remove Incomplete Low Sales and Volume Data, as Applicable

If the data source we select has sales and volume data at the package level for an included country, we will apply the exclusions for data with incomplete data and low sales and volume. That is, we will exclude data without both sales and volume data, with less than $1,000 in quarterly sales (expressed as U.S. currency), or with less than 1,000 units in quarterly volume.

c. Convert the Extracted Volume Data to the HCPCS Code Unit Level and Adjust for Volume Issues, Such as Intentional Overfill, as Applicable

We will adjust the remaining volume data to the same level as the HCPCS billing unit, as applicable. For example, if the data for a package size shows the volume is 1,000 units and each unit represents a 1 MG vial package and for another package size the volume is 500 units and each unit represents a 10 MG vial package, and both of these data are for a drug assigned to the same HCPCS code with a HCPCS billing unit of 1 MG, the adjusted volume data for these packages would be 1,000 units and 5,000 units, respectively, for a total adjusted volume of 6,000 units. The volume for the 1 MG vial package is unchanged because the amount of drug in one package (that is, 1 MG) equals the amount of drug in one HCPCS billing unit. The volume for the 10 MG vial package is changed to be 10 times higher because the amount of drug in one vial (that is, 10 MG) equals 10 times the amount of drug in one HCPCS billing unit.

Before this step is performed, as applicable, we will adjust the extracted volume information before converting it to the HCPCS billing unit level when the data source shows the package size of a drug product that is inconsistent with the manufacturer's information about that product based on the available product information, such as package labeling, compared to the data extracted from the data source. In addition, we will limit the number of billing units in a package when the available package labeling specifies use of a limited amount of drug is to be used from the package. For example, we will limit the number of billing units in a package for an aflibercept vial to one 2 mg dose in accordance with available package labeling, which specifies that each vial, regardless of the labeled volume, has one 2 mg dose. For injectable formulations for HCPCS codes with dosage specified as per dose, we will limit the number of billing units in a package to no more than one per vial. This approach was applied to illustrate the MFN Prices for J7324 (Orthovisc inj per dose) in Table 6.

d. Calculate the Unadjusted Country-Level Price for the MFN Model Drug's HCPCS Code for Each Included Country With Available Data in the Selected Data Source for That Drug

Using the data available after completing the prior steps, we will calculate the unadjusted country-level price for each included country with available data. The unadjusted country-level price represents the average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit.

We will use a calculation that is applicable to the data available at this step. If volume data are available, we will use a calculation that includes volume-weighting across the different data (which often represent different package sizes) of the drug included in the data source for the country to calculate the unadjusted country-level price. If volume data are not available, we will use a calculation that treats all packages of the drug included in the data source for the country equally, after converting the pricing data to the HCPCS code unit level, in calculating the unadjusted country-level price.

If sales and volume data are available, we will first sum the adjusted volume data for all package sizes for the drug. We will then sum the total sales for all package sizes for the drug, and divide that sum by the sum the adjusted volume data for all package sizes for the drug, resulting in an average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit. If the data source we select has ex-manufacturer or list prices and does not have volume data, we will calculate the number of HCPCS billing units in a package and divide the ex-manufacturer price or list price for a package by the number of HCPCS billing units in the package, resulting in a price per unit of drug for each package listed in the data source. We will then sum the price per unit of drug for each package listed in the data source for the drug and divide the sum by the number of packages listed in the data source for the drug, resulting in an average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit.

We will repeat this process for each country specified in § 513.140(b), to the extent international drug pricing information for the drug for the country is available from the selected data source. As explained previously and specified in § 513.140(c)(3)(i), we will use the highest tier data source, in accordance with the hierarchy, which includes data for the drug in at least one included country. If the selected data source for a drug for a calendar quarter does not include data from a particular included country, we will still calculate the MFN Price for that drug using the data from the selected data source based on the included countries from which there are data for the drug. We will not include any information from countries that did not have data in the selected data source for that drug. In cases where there is no data source that meets our criteria for using international drug pricing information (that is, there are no international sales, volume, or other pricing data available from any of the included countries in our international drug pricing information data sources, including data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website, for an MFN Model drug for any quarter beginning on or after October 1, 2019 up to and including the model performance period, we will not calculate an unadjusted country-level price (or GDP-adjusted country-level price) and will instead use the applicable ASP (which we will define as

the payment amount determined in accordance with section 1847A of the Act minus the applicable add-on percentage, for the MFN Model drug's HCPCS code) as the MFN Model Drug Payment Amount, as described in section III.E.6. of this IFC.

e. Calculate the GDP Adjuster for Each Included Country

As discussed previously, we want the MFN Price to account for the relative economic resources and purchasing power for each included country to be able to fairly compare country-level prices. As such, we will calculate a GDP adjuster, using a country's GDP per capita based on purchasing power parity, that will be used to adjust the unadjusted country-level price for each drug (whether based on international sales and volume data or international ex-manufacturer or list prices) to reflect the country's economic resources relative to the U.S. We believe that GDP per capita based on purchasing power parity represents a broadly used and reliable measure of a country's economic resources to ensure a meaningful comparison of country-level prices.

As previously mentioned, there are several existing sources for GDP data, including the CIA World Factbook,[57] the World Bank,[58] and the International Monetary Fund.[59] Our analyses suggest that the GDP data across these sources are highly associated with one another. We will use the CIA World Factbook as our source for GDP data as it is issued by a U.S. government agency and includes estimates for all current OECD member countries. The GDP adjuster will be based on the GDP per capita available from the CIA World Factbook at the end of the applicable ASP calendar quarter. We will use the most recent GDP per capita data available for each included country and the U.S. GDP per capita from the same year as the GDP per capita data that is available from the included country. For example, if the most recent GDP per capita from the comparison OECD country is from 2016 and the most recent U.S. GDP per capita is 2017, then we will use the GDP per capita from 2016 for both countries when comparing. In cases where we use international drug pricing information from a quarter other than the applicable ASP calendar quarter (that is, an earlier time period) to determine the unadjusted country-level price, we will use the GDP per capita data for that time period, if available, or the most recent earlier data available. That is, CMS will use the GDP per capita for the same year as the data used to calculate the unadjusted country-level price, if available, or the most recent earlier year available.

To create a simple, easily understandable GDP adjuster, each country's GDP adjuster will be a straight ratio of its GDP per capita based on purchasing power parity divided by U.S. GDP per capita, subject to the limitation described later in this section. The U.S. GDP per capita for 2017, the most current data available, was $59,800. Table 4 presents GDP per capita for 2017 and the GDP adjusters for each non-U.S. OECD member country, based on the U.S. GDP per capita of $59,800 for 2017, that we will use to calculate the MFN Drug Payment Amounts for performance year 1, quarter 1. In cases when an included country's GDP per capita and the U.S. GDP per capita are not updated in the CIA World Factbook at the same time, we will use the most recent GDP per capita for the included country and the U.S. GDP per capita from the same year to ensure that the GDP adjuster for an included country is calculated using GDP data from both countries from the same time period. For example, if at the end of an applicable calendar quarter a 2018 estimate of a country's GDP per capita based on purchasing power parity becomes available in the CIA World Factbook but the most recent U.S. GDP per capita available in the CIA World Factbook continues to be for 2017, we will continue to use data from 2017 for both countries to calculate the GDP adjuster for that country.

The GDP adjuster will be capped at 1 such that the adjuster will only increase the unadjusted country-level price for a drug; it will not decrease it. We will cap the GDP adjuster at 1 because its purpose is to adjust for countries' economic resources when lower than those of the U.S. Capping the GDP adjuster at 1 will ensure that we do not make an adjustment that would result in an amount that would be lower than the unadjusted country-level price. For example, if Country X with a higher GDP per capita based on purchasing power parity than the U.S., such as a GDP per capita ratio of 2, has an unadjusted country-level price of $100 for an MFN Model drug, we would use a GDP adjuster of 1.0 and calculate a GDP-adjusted country-level price of $100 rather than using a GDP adjuster of 2.0 and calculating a GDP-adjusted country-level price of $50.

TABLE 4—NON-U.S. OECD MEMBER COUNTRY GDP PER CAPITA (BASED ON PURCHASING POWER PARITY) AND GDP ADJUSTERS FOR PERFORMANCE YEAR 1, QUARTER 1

OECD countries	CIA GDP per capita, based on purchasing power parity (2017)	GDP adjuster for performance year 1, quarter 1
The following countries have a GDP per capita of at least 60 percent of U.S. GDP per capita:†		
Australia	$50,400	0.843
Austria *	50,000	0.836
Belgium *	46,600	0.779
Canada *	48,400	0.809
Denmark *	50,100	0.838
Finland *	44,500	0.744
France *	44,100	0.737
Germany *	50,800	0.849
Iceland	52,200	0.873
Ireland *	73,200	** 1.000
Israel	36,400	0.609

[57] *https://www.cia.gov/library/publications/the-world-factbook/fields/211rank.html.*

[58] *https://data.worldbank.org/indicator/ny.gdp.mktp.cd.*

[59] *https://www.imf.org/external/pubs/ft/weo/2019/01/weodata/weoselgr.aspx.*

TABLE 4—NON-U.S. OECD MEMBER COUNTRY GDP PER CAPITA (BASED ON PURCHASING POWER PARITY) AND GDP ADJUSTERS FOR PERFORMANCE YEAR 1, QUARTER 1—Continued

OECD countries	CIA GDP per capita, based on purchasing power parity (2017)	GDP adjuster for performance year 1, quarter 1
Italy *	38,200	0.639
Japan *	42,900	0.717
Republic of Korea	39,500	0.661
Luxembourg	105,100	** 1.000
Netherlands *	53,900	0.901
New Zealand	39,000	0.652
Norway	72,100	** 1.000
Spain	38,400	0.642
Sweden	51,200	0.856
Switzerland	62,100	** 1.000
United Kingdom *	44,300	0.741
The following countries have a GDP per capita below 60 percent of U.S. GDP per capita:		
Chile	24,600	0.411
Colombia	14,400	0.241
Czechia *	35,500	0.594
Estonia	31,700	0.530
Greece *	27,800	0.465
Hungary	29,600	0.495
Latvia	27,700	0.463
Lithuania	32,400	0.542
Mexico	19,900	0.333
Poland	29,600	0.495
Portugal	30,500	0.510
Slovakia	33,100	0.554
Slovenia	34,500	0.577
Turkey	27,000	0.452

* Indicates countries that were listed as potential included countries in the October 2018 ANPRM (83 FR 54557).
** Indicates that the GDP adjuster is capped at 1.000.
† The 2017 U.S. GDP per capita is $59,800.

f. Apply the Applicable GDP Adjuster To Calculate the GDP-Adjusted Country-Level Price for the MFN Model Drug

Next, we will apply the country-specific GDP adjuster to the unadjusted country-level price for that country by dividing the unadjusted country-level price by the country's GDP adjuster. The result will be the GDP-adjusted country-level price for the MFN Model drug for that country. We will repeat this calculation to produce a GDP-Adjusted Price for every country for which we have calculated an unadjusted country-level price for the MFN Model drug.

g. Identify the Lowest GDP-Adjusted Country-Level Price for the MFN Model Drug

We will examine the GDP-adjusted country-level prices for the MFN Model drug, and identify the lowest GDP-adjusted country-level price for the MFN Model drug. The lowest GDP-adjusted country-level price will be the MFN Price for the MFN Model drug.

h. Compare the MFN Price to the Applicable ASP

As a safeguard for beneficiaries, we will compare the MFN Price to the applicable ASP in order to ensure that beneficiaries are always paying the lowest amount of coinsurance available. If the applicable ASP is less than the MFN Price, we will establish the MFN Price as equal to the applicable ASP.

i. Identify the Applicable Phase-In Formula and Adjustments

As described in section III.E.5. of this IFC, we will phase-in the use of the MFN Price over the course of the MFN Model. As discussed in section III.E.9. of this IFC, we will also accelerate the applicable phase-in formula when the applicable ASP for an MFN Model drug rises faster than both a designated inflation factor and the change in MFN Price, and lower the MFN Drug Payment Amount below the MFN Price by a certain percentage if the applicable ASP for an MFN Model drug continues to increase faster than the inflation factor and the MFN Price after the full phase-in of the MFN Price. In this step of the process to calculate the MFN Drug Payment Amount, we will determine the applicable phase-in formula and whether any of these adjustments will apply.

j. Calculate the MFN Drug Payment Amount

As the last step, we will calculate the MFN Drug Payment Amount for the MFN Model drug using the applicable phase-in formula, which blends the applicable ASP and the MFN Price as described in section III.E.5. of this IFC. This calculation, including any adjustments that apply, will result in the MFN Drug Payment Amount for the MFN Model drug (except as otherwise specified).

5. Phase-In of the MFN Price

We will use a phase-in approach that will blend the MFN Price with the applicable ASP to allow MFN participants time to adjust to the model payment amounts and processes. The phase-in formula will be stable for a given performance year, whereas the MFN Price and applicable ASP will vary quarterly based on fluctuations in drug

prices in the U.S. and in included countries. We will phase-in the MFN Price by 25 percent per year for performance years 1 to 3 of the model, reaching 100 percent of the MFN Price for performance years 4 through 7 of the model. The phase-in formula uses a blend of the applicable ASP and MFN Price for an MFN Model drug as shown in Table 5. The MFN Drug Payment Amount will be based on 100 percent of the MFN Price starting in performance year 4, unless an adjustment that accelerates the phase-in applies as described in section III.E.9. of this IFC. Thus, the phase-in represents the outer bound in terms of the amount of time it will take for the MFN Drug Payment Amount to transition to 100 percent of the MFN Price.

We believe that a phase-in approach during the initial years of the model will enable MFN participants and the markets to adjust to the model's payment methodology, while enabling CMS to test the full phase-in of the MFN Price over a 7-year model performance period. As noted in section III.E.11. of this IFC, when MFN Model drugs get added to the MFN Model Drug HCPCS Codes List during the model performance period, their MFN Drug Payment Amount gets determined as set forth for the corresponding performance year, meaning that if an MFN Model drug were to be added during performance year 4, the MFN Drug Payment Amount will equal 100 percent of the MFN Price.

TABLE 5—PHASE-IN OF MFN PRICES BY PERFORMANCE YEAR

Performance year	Blend of the ASP and MFN price for an MFN model drug at the HCPCS code level
Year 1	75 percent applicable ASP and 25 percent MFN Price.
Year 2	50 percent applicable ASP and 50 percent MFN Price.
Year 3	25 percent applicable ASP and 75 percent MFN Price.
Year 4	100 percent MFN Price.
Year 5	100 percent MFN Price.
Year 6	100 percent MFN Price.
Year 7	100 percent MFN Price.

We are codifying the phase-in formula in § 513.210(b)(8).

6. Alternative Calculation for the MFN Drug Payment Amount

Over the course of the MFN Model, we may determine that the international drug pricing information data sources that we obtain do not contain any international drug pricing information (meaning no sales, volume, ex-manufacturer price, or list price data from any included country from any quarter beginning in the fourth calendar quarter of 2018 through the applicable quarter in the model performance period) for an MFN Model drug, for example, because the MFN Model drug is not approved for marketing in the included countries. For such cases, we will establish the MFN Drug Payment Amount at the applicable ASP for the applicable calendar quarter, subject to any adjustment in § 513.210(d) that applies, until international drug pricing information is available.

Because international drug pricing information may become available for a subsequent calendar quarter, we will use this method to establish the MFN Drug Payment Amount instead of excluding or removing drugs without any international drug pricing information from the model until international drug pricing information becomes available. We believe having a stable list of MFN Model drugs will be more predictable for MFN participants, lessening MFN participants' need to monitor changes to the MFN Model Drug HCPCS Codes List, and will avoid creating an opportunity for manufacturers to get their products out of the model by stopping the reporting of international drug pricing information. Based on our experience with international drug pricing information data sources, we expect the potential of no international drug pricing information for an MFN Model drug across all included countries will be limited. We note that our approach may increase model payments compared to non-model payments for MFN Model drugs with no international drug pricing information because the alternative add-on payment, a single flat add-on amount per dose (see section III.F. of this IFC), could be greater than the add-on payment outside of the model.

7. Illustrative MFN Drug Payment Amounts

To illustrate how CMS will calculate the MFN Drug Payment Amounts under the MFN Model in accordance with §§ 513.130 and 513.140, we applied the methodology for determining the applicable ASPs, MFN Prices, and MFN Drug Payment Amounts using historical ASP-based payment limits,[60] available international drug pricing information from 2019 for the included countries, and the MFN Model performance year 1 phase-in formula. Table 6 shows illustrative data for applicable ASPs, MFN Prices, and MFN Drug Payment Amounts for one billing unit for the HCPCS codes that are included on the performance year 1 MFN Model Drug HCPCS Codes List in Table 2. Actual MFN Drug Payment Amounts per billing unit for performance year 1, quarter 1, and thereafter will be calculated as specified in § 513.210. We will publish the quarterly MFN Drug Payment Amounts on a CMS website (such as the MFN Model website), similar to how the ASP Drug Pricing Files are posted online prior to the start of the calendar quarter. The performance year 1, quarter 1 MFN Drug Payment Amounts will be published on a CMS website before the start of the MFN Model.

Illustrative MFN Drug Payment Amounts per billing unit are listed in Table 6 by HCPCS code. For this illustration, we partnered with ASPE, which purchases licenses to data products maintained by IQVIA™ (formerly known as Quintiles-IMS). IQVIA's proprietary MIDAS data set[61] is a widely used source of drug sales and volume data.

[60] We used the 2019 Quarter 3 and Quarter 4 and 2020 Quarter 1 and Quarter 2 ASP data that align with manufacturer-reported data based on sales during 2019 to identify the applicable ASPs. The ASP pricing files are posted at links available here: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

[61] *https://www.iqvia.com/solutions/commercialization/brand-strategy-and-management/market-measurement/Midas.*

MIDAS data contain estimates of drug sales (called ''Monetary Value '' within the MIDAS data set) and volume (called ''Quantity'' within the MIDAS data set) that are based on audits of drug transactions in different countries and distribution channels (for example, retail pharmacies and hospitals). The audits underlying the MIDAS data collect sales and volume information at the ex-manufacturer (that is, prices as drugs are sold by manufacturers), ex-wholesaler, and/or retail levels. IQVIA applies a set of country- and channel-specific assumptions on markups between manufacturer, wholesale, and retail prices to estimate ex-manufacturer and retail sales. Sales information within the database is stated in local and U.S. currency, as of the transaction date or current date, and are expressed as ex-manufacturer, trade, and public (retail) sales.[62] MIDAS uses a variable called ''Molecule List'' (also called ''Moleculelist'') which identifies scientific and nonproprietary names for drug and biological products. Users extract data from the MIDAS database by selecting report filters, which are values for various data fields included in the database, such as ''Molecule List'' and ''NFC123'' (or ''New Form Code,'' a 3-digit code which identifies the dosage form[63]). The database has a standard method for identifying drugs within the U.S. and across countries, and a standard method for identifying drug forms. MIDAS data is updated monthly and retains up to 12 years of history.

CMS obtained a MIDAS data extract of available 2019 international drug pricing information for the included countries for the MFN Model drugs for performance year 1 from ASPE. After identifying the MFN Price for each drug, we applied the phase-in formula for performance year 1 (75 percent of the applicable ASP and 25 percent of the MFN Price) and applied the exceptions in § 513.210(d) when no international drug pricing information was available in the MIDAS data. In Table 6, the illustrative MFN Prices, calculated using available international drug pricing sales and volume information at the ex-manufacturer level, represent the lowest of the GDP-adjusted country-level prices available in the single data source we used. For a complete discussion of how CMS used international drug pricing information available through IQVIA and CMS data to calculate the illustrative applicable ASPs, MFN Prices, and MFN Drug Payment Amounts displayed in Table 6, we refer readers to the supplemental documentation available on the MFN Model website.[64] We also refer readers to the Medicare Part B Drug Spending Dash board[65] that can be used to search for brand name or generic name; search results present certain manufacturer information when available.

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[62] Ex-manufacturer sales are: Manufacturer Selling Price or Wholesaler Purchasing Price or Price to Wholesaler (PTW). Trade sales are: Wholesaler Selling Price or Pharmacy Purchase Price or Price to Chemist (PTC). Public (retail) sales are: Pharmacy Selling Price or Consumer Purchase Price or Price to the Public (PTP).

[63] For more information on the New Form Codes see: *https://www.ephmra.org/classification/new-form-codes/.*

[64] See: *https://innovation.cms.gov/initiatives/most-favored-nation-model/.*

[65] See: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB.*

TABLE 6. ILLUSTRATIVE MFN DRUG PAYMENT AMOUNTS PER BILLING UNIT

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
J0129	Abatacept injection	10 MG	Q1	$ 50.891	$ 12.977	$ 41.412	Australia
			Q2	$ 51.243	$ 12.821	$ 41.638	Australia
			Q3	$ 51.744	$ 12.862	$ 42.024	Australia
			Q4	$ 51.965	$ 12.883	$ 42.195	Australia
J0178****	Aflibercept injection	1 MG	Q1	$ 903.173	$ 399.359	$ 777.219	Norway
			Q2	$ 898.559	$ 396.237	$ 772.979	Norway
			Q3	$ 891.537	$ 386.957	$ 765.392	Norway
			Q4	$ 885.324	$ 376.125	$ 758.024	Norway
J0517	Inj., benralizumab, 1 mg	1 MG	Q1	$ 159.283	$ 102.884	$ 145.183	Germany
			Q2	$ 158.964	$ 91.677	$ 142.142	Germany
			Q3	$ 160.841	$ 88.523	$ 142.761	Australia
			Q4	$ 160.470	$ 88.221	$ 142.408	Australia
J0585	Injection,onabotulinumtoxina	1 UNIT	Q1	$ 5.777	$ 1.112	$ 4.611	United Kingdom
			Q2	$ 5.776	$ 0.466	$ 4.449	Ireland
			Q3	$ 5.775	$ 0.461	$ 4.447	Ireland
			Q4	$ 5.764	$ 0.459	$ 4.438	Ireland
J0717	Certolizumab pegol inj 1mg	1 MG	Q1	$ 7.672	$ 1.917	$ 6.233	Australia
			Q2	$ 7.569	$ 1.884	$ 6.148	Australia
			Q3	$ 7.742	$ 1.845	$ 6.268	Australia
			Q4	$ 7.535	$ 1.839	$ 6.111	Australia
J0881	Darbepoetin alfa, non-esrd	1 MCG	Q1	$ 3.610	$ 0.825	$ 2.914	Republic of Korea
			Q2	$ 3.634	$ 0.635	$ 2.884	Republic of Korea
			Q3	$ 3.604	$ 0.618	$ 2.857	Republic of Korea
			Q4	$ 3.462	$ 0.627	$ 2.753	Republic of Korea
J0885	Epoetin alfa, non-esrd	1000 UNITS	Q1	$ 10.813	$ 3.093	$ 8.883	Republic of Korea
			Q2	$ 10.407	$ 2.931	$ 8.538	Republic of Korea
			Q3	$ 9.966	$ 2.880	$ 8.194	Republic of Korea
			Q4	$ 9.451	$ 2.936	$ 7.822	Republic of Korea
J0897	Denosumab injection	1 MG	Q1	$ 18.023	$ 2.963	$ 14.258	Norway
			Q2	$ 18.185	$ 2.940	$ 14.374	Luxembourg
			Q3	$ 18.187	$ 2.873	$ 14.358	Norway
			Q4	$ 18.243	$ 2.794	$ 14.381	Norway
J1300	Eculizumab injection	10 MG	Q1	$ 217.433	$ 161.474	$ 203.443	United Kingdom
			Q2	$ 217.433	$ 159.473	$ 202.943	United Kingdom
			Q3	$ 217.433	$ 152.863	$ 201.291	United Kingdom

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
			Q4	$ 217.433	$ 159.631	$ 202.982	United Kingdom
J1439	Inj ferric carboxymaltos 1mg	1 MG	Q1	$ 1.029	$ 0.015	$ 0.776	Japan
			Q2	$ 1.035	$ 0.015	$ 0.780	Japan
			Q3	$ 1.042	$ 0.015	$ 0.786	Japan
			Q4	$ 1.033	$ 0.015	$ 0.779	Japan
J1602	Golimumab for iv use 1mg	1 MG	Q1	$ 20.819	$ 14.783	$ 19.310	Republic of Korea
			Q2	$ 20.358	$ 14.446	$ 18.880	Republic of Korea
			Q3	$ 19.490	$ 13.840	$ 18.077	Republic of Korea
			Q4	$ 19.030	$ 14.138	$ 17.807	Republic of Korea
J1745	Infliximab not biosimil 10mg	10 MG	Q1	$ 61.201	$ 27.427	$ 52.757	Austria
			Q2	$ 59.703	$ 26.741	$ 51.462	Australia
			Q3	$ 54.100	$ 25.685	$ 46.996	Austria
			Q4	$ 52.543	$ 22.508	$ 45.034	Australia
J1930	Lanreotide injection	1 MG	Q1	$ 59.634	$ 9.744	$ 47.161	Norway
			Q2	$ 58.796	$ 9.667	$ 46.514	Norway
			Q3	$ 60.051	$ 9.441	$ 47.398	Norway
			Q4	$ 62.125	$ 9.177	$ 48.888	Norway
J2182	Injection, mepolizumab, 1mg	1 MG	Q1	$ 28.343	$ 11.774	$ 24.201	Sweden
			Q2	$ 28.038	$ 11.424	$ 23.884	Sweden
			Q3	$ 27.631	$ 11.258	$ 23.538	Sweden
			Q4	$ 27.136	$ 10.841	$ 23.062	Norway
J2323	Natalizumab injection	1 MG	Q1	$ 19.143	$ 4.174	$ 15.401	Australia
			Q2	$ 19.096	$ 3.744	$ 15.258	Australia
			Q3	$ 19.719	$ 3.627	$ 15.696	Australia
			Q4	$ 19.701	$ 3.603	$ 15.676	Australia
J2350	Injection, ocrelizumab, 1 mg	1 MG	Q1	$ 54.167	$ 18.789	$ 45.323	Switzerland
			Q2	$ 54.167	$ 17.698	$ 45.050	Switzerland
			Q3	$ 54.167	$ 18.005	$ 45.126	Switzerland
			Q4	$ 54.167	$ 17.932	$ 45.108	Switzerland
J2353*****	Octreotide injection, depot	1 MG	Q1	$ 193.102	$ 27.519	$ 151.706	Spain
			Q2	$ 194.873	$ 27.217	$ 152.959	Spain
			Q3	$ 194.420	$ 26.939	$ 152.550	Spain
			Q4	$ 194.411	$ 25.376	$ 152.153	Spain
J2357	Omalizumab injection	5 MG	Q1	$ 34.955	$ 10.367	$ 28.808	Norway
			Q2	$ 34.696	$ 10.281	$ 28.592	Norway
			Q3	$ 35.242	$ 10.045	$ 28.943	Norway
			Q4	$ 35.044	$ 9.764	$ 28.724	Norway
J2505	Injection, pegfilgrastim 6mg	6 MG	Q1	$ 4,270.573	$ 780.548	$ 3,398.067	Germany
			Q2	$ 4,178.892	$ 661.054	$ 3,299.433	Austria

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
			Q3	$ 4,010.890	$ 566.107	$ 3,149.694	Australia
			Q4	$ 3,757.680	$ 493.426	$ 2,941.617	Australia
J2507	Pegloticase injection	1 MG	Q1	$ 2,344.568	N/A	$ 2,344.568	
			Q2	$ 2,370.328	N/A	$ 2,370.328	
			Q3	$ 2,473.369	N/A	$ 2,473.369	
			Q4	$ 2,444.249	N/A	$ 2,444.249	
J2778	Ranibizumab injection	0.1 MG	Q1	$ 337.116	$ 31.070	$ 260.604	Republic of Korea
			Q2	$ 332.240	$ 29.975	$ 256.673	Republic of Korea
			Q3	$ 327.618	$ 31.920	$ 253.694	Republic of Korea
			Q4	$ 323.876	$ 33.620	$ 251.312	Republic of Korea
J2785	Regadenoson injection	0.1 MG	Q1	$ 55.915	$ 19.846	$ 46.898	United Kingdom
			Q2	$ 55.870	$ 19.505	$ 46.779	Sweden
			Q3	$ 55.923	$ 18.788	$ 46.639	United Kingdom
			Q4	$ 56.011	$ 19.161	$ 46.799	Sweden
J2796	Romiplostim injection	10 MCG	Q1	$ 69.344	$ 28.025	$ 59.015	Japan
			Q2	$ 70.071	$ 18.245	$ 57.114	Australia
			Q3	$ 70.057	$ 17.824	$ 56.998	Australia
			Q4	$ 70.433	$ 17.840	$ 57.285	Australia
J3262	Tocilizumab injection	1 MG	Q1	$ 4.654	$ 0.878	$ 3.710	Australia
			Q2	$ 4.677	$ 0.863	$ 3.724	Australia
			Q3	$ 4.792	$ 0.860	$ 3.809	Australia
			Q4	$ 4.797	$ 0.866	$ 3.814	Australia
J3357	Ustekinumab sub cu inj, 1 mg	1 MG	Q1	$ 179.912	$ 40.633	$ 145.093	France
			Q2	$ 180.554	$ 39.529	$ 145.297	France
			Q3	$ 179.582	$ 38.768	$ 144.379	France
			Q4	$ 175.250	$ 37.857	$ 140.902	France
J3380	Injection, vedolizumab	1 MG	Q1	$ 18.992	$ 6.871	$ 15.961	France
			Q2	$ 18.740	$ 6.795	$ 15.753	France
			Q3	$ 19.096	$ 5.275	$ 15.641	Republic of Korea
			Q4	$ 19.024	$ 5.357	$ 15.607	Republic of Korea
J7324	Orthovisc inj per dose	PER DOSE	Q1	$ 138.594	$ 11.495	$ 106.819	Japan
			Q2	$ 135.280	$ 11.355	$ 104.299	Japan
			Q3	$ 132.474	$ 11.674	$ 102.274	Japan
			Q4	$ 127.383	$ 11.497	$ 98.411	Japan
J9022	Inj, atezolizumab,10 mg	10 MG	Q1	$ 72.809	$ 42.141	$ 65.142	Germany
			Q2	$ 72.649	$ 41.019	$ 64.742	Germany
			Q3	$ 73.450	$ 20.395	$ 60.186	Republic of Korea
			Q4	$ 73.022	$ 20.715	$ 59.945	Republic of Korea
J9034	Inj., bendeka 1 mg	1 MG	Q1	$ 22.454	$ 0.473	$ 16.959	Germany

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
			Q2	$ 21.556	$ 0.469	$ 16.284	Germany
			Q3	$ 20.495	$ 0.466	$ 15.488	Germany
			Q4	$ 19.980	$ 0.461	$ 15.100	Germany
J9035	Bevacizumab injection	10 MG	Q1	$ 76.681	$ 29.541	$ 64.896	Norway
			Q2	$ 76.587	$ 29.291	$ 64.763	Norway
			Q3	$ 76.078	$ 28.607	$ 64.210	Norway
			Q4	$ 75.052	$ 27.444	$ 63.150	Australia
J9041	Inj., velcade 0.1 mg	0.1 MG	Q1	$ 42.008	$ 14.837	$ 35.215	Canada
			Q2	$ 42.158	$ 13.011	$ 34.871	Canada
			Q3	$ 42.316	$ 10.029	$ 34.244	Canada
			Q4	$ 42.498	$ 8.070	$ 33.891	Canada
J9042	Brentuximab vedotin inj	1 MG	Q1	$ 153.836	$ 76.887	$ 134.599	United Kingdom
			Q2	$ 153.242	$ 75.908	$ 133.909	United Kingdom
			Q3	$ 159.787	$ 72.729	$ 138.022	United Kingdom
			Q4	$ 159.336	$ 76.009	$ 138.504	United Kingdom
J9047	Injection, carfilzomib, 1 mg	1 MG	Q1	$ 35.140	$ 17.144	$ 30.641	Switzerland
			Q2	$ 35.471	$ 17.036	$ 30.862	Switzerland
			Q3	$ 35.415	$ 17.332	$ 30.894	Switzerland
			Q4	$ 35.452	$ 17.261	$ 30.904	Switzerland
J9055	Cetuximab injection	10 MG	Q1	$ 58.596	$ 21.422	$ 49.303	Belgium
			Q2	$ 58.536	$ 21.183	$ 49.198	Belgium
			Q3	$ 59.628	$ 20.964	$ 49.962	Belgium
			Q4	$ 59.388	$ 20.874	$ 49.759	Belgium
J9145	Injection, daratumumab 10 mg	10 MG	Q1	$ 50.708	$ 47.053	$ 49.795	Japan
			Q2	$ 50.894	$ 42.527	$ 48.803	Republic of Korea
			Q3	$ 50.972	$ 41.538	$ 48.613	Republic of Korea
			Q4	$ 51.080	$ 42.189	$ 48.858	Republic of Korea
J9173	Inj., durvalumab, 10 mg	10 MG	Q1	$ 70.619	$ 61.519	$ 68.344	Germany
			Q2	$ 70.411	$ 60.844	$ 68.020	Germany
			Q3	$ 71.302	$ 60.221	$ 68.532	Germany
			Q4	$ 71.221	$ 56.940	$ 67.651	Germany
J9176	Injection, elotuzumab, 1mg	1 MG	Q1	$ 6.124	$ 3.888	$ 5.565	Germany
			Q2	$ 6.128	$ 3.895	$ 5.570	Germany
			Q3	$ 6.209	$ 3.859	$ 5.622	Germany
			Q4	$ 6.211	$ 3.789	$ 5.606	Germany
J9217	Leuprolide acetate suspnsion	7.5 MG	Q1	$ 216.526	$ 81.556	$ 182.784	Belgium
			Q2	$ 211.979	$ 78.666	$ 178.651	Belgium
			Q3	$ 217.051	$ 77.860	$ 182.253	Belgium
			Q4	$ 222.045	$ 103.103	$ 192.310	Spain

HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
J9228	Ipilimumab injection	1 MG	Q1	$ 144.395	$ 80.859	$ 128.511	Germany
			Q2	$ 144.460	$ 80.302	$ 128.421	Germany
			Q3	$ 146.398	$ 78.540	$ 129.433	Germany
			Q4	$ 146.442	$ 75.848	$ 128.793	Germany
J9264	Paclitaxel protein bound	1 MG	Q1	$ 11.608	$ 0.127	$ 8.738	Australia
			Q2	$ 11.805	$ 0.123	$ 8.884	Australia
			Q3	$ 11.843	$ 0.127	$ 8.914	Australia
			Q4	$ 11.998	$ 0.129	$ 9.031	Australia
J9271	Inj pembrolizumab	1 MG	Q1	$ 46.777	$ 23.308	$ 40.910	Switzerland
			Q2	$ 46.593	$ 23.162	$ 40.735	Switzerland
			Q3	$ 47.419	$ 23.563	$ 41.455	Switzerland
			Q4	$ 47.192	$ 23.468	$ 41.261	Switzerland
J9299	Injection, nivolumab	1 MG	Q1	$ 26.230	$ 8.321	$ 21.753	Japan
			Q2	$ 26.231	$ 7.438	$ 21.533	Japan
			Q3	$ 26.568	$ 7.415	$ 21.780	Japan
			Q4	$ 26.568	$ 7.393	$ 21.774	Japan
J9305	Pemetrexed injection	10 MG	Q1	$ 65.607	$ 1.920	$ 49.685	Canada
			Q2	$ 65.540	$ 1.882	$ 49.625	Canada
			Q3	$ 66.786	$ 0.623	$ 50.245	Australia
			Q4	$ 66.542	$ 0.611	$ 50.059	Australia
J9306	Injection, pertuzumab, 1 mg	1 MG	Q1	$ 11.557	$ 6.192	$ 10.216	Australia
			Q2	$ 11.594	$ 6.087	$ 10.217	Australia
			Q3	$ 11.903	$ 5.967	$ 10.419	Australia
			Q4	$ 11.921	$ 5.712	$ 10.368	Norway
J9311	Inj rituximab, hyaluronidase	10 MG	Q1	$ 41.810	$ 11.659	$ 34.273	Norway
			Q2	$ 41.064	$ 11.483	$ 33.669	Republic of Korea
			Q3	$ 40.442	$ 11.216	$ 33.136	Republic of Korea
			Q4	$ 40.032	$ 11.392	$ 32.872	Republic of Korea
J9312	Inj., rituximab, 10 mg	10 MG	Q1	$ 89.597	$ 22.642	$ 72.858	Norway
			Q2	$ 89.308	$ 22.446	$ 72.593	Republic of Korea
			Q3	$ 89.067	$ 21.935	$ 72.284	Norway
			Q4	$ 88.847	$ 15.631	$ 70.543	Australia
J9354	Inj, ado-trastuzumab emt 1mg	1 MG	Q1	$ 29.515	$ 18.764	$ 26.827	Canada
			Q2	$ 29.589	$ 18.790	$ 26.889	Canada
			Q3	$ 30.290	$ 19.050	$ 27.480	Canada
			Q4	$ 30.243	$ 19.034	$ 27.441	Canada
J9355	Inj trastuzumab excl biosimi	10 MG	Q1	$ 100.920	$ 21.917	$ 81.169	Republic of Korea
			Q2	$ 100.587	$ 21.008	$ 80.692	Republic of Korea
			Q3	$ 99.863	$ 20.521	$ 80.028	Republic of Korea

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HCPCS Code†	Short Description	HCPCS Code Dosage	2019 Quarter	Illustrative Applicable ASP*	Illustrative MFN Price **	Illustrative MFN Drug Payment Amount***	Illustrative MFN Country††
			Q4	$ 98.301	$ 20.837	$ 78.935	Republic of Korea
Q2043	Sipuleucel-t auto cd54+	Per infusion (minimum 50 million cells)	Q1	$ 41,532.639	N/A	$ 41,532.639	
			Q2	$ 43,749.244	N/A	$ 43,749.244	
			Q3	$ 43,342.102	N/A	$ 43,342.102	
			Q4	$ 45,270.100	N/A	$ 45,270.100	
Q5111	Injection, udenyca 0.5 mg	0.5 MG	Q1	$ 337.854	$ 65.046	$ 269.652	Germany
			Q2	$ 326.162	$ 55.088	$ 258.393	Austria
			Q3	$ 316.466	$ 47.176	$ 249.143	Australia
			Q4	$ 303.061	$ 41.119	$ 237.575	Australia

N/A means not available; international drug pricing information was not available in the data source CMS used.

† HCPCS codes on the performance year 1 MFN Model Drug HCPCS Codes List in Table 2, with short descriptions effective January 1, 2021.

††MFN Country means the country with the lowest GDP-adjusted country-level price.

*Based on the calendar quarter in which manufacturer sales occurred; note, the calendar quarter shown is two calendar quarters prior to when the applicable ASP was used to calculate the payment amounts under the methodology in section 1847A of the Act. For example, the applicable ASPs for Q1 2019 shown in this table align with the payment amounts shown in the July 2019 ASP Pricing File available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2019ASPFiles.

**Based on available international drug pricing sales and volume information for the calendar quarter for non-U.S. OECD countries with a GDP per capita (based on purchasing power parity) that is at least 60 percent of the U.S. GDP per capita in 2017.

*** The MFN Drug Payment Amount reflects the exception in § 513.210(d)(1) and equals the applicable ASP when the MFN Price is not available.

**** The MFN Price for J0178 (Aflibercept injection) is based on data for the ophthalmic formulation only.

***** The MFN Price for J2353 (Octreotide injection, depot) is based on data for long acting formulations only.

We note that, as codified in § 513.210(d)(5), and described in section III.E.10. of this IFC, the MFN Drug Payment Amount will not exceed the non-model drug payment amount for line items submitted with the JG modifier (or any successor modifier used to identify drugs purchased under the 340B program) after removing any add-on amount, if applicable.

8. Timing of Data and MFN Drug Payment Amount Calculations

As discussed in section III.E.4. of this IFC, we will calculate the MFN Drug Payment Amounts on a calendar quarter basis using the most recent ASP and correlated international drug pricing information (that is, data from the highest level of hierarchy available). Under the reporting requirements outlined in section 1927(b)(3)(A)(iii), manufacturers that report ASPs are required to submit them to CMS no later than 30 days after the last day of the previous quarter. CMS uses these data to calculate the ASP-based Medicare payment amounts for the next calendar quarter. As a result, there is a two-quarter lag between the time when sales reflected in the ASP occur and the time when these sales become the basis for Medicare payment amounts.

We will use international drug pricing information from the same time period (that is, the same calendar quarter), if available in accordance with the hierarchy specified in § 513.140(c)(3), in order to align information across the ASP Drug Pricing files and the data sources for international drug pricing information that we will use. This approach will consistently correspond to the two-quarter lag used for the ASP pricing files when an international drug pricing information data source at the highest level of the hierarchy specified in § 513.140(c)(3) is available. Table 7 illustrates how the information we will use to calculate the MFN Drug Payment Amounts for each calendar quarter during performance year 1 using data from the applicable ASP calendar quarter will align when an international drug pricing information data source at the highest level of the hierarchy specified in § 513.140(c)(3) is available. We will use the same approach for each performance year.

TABLE 7—ALIGNMENT OF PERFORMANCE YEAR CALENDAR QUARTERS FOR ASP AND MFN PRICE DATA BASED ON JANUARY 2021 MODEL START

Performance year	Performance year calendar quarter	ASP pricing file for calendar quarter	Applicable ASP calendar quarter	MFN price for calendar quarter*
1	2021, Quarter 1	2021, Quarter 1	2020, Quarter 3	2020, Quarter 3
1	2021, Quarter 2	2021, Quarter 2	2020, Quarter 4	2020, Quarter 4
1	2021, Quarter 3	2021, Quarter 3	2021, Quarter 1	2021, Quarter 1
1	2021, Quarter 4	2021, Quarter 4	2021, Quarter 2	2021, Quarter 2

*When an international drug pricing information data source at the highest level of the hierarchy specified in § 513.140(c)(3) is available.

For example, for the initial calculations to calculate payment amounts for the start of the MFN Model on January 1, 2021, the beginning of the first calendar quarter in 2021, we will use the January 2021 ASP Pricing File (which will be based on manufacturers' ASP for the third quarter of 2020, from July 1, 2020, to September 30, 2020) and international drug pricing information for the third quarter of 2020, from July 1, 2020, to September 30, 2020. For each subsequent calendar quarter for a performance year, the MFN Drug Payment Amount will be established by calculating the MFN Price based on more recent international drug pricing information, using data for the applicable ASP calendar quarter, if available, as illustrated in Table 7, and calculating the MFN Drug Payment Amount.

9. Adjustments to Phase-In Formula and Incentives for Manufacturers To Address Rising U.S. Drug Prices

In response to the October 2018 ANPRM, we received several comments asking that we consider including model design features to address potential spillover effects and cost-shifting to the commercial market and Medicare payment outside of the model geographic area. The commenters requested that CMS carefully consider the potential impacts of a potential model on other markets—including the potential for cost-shifting to other segments of the Medicare program, the Medicaid program, and the commercial market. The commenters recommended that in order to avoid unintended consequences and cost-shifting, CMS should closely monitor prices for included drugs and consider additional policies or actions if drug prices in other markets rise above certain pricing thresholds (for example, above the Consumer Price Index (CPI) or inflation).

We appreciate these concerns, as it is possible that, in response to the MFN Model, manufacturers may take steps to increase U.S. prices outside of the MFN Model, such as in the commercial and Medicare Advantage markets, which may be seen in increases in manufacturers' ASPs. In response to the concerns expressed in the October 2018 ANPRM comments and to minimize the possibility of a spillover impact on beneficiaries outside of the MFN Model, we will make adjustments to the phase-in formula in order to mitigate cost-shifting in the market and incentivize manufacturers of MFN Model drugs to maintain stable ASPs of MFN Model drugs to minimize the potential for spillover impacts. In addition to creating spillover impacts, rapid increases in ASP that outstrip not only U.S. inflation but also changes in international prices over time would reduce our ability to test the phase-in of the MFN Price over time, as the MFN Price's contribution to the MFN Drug Payment Amount could be obscured by a significant increase in the MFN Model drug's ASP.

As discussed in section III.E.5. of this IFC, we will phase-in the MFN Prices to allow MFN participants time to adjust to the MFN Model payment amounts and processes. Calculating the MFN Prices and MFN Drug Payment Amounts each calendar quarter will allow manufacturers to address the large difference between prices in the U.S. and in other countries for MFN Model drugs during the course of the MFN Model and serves as an incentive for manufacturers to refrain from raising U.S. prices faster than a reasonable inflation allowance. Furthermore, as discussed in section III.M. of this IFC, we are waiving requirements of section 1847A in order to exclude units of MFN Model drugs from the calculation of the manufacturer's ASP. However, if these incentives prove to be insufficient to deter manufacturers from raising U.S. prices for MFN Model drugs faster than a reasonable inflation allowance, we will adjust the calculation of the MFN Drug Payment Amount by adjusting the

phase-in formula for MFN Model drugs where such concerns are observed.

Specifically, to preserve the integrity of the model test as described previously, we will make an adjustment to the phase-in formula for an MFN Model drug if the applicable ASP or monthly U.S. list price (defined as Wholesale Acquisition Cost (WAC) available in a U.S. drug pricing compendium or if WAC is not available, other available list prices, such as Average Wholesale Price (AWP) available in a U.S. drug pricing compendium) increases faster than both inflation and the MFN Price. CMS will accelerate the phase-in of the MFN Price by 5 percentage points at the next quarterly update for each MFN Model drug with: (1) A greater cumulative percentage increase in either the applicable ASP [66] or any monthly U.S. list price for any of the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the Consumer Price Index for All Urban Consumers (CPI–U) [67] based on all items in U.S. city average and not seasonally adjusted; and (2) a greater cumulative percentage increase in either the applicable ASP or any monthly U.S. list price for any of the NDCs assigned to the MFN Drug's HCPCS code compared to the cumulative percentage increase in the MFN Price. To apply these conditions for an MFN Model drug, we will identify the cumulative percentage increase from a baseline to the applicable ASP calendar quarter. For all MFN Model drugs with an applicable ASP for the first quarter of performance year 1, we will set the baseline as the ASP calendar quarter for the applicable ASP for the first quarter of performance year 1 (that is, the third calendar quarter of 2020 (July 2020 through September 2020)). For all MFN Model drugs that do not have an applicable ASP for the first quarter of performance year 1 (for example, a drug that is first marketed in the U.S. after the start of the model), the baseline will be the ASP calendar quarter for the first applicable ASP based on the manufacturer's average sales price for that MFN Model drug that occurs after the third quarter of 2020. For example, the baseline for an MFN Model drug with its first applicable ASP based on the manufacturer's average sales price occurring in the second quarter of performance year 1 (that is, April 2021 through June 2021) will have a baseline of the fourth calendar quarter of 2020 (October 2020 through December 2020).

The cumulative percentage change will be calculated from the end of the baseline to the end of the applicable ASP calendar quarter. We will apply the adjustment to the phase-in formula similarly for all MFN Model drugs regardless of when the MFN Model drug is added to the MFN Model Drug HCPCS Codes List.

Further, if both conditions are not met, such as the cumulative percentage increase in any monthly U.S. list prices for the NDCs assigned to the MFN Drug's HCPCS code outpaces the cumulative percentage increase in CPI–U but is less than the cumulative percentage increase in the MFN Price, then the trigger conditions will not be met and the phase-in formula will not be accelerated. If the cumulative percentage change in the CPI–U or MFN Price is negative, we will use zero as the cumulative percentage increase in the CPI–U or MFN Price, as applicable, for the relevant quarter.

We will accelerate the phase-in formula by 5 percentage points as we believe this amount strikes a balance between moving the MFN Drug Payment Amount more quickly toward the MFN Price while still retaining the stepwise nature of the phase-in. As an example, in the case that both trigger conditions are met for an MFN Model drug during the applicable ASP calendar quarter for the second quarter of performance year 1, the phase-in formula would be 70 percent applicable ASP and 30 percent MFN Price for that quarter and remaining quarters in performance year 1, assuming both trigger conditions are not met in the ASP calendar quarters for the third and fourth quarter of performance year 1.

We will apply the acceleration of the phase-in formula for each calendar quarter of the MFN Model where both trigger conditions are met. That is, for an MFN Model drug that is subject to the accelerated phase-in of the MFN Price, we will further accelerate the phase-in of the MFN Price by an additional 5 percentage points at the next quarterly update if the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code continues to be greater than the cumulative percentage increase in the CPI–U and MFN Price. In the previous example, if both of the trigger conditions were met for the same MFN Model drug during the applicable ASP calendar quarter for quarters 3 and 4 of performance year 1, the phase-in formula would be 65 percent applicable ASP and 35 percent MFN Price for quarter 3 of performance year 1, and 60 percent applicable ASP and 40 percent MFN Price for quarter 4 of performance year 1. The accelerated phase-in of the MFN Price will not be reversed, but will remain in place for the duration of the model performance period for that drug, even if the manufacturer lowers its ASP and U.S. list prices after the accelerated phase-in is in effect.

Further, after the full phase-in of the MFN Price is reached, if both of the trigger conditions are met, there will be a decrease in MFN Model Drug Payment Amount equal to the largest difference in the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the CPI–U and in the MFN Price. This additional adjustment will lead to the affected drug's MFN Drug Payment Amount falling below the MFN Price for that drug. For example, for an MFN Model drug, if 100 percent of the MFN Price was already applied in the calculation of the MFN Model Drug Payment Amount for a quarter and its applicable ASP cumulatively increased by 14 percent, the largest cumulative percentage increase of any of the monthly U.S. list prices for the NDCs assigned to the HCPCS code was 13 percent, the CPI–U cumulatively increased by 12 percent, and the MFN Price cumulatively increased by 11 percent, we would reduce the MFN Drug Payment Amount for the quarter (in this case, previously established as to equal the MFN Price) by 3 percent (that is, the difference between 14 and 11) of the MFN Price.

Any such additional adjustment will apply for the duration of the model performance period, unless a larger additional adjustment is triggered. As with the adjustment before the full phase-in is reached, we will update the calculation for the additional adjustment for each additional calendar quarter of the model. That is, for an MFN Model drug that is subject to the additional adjustment of the MFN Price, each calendar quarter thereafter, we will calculate the largest difference between the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code and the cumulative percentage increase in CPI–U and in MFN Price and increase the additional adjustment if the result of the updated calculation results in a larger additional adjustment. CMS will not reduce the

[66] We note that the manufacturers' ASPs will be based on non-model sales only as codified in § 513.600(b) and as discussed in section III.M. of this IFC.

[67] All references to CPI–U are based on all items in U.S. city average and not seasonally adjusted.

additional adjustment based on the results of the updated calculation. We believe this policy will serve as a strong incentive for manufacturers to avoid taking steps that could cause spillover impacts and will help to address commenters' concerns.

10. Limitation on MFN Drug Payment Amount To Protect Beneficiaries

To avoid potentially increasing beneficiary cost-sharing or coinsurance, we are codifying in § 513.210(b)(6) to compare the MFN Price to the applicable ASP in order to ensure that beneficiaries are always paying the lowest amount of coinsurance available. If the applicable ASP is less than the MFN Price, we will establish the MFN Price as equal to the applicable ASP. In addition, in § 513.210(a), we are codifying that the allowed MFN Drug Payment Amount will not exceed the billed amount on the claim for the MFN Model drug. In addition, to maintain beneficiary protections for all claims paid under the OPPS, we are codifying in § 513.210(d)(4) that the MFN Drug Payment Amount cannot exceed the non-model drug payment amount for line items submitted with the JG modifier (or any successor modifier used to identify drugs purchased under the 340B program) after removing any add-on amount, if applicable. We will apply this limitation to line items submitted with the JG modifier. We refer readers to the Calendar Year (CY) 2021 OPPS/ASC Notice of Proposed Rulemaking (CMS–1736–P) [68] (85 FR 48880) for a discussion of CMS's proposal for CY 2021 and subsequent years to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent based on the results of the Hospital Acquisition Cost Survey for 340B—Acquired Specified Covered Drugs. If CMS finalizes the proposed OPPS payment policy to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, the MFN Drug Payment Amount for an MFN Model drug furnished by an MFN participant and billed with the JG modifier will be capped at ASP minus 34.7 percent. In such cases, the MFN participant will also receive the per-dose add-on payment amount described in section III.F. of this IFC.

In the CY 2021 OPPS/ASC Notice of Proposed Rulemaking, CMS proposed in the alternative to continue its current policy of paying ASP minus 22.5 percent for 340B-acquired drugs. If CMS finalizes this alternative proposal, the MFN Drug Payment Amount for an MFN Model drug furnished by an MFN participant and billed with the JG modifier will be capped at ASP minus 22.5 percent (85 FR 48890). In such cases, the MFN participant will also receive the per-dose add-on payment amount described in section III.F. of this IFC.

11. Method for Establishing MFN Drug Payment Amounts for Drugs Added to the MFN Model

We will add annually any top 50 drugs that are not already included on the MFN Model Drug HCPCS Codes List, after taking the exclusions in § 513.130(b) into account. In accordance with§ 513.210, we will calculate the MFN Price that will apply to drugs that are added to the list of MFN Model drugs and the applicable phase-in formula for a given performance year and adjustments will apply. We will apply the applicable phase-in formula for drugs that are added to the MFN Model Drug HCPCS Codes List, in order to simplify and maintain consistent payment policies for all MFN participants and MFN Model drugs. For example, for a drug added as an MFN Model drug for performance year 2, the phase-in formula will be a blend of 50 percent of the ASP and 50 percent of the MFN Price for the drug. Thus, Medicare Part B drugs that will be added to the MFN Model Drug HCPCS Codes List for performance year 2 and beyond will have an MFN Drug Payment Amount that will start more heavily based on the MFN Price than drugs that were included in earlier performance years. We believe this approach is appropriate because the MFN Model seeks to test a new payment methodology that takes into account the discounts that other countries enjoy and delaying the phase-in of the MFN Price for drugs that will be added to the MFN Model Drug HCPCS Codes List for performance year 2 and beyond will not allow CMS to fully evaluate the model payment test for such drugs during the model performance period.

For drugs added to the MFN Model Drug HCPCS Codes List in a later performance year, this approach could result in a more significant change in payment for the drug upon entry to the model compared to drugs that are included from the beginning of the model. Although there is the potential for a larger change in payment for drugs that are added later in the model, we believe that it is necessary to maintain the same phase-in for all included drugs to enable us to test the full phase-in of the MFN Price by performance year 4. We also believe that MFN participants are aware of which separately payable Medicare Part B drugs have high annual spending and therefore will have a basis for assessing which drugs that are not on the MFN Model Drug HCPCS Codes List in performance year 1 are more likely be added to the MFN Model Drug HCPCS Codes List in a later performance year. For future years, we seek comment on whether additional information that CMS could provide would be helpful to MFN participants for their planning purposes, for example drug utilization reports developed through the model monitoring activities that CMS could make available on the model website.

12. Payment Exceptions for MFN Model Drugs in Short Supply

Rather than broadly excluding drugs that are in short supply from the model, we will keep MFN Model drugs in the model while they are in short supply, but revert the MFN Drug Payment Amount to the applicable ASP, which could be the amount determined under section 1847A(e) of the Act if the conditions set forth in that provision are met, beginning with the first day of the next calendar quarter after the date on which the MFN Model drug is reported as ''Currently in Shortage'' by FDA, as available on these websites: *https://www.accessdata.fda.gov/scripts/drugshortages/* and *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages,* and continuing for subsequent calendar quarters as warranted. Once the MFN Model drug is no longer reported as ''Currently in Shortage'' by FDA, the MFN Model payment will resume the first day of the next quarter after the date on which it is no longer reported in shortage. For example, as noted in section III.D.2. of this IFC, one of the HCPCS codes with high aggregate 2019 Medicare Part B total allowed charges (J1569, Gammagard liquid infusion) represents a drug that is currently on the FDA shortages list. If this HCPCS code were to be included on the MFN Model Drug HCPCS Codes List and remain on the FDA shortages list, the MFN Drug Payment Amount will be the applicable ASP until the first day of the next quarter of the model performance period after it is no longer reported as ''Currently in Shortage'' by FDA. However, we note that we are excluding HCPCS codes that describe intravenous immune globulin from the MFN Model Drug HCPCS Codes List as discussed in section III.D.2 of this IFC.

[68] *https://www.govinfo.gov/content/pkg/FR-2020-08-12/pdf/2020-17086.pdf.*

13. Payment of Blood Clotting Factor Furnishing Fee Under the MFN Model

Currently, payment for the blood clotting factor furnishing fee under 42 CFR 410.63(c) is made along with payment for the blood clotting factor. Under the MFN Model, a HCPCS code that is used to bill for a blood clotting factor may be an MFN Model drug if such HCPCS code is included on the MFN Model Drug HCPCS Codes List. To maintain the current payment approach for the blood clotting factor furnishing fee during the MFN Model, we are codifying in § 513.210(e), that when applicable, the blood clotting furnishing fee under § 410.63(c) will be payable along with the MFN Drug Payment Amount. We believe this approach will eliminate the need to establish different billing instructions for MFN Model drugs that are blood clotting factors.

F. MFN Model Alternative Add-On Payment

1. Overview of the Alternative Add-On Payment

In the October 2018 ANPRM, we sought public comment on testing an alternative add-on payment to the current system, required by section 1847A of the Act, under which Medicare Part B pays a fee based on 6 percent of the ASP of the drug so that the dollar amount of the add-on increases with the price of the drug rather than reflecting the service being performed. In general, the amount of add-on realized by providers and suppliers has been described by commenters as 4.3 percent as a result of sequestration.[69] In the October 2018 ANPRM, we described our belief regarding how a potential model could pay a drug add-on amount that would be different from the current drug add-on amount. We sought public comment on potential ways to structure the alternative add-on, including but not limited to: An amount based on drug class, the physician's specialty, or the practice's historical billing patterns, with a possible bonus pool tied to clinically appropriate utilization. We requested feedback on several design topics, such as how we could best define and determine the alternative add-on payment amount, whether CMS should develop an encounter-based or monthly add-on payment approach, and potential inclusion of a quality bonus pool to incentivize evidence-based care. We stated that our goal was to maintain relative stability in provider and supplier revenue through an alternative drug add-on payment for furnishing drugs that removes the current percentage-based drug add-on payments.

In response to the October 2018 ANPRM, we received feedback from a number of stakeholder groups on the structuring of an alternative add-on payment. Overall, there was no consensus on the best approach to designing an alternative add-on payment, though several commenters supported calculating the alternative add-on payment in such a way that model participants would be held harmless. Some commenters supported the idea of testing an alternative add-on payment that is not tied to increases in drug prices over time, with one commenter noting that this could promote revenue stability. One commenter noted an approach that varies the alternative add-on payment between different drugs would risk creating perverse incentives in prescribing decisions between alternative treatment options. Several commenters supported a flat fee with more than one tier. Several commenters expressed concern about linking a bonus pool to prescribing lower cost drugs. One commenter opposed reducing the add-on amount to allow for a bonus pool.

After considering the comments we received, we were persuaded that potential model requirements to qualify for a modest quality bonus would be challenging and may be burdensome for MFN participants to implement and adhere to consistently for all MFN beneficiaries, and would add potential financial risk for MFN participants, which is not necessary for purposes of testing an alternative add-on payment approach under the MFN Model. Thus, we are not including a quality bonus in the MFN Model. We were also persuaded that the alternative add-on should be designed in as straightforward a manner as possible to minimize administrative burden for MFN participants and potential confusion for beneficiaries.

We will pay MFN participants a single add-on payment amount per dose of an MFN Model drug; this payment will not vary based on the amount of drug furnished in a dose, billing units billed on the claim line, or by MFN participant or specialty. The goals for the model's approach to the alternative add-on payment are to test an innovative way to pay the add-on portion of the drug payment, boost add-on revenue for MFN participants on average based on historical overall add-on revenue, create an incentive to encourage appropriate drug utilization by breaking the link between the manufacturer's drug price and the calculation of the Medicare Part B payment for the add-on amount, and remove or reduce the incentive to furnish higher-cost drugs inherent in the current methodology.

With the MFN alternative add-on payment, we will test a single add-on payment amount that will paid per dose, where ''dose'' for the purposes of the MFN alternative add-on payment is defined as the number of HCPCS billing units reported on a claim line[70] (also called service line or line item). We are codifying this alternative add-on payment at § 513.220. We will waive beneficiary cost-sharing for the add-on payment. As such, the add-on approach will test a separate standardized add-on payment amount per dose that is not tied to the Medicare Part B payment amount for a drug. We will start with an amount that is calculated based on 6.1224 percent of historical applicable ASPs for 2019 final action claim lines for the selected MFN Model drugs for the beginning of performance year 1 as further described in § 513.220, trended forward using an inflationary adjustment for the start of performance year 1. With this approach, the per-dose add-on payment amount will be calculated once at the beginning of the model and will not be recalculated as the MFN Model Drug HCPCS Codes List changes. For each calendar quarter thereafter, beginning with performance year 1, quarter 2, we will update the per-dose add-on payment amount using an inflation factor.

For the MFN Model drugs for the beginning of performance year 1 that are biosimilar biological products, we will use 6.1224 percent of the historical applicable ASPs for the reference biological product in the calculation of the per-dose add-on amount rather than 6.1224 percent of the historical

[69] Stakeholders have reported that the add-on percentage is slightly further reduced when the OPPS beneficiary cost-sharing limitation applies. Further, we note that current payments under the OPPS for certain drugs when the drug is acquired under the 340B program are made based on ASP–22.5 percent and are not considered to include a drug add-on payment amount. We refer readers to to the Calendar Year (CY) 2021 OPPS/ASC Notice of Proposed Rulemaking (CMS–1736–P) (85 FR 48880) for a discussion of CMS's proposal for CY 2021 and subsequent years to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent based on the results of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs. We also refer readers to the alternative proposal in the CY 2021 OPPS/ASC Notice of Proposed Rulemaking (85 FR 48890) to continue the current policy of paying ASP–22.5 percent for 340B drugs and biologicals under the OPPS.

[70] An exception is when a claim line is billed with the modifier JW, indicating discarded drug.

applicable ASPs for the biosimilar biological product to align with the determination of the add-on amount to such products under section 1847A. Based on the performance year 1 MFN Model Drug HCPCS Codes List in Table 2, this applies to Q5111 (Injection, udenyca 0.5 mg).

We selected 6.1224 percent because that amount results in an add-on pool that will allow MFN participants to realize, on average, a 6 percent add-on per dose after sequestration, which generally applies.[71] In the absence of actual drug acquisition costs for eligible providers and suppliers, we believe it is appropriate to use an amount for the add-on pool that represents, on average, a 40 percent increase compared to 4.3 percent of ASP in use in the baseline period to achieve a goal of the model to provide increased add-on revenue for MFN participants on average.

2. Per-Dose Add-On Payment Amount Methodology

a. Calculation of the Single Per-Dose Add-On Payment Amount

In § 513.220(b), we specify how we calculated a single per-dose add-on payment amount for the start of the MFN Model. Using 2019 historical claims data, we calculated a per-dose add-on payment amount by applying the applicable ASP (that is, the payment amount determined in accordance with section 1847A of the Act for a quarter minus the applicable add-on percentage) to the identified 2019 claims lines, based on the calendar quarter in which the claim's date of service falls, which corresponds to the manufacturer-reported ASPs from two calendar quarters prior, with an exception for biosimilar biological products as described previously. We used all 2019 Medicare Part B FFS claims lines for separately paid drugs (by HCPCS code) included on the MFN Model HCPCS Codes List for the beginning of performance year 1 that were furnished by eligible Medicare-participating providers and suppliers (that is, entities that are eligible to be an MFN participant). We excluded claims submitted by excluded providers and suppliers described in § 513.100(c) (such as CAHs, and cancer hospitals) as well as certain claims described in § 513.100(d) (such as claims processed by the DME MAC), as applicable in 2019, as well as claims where Medicare was not the primary payer. We included all relevant claim lines for an MFN Model drug with an allowed charge greater than zero dollars in the calculation. As we used nearly all 2019 claims for drugs included on the MFN Model HCPCS Codes List for the beginning of performance year 1 furnished from any eligible Medicare-participating provider or supplier, we believe that one calendar year provided sufficient data for purposes of calculating a single per-dose add-on payment amount. Calendar year 2019 represents the same baseline year that we used to select the MFN Model drugs for the beginning of performance year 1, as identified in Table 2.

Once all relevant 2019 claim lines were identified for each drug (by HCPCS code) on the MFN Model HCPCS Codes List for the beginning of performance year 1, we multiplied the number of HCPCS units billed on each claim line by 6.1224 percent of the 2019 applicable ASP (which we define as the payment amount determined in accordance with 1847A of the Act less the applicable add-on percentage for the MFN Model drug's HCPCS code) for the calendar quarter that matches the claim line's date of service and then summed across all claim lines for that drug to yield a total add-on spending amount for that drug. For biosimilar biological products, we used the applicable ASP for the reference biological product.

Then we pooled together the total add-on spending amounts for all drugs on the MFN Model HCPCS Codes List for performance year 1 and the total number of claim lines for those drugs (excluding claim lines billed with the JW modifier). Lastly, we calculated the per-dose add-on payment amount as the total pooled add-on spending amount divided by the total pooled number of claim lines.

Using the drugs (by HCPCS code) included on the performance year 1 MFN Model Drug HCPCS Codes List in Table 2, available 2019 claims data subject to the exclusions and exception previously noted, and applicable ASPs from 2019, we calculated a single per-dose add-on payment amount in the amount of $146.55. This amount represents the single per-dose add-on payment amount for a dose of any MFN Model drug prior to application of the inflationary factor as described in section III.F.2.b. of this IFC.

b. Trending the Single Per-Dose Add-On Payment Amount Forward Each Calendar Quarter During the MFN Model

We will trend forward the single per-dose add-on payment amount each calendar quarter during the MFN Model to account for inflation over time by using a cumulative inflationary factor as described in this section of this IFC. We will not use changes in ASP or MFN Drug Payment Amount to trend forward the single per-dose add-on payment amount to align with our intention to test the removal of the link between a drug's add-on payment and its price.

As specified in § 513.220(b)(7), after calculating the single per-dose add-on payment amount, we multiplied the single per-dose add-on payment amount ($146.55) by an inflationary factor, which equals the percentage increase in the CPI–U from the midpoint of the baseline year (2019) through the first month of the calendar quarter prior to the start of the model (that is, the percentage increase in CPI–U from July 2019 through October 2020). The resulting per-dose alternative add-on payment amount for the first calendar quarter of performance year 1 (January 1, 2021 through March 31, 2021) is $148.73.

To calculate the per-dose alternative add-on payment amount for each subsequent calendar quarter during the model performance period, as specified in § 513.220(c), we will multiply the performance year 1, quarter 1 alternative add-on payment amount by a cumulative inflation factor that will ensure the amount will remain equal to or greater than the alternative add-on payment amount calculated for performance year 1, quarter 1. We will calculate a cumulative inflation factor as equal to the percentage increase in the CPI–U from October 2020 through the first month after the end of the applicable ASP calendar quarter. If the cumulative percentage change in the CPI–U is negative, we will use an inflation factor of 1. For example, the cumulative inflation factor for performance year 1, quarter 2 (that is, April 1, 2021 through June 30, 2021) will be the percentage increase in the CPI–U from October 2020 through January 2021. Similarly, the cumulative inflation factor for performance year 1, quarter 3 will be the percentage increase in the CPI–U from October 2020 through April 2021.

As discussed in section III.G. of this IFC, MFN participants will use a new HCPCS code (M1145, MFN drug add-on, per dose) to bill for and receive the alternative add-on payment amount for each dose of an MFN Model drug that is billed on the claim.

3. Discussion of the Per-Dose Add-On Payment Approach

The per-dose add-on payment amount approach will test an alternative way to

[71] Note that Section 3709 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act temporarily suspends Medicare sequestration from May 1, 2020 to December 31, 2020. Available at: *https://www.govinfo.gov/content/pkg/BILLS-116hr748enr/pdf/BILLS-116hr748enr.pdf.*

calculate the add-on payment that is not tied to the sales price of the drug that is furnished. This approach also aims to boost add-on revenue, on average, for MFN participants by setting the per-dose add-on payment amount based on 6.1224 percent of historical ASP payment allowances trended forward for inflation. However, the impact on MFN participants will vary based on the MFN participant's prescribing patterns, including the amount and types of MFN Model drugs they furnish to Medicare FFS beneficiaries.

Compared with the current add-on payment policy, on an average per dose basis based on 2019 historical claims, the single per-dose add-on approach will initially decrease add-on payments for MFN Model drugs with relatively higher historical applicable ASP-based payment amounts per dose and increase add-on payments for MFN Model drugs with relatively lower historical applicable ASP-based payment amounts per dose. Average 2019 historical add-on payment amounts per dose for the MFN Model drugs for performance year 1 ranged from $10.44 to $2,575.47 per average dose for a drug. Based on 2019 claims, on average, a single per-dose add-on payment amount, calculated as described in this IFC and after sequestration is applied, will represent an increase in the add-on payment amount for 70 percent of doses on average compared to the effective historical add-on amount of 4.3 percent of the applicable ASP after sequestration.

To examine the potential impact of the single per-dose add-on approach on MFN participants using 2019 claims data, we considered the overall potential change in the add-on payment amount at the eligible entity level, specialty level, and type of provider and supplier. That is, for this entity level analysis, we grouped 2019 claim lines for the drugs (by HCPCS code) identified in Table 2 based on the provider's or supplier's CMS Certification Number (''CCN'') or Taxpayer Identification Number (''TIN''). To examine the potential impact of the single per-dose add-on payment amount at the specialty level, we assigned claims to a specialty category based on the primary specialty of the National Provider Identifier (NPI) associated with the furnishing of the drug as listed in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). Eligible providers were assigned to the specialty that was most frequently associated with their 2019 claims for the drugs (by HCPCS code) identified in Table 2. We also used the type of bill to examine the potential impacts on various types of providers and suppliers.

These analyses highlight that different subsets of providers and suppliers will potentially gain (or lose) under the single per-dose add-on approach. For 340B covered entities that were paid under the OPPS during calendar year 2019, the entirety of the alternative add-on payment amount represent an increase in payment when drugs are acquired under the 340B program. Thus, we removed these entities from the following analyses.

To explore the potential entity level change in the add-on amount for the single per-dose add-on payment approach, we assigned each CCN or TIN to only one specialty based on the specialty code with the highest total allowed spending for the entity's claim lines, regardless of setting (for example, hospitals, ASCs, and physician office). We also assigned each specialty a value of ''low,'' ''medium,'' or ''high,'' based on the percentage of its Medicare revenue that is related to Part B drugs, such that ''high'' means the specialty's drug revenue is more than 50 percent of its total Medicare revenue, ''medium'' means the specialty's drug revenue is 25 to 50 percent of its total Medicare revenue, and ''low'' means the specialty's drug revenue is less than 25 percent of its total Medicare revenue.

Based on the single per-dose add-on payment amount of $146.55 (prior to the application of the inflationary factor that applies during the model) and using 2019 drug utilization, MFN participants will fare, on average, 40 percent better overall across all specialties with the per-dose add-on payment amount than they did historically based on 4.3 percent of ASP after sequestration. Some MFN participants will see more than a 40 percent increase in revenue related to the MFN add-on payment amount compared to their 2019 historical Part B drug claims, and others will see less than a 40 percent increase, including some who will see a reduction in add-on revenue. Based on our analysis, in general, physician practices will be better off under the per-dose add-on payment approach than hospital outpatient departments, and single specialty practices will be better off than multi-specialty practices. Table 8 shows the estimated variation in impacts for the top specialties by comparing 2019 baseline add-on payments based on 4.3 percent of the applicable ASP with a post-sequestration single per-dose add-on payment amount (that is, for this comparison, we used the per-dose add-on payment amount prior to the application of the inflationary factor ($146.55) and applied the effects of sequestration for this comparison). The Entity-Level Percentage Change By Percentile portion of Table 8 shows the distribution of entities based on size of the difference between their 2019 baseline add-on payments (based on 4.3 percent of the applicable ASP) and the single per-dose add-on amount (post-sequestration). Each row shows the size of the impact for the given specialty. The 5th percentile will experience the largest negative impact whereas the 95th percentile will experience the largest positive impact.

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TABLE 8: ESTIMATED IMPACT BY SPECIALTY FOR THE PER-DOSE ADD-ON AMOUNT (BASED ON 2019 CLAIMS DATA)

Specialty*	Number of Entities**	Percentage of MFN Model Drug Spend†	Proportion of Specialty Revenue that is for Medicare Part B Drugs	Overall Specialty-Level Percentage Change (on average)	Entity-Level Percentage Change By Percentile***				
					5th Percentile	25th Percentile	50th Percentile	75th Percentile	95th Percentile
Hematology/Oncology	2083	29.2%	High	-8%	-48%	-24%	-7%	25%	493%
Ophthalmology	3175	18.0%	Medium	140%	69%	104%	349%	884%	4253%
Internal Medicine	5249	14.1%	Low	4%	-36%	7%	210%	652%	23511%
Rheumatology	2020	10.9%	High	9%	-47%	-9%	11%	62%	356%
Medical Oncology	624	8.3%	High	-13%	-49%	-25%	-9%	22%	333%
Neurology	2681	3.7%	Low	-21%	-88%	-62%	153%	201%	470%
Nurse Practitioner	2763	1.9%	Low	32%	-34%	103%	211%	393%	3706%
Hematology	509	1.5%	High	-6%	-52%	-28%	-7%	31%	356%
Urology	2385	1.5%	Low	143%	54%	169%	280%	414%	994%
Gastroenterology	1778	1.5%	Low	-20%	-46%	-29%	-7%	83%	493%
Family Practice	3595	1.0%	Low	115%	-21%	203%	214%	372%	35294%
Allergy/Immunology	1325	1.0%	Medium	46%	-29%	21%	54%	89%	31863278%
Physician Assistant	2079	0.6%	Low	222%	-25%	189%	233%	780%	2361%
Cardiology	2567	0.5%	Low	1284%	21%	1408%	1414%	1427%	2111%
Pulmonary Disease	905	0.5%	Low	37%	-29%	7%	31%	96%	36000%
Orthopedic Surgery	1678	0.4%	Low	794%	103%	527%	827%	1215%	2316%
Obstetrics/Gynecology	1285	0.4%	Low	55%	-44%	206%	214%	290%	1313%
Radiation Oncology	724	0.3%	Low	1%	-61%	-28%	20%	216%	584%
Endocrinology	1032	0.3%	Low	194%	67%	211%	212%	218%	19227%
Gynecological/Oncology	119	0.3%	High	-33%	-59%	-45%	-30%	-16%	356%
Infectious Disease	152	0.3%	Medium	-10%	-54%	-24%	42%	221%	3911%
Physical Medicine and Rehabilitation	1215	0.3%	Low	159%	28%	96%	189%	478%	1541%
Nephrology	1068	0.2%	Low	634%	-30%	424%	987%	1535%	3934%
Hematopoietic Cell Transplantation & Cellular Therapy	48	0.1%	Low	-15%	-45%	-27%	-15%	31%	287%
Hospitalist	398	0.1%	Low	8%	-62%	-5%	209%	348%	2977%
Dermatology	529	0.1%	Low	-31%	-72%	-46%	67%	556%	786658%
Interventional Cardiology	546	0.1%	Low	1383%	121%	1397%	1414%	1428%	1792%
General Practice	525	0.1%	Low	62%	-42%	96%	216%	334%	18269%
Interventional Pain Management	374	0.1%	Low	149%	-4%	189%	230%	592%	2316%
Pediatric Medicine	172	0.1%	Low	1%	-64%	-6%	74%	215%	2977%
Sleep Medicine	304	0.1%	Low	20%	-80%	-29%	22%	101%	379%
General Surgery	589	0.1%	Low	23%	-47%	4%	211%	488%	2225%
Emergency Medicine	695	0.1%	Low	106%	-61%	-16%	88%	369%	2908%
Ambulatory Surgical Center	460	0.1%	Low	300%	157%	290%	436%	509%	57743%
Sports Medicine	243	0.1%	Low	965%	189%	534%	781%	1290%	2361%

*Some MFN participants may be multispecialty.
** Estimated number of entities in the specialty.
*** Large percentage changes are due to a small number of drugs furnished by entities in the category.
† Table 2 provides the MFN Model Drugs (by HCPCS code) used for this analysis; this column provides the percentage of total 2019 Medicare spending by specialty for these drugs.

Based on these data, as shown in Table 8, all but 9 of the top 35 specialties (in terms of overall 2019 allowed dollars) impacted by the MFN

Model will on average see increases in add-on revenue compared to 4.3 percent of the applicable ASP with a single payment amount (the exceptions are hematology/oncology, medical oncology, neurology, hematology, gastroenterology, gynecological/oncology, infectious disease, hematopoietic cell transplantation & cellular therapy, and dermatology). At the 25th percentile, 57 percent of the entities will see increased add-on revenue for the top 35 specialties with the single per-dose add-on payment amount; whereas at the 50th percentile, 83 percent of the entities will see increased add-on revenue for the top 35 specialties with the single per-dose add-on payment amount. Please note that some of the large percentage increases seen shown in the 95th percentile column are likely driven by the small volume of drugs furnished by entities in this percentile.

We observed that volume is not consistently associated with whether an entity will be better or worse off under the per-dose add-on payment approach when we look at the single per-dose add-on amount approach for the top five specialties in terms of total aggregate Medicare spending on MFN Model drugs in 2019: internal medicine, hematology/oncology, ophthalmology, rheumatology, and medical oncology. When we specifically looked at the top, middle, and bottom of a distribution of all entities based on how much better or worse off each entity will be under the per-dose add-on payment amount compared to their add-on revenue (based on their 2019 claims), we found that entities in the top 5 percent (that is, those that will do the best) had very low volume (that is, few claims for these drugs in 2019 claims). Entities in the bottom 5 percent (that is, those that will do the worst) tended to have lower volume than the middle 10 percent, though volume was highest in the bottom 5 percent of entities in the internal medicine and ophthalmology specialties. Overall, entities that will be worse off compared to their add-on revenue (based on their 2019 claims) under the per-dose add-on payment approach tended to furnish more drugs with higher drug add-on payment amounts per dose more frequently than the entities that will be better off. We estimate that similar impacts will be experienced across the performance years unless ASPs for MFN Model drugs rise faster than inflation, in which case the overall increase in add-on revenue compared to non-model add-on revenue will diminish over time.

4. Beneficiary Cost-Sharing Responsibilities

In response to the October 2018 ANPRM, which suggested continuing beneficiary cost-sharing for the alternative add-on payment, some commenters suggested that CMS should ensure any alternative add-on payment does not increase out-of-pocket costs for beneficiaries. Other commenters noted that an alternative add-on payment could be confusing to beneficiaries since currently they pay cost-sharing based on a single amount, versus separate amounts, such as the MFN Model Drug Payment Amount and alternative add-on that we are including in the MFN Model. We appreciate these commenters' feedback.

To support reducing out-of-pocket drug costs and minimizing potential confusion for MFN beneficiaries related to the alternative add-on payment amount, and decreasing administrative burden for MFN participants, we will waive beneficiary cost-sharing (coinsurance and deductible amounts) on the portion of the allowed MFN Model Payment amount that is based on the alternative add-on payment. Under the MFN Model, the MFN Drug Payment Amount will be subject to beneficiary coinsurance and the annual deductible amount. MFN participants will continue to collect beneficiary cost-sharing applicable to the portion of the allowed payment amount that is based on the MFN Drug Payment Amount. For the alternative add-on, Medicare will pay the entire allowed payment amount that is based on the alternative add-on payment to ensure that beneficiaries do not experience an increase in cost-sharing under the MFN Model as a result of testing an alternative add-on amount. That is, beneficiaries will not owe any coinsurance or amount for the annual deductible for the per-dose add-on payment amount.

G. Billing and Claims Processing Approach

We intend to issue model-specific claims submission instructions that MFN participants will be required to follow. Currently, for separately payable Part B drugs, providers and suppliers submit separate claim lines for each drug. Among the information included in each claim line for the applicable bill type, providers and suppliers specify the appropriate HCPCS code to indicate the drug that was furnished, the number of billing units to indicate the total amount of the drug that was furnished, billing code modifiers as necessary, and a billing amount (or charge). In general, providers and suppliers routinely use one claim line to bill for a furnished drug dose, and using billing modifiers when doing so may be necessary to comply with billing instructions. In certain situations, a second claim line may be necessary to report the amount of drug that was furnished, for example, when the number of billing units necessary to indicate the dosage given exceeds the character size of the units field or when appropriately discarded drug is billed. When applicable, a separate line item is billed with the modifier JW to identify the amount of unused drugs (or biologicals) from single use vials or single use packages that was appropriately discarded. The Medicare claims processing system calculates payment for the amount of discarded drug when the modifier JW is present. MFN participants will be required to submit a separate claim line using a new model-specific HCPCS code (M1145, MFN drug add-on, per dose) to bill for and receive the alternative add-on payment amount for each dose of an MFN Model drug that is billed on the claim. The MFN participant will indicate in the units field of the claim line with HCPCS code M1145 the number of doses of a separately payable MFN Model drug that are billed on the claim. To do so, the MFN participant will count the number of claim lines with a HCPCS code that is included on the applicable MFN Model Drug HCPCS Codes List (based on the date of service), including all claim lines when the number of billing units necessary to indicate the dosage given exceeds the character size of the units field and the claim has more than one claim line for such MFN Model drug (we note that this is expected to be a rare situation), and excluding the number of claim lines billed with the JW modifier. This approach will allow the Medicare claims processing system to apply the alternative add-on payment amount for each dose, and not apply beneficiary cost-sharing to the alternative add-on payment amount. MFN participants will still bill for wastage as they otherwise would, using a separate claim line and the JW modifier, and the payment for such claim lines will be based on the MFN Drug Payment Amount (the alternative add-on payment amount is not applicable to such claim lines).

This billing and claims processing approach will initiate from the MFN participant's billing system and will establish a clear mechanism for MFN participants to track when the alternative add-on amount was billed and paid. This approach will simplify Medicare claims processing changes for the MFN Model. However, this

approach may increase administrative burden for MFN participants and requires MFN participants to count the number of claim lines for MFN Model drugs included on a claim, indicate this number in the units field of the claim line for the alternative add-on (using HCPCS code M1145), and submit a billing amount (or charge) on the claim line for the alternative add-on. In addition, the alternative add-on payment amount will be updated quarterly. Because Medicare allows the lesser of the applicable payment amount or the billed amount, MFN participants will have to ensure that they submit an appropriate billing amount (or charge) for the alternative add-on for the applicable quarter. Because the same HCPCS code will be used to bill for the alternative add-on for all MFN Model drugs, we believe this approach minimizes, but does not eliminate, the additional administrative burden for MFN participants.

We are waiving program requirements in section 1833(a)(1)(S), section 1833(a)(1)(G) and section 1833(t) of the Act, respectively to allow flexibility in the way in which claims subject to the MFN Model payment will be processed. Section 1833(a)(1)(S) of the Act specifies that the Medicare payment for drugs and biologicals not paid on a cost or prospective payment basis is 80 percent of the lesser of actual charge or the amount established in section 1842(o) of the Act. Similarly, section 1833(a)(1)(G) of the Act specifies that the amounts paid with respect to facility services furnished in connection with certain surgical procedures and with respect to services furnished to an individual in an ASC shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system. Section 1833(t) of the Act specifies how payment under the OPPS is calculated including beneficiary copayment. Specifically, we are waiving these program requirements to the extent necessary to allow the total allowable model payment for the service as specified in § 513.210 and § 513.220 (that is, the sum of the allowed MFN Drug Payment Amount and the allowed alternative add-on payment amount) and to not apply beneficiary cost-sharing to the alternative add-on payment amount.

H. Quality Measures

The October 2018 ANPRM stated our intention to include quality measures as part of the potential IPI Model, and our interest in several categories of potential measures, specifically: patient experience measures, medication management measures, medication adherence measures, and measures related to patient access and utilization. We sought public input on ways to assess quality of care for purposes of real-time monitoring of utilization, hospitalization, mortality, shifts in site-of-service and other important indicators of patient access and outcomes, without requiring providers or suppliers to report additional data. We received numerous comments in response to the October 2018 ANPRM on this topic. Several commenters expressed concern that testing alternative payments for Part B drugs in general may impact beneficiaries' access to care and may impact the overall patient experience of care. Some commenters requested that any quality measurement not add burden to model participants. Some commenters also discussed the importance of adherence to nationally recognized clinical guidelines in treatment decisions, stating that adherence to nationally recognized clinical guidelines would reduce drug spending while also maintaining and possibly increasing quality of care.

We appreciate the public feedback on ways we could structure a model to enhance and monitor quality of care. In the MFN Model, we will implement robust monitoring activities, such as analyzing claims data, using patient survey data, and site visits, to identify any unintended consequences and ensure that MFN beneficiaries' access to medications is not impeded and that quality of care is preserved or enhanced. Further, we believe the following principles are appropriate for a quality measurement approach for the MFN Model: (1) Use quality measures for the purpose of monitoring quality of care and beneficiary access to treatment and experience with care; (2) avoid unnecessary participant reporting burden as many providers and suppliers are currently reporting quality measures to other programs and payers, for example, the MFN Model should use claims-based measures where appropriate; and (3) establish standards for adding quality measures, if necessary, during the model. We believe that this approach will allow CMS to test the MFN Model's alternative drug payment methodology, while creating a safeguard for beneficiary access and quality of care, as well as a means to monitor patient access and quality of care. We are also sensitive to concerns regarding adding administrative burden to MFN participants and beneficiaries and, thus, seek to minimize burden on them. As such, in § 513.400(b)(1) we will collect only one quality measure, focused on patient experience, to help better understand the impact of the MFN Model on beneficiary access and quality of care. This survey will be fielded by CMS to avoid any quality measure reporting burden for MFN participants, although there will be reporting burden on beneficiaries. CMS will also monitor for quality as outlined in section III.I.4. of this IFC, including monitoring access to medications through rapid analysis of claims data, using monthly claims extracts that will provide frequent assessments of beneficiary access to MFN Model drugs and that complement existing methods to receive, assess, and respond to beneficiary and health care provider feedback on the MFN Model.

For the patient experience focused quality measure, we will use a patient experience survey, which we will field periodically to a sample of Medicare beneficiaries, beginning in performance year 1. The patient experience survey will be administered to these beneficiaries by a third party contractor throughout the model performance period. A sample of beneficiaries will be surveyed regarding their experience of care, access, or other issues they experienced under the MFN Model, and we may also sample beneficiaries who are not in the MFN Model. Beneficiaries will not be required to complete the survey.

Survey results will be used to monitor the impact of the MFN Model on MFN beneficiaries' care experience and potentially to inform educational materials for MFN participants. As is outlined in section III.I.4. of this IFC, claims data will also be monitored to assess patient access and outcomes.

If during the model the patient experience of care quality measure and claims-based monitoring strategies are found to be insufficient to adequately measure the quality of care that MFN beneficiaries are receiving or MFN participants are providing, CMS may specify additional measures to monitor quality. If additional quality measures are added, they will meet the following criteria: (1) Additional measures would be among one or more of the following categories: Patient experience of care, patient activation, shared decision making, adherence, utilization, and process measures; (2) Additional measures would not add significant burden to MFN participants or beneficiaries; and (3) Additional measures would utilize an instrument that CMS has used previously in a model to adjust payment or for monitoring or evaluation. We are codifying the inclusion of the patient

experience quality measure and its use as well as the criteria for adding measures during the MFN Model in § 513.400.

I. Beneficiary Protections and Monitoring Actions

We are interested in enhancing protections for beneficiaries included in the MFN Model. In addition to existing beneficiary protections, we will actively monitor the MFN Model to ensure it is operating effectively and meeting the needs of beneficiaries, providers and suppliers, and the Medicare program. We will coordinate with the Medicare Beneficiary Ombudsman and other customer facing components to ensure that any MFN Model-related beneficiary complaints, grievances, or requests for information submitted are responded to in an appropriate and timely manner, per CMS protocol.

We believe it will also be necessary to have additional protections in place in the MFN Model to ensure that beneficiaries retain their existing rights and are not harmed by the model test. Further, we believe it is important for beneficiaries to know and understand their rights as beneficiaries who are receiving care from MFN participants. We therefore believe it is necessary to include certain policies regarding beneficiary choice, appeals, and the availability of services.

1. Beneficiary Freedom of Choice

A beneficiary's ability to choose his or her provider or supplier is an important principle of Medicare fee-for-service and is reflected in section 1802 of the Act. We are codifying in § 513.410(a) that any MFN participant must not commit any act or omission, nor adopt any policy that inhibits a beneficiary from exercising his or her freedom to choose to receive care from any Medicare participating provider or supplier or any provider or supplier who has opted out of Medicare. We believe these provisions are necessary to ensure the MFN Model does not prevent beneficiaries from the general rights and guarantees provided under Medicare.

2. Appeals Processes and Financial Hardship Exemption

a. Appeals Processes

In § 513.410(b), we are codifying that MFN beneficiaries and their assignees will have access to the existing formal claims appeals process under 42 CFR part 405, subpart I. In other words, once an MFN Model drug is furnished by an MFN participant to a beneficiary and a claim is submitted and processed for payment, that claim will be eligible for the current Medicare claims appeals processes. If a beneficiary receives an MFN Model drug from an MFN participant it does not mean that he or she should lose this right, but instead this right should necessarily be applicable to included beneficiaries as it would be if they were not a part of the MFN Model.

b. Financial Hardship Exemption

To include financial protection for physicians and other MFN participants, specifically those who furnish substantial amounts of MFN Model drugs as part of the services they furnish to Medicare FFS beneficiaries, especially MFN Model drugs with the greatest difference between the MFN Price and the applicable ASP, we are including a financial hardship exemption codified in § 513.230. The financial hardship exemption process for MFN participants will be available in the event unintended consequences arise to ensure access to MFN Model drugs for MFN beneficiaries and financial protections for MFN participants who are unable to obtain MFN Model drugs at or below the MFN Model Payment for such drugs and are significantly affected by their participation in the MFN Model.

The financial hardship exemption process will occur independently of existing Medicare claims processing and appeals processes. In § 513.230(a), we codify that a financial hardship exemption for a performance year may be granted to an MFN participant by CMS, in its sole discretion and will not be subject to appeal, when the provisions in § 513.230 are met. This means that a financial hardship exemption, if granted, will be applied at the MFN participant level (as defined in § 513.2). As further described in this section of this IFC, a financial hardship exemption will be limited to cases where the MFN participant experienced a financial loss.

Specifically, to be eligible for a financial hardship exemption, the MFN participant must submit its request for a financial hardship exemption to CMS in accordance with the submission process that CMS will post on the MFN Model website prior to October 1, 2021, and in the form and manner and with the content that will be specified by CMS, including without limitation the requirements specified in § 513.230(b). Such requests must be submitted to CMS within 60 calendar days following the end of the performance year for which the MFN participant seeks a financial hardship exemption. The MFN participant must include the following in its request for a financial hardship exemption:

- Evidence of methods used to obtain each MFN Model drug that was furnished by the MFN participant during the performance year to any patient;
- Average net acquisition cost for each MFN Model drug (inclusive of all on-invoice prices and price reductions, off-invoice discounts, any adjustments thereto, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to MFN beneficiaries;
- Average net acquisition cost for each MFN Model drug (inclusive of all on-invoice prices and price reductions, off-invoice discounts, any adjustments thereto, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries;
- Statement of any remuneration received by the MFN participant from manufacturers of MFN Model drugs, wholesalers, and distributors that is not reflected in the MFN participant's average net acquisition costs with a justification of why such remuneration should not be treated as a price concession related to the purchase of an MFN Model drug;
- Administrative information, including: MFN participant's name, TIN or CCN (as applicable), contact name, phone number, and email address; and
- The MFN participant's attestation that—

++ It experienced a reduction in Medicare Part B FFS payments for separately payable drugs on a per beneficiary basis during the performance year as compared to the prior year (that is, the four calendar quarters immediately preceding the performance year) due to its inability to obtain one or more of the MFN Model drugs at or below the MFN Model Payments for such drugs during the performance year;

++ It has not received and will not receive any remuneration from manufacturers of MFN Model drugs, wholesalers, and distributors related to the purchase of an MFN Model drug that was furnished by the MFN participant during the performance year that is not reflected in the MFN participant's submission; and

++ Its submission is true, accurate, and complete.

In addition, MFN participants must use a template that CMS will post on the MFN Model website for submission of their net acquisition costs for MFN Model drugs and administrative information. This template will be

similar to the template CMS provided for the 2020 Hospital Survey for Specified Covered Outpatient Drugs (SCODs) Average Acquisition Cost.[72] The MFN participant will submit the other required materials to CMS along with the template.

In § 513.230(c), we codify the standards that CMS will use to determine if an MFN participant is granted a financial hardship exemption. Specifically, to be eligible for the financial hardship exemption, we codify in § 513.230(c)(2)(i) that the MFN participant must submit a timely, complete request for a financial hardship exemption in accordance with the requirements specified in § 513.230(b) that in the sole discretion of CMS demonstrates all of the following:

- The MFN Participant exhausted all reasonable methods to obtain the MFN Model drugs at or below the MFN Model Payments for such drugs during the performance year.
- The MFN participant's average net acquisition cost for each MFN Model drug (including on- and off-invoice discounts or adjustments) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries was not less than the MFN participant's average net acquisition costs for such MFN Model drug (including on- and off-invoice discounts or adjustments) that was furnished by the MFN participant during the performance year to MFN beneficiaries.
- Any remuneration the MFN participant received from manufacturers of MFN Model drugs, wholesalers, and distributors that was not reflected in the MFN participant's average net acquisition costs was not a price concession related to the purchase of an MFN Model drug.

In addition, in § 513.230(c)(2)(ii), we are codifying that the agency in its sole discretion must also determine that the MFN participant's excess reduction amount per beneficiary (as determined by CMS in accordance with § 513.230(d)(6)) is greater than zero. That is, the MFN participant must have experienced a reduction in Medicare FFS allowed charges for separately payable Medicare Part B drugs on a per beneficiary basis during the performance year as compared to the prior year (that is, the four calendar quarters immediately preceding the performance year) that is greater than 25 percent of the MFN participant's total Medicare Part A and Medicare Part B FFS allowed charges on a per beneficiary basis during the prior year. We are establishing a threshold of 25 percent of the MFN participant's total Medicare Part A and Medicare Part B FFS allowed charges on a per beneficiary basis as a criterion to qualify for the financial hardship exemption because the exemption is designed to be limited to MFN participants that experience a significant year-to-year reduction in total allowed charges as a result of the MFN Model. We believe this threshold will protect MFN participants from significant financial hardship under the MFN Model while also preserving the model test of aligning payment for Medicare Part B drugs with the lowest international prices using a phase-in approach.

Incomplete financial hardship exemption requests will not be considered by CMS.

In § 513.230(d), we are codifying how CMS will calculate the MFN participant's excess reduction amount per beneficiary. CMS will calculate the MFN participant's excess reduction amount per beneficiary using available final action claims data that are estimated to be more than 90 percent complete (claims are generally complete within 2 months after the service month) where Medicare was the primary payer, as determined by CMS. This approach will not include non-claims based payments or other transactions, for example, performance-based payment or repayments. CMS will calculate, for dates of service within the performance year, the MFN participant's total allowed charges for separately payable Medicare Part B drugs, and the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than $0. Then, CMS will divide the MFN participant's total allowed charges for separately payable Medicare Part B drugs for dates of service within the performance year by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than $0 with a service date within the performance year. CMS will repeat this calculation using the available claims data for the prior year, to calculate the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the prior year. Then, CMS will subtract the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the performance year from the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the prior year. This difference will then be compared to 25 percent of the MFN participant's average per beneficiary total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year, using subtraction as described in § 513.230(d)(6). The latter quantity will be calculated by identifying 25 percent of the MFN participant's total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year, then dividing this amount by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than $0 with a date of service within the prior year. If the resulting amount, called the excess reduction amount per beneficiary, is greater than zero, then the MFN participant will meet this eligibility criterion for the financial hardship exemption.

In § 513.230(e)(1), we are codifying that if CMS in its sole discretion grants a financial hardship exemption to an MFN participant for a performance year, CMS shall provide to such MFN participant, a reconciliation payment for the performance year. To calculate the reconciliation amount for the MFN participant, CMS will multiply the excess reduction amount per beneficiary by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than $0 with a service date within the performance year.

The reconciliation payment amount will be paid by a CMS contractor using Medicare Part B funds as soon as practical after CMS notifies the MFN participant of CMS's decision regarding the MFN participant's financial hardship exemption request and the amount of the reconciliation payment, if any, to be made to the MFN participant. In § 513.230(e)(2), we are codifying that there will be no appeal of the amount of the reconciliation payment, if any, to be made to the MFN participant. In addition, the reconciliation payment amount will not be subject to beneficiary cost sharing (including any deductible or coinsurance) because the reconciliation payment will not be tied to specific beneficiary claims, beneficiaries will have been responsible for 20 percent cost-sharing on the allowed payment amounts for the

[72] The template for the 2020 Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS–10709; OMB 0938–1374) available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.*

Medicare Part B drugs they received during the performance year, and steps to seek additional cost-sharing from beneficiaries would likely cause significant confusion and burden for beneficiaries and MFN participants.

We do not foresee that many MFN participants will qualify for a reconciliation payment for performance year 1, because the estimated overall reduction in Medicare Part B drug payment during performance year 1 is 7 percent on average. This reflects the MFN Price phase-in formula in section III.E.5. of this IFC which will begin with the MFN Price making up 25 percent of the MFN Drug Payment Amount and the alternative add-on payments in section III.F. of this IFC will represent a 40 percent increase on average for MFN participants relative to historical Medicare add-on payments. Given the financial hardship execption threshold of 25 percent of the MFN participant's total Medicare Part A and Medicare Part B FFS allowed charges on a per beneficiary basis in the prior year will be determined at the entity level, MFN participants with a high proportion of their overall Medicare payments related to MFN Model drugs will be more likely to qualify for the hardship exemption if their Medicare Part B drug allowed charges on a per beneficiary basis during a performance year were to decrease significantly compared to the prior year. MFN participants that are hospitals will likely have significant Medicare Part A revenues and purchasing abilities that will lessen the likelihood that they will qualify for a financial hardship exemption based on their experience in the MFN Model during performance year 1. Non-hospital MFN participants will be more likely to potentially qualify in later performance years.

For future years, we seek comment on whether an alternative threshold might better protect beneficiary access to MFN Model drugs or mitigate impacts on physicians and other MFN participants under the MFN Model. For example, we are interested in whether a uniform threshold should be applied for all MFN participants, and whether certain physician specialties or types of MFN participants would find the threshold insufficient in protecting beneficiary access to MFN Model drugs. For future rulemaking, we also seek comment on how CMS could refine the design of the financial hardship exception to advance the model goals to reduce program expenditures and maintain or improve quality of care.

CMS pledges to maintain confidentiality of individual financial hardship exemption requests to the extent provided by law. However, CMS may make public descriptive information about MFN participants that are granted a financial hardship exemption and the extent to which they were unable to obtain MFN Model drugs at or below the MFN Model Payment for such drugs. We do not intend to make such information available in an individually identifiable manner.

3. Availability of Services

The MFN Model is designed to test potential improvements to the delivery of and payment for healthcare to reduce Medicare expenditures while preserving or enhancing the quality of care for beneficiaries. As such, an important aspect of testing models is that beneficiaries must continue to have access to and receive needed care.

In § 513.410(c), we are codifying that MFN participants must not take any action to select or avoid treating beneficiaries based on their diagnoses, care needs, income levels, or other factors that would render them ''at-risk beneficiaries'' as that term is defined at 42 CFR 425.20 (''lemon dropping''). We will use monitoring to ensure that MFN participants are complying with this requirement. We believe that this is a necessary precaution to protect beneficiaries against potential beneficiary selection bias from MFN participants and ensure that MFN beneficiaries retain access to medically necessary treatment.

4. Monitoring and Compliance Activities

Consistent with other CMS Innovation Center models, CMS will implement a monitoring program for the MFN Model to ensure that the MFN Model is implemented safely and appropriately. Given that MFN participants will receive model-specific payments and access to payment rule waivers while participating in the MFN Model, we believe that enhanced compliance review and monitoring of MFN participants is necessary and appropriate to ensure the integrity of the MFN Model. In addition, as part of the CMS Innovation Center's assessment of the impact of new models such as the MFN Model, we have a special interest in ensuring that model tests do not interfere with ensuring the integrity of the Medicare program. Our interests include ensuring the integrity and sustainability of the MFN Model and the underlying Medicare program from both a financial and policy perspective, as well as protecting the rights and interests of Medicare beneficiaries. For these reasons, as a part of the models currently being tested by the CMS Innovation Center, CMS or its designee(s) monitors model participants to assess compliance with model terms and with other applicable program laws and policies. We believe our monitoring efforts help ensure that model participants are furnishing medically necessary covered services and are not falsifying data, increasing program costs, or taking other actions that compromise the integrity of the model or are not in the best interests of the model, the Medicare program, or Medicare beneficiaries.

In § 513.420, we are codifying a framework for conducting compliance monitoring activities for the MFN Model that is consistent with the standard practices in other CMS Innovation Center models. Under the monitoring policy at § 513.420(b), MFN participants will be monitored to assess compliance with the MFN Model requirements, to determine the effects of the MFN Model on MFN beneficiaries, providers, suppliers, and on the Medicare program and to facilitate real time identification and response to potential issues. Further, under § 513.420(a)(2), an MFN participant will be required to notify CMS within 15 calendar days after becoming aware that the MFN participant is under investigation or has been sanctioned by the federal, state, or local government, or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing rights).

In § 513.420(b)(2), we are codifying that when we are conducting compliance monitoring and oversight activities, CMS or our designees will be authorized to use any relevant data or information, including without limitation Medicare claims submitted for items or services furnished to MFN beneficiaries. In § 513.420(b)(3), we are codifying that MFN participants will be required to cooperate with the model monitoring and evaluation activities, comply with the government's right to audit, inspect, investigate, and evaluate any documents or other evidence regarding implementation of the MFN Model, and to retain and provide the government with access to records.

In § 513.420(b)(1), we are codifying that monitoring activities will include, but will not be limited to: (1) Documentation requests sent to the MFN participant, including surveys and questionnaires; (2) audits of claims data, medical records, and other data from the MFN participant; (3) interviews with any individual or entity participating in the MFN Model, including members of the MFN participant's leadership,

management, and staff; (4) interviews with beneficiaries and their caregivers; (5) site visits to the MFN participant; and (6) tracking complaints and appeals. We believe these specific monitoring activities, which align with those currently used in other models being tested by the CMS Innovation Center, are necessary in order to ensure compliance with the terms and conditions of the MFN Model and to protect beneficiaries from potential harms that may result from activities of an MFN participant, such as attempts to reduce access to medically necessary covered services or appropriate drugs.

We anticipate that monitoring of the MFN Model activities will include gathering and analyzing data captured through the Ombudsman's service, the evaluation of the MFN Model, the patient experience survey, and audits of charts, claims data, medical records, among other data as available. As previously noted in this IFC, one purpose of monitoring and analyzing these data sources will be to provide timely information about the effects of the MFN Model on MFN beneficiaries, providers, suppliers, and on the Medicare program, and to facilitate real time identification and response to potential issues. We anticipate that these findings will inform model oversight and the potential need for action to address identified issues.

In § 513.420(c), we outline parameters for site visits. We will require that MFN participants cooperate in periodic site visits conducted by CMS or its designee. Such site visits will be conducted to facilitate the model implementation.

In order to operationalize this model, CMS or its designee will provide the MFN participant with no less than 15 calendar days advance notice of a site visit, to the extent practicable. Furthermore, to the extent practicable, CMS will attempt to accommodate a request that a site visit be conducted on a particular date, but that the MFN participant will be prohibited from requesting a date that was more than 60 calendar days after the date of the initial site visit notice from CMS. We believe the 60-calendar day period will reasonably accommodate MFN Model participants' schedules while not interfering with the operation of the MFN Model. Further, we will require MFN participants to ensure that personnel with the appropriate responsibilities and knowledge pertaining to the purpose of the site visit be available during any and all site visits. We believe this is necessary to ensure an effective site visit and prevent the need for unnecessary follow-up site visits.

Finally, CMS or its designee can perform unannounced site visits to all physical locations of MFN participants at any time to investigate concerns related to the health or safety of beneficiaries or other patients or other program integrity issues, notwithstanding these provisions. Further, nothing in part 513 will limit CMS from performing other site visits as allowed or required by applicable law. We believe that, regardless of the model being tested, CMS must always have the ability to timely investigate concerns related to the health or safety of beneficiaries or other patients, or program integrity issues, and to perform functions required or authorized by law. In particular, we believe that it will be necessary for us to monitor, and for MFN participants to be compliant with our monitoring efforts, to ensure that they are not denying or limiting the coverage or provision of medically necessary covered services to beneficiaries in an attempt to change the MFN Model results or their MFN Model payments, including discrimination in the provision of services to at-risk beneficiaries (for example, due to eligibility for Medicaid based on disability).

We intend to monitor MFN participants through any of the previously described monitoring activities (such as documentation requests, audits of claims data, audits of medical records, etc.) to ensure that MFN Model drugs are not being inappropriately billed (for example, excessive doses or units). We anticipate that this monitoring activity will discourage MFN participants from furnishing smaller and more frequent doses of MFN Model drugs to beneficiaries in order to maximize the alternative add-on payments. If it is found that an MFN participant has been engaged in inappropriate billing, then we will use applicable remedial actions set forth in § 513.440(a)(2).

We may employ longer-term analytic strategies to confirm our ongoing analyses and detect more subtle or hard-to-determine changes in care delivery and beneficiary outcomes. Some determinations of beneficiary outcomes or changes in treatment delivery patterns may not be able to be built into ongoing claims analytic efforts and may require longer-term study.

a. Reduced Access

We will monitor claims data from MFN participants—for example, to compare MFN participants' case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. To the extent that the use of a patient experience survey includes items focused on access, we will analyze these data as well to determine whether MFN beneficiaries continue to be able to access the right drug at the right time. We will use these data to promote transparency and develop an understanding of the MFN Model's effects. We intend to review and audit MFN participants if we have reason to believe that they are compromising beneficiary access to care.

We intend to conduct analyses of claims data, such as monthly updates and historic comparisons of trends including drug utilization, program spending, and prescribing patterns (including observing for any shift to compounded or other categories of drugs that are not included in the MFN Model) as well as changes in site of service delivery, mortality, hospital admissions, and other indicators present in claims data. We will monitor physician visits, days in a hospital, and other services as part of the thorough look at how MFN beneficiaries are receiving care to determine whether any treatment patterns are changing systematically. We will use the monitoring results to detect potential issues with beneficiary access to care or potential provider and supplier payment issues.

b. Quality of Care Monitoring

We anticipate that quality monitoring activities may include claims and survey data analytics, site visits, medical record review, and tracking patient complaints and appeals. We will also use the most recent claims data available to track utilization and beneficiary outcomes under the MFN Model. We believe this type of monitoring is important as we want to ensure to the greatest extent possible that patients continue to receive high-quality care.

We believe that this set of monitoring activities will allow us to promptly identify any unintended consequences of the MFN Model. We anticipate that by identifying unintended potential consequences of the MFN Model, that we will then be able to determine methods to address or alleviate those potential consequences.

c. Remedying Improper Payment

We anticipate that our monitoring activities may identify instances of incorrect MFN Model payments. As such, we are codifying that CMS is authorized to correct model-specific payments under § 513.420(d). Specifically, under this section if CMS discovers that it has made or received

an incorrect model-specific payment under the terms of the MFN Model, then CMS may make payment to, or demand payment from, the MFN participant. Should these monitoring activities identify a need for additional protections, we will consider appropriate action.

d. Compliance With Laws

MFN participants will remain subject to all existing requirements and conditions for Medicare participation as set out in Federal statutes and regulations and provider and supplier agreements, unless waived under the authority of section 1115A(d)(1) of the Act solely for purposes of testing the MFN Model. In § 513.420(a)(1), we therefore require that MFN participants must comply with all applicable laws and regulations. We note that a law or regulation is not ''applicable'' to the extent that its requirements have been waived under section 1115A(d)(1) of the Act solely for purposes of testing the MFN Model.

5. Enforcement Authority and Remedial Action

We are codifying at § 513.440(b) that nothing contained in the terms of the MFN Model or part 513 will limit or restrict the authority of the HHS Office of Inspector General (OIG) or any other Federal Government authority, including its authority to audit, evaluate, investigate, or inspect the MFN participant.

It is necessary for CMS to have the ability to impose remedial actions to address non-compliance with the requirements of the MFN Model and to ensure that the MFN Model does not interfere with the program integrity interests of the Medicare Program. Thus, in § 513.440(a)(1), CMS may take remedial action against an MFN participant if CMS determines, in CMS' sole discretion, that the MFN participant—

- Has failed to comply with any applicable Medicare program requirement, rule, or regulation;
- Has failed to comply with any of the terms of the MFN Model, including applicable requirements of part 513;
- Systematically engaged in the under delivery or over delivery of an MFN Model drug;
- Has taken any action that threatens the health or safety of an MFN beneficiary or other patient;
- Has undergone a change of control that presents a program integrity risk;
- Has submitted false data or made false representations, warranties, certifications or attestations in connection with any aspect of the MFN Model;
- Has avoided at-risk beneficiaries, as this term is defined in § 425.20;
- Has avoided patients on the basis of payer status;
- Is subject to any sanctions or final actions of an accrediting organization or a Federal, State, or local government agency;
- Takes any action that CMS determines for program integrity reasons is not in the best interests of the MFN Model, or the Medicare program, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the MFN Model or Medicare program;
- Is subject to investigation or action by HHS (including the HHS Office of the Inspector General (OIG)) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act *qui tam* matter in which the Federal Government has intervened, or similar action;
- Is the subject of administrative enforcement action imposed by CMS; or
- Has failed to demonstrate improved performance following any remedial action imposed by CMS.

In § 513.440(a)(2), we are codifying that if CMS determines that one or more grounds for remedial action exists, CMS may take one or more of the following remedial actions:

- Notify the MFN participant of the violation.
- Require the MFN participant to provide additional information to CMS or its designees.
- Require the MFN participant to develop and implement a corrective action plan in a form and manner and by a deadline specified by CMS.
- Subject the MFN participant to additional monitoring, auditing, or both.
- Remove the MFN participant from the MFN Model;
- Recoup model-specific payments.
- Such other action as may be permitted under the terms of § 513.420.

6. Audits and Record Retention

By virtue of participation in the MFN Model, MFN participants will receive model-specific payments and access to payment rule waivers. We therefore believe that CMS' ability to audit, inspect, investigate, and evaluate records and other materials related to participation in the MFN Model is necessary and appropriate. In order to expand a phase 1 model tested by the CMS Innovation Center, among other things, the Secretary must first determine that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals. Thus, there is a particular need for CMS to be able to audit, inspect, investigate, and evaluate records and materials related to participation in CMS Innovation Center models to allow us to ensure that the model is not denying or limiting the coverage or provision of benefits for beneficiaries.

We note that there are audit and record retention requirements under the Medicare Shared Savings Program (42 CFR 425.314) and in current models being tested under section 1115A (such as under 42 CFR 510.110 for the CMS Innovation Center's Comprehensive Care for Joint Replacement Model). Building off those existing requirements, in § 513.430(a), the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, have a right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of the MFN Model. Additionally, in order to align with the policy of current models being tested by the CMS Innovation Center, we are codifying in §§ 513.430(b) and (c) that MFN participants must—

- Maintain and give the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the MFN Model, including without limitation, documents and other evidence regarding all of the following:

++ The MFN participant's compliance with the terms of the MFN Model, including new subpart E of part 513.

++ Quality measure information and the quality of services performed under the terms of the MFN Model, including new subpart E of part 513.

++ Patient safety.

++ The accuracy of model-specific payments under the MFN Model.

++ Utilization of items and services furnished under the MFN Model.

++ Any other program integrity issues.

- Maintain the documents and other evidence for a period of 6 years from the last payment received by the MFN participant under the MFN Model or from the date of completion of any audit, evaluation, inspection, or

investigation, whichever is later, unless—

++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MFN participant at least 30 calendar days before the normal disposition date; or

++ There has been a termination, dispute, or allegation of fraud or similar fault against the MFN participant in which case the records must be maintained for an addition 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

If CMS notifies the MFN participant of the special need to retain records or group of records at least 30 calendar days before the normal disposition date, the records must be maintained for such period of time determined by CMS.

J. Interaction With Other Models and Programs

1. Approach for Overlap With Other Models

In designing each CMS Innovation Center model, CMS considers potential overlap between a new model and other ongoing and potential models and programs. Based on the type of overlap, such as health care provider or beneficiary, operating rules may be established for whether or not health care providers and beneficiaries can be part of both models as well as how to handle overlap when it occurs. These policies help to ensure that the evaluation of model impact is not compromised by issues of model overlap and that double counting of beneficiaries and dollars across different models does not occur.

In response to the October 2018 ANPRM, several commenters expressed concern regarding model overlap, specifically with the Oncology Care Model (OCM) and initiatives involving accountable care organizations (ACOs). Some commenters noted that OCM participants should be excluded from the potential IPI Model or excluded from mandatory participation. Some commenters also requested that ACO initiatives take precedence in terms of calculating shared savings as well as for clarity on how overlap between ACO initiatives and the potential IPI Model would work.

We appreciate commenters' request for detailed information about model overlap policies. In developing the MFN Model, CMS conducted an internal review of which models will have potential overlap with the MFN Model. As a result of our review, we expect there will be situations where a Medicare beneficiary who receives an MFN Model drug will also be assigned, aligned, or attributed to another CMS Innovation Center model or CMS program. Overlap could also occur among providers and suppliers at the individual or organization level, for example, a health care practitioner or a physician group practice could participate in multiple CMS Innovation Center models and CMS programs concurrently. Of note, some existing models and programs will not have overlap at the health care practitioner or participant level due to the way in which the model or program operates and makes payments.

We believe that the MFN Model is operationally compatible with existing models and programs that provide opportunities to improve care and reduce spending, especially total cost of care-focused CMS programs and Innovation Center models. The MFN Model will test an innovative way to pay for Medicare Part B drugs that seeks to address any existing incentives for prescribing higher cost drugs and ways to lower costs for beneficiaries and the Medicare program; total cost of care-focused CMS programs and Innovation Center models incentivize more appropriate provision of care across multiple clinical areas, including use of Medicare Part B drugs; the MFN Model addresses only use of certain Medicare Part B drugs. To some degree, incentives for inappropriate use of higher cost drugs are reduced, and intended effects of the MFN Model are already built into total cost of care-focused models, so the addition of the MFN Model should not have further effects in those programs. We do not plan to make adjustments to the MFN Drug Payment Amount or MFN alternative add-on payment due to overlap between the MFN Model and another model or program, unless such model tests an alternative approach to the add-on portion of payment for Medicare Part B drugs as specified in § 513.220(d)(2). However, for certain models and programs, adjustments to those models and programs may be necessary to account for payment changes under the MFN Model.

Because the MFN Model will focus on approximately 50 separately payable Medicare Part B drugs, when claims are considered from all beneficiaries aligned with or assigned to some other Innovation Center models or CMS programs that focus on total cost of care, such as the Medicare Shared Savings Program, we do not expect that the MFN Model will have a significant impact on shared savings, total cost of care, or other benchmarks and measures. Therefore, changes to benchmarks, targets, and reconciliation methodologies may not be necessary, and will be determined by each other model, program, or initiative as appropriate.

However, we recognize that the design of some other models, programs, and initiatives could create unique challenges at the organization, clinician, or beneficiary level. As a result, we will work with such models, programs, or initiatives to resolve any potential overlaps that could result in overpayment of savings due to double counting of the impact of a result that could be attributed to the interventions from two different models. For example, OCM focuses on improved care management and coordination for Medicare beneficiaries with cancer who receive chemotherapy during 6-month episodes of care. An OCM practice has the opportunity to receive a performance-based payment if it reduces the total cost of care in its OCM episodes compared to a target. Based on the performance year 1 MFN Model Drug HCPCS Codes List, we anticipate substantial overlap between MFN participants and MFN beneficiaries with OCM practices and OCM beneficiaries. To avoid paying performance-based payments in OCM that are due simply to the drug payment change that will occur under the MFN Model and not to changes in care delivery, for OCM, we will adjust reconciliation calculations such that the drug payments included in OCM episode expenditures will be calculated as if the MFN Model were not occurring. OCM participants will be notified and provided with further information through OCM's typical channels of communication.

As discussed in the section III.C.1. of this IFC, CMMI has already waived section 1833(t) of the Act for certain acute care hospitals due to their participation in models under section 1115A of the Act for which payment for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis. For the first and second quarters of performance year 1, we will exclude these entities from the MFN Model with limitation. That is, the acute care hospitals that participate in another CMS Innovation Center model under which they are paid for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, on a fully capitated or global budget basis under a waiver under such model of section 1833(t) of the Act, such as the Maryland Total Cost of Care Model and the Pennsylvania Rural Health Model, will be excluded

from the MFN Model. For the third quarter of performance year 1 and beyond, acute care hospitals that participate in a CMS Innovation Center model under which they are paid for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, on a fully capitated or global budget basis under a waiver under such model of section 1833(t) of the Act will be excluded from the MFN Model if the parameters of the other CMS Innovation Center model adjust for the difference in payment for MFN Model drugs between the MFN Model and non-MFN Model drug payments such that savings under the MFN Model are incorporated into the other CMS Innovation Center model's parameters (for example, the annual global budget) for the duration of the MFN Model. These exclusions will apply only during the period of the hospital's participation in such model under which it is paid on a fully capitated or global budget basis. Upon termination of such participation for any reason or if the model is revised such that the waiver of section 1833(t) of the Act no longer applies under such model, the hospital—if it otherwise meets the definition of MFN participant—will be required to participate in the MFN Model.

We anticipate model overlap may occur between the MFN Model and future CMS models or programs not yet implemented. As discussed in section III.F.5. of this IFC, if there are MFN participants that concurrently participate in a future CMS model that also tests an alternative approach to the add-on portion of payment for Part B drugs, we will not make the MFN alternative add-on payment to those MFN participants for those MFN Model drugs that overlap with the other model. Instead, we will follow the other model's approach to making an alternative add-on payment. We expect this overlap policy will maintain the intended financial effects of the MFN Model, while allowing operational compatibility with other models that test alternative approaches to Medicare Part B drug payment.

2. Quality Payment Program

The MFN Model will not qualify as an Advanced APM under the Quality Payment Program. Specifically, the MFN Model does not require participant health care providers to use CEHRT, does not base payment to participant health care providers on quality measures, and does not satisfy the financial risk criteria because it does not involve requiring participating APM Entities to bear risk for monetary losses of more than nominal amounts under the APM and is not a Medical Home Model expanded under section 1115A(c) of the Act. The MFN Model also will not qualify as a MIPS APM, because it does not hold participant health care providers financially accountable for both the cost and quality of care provided to Medicare beneficiaries.

K. Interaction With Other Federal Programs

The MFN Model may have impacts on other federal programs, such as Medicaid, the 340B Program, the Veterans Health Administration, the Department of Defense, the Public Health Service, the Coast Guard, and Medicare.

1. Impact on Medicaid

a. Impact on Medicaid ''Best Price''

With respect to single source or innovator multiple source drugs (which Medicaid recognizes to include biologicals), the term ''Medicaid Best Price'' is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity within the U.S. with certain exclusions. That is, a manufacturer's best price determination represents the lowest price available from the manufacturer during a rebate period (a quarter) to best price eligible entities or purchasers in the U.S. only.

Since the MFN Drug Payment Amount will be paid to MFN participants for each MFN Model drug as a Medicare payment, and it will not be a ''price available from the manufacturer,'' the MFN Drug Payment Amounts themselves will not be included in the manufacturer's determination of best price. However, in order for MFN participants to purchase MFN Model drugs at prices that does not lead to financial loss, the manufacturer will need to make available prices that are competitive with the MFN Drug Payment Amounts. We expect that the MFN Drug Payment Amounts will likely drive manufacturer drug prices available to MFN participants down over the course of the model, and the model may indirectly impact a manufacturer's best price to the extent that a manufacturers' U.S. best price will be lower than what it would be otherwise. In other words, if during the course of the MFN Model, market forces result in manufacturers reducing prices available to MFN participants, such available prices to MFN participants will be considered in a manufacturer's determination of best price and could potentially lower best price and possibly increase Medicaid rebates.

Specifically, if the manufacturer lowers prices available to an MFN participant at or below the MFN Drug Payment Amount, such prices will be considered in the manufacturer's determination of best price and may reset the manufacturer's best price if the reduced price is lower than the manufacturer's best price that would otherwise apply. This is particularly possible because the MFN Drug Payment Amount, which is expected to be lower than the payment amounts for the same drugs outside of the model, will include the impact of pricing outside of the U.S., which is typically lower than prices in the U.S., and will likely impact the prices made available by the manufacturer in the U.S.

b. Impact on Average Manufacturer Price (AMP)

AMP is defined at section 1927(k)(1) of the Act. Generally, AMP is determined based on the average price paid to the manufacturer for a covered outpatient drug in the U.S. by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer with certain exclusions. Because the MFN Model will focus on certain Part B drugs that are furnished in the outpatient setting and these drugs are most likely injected or infused, the AMP for an MFN Model drug is likely determined using the AMP computation for 5i drugs,[73] which includes sales that are not generally dispensed through retail community pharmacies (see section 1927(k)(1)(B)(i)(IV) of the Act, 42 CFR 447.504(d)), such as sales to physicians, pharmacy benefit managers (PBMs) and hospitals. Thus, a manufacturer's sales of MFN Model drugs to MFN participants (or price paid by MFN participants) will be included in the AMP or 5i AMP. If, as described in section III.K.1.a. of this IFC, the manufacturer lowers prices available to an MFN participant at or below the MFN Drug Payment Amount, the manufacturer's AMP for an MFN Model drug may be lower. If a drug's AMP decreases, it may result in potentially lowering the applicable Medicaid drug rebate paid (the rebate, in part, is based on a percentage of AMP). However, the MFN Model may also lower a manufacturer's best price for an MFN Model drug as previously discussed. The resulting effect on the Medicaid

[73] Inhalation, infusion, instilled, implanted or injectable drugs.

drug rebate will depend upon the relationship of any AMP change and any best price change.

We also note that if the AMP for an MFN Model drug is lowered it may be more likely that, in accordance with section 1847A of the Act, the Inspector General may find that the ASP for an MFN Model drug exceeds the AMP for such drug, and that the circumstances in which 103 percent of AMP is substituted for ASP in CMS's determination of the non-model payment allowance for such drug would occur. We refer readers to section III.L. of this IFC for a discussion of excluding units of MFN Model drugs from manufacturers' ASP, which may also increase the likelihood that the ASP for an MFN Model drug will be greater than the AMP for such drug.

2. Interaction With 340B Program

The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program that allows certain hospitals and other health care providers (''covered entities'') to obtain discounted prices on ''covered outpatient drugs'' (as defined at 1927(k)(2) of the Act) from drug manufacturers. HRSA calculates a 340B ceiling price for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug that is provided to an eligible patient. Several types of hospitals as well as clinics that receive certain federal grants from the HHS may enroll in the 340B program as covered entities. Such entities will be included in the MFN Model and will be subject to the MFN Model payment test. That is, these 340B covered entities will be MFN participants and receive the MFN Drug Payment Amount and alternative add-on payment. To the extent these entities receive payment under the model that is lower than their current Medicare payment, there may be fewer resources available for their 340B program activities.

Under the MFN Model, MFN participants will be paid for MFN Model drugs according to the payment approach discussed in section III.E. of this IFC. If the MFN participant is a 340B covered entity, the drug portion of the model payment will be the lower of the MFN Drug Payment Amount or the non-model payment amount paid to 340B covered entities for 340B drugs under the OPPS for the MFN Model drug for that corresponding calendar quarter. The MFN alternative add-on payment will be paid to MFN participants that are 340B covered entities in the same way as MFN participants that are non-340B covered entities.

We are including certain 340B covered entities in the MFN Model in order to test the innovative payment approach, including the alternative (per-dose) add-on payment amount, broadly. MFN participants that are 340B covered entities may need to enhance their direct contracting with manufacturers in order to obtain MFN Model drugs within the MFN Drug Payment Amount. Our analyses estimate that 340B covered entities will realize a total add-on percentage amount of 4.5 percent in the first year of the model due to the mix of MFN Model drugs they historically furnish. The amount of the alternative add-on that 340B entities realize will be an increase in revenue compared to their historical baseline. However, these entities will face the same or increased burden from model participation. Thus, we believe the modest increase in add-on revenue that will be paid to these entities through the alternative add-on payment approach will potentially be offset through higher facility costs for acquiring included drugs (for example, higher costs for direct contracting). Programs that support vulnerable Americans are a vital safety net. We refer readers to section III.C. of this IFC where we discuss providers and suppliers that will be MFN participants. We discuss potential impacts on 340B covered entities in more detail in section VI. of this IFC.

a. Impact on 340B Ceiling Price

Covered entities that enroll in the 340B Program can purchase covered outpatient drugs at no more than a ''ceiling price,'' which is calculated as AMP minus Medicaid unit rebate amount. We note that a ceiling price is just a ceiling; some 340B hospitals can obtain covered outpatient drugs at less than the ceiling price. Since the Medicaid unit rebate amount is based partly on AMP minus best price, to the extent the MFN Model affects a drug's AMP and best price, the 340B prices will be affected. We discuss the potential impacts on a drug's AMP and best price in section III.K.1. of this IFC.

3. Interaction With Medicare

a. Medicare Part B

As discussed in section VI. of this IFC, we believe the MFN Model will result in lower Medicare spending for MFN Model drugs, including lower program spending and lower beneficiary cost-sharing, and in overall reduced Medicare Part B Trust Fund expenditures, which in turn will lower Medicare FFS expenditures and beneficiaries' Part B premiums.

As discussed in section III.K. of this IFC, manufacturers' ASPs for MFN Model drugs may be higher or lower than they otherwise would be absent the MFN Model. In turn, non-model Medicare Part B FFS payment for MFN Model drugs could be higher or lower. We are excluding from the calculation of the manufacturer's ASP any units of an MFN Model drugs furnished to MFN beneficiaries and billed by MFN participants. Thus, during the MFN Model, manufacturers' ASPs for MFN Model drugs could be higher or lower than they might be absent the model, resulting in Medicare payments to providers and suppliers that are not MFN participants that would be higher or lower than what the payments would have been absent the model.

We note that if the AMP for an MFN Model drug is lowered it may be more likely that, in accordance with section 1847A of the Act, the Inspector General may find that the ASP for an MFN Model drug exceeds the AMP for such drug, and that the circumstances in which 103 percent of AMP is substituted for ASP in CMS's determination of the non-model payment allowance for such drug would occur.

b. Medicare Advantage

Medicare Advantage (MA) plans will not be MFN participants. We note that when MA plans pay non-contracted, out of network providers who have administered an MFN model drug to an enrollee, the amount paid will be based on the non-model Medicare FFS payment amount (that is, the amount that MA plans pay to these providers will not be the MFN Model payment amounts).

As discussed in section VI. of this IFC, we expect the MFN Model will lower overall Medicare FFS expenditures; that is, Medicare Part B MFN Drug Payment Amounts will be lower than such payment would be absent the model, the Medicare Part B alternative add-on payments will be greater than such payment would be absent the model, there could be increases in Medicare Part A spending, and taken together the model will result in an overall reduction in Medicare expenditures. The overall decrease in Medicare FFS expenditures will be considered in determining the historical FFS claims experience for calculating the rates for plan service areas. Payments to Medicare Advantage Organization plans are anticipated to be lower than they would be absent the model. At a high level, the FFS

component of the non-ESRD MA rates is based on the product of the projected national per-capita spending and a county-level relative cost index. Thus, the MA ratebook calculations will reflect changes in actual FFS spending due to the impact of the MFN Model. We note that this approach is consistent with treatment of payments made under other CMS Innovation Center models and the Medicare Shared Savings Program.

As discussed in more detail in section VI. of this IFC, we estimate that total payments to MA plans over the 7-year course of the model will be substantially lower as a result of reduced FFS spending under the MFN Model, that is, total payments to MA plans may be approximately $49.6 billion lower in the OACT estimate and $28.5 billion lower in the ASPE estimate. We note that there is much uncertainty around the assumptions for these estimates.

L. Exclusion of Certain MFN Model Sales From Manufacturers' Calculation of ASP for MFN Model Drugs

In accordance with sections 1847A and 1927(b)(3)(A)(iii) of the Act, manufacturers [74] [75] submit ASP data for their products to CMS on a quarterly basis. The manufacturer's ASP is based on sales to all purchasers in the U.S. with limited exceptions (that is, exclusions are limited to sales exempt from best price (as defined in section 1927(c)(1)(C)(i) of the Act), sales at a nominal charge, and units sold to a CAP vendor), and is net of discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than certain rebates specified in section 1927 of the Act). Specific ASP reporting requirements are set forth in section 1927(b)(3) of the Act. In accordance with sections 1847A and 1927(b)(3) of the Act, manufacturers report most ASP data by National Drug Code (NDC), which identifies products in terms of the labeler, product, and package size and type. The reported ASP data are used to establish the Medicare payment amounts. In general, Medicare's payment limit for most separately payable Part B drugs is based on the methodology in section 1847A of the Act, that is, 106 percent of the volume-weighted average of manufacturers' ASP for a drug (at the billing and payment code level), and is updated quarterly. The payment requirements in section 1847A of the Act will be waived for purposes of testing the MFN Model as discussed in section III.M.1. of this IFC, but will continue to apply outside of the model as discussed in this section.

Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care furnished to beneficiaries. The MFN Model will test an alternative approach for determining Medicare's payment limit for MFN Model drugs, which will phase down the Medicare payment amount for selected Part B drugs to more closely align with available international prices, and test an alternative add-on payment. Under the MFN Model, the model's payment test will apply when Medicare makes separate payment for an MFN Model drug that was furnished on an outpatient basis by an MFN participant to an MFN beneficiary within the model's nationwide geographic area.

In designing the MFN Model, we considered ways to mitigate potential impacts on manufacturers' ASPs stemming from price concessions given to MFN participants for purchases related to the MFN Model and on Medicare payment for units of MFN Model drugs that are not subject to the MFN Model payment test. For example, sales to MFN participants may include larger price concessions than are typical today, resulting in lower net sales prices as compared to what net sales prices would be absent the MFN Model. As such, the manufacturer's ASP for an MFN Model drug, which will reflect the average price for all non-excluded sales—including sales to MFN participants to the extent applicable—may be lower than the manufacturer's ASP would be absent the MFN Model. Because CMS will base the non-model Medicare payment limit for an MFN Model drug on 106 percent of the manufacturer's ASP, payment to providers and suppliers for such drug outside of the model may be lower than it otherwise would be absent the MFN Model. To conduct the MFN Model test it is necessary to minimize this potential spillover effect for providers and supplier that are not MFN participants to best observe the impacts of the payment change. Thus, we will exclude from the calculation of the manufacturer's ASP any units of MFN Model drugs billed by MFN participants where the MFN Drug Payment Amount is based on available international drug pricing information and Medicare Part B is the primary payer. policy will only apply when the MFN Price is based on available international drug pricing information. That is, the policy will not apply when there is no available international drug pricing information and the MFN Price is equal to the applicable ASP because there will be no concern for spillover impacts in such cases. We are waiving requirements of section 1847A of the Act as necessary to exclude such units of MFN Model drugs from the calculation of the manufacturer's ASP. We will also indicate the MFN Drug Payment Amounts that are (and are not, when applicable) based on available international drug pricing information within the quarterly MFN Model drug pricing files posted on a CMS website.

This approach is responsive to comments we received in response to the October 2018 ANPRM. Several commenters requested clarification about how sales for purposes of the model would be taken into account in computing the ASP under section 1847A of the Act. Some commenters who expressed concern about potential spillover effects of the potential model payment test recommended that purchases made for use under the potential model be excluded from the ASP calculation. Based on our interactions with stakeholders, particularly those with experience operating chargebacks related to the 340B program, we believe our exclusion of units of MFN Model drugs that are billed by MFN participants and have the MFN Drug Payment Amount paid by Medicare from manufacturers' ASPs will be feasible. Manufacturers have existing processes and tools to exclude various prices from the calculation of their ASPs, and excluding certain MFN Model related units of MFN Model drugs could be similar.

Distribution management systems are employed throughout the drug distribution system to order drugs, track sales and shipments, trace custody, manage price and customer lists, record financial transactions, and support other industry processes. Separate purchasing accounts are often used to align with purchasing arrangement terms, and

[74] For the purposes of reporting under section 1847A of the Act, the term ''manufacturer'' is defined in section 1927(k)(5) of the Act and means any entity engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products; either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. The term manufacturer does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. However, manufacturers that also engage in certain wholesaler activities are required to report ASP data for those drugs that they manufacture. Note that the definition of manufacturers for the purposes of ASP data reporting includes repackagers.

[75] Manufacturer is also defined in 42 CFR 447.502.

through a process called the ''chargeback process,'' manufacturers reduce the final drug prices to wholesalers and other distributors to reflect the purchasing terms and contract prices that apply to the end purchaser. End purchasers of drugs who purchase under more than one contract use virtual inventory or replenishment purchasing tools or business processes to manage their purchases under their various contract arrangements. For example, a provider or supplier that belongs to more than one group purchasing organization could use such tools or business processes to track drug purchasing, maintain records toward volume targets and, should the need to return a product occur, conduct returns. However, based on stakeholder feedback, we understand that all MFN participants are unlikely to have such tools in place. Hospitals, particularly those that participate in the 340B program, are more likely to currently have these tools compared to other hospitals, physician offices and ASCs. Thus, manufacturers may establish mechanisms to obtain information from MFN participants about the number of units of MFN Model drugs that were furnished to MFN beneficiaries and for which payment under § 513.210 was allowed, which would increase MFN participants' activities related to the model.

CMS also seeks to minimize the potential for excessive increases in non-model Medicare drug payment amounts during the MFN Model. For example, during the model, manufacturers' ASPs may increase causing a concomitant increase in non-model Medicare drug payment amounts outside of the model if: (1) The policy that manufacturers not include units of an MFN Model drug billed by MFN participants where the MFN Drug Payment Amount is paid by Medicare and Medicare Part B is the primary payer in the manufacturer's ASP for the MFN Model drug results in higher ASPs; or (2) manufacturers raise drug prices or lower existing discounts for U.S. sales that are not subject to the model's payment test. Because manufacturers will continue to have the ability to set their own drug prices, as a behavioral response to the MFN Model, manufacturers could raise prices for MFN Model drugs in the United States in part to make up for price concessions that may be given to model participants.

We believe the policy for manufacturers not to include in the manufacturer's ASP units of an MFN Model drug administered to an MFN beneficiary and billed by MFN participants where the MFN Drug Payment Amount applied by Medicare is based on available international drug pricing information and Medicare is the primary payer will minimize the potential for manufacturers to choose to increase purchase prices for non-model participants and for MFN participants' purchases of MFN Model drugs for use outside of the MFN Model. Additionally, we believe that the adjustments to the MFN Price phase-in, as described in section III.E. of this IFC, will also minimize the potential for manufacturers to increase prices for non-model participants and non-model purchases. We also believe this policy is necessary for a rigorous test of the model payment for MFN drugs because price concessions tied to the model will not lower Medicare payment when MFN Model drugs are purchased for use outside the model, which would limit our ability to observe the impacts of the payment change.

We will not collect the number of units that manufacturers exclude from ASP as part of their ASP submission to CMS to avoid establishing a new data collection effort and to minimize administrative burden for manufacturers.

As an alternative approach, we considered whether manufacturers should exclude from the manufacturer's ASP for the MFN Model drug price concessions on units of an MFN Model drug billed by MFN participants where the MFN Drug Payment Amount applied by Medicare is based on available international drug pricing information and Medicare is the primary payer. We believe that excluding from the manufacturer's ASP price concessions on units of an MFN Model drug billed by MFN participants where the MFN Drug Payment Amount applied by Medicare is based on available international drug pricing information and Medicare is the primary payer, and not excluding the manufacturer's ASP the units of an MFN Model drug billed by MFN participants where the MFN Drug Payment Amount is applied by Medicare is based on available international drug pricing information and Medicare is the primary payer would inappropriately raise the ASP. We believe this is the case because those units would likely be factored into the manufacturer's ASP calculation as undiscounted sales. Thus, this approach, while it may be less complex, would likely lead to inappropriately higher Medicare payment outside of the model.

We are waiving requirements in section 1847A(c) to the extent necessary to exclude from the calculation of the manufacturer's ASP any units of an MFN Model drug administered to an MFN beneficiary and billed by MFN participants where the MFN Drug Payment Amount applied by Medicare is based on available international drug pricing information and Medicare is the primary payer. Consistent with section 1847A(c)(5) of the Act, we will issue program instructions to further describe how the waiver will impact manufacturers' calculation of the manufacturer's ASP. For example, we envision that manufacturers will take reasonable steps and make reasonable assumptions to exclude applicable units. We note that all other existing statutory requirements and regulations will continue to apply. For example, manufacturers who misrepresent or fail to report manufacturer ASP data will remain subject to civil monetary penalties, as applicable and described in sections 1847A and 1927(b) of the Act and codified in regulations at § 414.806.

M. Program Waivers and Model Termination

1. Waivers of Medicare Program Requirements for Purposes of Testing the Model

We will test the MFN Model under the authority of section 1115A of the Act and waive certain Medicare program requirements as necessary solely for purposes of testing the model. Under section 1115A(d)(1) of the Act, the Secretary may waive the requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 of the Act (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. The purpose of these waivers will be to allow Medicare to test the MFN Model described in this IFC, with the goal of reducing Medicare expenditures while improving or maintaining the quality of beneficiaries' care.

In § 513.500, we waive program requirements that are necessary solely for purposes of testing the MFN Model—

- Sections 1833(t)(6) and 1833(t)(14) of the Act and 42 CFR 419.62 and 419.64 related to Medicare payment amounts for drugs and biologicals under the OPPS as necessary to permit testing of an adjusted payment amount for MFN Model drugs using the pricing approaches described in this IFC;
- Section 1833(i)(2)(D) of the Act related to Medicare payment to ASCs for drugs and biologicals as necessary to permit testing of an adjusted payment

amount for MFN Model drugs using the pricing approaches described in this IFC;

- Sections 1847A(b) and 1847A(c) of the Act and 42 CFR 414.904 and 414.802 related to use of the ASP-based, WAC-based, or other applicable payment methodology and calculation of manufacturers' ASP as necessary to permit testing of an adjusted payment for MFN Model drugs and to exclude certain units of MFN Model drugs from manufacturers' ASPs;
- Section 1833(a)(1) of the Act related to Medicare payment portion of the allowed payment amount for an included MFN Model drug that is determined under § 513.220 as necessary to permit testing of an innovative payment approach for the alternative add-on payment amount;
- Section 1833(a)(1)(S) related to Medicare payment for drugs and biologicals at 80 percent of the lesser of actual charge or the amount established in section 1842(o) of the Act as necessary to allow CMS to not apply beneficiary cost-sharing to the alternative add-on payment amount;
- Section 1833(a)(1)(G) of the Act related to the amounts paid with respect to facility services furnished in connection with certain surgical procedures and with respect to services furnished to an individual in an ASC shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system as necessary to allow CMS to not apply beneficiary cost-sharing to the alternative add-on payment amount;
- Section 1833(t) of the Act related to how Medicare payment under the OPPS is calculated including beneficiary copayment to allow CMS to not apply beneficiary cost-sharing to the alternative add-on payment amount; and
- Section 1833(t)(9)(B) of the Act related to the requirement that Medicare account for adjustments to ensure that the amount of expenditures under the OPPS for the year does not increase or decrease from the estimated amount of expenditures under the OPPS that would have been made if the adjustments had not been made (that is, OPPS budget neutrality). CMS intends to continue to maintain budget neutrality under the OPPS as it currently does, including as described in 42 CFR 419.32(d)(1). This includes continuing to use the applicable payment amount for each separately payable drug under that payment system, rather than the MFN Drug Payment Amount and alternative add-on payment amount. CMS may consider using volume for drugs included in the MFN Model for purposes of the budget neutrality calculations under the OPPS beginning in 2022, but would utilize the applicable OPPS payment amount for the drug or biological, rather than the MFN Drug Payment Amount. We believe a waiver of the OPPS budget neutrality requirements for Part B drugs furnished under the MFN Model is necessary solely for purposes of testing the MFN Model because if reductions in Medicare Part B drug expenditures were redistributed through the OPPS budget neutrality process to non-drug Part B services under the OPPS, the model would change pricing for numerous other services that are not related to Part B drugs. This would make it difficult to determine the independent impact of a change in Part B drug payment levels to MFN Model pricing if there is also a corresponding change in the payment amount for all non-drug hospital outpatient items and services as a result of the OPPS budget neutrality requirements.

Our intent is to include a waiver for all program requirements in title XVIII of the Act as may be necessary solely to test separate payment for MFN Model drugs furnished to MFN beneficiaries by MFN participants. To the extent that MFN participants receive separate payment for MFN Model drugs under program requirements that we have not listed in § 513.500, we waive such requirements as necessary to effectuate part 513.

2. Model Termination

CMS may terminate the MFN Model for reasons including, but not limited to, the following: CMS determines that it no longer has the funds to support the model; or CMS terminates the model in accordance with section 1115A(b)(3)(B) of the Act. As provided by section 1115A(d)(2) of the Act, termination of the model under section 1115A(b)(3)(B) of the Act is not subject to administrative or judicial review. We are codifying these policies in § 513.1000.

N. Evaluation

We will conduct an evaluation of the MFN Model, as required under section 1115A(b)(4) of the Act. The evaluation of the MFN Model will include an analysis of the quality of care furnished under the model and the changes in spending under Medicare by reason of the model.

There will be several populations of interest for the MFN Model evaluation. A population of interest for the evaluation will be Medicare beneficiaries who are likely to receive one of the MFN Model drugs based on recent diagnoses and/or prior treatment. One possible prescriber behavior change due to the MFN Model could be shifts from prescribing MFN Model drugs to other alternative Part B or Part D drugs or vice versa. A population defined by recent diagnoses and/or prior treatment will capture the model's impact on beneficiaries affected by these prescribing behavioral changes due to the model. Other populations such as, but not limited to, MFN Model drug users and subgroups of particular patient populations (for example, cancer, rheumatoid arthritis, ophthalmologic conditions) will be considered in the evaluation.

For each of the populations of interest, we will create separate impact estimates for two types of outcomes: Medicare spending and drug/other health care utilization. Medicare spending will be examined in terms of total Part B drug spending for MFN Model drugs, total Part B drug spending for any Part B drugs, total Parts A and B spending, and potentially other spending measures for specific types of health care services (for example, inpatient hospital spending). The evaluation of the model's impact on quality of care will examine drug access, measured by utilization (for example, rates of any use and duration of use) of both Part B (both MFN Model drug and non-MFN Model drugs) and Part D drugs. We will also examine non-drug health care utilization that may change as a result of the MFN Model to estimate any impacts on access to care. Examples of other non-drug health care utilization include hospitalizations, emergency department visits, and condition-specific utilization related to a given subgroup of beneficiaries. The impact estimates will reflect the collective effect of the MFN Model's changes to Medicare payments and beneficiary cost-sharing for MFN Model drugs.

Because the MFN Model will be a nationwide, mandatory model, we must employ an evaluation design that does not require an independent comparison group to establish the counterfactual (what would have happened in the absence of the model). The term ''interrupted time series'' (ITS) refers to the situation in which multiple observations for the treatment group are available both before and after the intervention is implemented.[76] ITS models can be employed both with and

[76] Wagner, A.K., Soumerai, S.B., Zhang, F. and Ross-Degnan, D. (2002), Segmented regression analysis of interrupted time series studies in medication use research. Journal of Clinical Pharmacy and Therapeutics, 27: 299–309. doi: 10.1046/j.1365–2710.2002.00430.x.

without comparison groups, and be used to imply causality without comparison groups.[77] The design is used when data are available both for the pre-intervention period and the post-intervention period, and the intervention takes place at a specific, identifiable point in time.[78] The time-relationship between the data points can then be used to estimate treatment effects. The trends from the pre-intervention period establish a baseline that is used to project what would be expected in the absence of the intervention. The typical ITS approach assumes linear trends before and after the intervention, but ITS models can be made more general to address potential non-linear trends.[79] [80] Intervention effects are demonstrated when observations gathered after the intervention start period deviate from the baseline projections.

Using this design for evaluating the effects of an intervention—that is, implying a causal relationship between the intervention and its target outcomes—relies on a strict set of conditions. As previously described, when there is no comparison group, the counterfactual is established as the continuation of the pre-intervention trend for the treated group. The intervention impact is estimated as the difference between the actual post-intervention trend and the pre-intervention trend extended.

The most common statistical method for analyzing ITS data is called segmented regression.[81] [82] Segmented regression focuses on two parameters, the level (intercept) and the trend (slope). For observations before the model, we will have a level (intercept) and trend (slope). After the model begins, the data may exhibit changes in any one of these features. The fundamental idea behind segmented regression is to estimate a regression specification with a linear trend for the data points before the model and estimate a regression specification with a linear trend for the data points after the model start. The level and trend before and after the model start will then be compared. We will use quarterly observations for the pre- and post-model start time periods ending with the most recent data that will be currently available. Given the MFN Model design, we provide our specification in this section of this IFC for the longitudinal regression using a more general specification of the trends to capture the non-linear nature of the data.

In the longitudinal regression equation provided in this section of this IFC, the vector X_{it} consists of factors that will change from the pre-model time period to the model performance period and may include, but is not necessarily limited to, the medical care component of the Consumer Price Index (CPI–U), national unrelated policy changes, economic factors (for example, unemployment rate). The unit of analysis (for example, a hospital referral region (HRR) as defined by the Dartmouth Atlas [83] or beneficiary) on which the quarterly observations are measured will be allowed to vary in order to estimate the model's impact at these different levels of aggregation. The anticipated statistical model specification includes a polynomial time trend variable f(t) to account for trends in spending and utilization over time. In addition, the statistical model includes separate indicator variables ($I_{t=k}$) for each of the model performance period quarters, which will allow for estimates of the model's impact in each performance period quarter relative to the entire pre-period after adjusting for the time trend and other factors.

$$Y_{it} = b_0 + b_1 \cdot X_{it} + b_2 \cdot f(t) + a_1 \cdot I_{t=1} + a_2 \cdot I_{t=2} + a_3 \cdot I_{t=3} + a_4 \cdot I_{t=4} + \ldots + u_{it}$$

Where:

Y_{it} = outcome (see the previous section for cost and utilization measures), for a particular unit of analysis in a specific quarter

X_{it} = vector of adjustment factors

f(t) = polynomial function to account for time trend

$I_{t=k}$ = denotes an indicator for time period k (all after model implementation)

u_{it} = unaccounted variation

i = unit of analysis (for example, beneficiary, HRR)

t = time quarter ($-12, -11 \ldots 0, 1, 2, 3 \ldots$) using a 3 year pre-model time period, with 0 indicating the start of the model

$b_0, b_1, b_2, a_1 \ldots a_n$ are the statistical model coefficients

b_0 = the statistical model intercept

b_1 = vector of estimates for the adjustment factors

b_2 = estimate of the time trend f(t) across the pre-period and model performance period

a_1 thru a_n = estimate of change per model performance period quarter (t) relative to entire pre-period

With the statistical model specification as previously described, in an initial, exploratory data assessment, the null hypothesis (H_o: $a_1 = a_2 = a_3 = a_4 = \ldots = a_n = 0$) will be that there is no change in each of the model performance period quarters when compared to the pre-period after adjusting for the time trend and the other factors. The corresponding alternate hypothesis (H_a: a_1 or a_2 or a_3 or a_4 or $\ldots a_n \neq 0$) will be that any of the model performance period quarters is statistically significantly different than the pre-model time period, suggesting that the model either positively or negatively impacted Medicare spending and quality of care in at least one model performance period quarter. These null and alternate hypotheses will apply to each outcome and population of interest.

The assessment just described will not directly indicate success or failure of the model. CMS will need to observe a consistent statistically significant directional pattern over multiple consecutive time periods for the outcome and population of interest in order to draw sound conclusions about the model's impact. Based on a combination of results from exploratory data assessment and policy goals, CMS will set a hypothesis that encompasses the chosen outcome and population of interest. This hypothesis will be tested using data that is different from what was used in the exploratory assessment—for instance, due to being gathered later in time or consisting of a different randomly assigned subset of contemporaneous data.

Statistical inference will be conducted using cluster-robust standard errors.[84] Cluster-robust standard errors account for serial correlation as well as spatial correlation within geographies (such as an HRR). We will conduct hypothesis testing using an alpha-level of 5 percent

[77] Sheingold, S., Bir, A, (2019), Evaluation for Health Policy and Health Care: A Contemporary Data Driven Approach, Sage Publications.

[78] Bernal, J.L., Cummins, S., Gasparrin, A., (2017) Interrupted time series regression for the evaluation of public health interventions: A tutorial, International Journal of Epidemiology, 2017, Vol. 46, No. 1: 348–355, doi: 10.1093/ije/dyw098.

[79] Kontopantelis, E., Doran, T., Springate, D.A., Buchan, I Reeves, D, (2015), Regression based quasi-experimental approach when randomisation is not an option: Interrupted time series analysis, BMJ 2015;350:h2750, doi: 10.1136/bmj.h2750.

[80] Valsamis, E.M., Ricketts, D., Husband, H., and Rogers, B.A. (2019), Segmented linear regression models for assessing change in retrospective studies in healthcare. Computational and Mathematical Methods in Medicine. doi: 10.1155/2019/9810675.

[81] Wagner, A.K., Soumerai, S.B., Zhang, F. and Ross-Degnan, D. (2002), Segmented regression analysis of interrupted time series studies in medication use research. Journal of Clinical Pharmacy and Therapeutics, 27: 299–309. doi: 10.1046/j.1365–2710.2002.00430.x.

[82] Valsamis, E.M., Ricketts, D., Husband, H., and Rogers, B.A. (2019), Segmented linear regression models for assessing change in retrospective studies in healthcare. Computational and Mathematical Methods in Medicine. doi: 10.1155/2019/9810675.

[83] *https://www.dartmouthatlas.org/faq/#research-methods-faq.*

[84] Cameron, A.C., & Miller, D.L. (2015). A practitioner's guide to cluster-robust inference. *Journal of Human Resources, 50*(2), 317–372.

and CMS will report the p-value and standard error to allow for inferences at other alpha-levels.

As an illustration of a potential subgroup analysis and the expected changes that could be detected in the MFN Model evaluation, CMS identified two groups of Medicare cancer patients using 2018 data. CMS defined the first narrower group as Medicare cancer patients who received an MFN Model drug. CMS defined the second broader group as Medicare cancer patients who either received an MFN Model drug or would have been considered eligible to receive an MFN Model drug. Specifically, CMS estimated that in 2018 approximately 400,000 Medicare beneficiaries were being treated for the most prevalent cancer types (that is, colorectal, endometrial, breast, lung, prostate, and certain forms of leukemia and lymphoma) and received an MFN Model drug. These 400,000 Medicare beneficiaries were identified using the inclusion and exclusion criteria for the model, including the use of an MFN Model drug. Cancer treatment was determined by the utilization of Part B and/or Part D cancer drugs and the presence of cancer diagnosis codes on Parts A and B claims. A subgroup analysis that requires MFN Model drug use, as in the narrower definition that identified 400,000 Medicare beneficiaries being treated for cancer and who received an MFN Model drug, would exclude cancer patients using an alternative non-MFN Model drug cancer therapy. A broader cancer population definition based on any Part B and/or Part D cancer drug use or just an incident cancer diagnosis based on new evidence of diagnosis codes on Parts A and B claims in the current year would capture the model's impact on beneficiaries affected by prescribing behavioral changes due to the model. This second broader cancer subgroup population definition applied to approximately 1.1 million Medicare beneficiaries in 2018.

CMS believes that looking for unintended consequences will be critical for the monitoring and evaluation of the MFN Model. In the narrower definition of the cancer subgroup, CMS expects that approximately 100,000 Medicare cancer patients who receive a MFN Model drug will be eligible for inclusion in the quarterly evaluation analysis. In the broader cancer subgroup population, CMS expects that approximately 280,000 Medicare cancer patients will be included in the quarterly evaluation analysis. With a nationwide MFN Model (and the assumptions of an alpha-level of 5 percent and power of 80 percent), CMS will have the sample sizes needed in these two populations to detect small changes in Medicare total cost of care (approximately a 1 percent change), drug access, and other important measures of quality of care. With multiple quarterly assessments of the impact of the model on subgroup populations, CMS will be able to intervene early in the model's performance period should any potential unintended consequences be detected in the potential subgroups of interest. Although CMS uses the cancer subgroup patient population in the previously discussed example, we recognize that other patient populations (for example, patients diagnosed with rheumatoid arthritis and wet macular degeneration) and certain types of providers could be differentially impacted by the MFN Model. These other patient and provider subgroups will be of interest in the evaluation. The model's impact on the Medicaid program and commercial insurance (including Medicare Advantage) population is also of interest.

The evaluation will explore the experiences of MFN participants (beneficiaries and providers) and other stakeholders affected by the changes in payment and conditions included in the model. In particular, CMS will interview MFN participants and beneficiaries, either by focus groups, surveys, or one-on-one stakeholder interviews, to assess the model's influence on access to and quality of care, and administrative burden from their perspectives. Further, CMS intends to ask beneficiaries about their total out of pocket costs under the MFN Model to determine if those costs were reduced. MFN participants will be asked for their opinions about the MFN Model's payment changes to the drug and add-on payment amounts separately. The evaluation will also include qualitative analyses of primary data collected from MFN participants and beneficiaries. The results of the qualitative analyses will be used to provide additional context for the results of the quantitative analyses on health care spending and to help further explain the observed changes.

Evaluation reports detailing the results and findings will be developed and publicly posted on the CMS website. The evaluation reports will include the results of the quantitative and qualitative analyses of the MFN Model's impact on spending and quality of care and the model's implementation as described in this section. The evaluation reports covering the earlier performance years of the MFN Model will be used in the decision making process on whether or not to continue the MFN Model into performance years 5 to 7.

The evaluation may require that MFN participants collect and submit additional data specifically for the evaluation (please see § 513.100(e) and § 513.100(f)). Such requirements for additional data to carry out model evaluation will be in compliance with 42 CFR 403.1110(b), which requires entities participating in the testing of a model under section 1115A to collect and report such information, including protected health information (as defined at 45 CFR 160.103), as the Secretary determines is necessary to monitor and evaluate the model.

O. Limitations on Review

In § 513.450, we are codifying the preclusion of administrative and judicial review under section 1115A(d)(2) of the Act. Section 1115A(d)(2) of the Act states that there is no administrative or judicial review under section 1869 or 1878 of the Act or otherwise for the all of the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites, or participants to test models selected.
- The elements, parameters, scope, and duration of such models for testing or dissemination.
- Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.
- The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of the Act.
- Determinations about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such section.

We interpret the preclusion from administrative and judicial review regarding the CMS Innovation Center's selection of organizations, sites, or participants to test models selected to preclude from administrative and judicial review CMS' selection of an MFN participant, as well as CMS' decision to terminate an MFN participant, as these determinations are part of CMS' selection of participants for CMS Innovation Center model tests.

We interpret the preclusion from administration and judicial review regarding the elements, parameters, scope, and duration of models for testing or dissemination to preclude from administrative and judicial review the following CMS determinations made in connection with the MFN Model:

- The selection of the model geographic area for the MFN Model by CMS;
- The selection of MFN Model drugs by CMS; and
- The selection of included international data, including selection of countries, international drug pricing databases, and international drug pricing information.

In addition, we interpret the preclusion from administrative and judicial review regarding the elements of the MFN Model to preclude from administrative and judicial review the methodology for determining MFN Prices, MFN Drug Payment Amounts, Alternative Add-on Amounts, and reconciliation payments related to financial hardship exemptions.

V. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of CMS Innovation Center Models. As a result, the information collection requirements contained in this IFC need not be reviewed by the Office of Management and Budget. However, costs incurred through information collections are included in section VI.C.5. of this IFC.

V. Response to Comments

Because of the large number of public comments we normally receive on documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This IFC is necessary to address the current Medicare Part B payment system for separately payable Medicare Part B drugs, which has several features that may be incentivizing avoidable costs and causing greater utilization of higher priced drugs. By testing ways to address these payment issues, the MFN Model seeks to improve quality of care, address features of the current payment system that may be incentivizing unnecessary Medicare Part B drug spending and utilization of high cost drugs, and ensure that the Medicare program and its beneficiaries pay generally comparable prices for Medicare Part B drugs relative to certain other countries.

As detailed in section III of this IFC, this IFC will establish a 7-year nationwide MFN Model alternative payment test for approximately 50 separately payable Medicare Part B drugs furnished by certain providers and suppliers. As discussed in section III.C. of this IFC, MFN participants will include Medicare-participating providers and suppliers that furnish MFN Model drugs, with certain exclusions. Most of the MFN participants will be: Physicians; non-physician practitioners; supplier groups; HOPDs (including on- and off-campus outpatient provider-based departments, but excluding cancer hospitals, children's hospitals, CAHs, and other hospitals exempt from the OPPS); and ASCs. When other providers and suppliers that are not excluded bill for separately payable MFN Model drugs (for example, pharmacies and independent diagnostic testing facilities), they will be included in the MFN Model as MFN participants; based on 2018 Medicare Part B claims data, their aggregate annual volume of separately payable Part B drugs was less than $3.6 million. MFN participants will be subject to the participation requirements described in section III. of this IFC.

B. Overall Impact

We have examined the impacts of this IFC, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. This IFC triggers these criteria.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, reflects the economic impact of the policies contained in this IFC.

C. Detailed Economic Analysis

The MFN Model will test different payment rates for certain separately payable Medicare Part B drugs and their associated drug add-on payment. The payment rates for these Medicare Part B drugs will be phased in over 4 years, ultimately arriving at the lowest price for a particular drug from a selected group of countries. Eligible providers and suppliers participating in the 340B program will be paid the lesser of this amount or the payment outside the model for MFN Model drugs they purchase under the 340B program. This IFC includes a single alternative add-on payment, with MFN participants receiving an amount that represents 6 percent (after sequestration) of the average sales price (ASP) baseline for the initial set of included drugs trended forward. The phased-in MFN Price discount relative to applicable ASP is shown in Table 9, assuming the relationship remains constant.

TABLE 9—MOST FAVORED NATION DISCOUNT FROM ASP BY CALENDAR YEAR

Calendar year	2021	2022	2023	2024	2025	2026	2027
MFN Price impact	−16%	−33%	−49%	−65%	−65%	−65%	−65%

The model will require participation by eligible providers and suppliers for the selected separately payable Medicare Part B drugs included in the model. Certain provider types, defined previously in this IFC, will be excluded from the model. We assume that acute care hospitals that are paid for outpatient hospital services on a fully capitated or global budget basis under a waiver under such model of section 1833(t) of the Act will be excluded from the MFN Model.

Because current payment rates for 340B covered entities that are paid under the OPPS (hereafter called 340B providers) are different from those for other providers and suppliers (hereafter called non-340B providers), the impact of the MFN Model varies between the two provider types, and therefore OACT and ASPE estimated the financial impacts separately. Similarly, both analyses calculated the impact of the drug add-on payment separately from the MFN Price impact. Since the drug add-on payment inside the model will not be subject to beneficiary cost sharing, and will be an additional payment to 340B covered entities, the associated Medicare expenditures are higher.

The baseline for these analyses is shown in Table 10, separately for OPPS 340B providers, OPPS non-340B providers, and physician settings. These values include all drugs, exclude providers and suppliers that are exempt from the model, and assume that 53% of the hospital outpatient claims will be from 340B providers. These payments were then adjusted for beneficiary responsibility, add-on payments, and federal payments relative to ASP. These values are on a pre-COVID–19 basis, and the baseline is not are adjusted for the effects of the pandemic. Similarly, the impact analysis does not include the effects of the COVID–19 pandemic. Many assumptions such as utilization, mortality, and morbidity are more uncertain than usual due to the pandemic. The direction and magnitude of the financial impact of the pandemic on Part B drug spending is uncertain. For example, higher mortality due to COVID–19 could lead to lower drug utilization. A COVID–19-related drug discovery could lead to higher drug utilization. Beneficiaries seeking treatment for quality of life improvement may defer care during the pandemic.

TABLE 10—BASELINE EXPENDITURES FOR CLAIMS INCLUDED IN THE MFN MODEL

	(In billions)								
	2020	2021	2022	2023	2024	2025	2026	2027	2020–27
OPPS Non-340B Providers	$6.1	$6.7	$7.5	$8.3	$9.2	$10.1	$11.2	$12.3	$71.4
OPPS 340B Providers	6.9	7.6	8.4	9.4	10.4	11.4	12.6	13.9	80.5
Other Providers and Suppliers	19.4	21.2	23.3	25.7	28.1	30.8	33.8	37.0	219.3
Total	32.4	35.5	39.2	43.4	47.6	52.4	57.5	63.2	371.3

As the model does not dictate the price that a drug manufacturer must charge an MFN participant, there are many possible behavioral responses by manufacturers, providers, suppliers, and beneficiaries. Because the estimates are highly sensitive to these behavioral assumptions, OACT provided three scenarios: (i) An OACT estimate; (ii) an illustrative estimate based on pricing-effects only; and (iii) an additional illustration under the assumption that manufacturers will refuse to change prices and MFN participants will be unwilling to administer drugs for which model payment will be below their acquisition cost. ASPE also developed a bottom-up estimate built from analysis of the IFC's likely potential effects on different types of separately payable Part B drugs.

To better understand the values shown in the three OACT scenarios, the ASPE estimate, and the policy of the model, consider the following example. Suppose the current ASP for a given drug is $100. The total payment to the provider for this drug under the current system is $104.30, inclusive of the federal payment for the drug and the add-on, beneficiary cost-sharing, and net of sequestration. Now suppose the MFN Price of this drug is also $100. The total payment to the provider under the model would be $104.40. Under the model, the drug payment after sequestration is unchanged ($98.40) but the add-on increases from $5.90 to $6.00.

1. OACT Estimate

Manufacturers could adopt several strategies in response to the model, such as (i) charging a lower price to providers and suppliers inside the model; (ii) refusing to adjust their price from the non-model amounts; or (iii) altering the availability and terms of their international prices. Given that the international price data represent a challenge to their U.S. market revenues, manufacturers are expected to devote considerable resources to the third option. This assumption is included in the OACT estimate as a different discount relative to ASP compared with the values in Table 9. For drugs with significant use outside of Medicare, manufacturers may be willing to sacrifice utilization and revenue within the model. For drugs that are used primarily in the Medicare program, manufacturers may believe that offering some pricing relief is necessary to preserve a significant portion of their revenue.

Eligible providers and suppliers will need to decide if the difference between the amount that Medicare will pay and the price that they must pay to purchase the drugs would allow them to continue offering the drugs. For 340B providers, the payment rates in the first year will match their payments outside the model. Accordingly, no change to utilization or costs is expected under the model in the first year for 340B providers. In later years, the impact varies depending on the assumed change to international price data. For non-340B providers, some may be

willing to provide the drugs under a lower payment rate to retain utilization on other associated services.

Should an eligible provider or supplier be unable to offer access to the included drugs, beneficiaries will be left with several options. They could seek access to the drugs by traveling to an excluded provider or supplier, access the drugs through a 340B provider in the model, or forgo access.

It should be noted that this model does not have a reliable precedent in the U.S. market; consequently, there is an unusually high degree of uncertainty in these assumptions, particularly with respect to the behavioral responses. To illustrate this uncertainty, three potential financial effects are included in this analysis; a full range of potential behavioral effects are presented under an Extreme Disruption scenario where non-340B utilization of affected drugs drops to zero percent and under a Pricing-Effects Only scenario where all currently projected utilization is assumed to be retained. The OACT estimate reflects one reasonable set of assumptions for potential changes in manufacturer, provider, and supplier behavior. Other estimates outside the range of the three scenarios could be reasonable as well, due to the wide range of potential responses.

The OACT assumptions consider that the separately payable Medicare Part B drugs make up approximately 5 percent of the overall U.S. prescription drug market. Drug manufacturers could see this model as an obstacle to their pricing throughout the market, which could cause strong resistance to the model. The OACT assumptions reflect that some manufacturers will adhere to their current pricing instead of lowering sales prices in response to the model. This behavior may persist in spite of pricing in other sectors of the market or other countries that demonstrates an ability to offer the drug at the model payment rates, and would result in unmet demand for these Medicare Part B drugs. After considering the relative size of the Medicare Part B market, the current price control of drug manufacturers, the size of the model price reductions, the nature of the Medicare Part B drug providers and suppliers, the flexibility that manufacturers may have in adjusting pricing and arrangements in other countries, and many other factors, actuarial judgment was applied to determine the assumptions that are reflected in the OACT estimate, as shown in Table 11.

Beneficiaries lacking continued availability of their drugs through their current provider or supplier are assumed to seek access outside the model, to obtain their drugs through 340B providers, or to forgo access. The schedule of the phase-in to the MFN price gives manufacturers incentive to adjust or reduce access to international price data quickly. Accordingly, manufacturers are assumed to raise the published international prices beginning in 2022 and to retain a 25-percent MFN Price discount relative to applicable ASP.

As a result of this expected behavior from manufacturers, 340B provider payments will see a 3-percent reduction compared to the current Medicare payment in 2022 and subsequent years. This 3-percent reduction represents the impact of the 25-percent MFN Price discount relative to the OPPS payment to 340B providers of ASP less 22.5 percent, as that is the current payment formula for 340B providers. This represents a relatively small price change and is assumed to occur later in the model, so will be more predictable than the payment changes for non-340B providers. As a result, manufacturers and 340B providers are assumed to come to an agreement to continue to provide for all of their utilization.

Because all regions are covered under the model, beneficiaries seeking a provider outside of the model will be limited to an excluded provider or supplier, such as a critical access hospital. Based on the historical trend of drug spending by excluded providers and suppliers as a percentage of total Medicare Part B drugs, the OACT estimate reflects only 1 percent of use shifting to non-model providers. Furthermore, because the OPPS payment to 340B providers will be reduced year two through year seven of the model, and because their capacity is limited, 10 percent of use is assumed to shift to 340B providers. Other utilization not covered by providers and suppliers continuing to provide access in the model or by excluded providers and suppliers is assumed to be utilization not covered by the Medicare benefit.

TABLE 11—ASSUMPTIONS REFLECTED IN OACT ESTIMATE

	2021 (%)	2022 (%)	2023 (%)	2024 (%)	2025 (%)	2026 (%)	2027 (%)
Non-340B providers:							
Behavior:							
Continued Availability	80	75	70	70	70	70	70
Altered Availability:							
Move to non-MFN	1	1	1	1	1	1	1
Move to 340B	10	10	10	10	10	10	10
No Access	9	14	19	19	19	19	19
Total	100	100	100	100	100	100	100
MFN Price impact	−16	−25	−25	−25	−25	−25	−25
340B providers:							
Behavior:							
Continued Availability	100	100	100	100	100	100	100
MFN Price impact	0	−3	−3	−3	−3	−3	−3

Table 12 shows the estimated financial impacts under the model based on the assumptions in Table 11. Medicare savings are estimated to be $85.5 billion, net of the premium offset. While there are significant savings as a result of this model, a portion of the savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization. This estimate does not capture any impacts to other program costs as a result of lower utilization. This estimate is on a pre-COVID–19 basis, and is not adjusted for the effects of the pandemic.

To the extent that manufacturers discount their products for Medicare sales, there may be a reduction in Medicaid Best Price or AMP. Reductions in Best Price could result in increased Medicaid rebates and thus lower Medicaid costs. However, reductions in AMP generally result in

lower statutory and inflationary rebates under the Medicaid program. Therefore, if the manufacturer discounts a drug so that it is closer to the Medicaid best price, there is a possibility of increased Medicaid costs as a result of the model. Furthermore, the effects on AMP may be reduced or eliminated, if manufacturers respond by increasing prices in the private health insurance market. These estimates do not include secondary impacts to other sectors of the market as a result of the changes in Medicare payments under the model in part due to the significant uncertainty around manufacturer pricing behavior in response to this model.

TABLE 12—ESTIMATED FINANCIAL IMPACT OF MFN MODEL

	(In billion dollars)							
	2021	2022	2023	2024	2025	2026	2027	2021–27
Drug price reduction:								
FFS impact *	−4.7	−7.5	−9.3	−10.2	−11.2	−12.3	−13.5	−68.7
Gross impact (FFS+MA) **	−4.7	−7.5	−17.6	−19.5	−21.6	−24.0	−26.5	−121.4
Net of premium offset ***	−3.5	−5.6	−13.2	−14.6	−16.2	−18.0	−19.9	−91.1
Medicaid impact	−0.4	−0.6	−1.3	−1.5	−1.6	−1.8	−2.0	−9.1
Federal	−0.2	−0.3	−0.8	−0.8	−0.9	−1.0	−1.1	−5.2
State	−0.2	−0.2	−0.6	−0.6	−0.7	−0.8	−0.9	−3.9
Drug add-on payment:								
FFS impact	0.6	0.6	0.5	0.6	0.6	0.7	0.8	4.4
Gross impact (FFS+MA)	0.6	0.6	1.0	1.1	1.2	1.4	1.5	7.4
Net of premium offset	0.4	0.4	0.7	0.8	0.9	1.0	1.2	5.6
Medicaid impact	−0.1	−0.1	−0.1	−0.1	−0.1	−0.1	−0.2	−0.8
Federal	−0.1	−0.1	−0.1	−0.1	−0.1	−0.1	−0.1	−0.5
State	0.0	0.0	0.0	−0.1	−0.1	−0.1	−0.1	−0.4
Total impact:								
FFS impact	−4.1	−7.0	−8.8	−9.6	−10.6	−11.6	−12.7	−64.4
Gross impact (FFS+MA)	−4.1	−7.0	−16.6	−18.4	−20.4	−22.6	−25.0	−114.0
Net of premium offset	−3.1	−5.2	−12.4	−13.8	−15.3	−16.9	−18.7	−85.5
Medicaid impact	−0.4	−0.7	−1.4	−1.6	−1.8	−1.9	−2.1	−9.9
Federal	−0.3	−0.4	−0.8	−0.9	−1.0	−1.1	−1.2	−5.7
State	−0.2	−0.3	−0.6	−0.7	−0.8	−0.8	−0.9	−4.3

* Projected spending impact in the traditional Medicare FFS program under the model.
** Projected spending impact in both Medicare FFS and Medicare Advantage (MA).
*** Premium offset represents the change in the Part B premium income that would result from the change in Part B drug expenditures.

These impacts are based on the President's Fiscal Year 2021 Budget baseline for Medicare Part B drugs, including those dispensed by 340B providers. Due to rounding, the sum of values in the table may differ slightly from the total results in the table. In addition to the behavioral assumptions in Table 11, these estimates reflect a number of other technical assumptions, including the following:

- Amounts illustrate the potential impact on Medicare Part B drug spending, assuming the reductions are achievable and realized.
- Amounts are presented by calendar year and are based on the date the service is incurred and have therefore not been adjusted to reflect when payment is made.
- The model runs from January 1, 2021 through December 31, 2027. If any of the provisions of this rule are not effective on January 1, 2021, the impacts will differ.
- The model will include the top 50 Medicare Part B drugs with the highest spending each year and will account for roughly 73 percent of Medicare Part B drug spending in each affected year.
- All included providers and suppliers receive an add-on payment of 6 percent (after sequestration) of the average sales price (ASP) and this add-on payment is not subject to beneficiary cost sharing.
- The impacts reflect changes to payments to Medicare Advantage plans starting in 2023.
- The premium offset is 25 percent of the gross impact.
- The Medicaid impact represents the portion of beneficiary cost sharing paid on behalf of dual-eligible beneficiaries (split 57 percent/43 percent between Federal and State).
- The Medicaid impact does not account for the potential impacts to AMP or Best Price in the Medicaid program.

a. Pricing Effects Only Illustration

As mentioned previously, there is much uncertainty around the behavioral assumptions underlying the estimated financial impacts. To show the effects of the model absent any provider or beneficiary behavioral responses, OACT calculated the impacts of the payment changes alone. These values reflect the pricing changes inside the model, as shown in Table 9, and the assumption that manufacturers and MFN participants are able to continue to provide access to all drugs. Again, because 340B providers will receive the lesser of the model payment amount or the amount outside the model for the drug, no impact to their costs is expected for the first year. Results for this illustration are shown in Table 13, and they reflect the same technical assumptions as the OACT estimate. The net impact on Medicare after the premium offset is a savings of $155.6 billion over the 7-year period, and none of the impact would be due to lost utilization.

TABLE 13—ESTIMATED IMPACT OF PRICING EFFECTS ONLY ILLUSTRATION

	(In billion dollars)							
	2021	2022	2023	2024	2025	2026	2027	2021–27
Drug price reduction:								
FFS impact *	−3.1	−7.3	−13.1	−20.1	−23.0	−25.3	−27.7	−119.7
Gross impact (FFS+MA) **	−3.1	−7.3	−24.7	−38.5	−44.4	−49.2	−54.5	−221.8
Net of premium offset ***	−2.4	−5.5	−18.5	−28.9	−33.3	−36.9	−40.9	−166.4
Medicaid impact	−0.2	−0.5	−1.9	−2.9	−3.3	−3.7	−4.1	−16.6
Federal	−0.1	−0.3	−1.1	−1.6	−1.9	−2.1	−2.3	−9.5
State	−0.1	−0.2	−0.8	−1.2	−1.4	−1.6	−1.8	−7.2
Drug add-on payment:								
FFS impact	0.9	1.0	1.1	1.2	1.3	1.4	1.6	8.3
Gross impact (FFS+MA)	0.9	1.0	2.0	2.2	2.5	2.8	3.1	14.4
Net of premium offset	0.7	0.7	1.5	1.7	1.9	2.1	2.3	10.8
Medicaid impact	−0.1	−0.1	−0.1	−0.1	−0.1	−0.1	−0.1	−0.8
Federal	0.0	−0.1	−0.1	−0.1	−0.1	−0.1	−0.1	−0.5
State	0.0	0.0	0.0	0.0	−0.1	−0.1	−0.1	−0.3
Total impact:								
FFS impact	−2.3	−6.4	−12.0	−19.0	−21.7	−23.9	−26.2	−111.4
Gross impact (FFS+MA)	−2.3	−6.4	−22.7	−36.3	−41.9	−46.5	−51.4	−207.4
Net of premium offset	−1.7	−4.8	−17.0	−27.2	−31.5	−34.9	−38.6	−155.6
Medicaid impact	−0.3	−0.6	−2.0	−3.0	−3.5	−3.8	−4.2	−17.4
Federal	−0.2	−0.4	−1.1	−1.7	−2.0	−2.2	−2.4	−9.9
State	−0.1	−0.3	−0.8	−1.3	−1.5	−1.6	−1.8	−7.5

* Projected spending impact in the traditional Medicare FFS program under the model.
** Projected spending impact in both Medicare FFS and Medicare Advantage (MA).
*** Premium offset represents the change in the Medicare Part B premium income that would result from the change in Medicare Part B expenditures.

b. Extreme Disruption Illustration

To cover the spectrum of possible outcomes, the impact of a greater behavioral response from manufacturers and MFN participants was also considered. Under this scenario, it is assumed that non-340B providers and suppliers will not be able to obtain any of the current drugs inside the model. All non-340B utilization will then be divided among the three beneficiary choices of traveling to an excluded provider or supplier, using a 340B provider, or forgoing access. Because there are a small number of excluded providers and suppliers, OACT assumed they only have capacity for a 25 percent increase in utilization. Additionally, manufacturers are assumed to not change the international prices; as a result, 340B providers will have reduced reimbursement beginning in 2022, when the MFN Price dips below the baseline payment of ASP less 22.5 percent—leading to reduced beneficiary access through 340B providers as well. The financial hardship exemption could possibly apply under this scenario, but as this payment is retrospective and the losses prior to the payment would be severe, it is unclear whether providers will be in a position to request the exemption.

The illustrative results under these assumptions are shown in Table 14. They weredeveloped with the same technical assumptions listed under the OACT estimate. The overall impact of the model would be a substantial savings to Medicare of $286.3 billion, but nearly half of that impact would be due to lost utilization.

TABLE 14—ESTIMATED IMPACT OF EXTREME DISRUPTION ILLUSTRATION

	(In billion dollars)							
	2021	2022	2023	2024	2025	2026	2027	2021–27
Drug price reduction:								
FFS impact *	−17.6	−21.2	−26.9	−30.5	−33.7	−37.0	−40.6	−207.5
Gross impact (FFS+MA) **	−17.6	−21.2	−50.9	−58.4	−65.0	−72.0	−79.7	−364.8
Net of premium offset ***	−13.2	−15.9	−38.2	−43.8	−48.7	−54.0	−59.8	−273.6
Medicaid impact	−1.3	−1.6	−3.8	−4.4	−4.9	−5.4	−6.0	−27.4
Federal	−0.8	−0.9	−2.2	−2.5	−2.8	−3.1	−3.4	−15.6
State	−0.6	−0.7	−1.6	−1.9	−2.1	−2.3	−2.6	−11.8
Drug add-on payment:								
FFS impact	−0.6	−0.8	−1.2	−1.5	−1.6	−1.8	−1.9	−9.4
Gross impact (FFS+MA)	−0.6	−0.8	−2.3	−2.8	−3.1	−3.4	−3.8	−16.9
Net of premium offset	−0.5	−0.6	−1.8	−2.1	−2.3	−2.6	−2.9	−12.7
Medicaid impact	−0.1	−0.1	−0.1	−0.1	−0.1	−0.1	−0.2	−0.8
Federal	−0.1	−0.1	−0.1	−0.1	−0.1	−0.1	−0.1	−0.5
State	0.0	0.0	0.0	−0.1	−0.1	−0.1	−0.1	−0.4
Total impact:								
FFS impact	−18.2	−22.0	−28.2	−32.0	−35.3	−38.7	−42.5	−217.0
Gross impact (FFS+MA)	−18.2	−22.0	−53.2	−61.2	−68.1	−75.5	−83.5	−381.7
Net of premium offset	−13.7	−16.5	−39.9	−45.9	−51.1	−56.6	−62.6	−286.3
Medicaid impact	−1.4	−1.7	−3.9	−4.5	−5.0	−5.5	−6.1	−28.2
Federal	−0.8	−1.0	−2.2	−2.6	−2.9	−3.2	−3.5	−16.1

TABLE 14—ESTIMATED IMPACT OF EXTREME DISRUPTION ILLUSTRATION—Continued

	(In billion dollars)							
	2021	2022	2023	2024	2025	2026	2027	2021–27
State	−0.6	−0.7	−1.7	−1.9	−2.2	−2.4	−2.6	−12.1

* Projected spending impact in the traditional Medicare FFS program under the model.
** Projected spending impact in both Medicare FFS and Medicare Advantage (MA).
*** Premium offset represents the change in the Medicare Part B premium income that would result from the change in Medicare Part B expenditures.

c. Additional Considerations

Because the model will make substantial changes to payment for Medicare Part B drugs, there are many other potential responses not considered in this analysis. It is possible that manufacturers could increase prices for non-Part B drugs, which would affect both private market and Part D expenditures, although that potential impact has not been quantified for this estimate. It is also possible that moving to a flat add-on payment from a percentage of drug cost will have additional effects, which are not considered in the OACT analysis. The analysis is on a pre-COVID–19 basis, and neither the baseline nor the impact analysis are adjusted for the effects of the pandemic.

2. ASPE Estimate

The behavioral responses of manufacturers, providers, suppliers, and beneficiaries to the MFN Model are critical to estimating its impact on key outcomes. Lack of direct experience with policies such as the MFN Model, however, results in great uncertainty for making these behavioral assumptions. For a robust approach, ASPE made a number of assumptions based on published literature and expert consensus, and applied such assumptions on a drug-by-drug basis. Please note that ASPE has not adjusted the assumptions and estimates based on the effects of the COVID–19 pandemic.

The behavioral assumptions in this approach first address manufacturers' responses in the international market that might increase MFN Prices; and then the potential responses to the MFN Drug Payment Amounts by the manufacturers and providers and suppliers that purchase MFN Model drugs and submit a claim to Medicare after administering such drugs to beneficiaries. In general, these assumptions represent the proposition that manufacturers prefer to sell their products, even at lower prices, as long as net revenues (net sales prices minus production and distribution costs) remain positive; and that providers and suppliers are committed to maintaining effective treatments for beneficiaries either by negotiating lower prices, accepting reduced revenue, or finding effective Medicare Part B or Part D alternative treatments.

To assess the likelihood of each of the alternative manufacturer responses to the MFN Model, ASPE reviewed published literature on the impacts and interviewed a small cohort of experts regarding the potential impacts. Published literature suggests that when a large country establishes an international reference price, smaller reference countries experience price increases and longer launch delays for new products.[85] ASPE's conversations with experts suggested that as a result of the MFN Model, prices in other countries could increase at the ex-manufacturer level, potentially up to current ASP levels, and manufacturers could change formulations of MFN Model drugs to lessen the impact of the model. The experts generally believe that manufacturers will be able to price discriminate between the Medicare Part B market and other markets within the U.S. Potential utilization impacts will thus be limited to Medicare Part B beneficiaries, as payments to providers and suppliers for drugs provided to other patients will not be affected by the model.

Considering this information, ASPE made a series of assumptions for a base analysis. First, ASPE considered a static group of 50 drugs for this analysis. Based on the literature and interviews with experts, ASPE assumed manufacturers of newly launched brand products that become MFN Model drugs would adjust their international pricing strategies so that the MFN Payment Amount will be equal to ASP absent of the MFN Model. This assumption does not necessarily mean that net international prices (ex-manufacturer sales prices minus the value of rebates or other financial concessions) will be equal to the ASP. In addition, ASPE assumed that manufacturers of currently marketed drugs outside but near the top 50 Medicare Part B drugs based on annual allowed charges (with certain exclusions and exemptions) will lower their U.S. prices in an attempt to prevent them from becoming MFN Model drugs. To compensate for this response, ASPE assumed that manufacturers will increase prices for non-MFN Model drugs. Since companies often sell many different drugs, ASPE assumed they will have some flexibility to allocate discounts between different drugs to ensure no currently marketed non-MFN Model drugs enter the top 50 while maintaining near constant revenues. In some cases, there are relatively new drug products that may not have launched or may be recently launched in the included countries that may enter the top 50. In those cases, ASPE assumed the manufacturers will re-evaluate their international pricing strategies to ensure the MFN Price is comparable to ASP absent of the MFN Model. ASPE assumed that these changes to U.S. prices of non-MFN Model drugs will ultimately fully offset one another in terms of Medicare Part B drug spending as well.

For the 50 MFN Model drugs, the MFN Price ultimately depends on the prices for the drugs in the included countries. The exact mechanisms in which prices are determined in included countries differ by country and sometimes by product. These mechanisms include national (or sub-national tendering[86]), therapeutic-level reference pricing, international reference pricing, cost-effectiveness analysis, and negotiation. These mechanisms generally result in lower observed prices in other countries compared to the U.S., and these differences tend to be larger for products that have more competition than in the U.S. (such as more biosimilar competition) or have only a marginally better clinical profile than a cheaper

[85] Patricia M. Danzon, ''The Economics of the Biopharmaceutical Industry'', in Sherry Glied and Peter C. Smith (eds.), *The Oxford Handbook of Health Economics,* Oxford University Press 2011, pp. 520–554.

[86] Tendering is a formal procedure to purchase medications using competitive bidding for a particular contract.*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5628685/.*

therapy. Since the U.S. price under this model depends on the prices in other countries, the model will likely result in increased observed prices in other countries. This does not mean that net prices will necessarily increase as countries will try to find ways to prevent spending increases while limiting disruption in their drug markets. In this analysis, ASPE considered the potential impact at the drug-level because the context of each drug may determine the MFN Price.

ASPE modeled the pricing response to the change in direct drug payment for each of the 50 MFN Model drugs shown in Table 6 of this IFC. ASPE assumed that any changes in international sales prices for included countries would not occur until the beginning of the second performance year of the MFN Model. ASPE modeled the manufacturer pricing response based on available 2019 international drug pricing information, using the sales and volume data that CMS used to calculate the MFN Prices shown in Table 6 of this IFC. ASPE did not model how manufacturers and providers might take into account the changes to the add-on.

If there was only one related brand for the included countries,[87] then ASPE assumed the MFN Price for a drug will increase to the average price of the drug for the included countries plus 10 percent (with the cap of ASP). ASPE made this assumption because at this point the market size of the included countries is roughly the size of the Medicare Part B market for many of the MFN Model drugs. ASPE applied this approach to 34 of the 50 MFN Model drugs. ASPE assumed that the MFN Price will not likely increase by more than this because, even if the net price is constant for purchasers in the included countries, these countries may seek to avoid larger increases in transaction prices. In the case of drugs with no international spending in 2019, ASPE assumed that the model would have no impact. ASPE applied this approach to 2 of the 50 MFN Model drugs. When the MFN Price was calculated based on international drug pricing information for a country with access to biosimilar products or a competitor brand product that is not one of the MFN Model drugs, ASPE assumed smaller international price increases because the MFN Model would reduce the incentive for the manufacturer of an MFN Model drug to compete in those international markets. This approach applied to 8 of the 50 MFN Model drugs. When the MFN Price was calculated using international drug pricing information for a non-innovator unbranded product, ASPE assumed that the MFN Price would not increase. This assumption applied to 6 of the 50 MFN Model drugs.

After analyzing price changes internationally, ASPE analyzed the potential for beneficiaries to switch to other products with, for example, the same active ingredient within the U.S. and billed with HCPCS codes that are not among the MFN Model drugs. First, ASPE assumed that when a manufacturer has multiple branded products with different indications represented by the same HCPCS code, the manufacturer will work to obtain a new HCPCS code for the product in which Medicare Part B makes up a smaller portion of its overall market. In addition, the manufacturer will restrict the amount of product sold that could be billed under this new HCPCS code so that such products will not become included in the MFN Model. This assumption applied to one of the MFN Model drugs. ASPE also assumed that if an MFN Model drug is available within the U.S. in a formulation that will be covered under Medicare Part D, the manufacturer will work to shift 90 percent of the utilization from Medicare Part B to Medicare Part D. This assumption impacted 2 of the 50 MFN Model drugs.

In addition to these assumptions, ASPE made assumptions about potential generic entry for some of the MFN Model drugs. ASPE assumed that MFN Model drugs with generic drugs approved within the included countries or currently subject to on-going Paragraph 4 patent challenges would have generic competition by performance year 3. This assumption impacted 6 of the 50 MFN Model drugs.

After examining the potential price impacts and other utilization changes described previously, ASPE examined the potential for utilization impacts. In general, economic theory and the experts ASPE interviewed suggested that manufacturers will adjust U.S. prices to maintain sales as long as price is greater than marginal costs of producing and distributing the drug. ASPE also assumed that manufacturers will have substantial ability to price discriminate—that is, adjust pricing for Medicare-participating providers and suppliers to reflect discounts for their Medicare Part B patient share as opposed to all patients. Nonetheless, ASPE still considered the potential that price discrimination will be less than perfect for some drugs. In these cases, a manufacturer might refuse to negotiate lower prices for MFN beneficiaries if doing so threatens its ability to sell in other segments of the U.S. at a positive margin. That is, would the loss in revenues from selling for all purchasers at a reduced price exceed the loss in revenues from losing the MFN beneficiary share of business for that drug? To examine this issue, ASPE estimated the Medicare Part B share of each MFN Model drug compared with the estimated U.S. market. If it seemed likely that a manufacturer will have higher revenues selling to all purchasers at prices slightly above the MFN Drug Payment Amount than not selling to MFN participants for MFN beneficiary use, ASPE assumed the manufacturer will not restrict MFN beneficiaries' access to an MFN Model drug under Medicare Part B. This included examining if the MFN Model drugs had U.S. competitors. Since MFN participants likely treat both Part B beneficiaries and non-Part B beneficiaries (including individuals with employer, individual market, or Medicaid coverage), an MFN participant may select an alternative therapy marketed by a competitor that can be provided to both types of patients. As a result, manufacturers will have an incentive to work to maintain utilization so long as the MFN Payment Amount is not too low.

In cases where manufacturers might refuse to lower U.S. prices sufficiently to make it financially feasible for MFN participants to furnish the drug and receive the MFN Payment Amount, ASPE examined whether there were products that had similar therapeutic effects to a MFN Model drug. ASPE assumed that Medicare Part B beneficiaries will be switched to the potential alternative products. ASPE made these assessments for each performance year. ASPE assumed that half of Medicare Part B beneficiaries will continue accessing their current drugs through 340B providers. Such changes in drug utilization or service providers will likely result in additional burdens for patients. ASPE did not quantify these impacts.

Additionally, for biological drugs for which there are licensed biosimilar products, ASPE assumed that there will be at least one biosimilar manufacturer that is willing to provide its product at MFN payment levels if the reference manufacturer would not supply this drug. We note however that if reference manufacturers are willing to sell at MFN payment levels, providers may not have any incentive to use biosimilar products. The extent to which providers may use biosimilar products will depend on whether they are easier to

[87] For this analysis, we included available sales and volume data for the brand drug manufacturer and any parallel importers of the brand drug.

access instead of a product subject to the model. The biosimilar manufacturers will need to balance those considerations with the possibility that sufficiently large sales may also result in that product becoming an MFN Model drug. ASPE assumed any utilization changes that occur will result in zero net changes in spending. ASPE made no assumptions about the potential entry of biosimilar products for reference products that currently do not have biosimilar competition in the U.S. or referenced countries.

The overall utilization impact is the sum of the impacts for each of the 50 MFN Model drugs. These impacts reflect, on a drug by drug basis, the assumptions outlined previously. Specifically, where estimates reduced utilization, it reflects assumptions that either manufacturers will be unwilling to reduce prices to MFN participants, viable substitute drugs are not available for all affected patients, or both. In such cases, ASPE assumed that half of the impacted beneficiaries will be able to still access the MFN Model drug through a 340B provider.

ASPE calculated the potential impacts of the MFN Model by calendar year. ASPE assumed that at the end of the MFN Model, there will be no continued impacts because Medicare Part B payments for MFN Model drugs will immediately be based on non-model payment policies at the end of the MFN Model. Given the predictable 7-year model performance period, ASPE assumed manufacturers and MFN participants will have sufficient time to structure their agreements to ensure a seamless transition after the end of the MFN Model.

Table 15 summarizes the results of the ASPE analysis.

TABLE 15—ASSUMPTIONS REFLECTED IN ASPE ESTIMATE

	2021 (%)	2022 (%)	2023 (%)	2024 (%)	2025 (%)	2026 (%)	2027 (%)
Non-340B providers:							
Behavior:							
Continued Availability	100.0	100.0	97.7	95.9	96.2	96.5	96.7
Altered Availability:							
Shift to other drugs	0.0	0.0	1.1	2.1	1.9	1.8	1.6
Move to 340B	0.0	0.0	1.1	2.1	1.9	1.8	1.6
No Access	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total	100	100	100	100	100	100	100
MFN Price impact	−11.4	−14.3	−18.1	−20.5	−19.4	−17.9	−16.5
340B providers:							
Behavior:							
Continued Availability	100	100	100	100	100	100	100
MFN Price impact	0	0	0	0	0	0	0

ASPE estimated the Medicare FFS program impacts of the change from ASP-based payment to MFN-based payment.[88] The Medicare FFS impact includes changes in spending for Medicare Parts B and D.

For patients that switch to 340B providers, ASPE estimated the spending change based on the difference in the MFN Model payment for drugs acquired under the 340B program and the current Medicare Part B OPPS payment policy.

These impacts are generally considered transfer impacts of the model. To estimate these impacts, ASPE took an approach similar to OACT. ASPE used the direct reduction in Medicare Part B payments due to lower MFN payment amounts and translated that into transfers from the healthcare system to the government, beneficiaries, and Medicaid. In addition to the direct effects of lower payments and associated cost-sharing, the model results in downstream transfers associated with changes in Part B premiums and government payments to Medicare Advantage Plans. Like OACT, ASPE estimated Medicaid impacts based on changes to federal and state shares of prescription drug costs for dual eligibles but did not estimate impacts on Medicaid that may result from changes in net payments under the Medicaid Drug Rebate Program.

Overall, the model results in changes to federal spending in Medicare (including Part B, and Part D) from the model price and utilization impacts, changes in federal and state spending on Medicaid resulting from changes to the governmental obligation of Medicare cost-sharing for dual eligible beneficiaries, and changes in federal spending associated with add-on payment changes in the model. The model also results in changes to beneficiary spending resulting from changes in cost-sharing for drugs, changes in beneficiary premiums, and changes to cost-sharing associated with the add-on payment. These transfers on net balance out with reduced revenues for healthcare providers (which may be completely or mostly offset by the reduced cost of acquiring drugs), reduced revenues for pharmaceutical manufacturers, and reduced revenues for MA plans.

Based on our estimates of annual impacts on prescription drug pricing and annual add-on payments, ASPE did not model any impacts from the provider hardship payments. Eligibility for the hardship exemption will be based on year-over-year losses above 25 percent of total Medicare Part A and Part B payments, including payments for Medicare Part B drugs outside the model and payments for Medicare Part A and Medicare Part B services other than prescription drugs. We expect that few, if any, providers will have annual losses above this level, and that those who do may be insolvent and therefore unable to obtain retrospective hardship payments. We note in this regard that a hypothetical provider could experience revenue losses of 24.9 percent per year in each of the model's seven years, resulting in an 86.5 percent loss of revenue in Performance Year 7

[88] An indirect benefit of this IFC may be reduced distortions in the labor markets taxed to support the Medicare Trust Fund. Such distortions are sometimes referred to as marginal excess tax burden (METB), and Circular A–94—OMB's guidance on cost-benefit analysis of federal programs, available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A94/a094.pdf-suggests* that METB may be valued at roughly 25 percent of the estimated transfer attributed to a policy change; the Circular goes on to direct the inclusion of estimated METB change in supplementary analyses. If secondary benefits—such as reduced marginal excess tax burden is, in the case of this IFC—are included in regulatory impact analyses, then secondary costs must be as well, in order to avoid inappropriately skewing the net benefits results, and including METB only in supplementary analyses provides some acknowledgement of this potential imbalance.

compared with the pre-model base year and a 62.7 percent loss of revenue over the seven-year demonstration period, without qualifying for the hardship payments in any year.

Table 16 shows the net transfer impacts resulting from changes in Medicare B, and D. According to the ASPE estimate, this model would result in a net reduction of $87.8 billion in beneficiary, federal government, and state government spending over the 7 years of the model.

TABLE 16—ESTIMATED TRANSFER IMPACT OF MFN MODEL—ASPE ESTIMATE

	2021	2022	2023	2024	2025	2026	2027	2021–27
Part B Drug Price Reduction:								
Federal Government Spending	−2.4	−3.4	−8.4	−10.0	−10.3	−10.7	−10.8	−56.0
State Government Spending	−0.1	−0.1	−0.4	−0.4	−0.4	−0.5	−0.5	−2.4
Beneficiary Spending*	−1.4	−2.0	−5.0	−5.9	−6.2	−6.4	−6.4	−33.4
MA Plan Revenue	0.0	0.0	−4.8	−5.9	−6.1	−6.5	−6.5	−29.8
Health Care System Revenue**	−4.0	−5.5	−8.9	−10.5	−10.9	−11.1	−11.1	−61.9
Part D Drug Switching:								
Federal Government Spending	0.0	0.0	0.3	0.3	0.3	0.3	0.3	1.7
State Government Spending	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
Beneficiary Spending*	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.7
Health Care System Revenue**	0.0	0.0	0.5	0.5	0.5	0.5	0.5	2.5
Add-on Payment Impact:								
Federal Government Spending	0.2	0.2	0.4	0.3	0.4	0.4	0.4	2.2
State Government Spending	0.0	0.0	0.0	0.0	0.0	0.0	0.0	−0.3
Beneficiary Spending*	−0.1	−0.1	−0.1	−0.1	−0.1	−0.1	−0.1	−0.5
MA Plan Revenue	0.0	0.0	0.2	0.3	0.3	0.3	0.3	1.3
Health Care System Revenue**	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
Total Impact:								
Federal Government Spending	−2.2	−3.2	−7.7	−9.3	−9.7	−10.0	−10.0	−52.1
State Government Spending	−0.1	−0.2	−0.4	−0.4	−0.5	−0.5	−0.5	−2.5
Beneficiary Spending*	−1.6	−2.1	−4.9	−5.9	−6.1	−6.3	−6.3	−33.2
MA Plan Revenue	0.0	0.0	−4.6	−5.6	−5.8	−6.2	−6.2	−28.5
Health Care System Revenue**	−3.9	−5.5	−8.4	−10.0	−10.3	−10.6	−10.6	−59.3

*Beneficiary spending includes spending by beneficiary Medigap plans.
**Health care system revenue includes revenue accrued by health care providers, hospitals, pharmacies, and pharmaceutical manufacturers.

Based on this analysis, the model has the potential to generate impacts internationally. In particular, this model may result in higher prices or longer launch delays for new products in other OECD countries. ASPE did not attempt to quantify the impact of higher prices on utilization or the impact of these delays. The health effects of such delays depend on which products experience these delays and the potential alternative treatments. In addition, foreign governments may seek to mitigate these impacts by accepting higher prices for the products or pursuing alternative price arrangements that are less transparent.

3. Aggregate Effects on the Market

There may be spillover effects in the non-Medicare market, or even in the Medicare market outside Part B as a result of the MFN Model. Testing changes in Medicare Part B drug payment policy may have implications for non-Medicare payers. During the MFN Model, manufacturers' ASPs may increase or decrease, which may cause the payment limits in the quarterly Medicare ASP payment files to increase or decrease. Other payers that align their payments for drugs included in the MFN Model with the quarterly Medicare ASP payment files could therefore be impacted. Because the extent to which other payers align with Medicare Part B drug payments is unknown, we are not able to quantify the potential impacts of the MFN Model in this regard.

Private secondary payers that pay for beneficiary cost-sharing, such as Medigap plans and employer retiree coverage, will likely be impacted by the MFN Model. For MFN beneficiaries, cost-sharing on MFN Model drugs would be less than the amount that will apply outside of the model. If manufacturers generally raise drug prices in response to the MFN Model, the amount of cost-sharing paid by beneficiaries and secondary payers may increase; the opposite will occur if manufacturers decrease drug prices. Similarly, private primary insurers may be impacted if manufacturers change drug pricing as a result of the MFN Model. Market-wide changes in drug prices, including drugs not covered by Medicare Part B, will impact any individual who receives such drugs. In addition, to the extent manufacturers lower their overall prices for drugs, manufacturers may realize lower revenue as a result of the MFN Model. It is possible that manufacturers will increase international or domestic drug prices, reduce marketing and other expenses, or implement other efficiency measures to reduce their operating costs. Given the uncertainty of manufacturers' potential behavioral responses to the MFN Model, we are unable to quantify these potential spillover effects of the MFN Model. We welcome comments on these potential impacts and evidence on how this rule could affect other payers, patients, and drug manufacturers.

Some of this final rule's important tradeoffs occur over the long run. We request comment on whether the drug products affected by this IFC are likely to be currently over- or under-incentivized, including evidence from the research literature on optimal patent length, and on the effects of the IFC on drug manufacturers' incentives.

4. Estimated Effect and Burden of MFN Model Changes on Medicare Beneficiaries

We estimate that aggregate beneficiary Medicare Part B cost-sharing within the context of the MFN Model will decrease as the MFN Drug Payment Amount will not exceed 100 percent of the amount that applies outside the MFN Model (that is, the applicable ASP or WAC or payment limit that applies to drug acquired under the 340B program) and that beneficiaries will not have a cost-sharing liability for the alternative drug

add-on payment amount. Coinsurance for most separately payable drugs is set at 20 percent of the payment rates, subject to limitation in the hospital outpatient and ASC settings. To the extent that prescribing patterns shift toward lower cost drugs under the MFN Model, in aggregate, beneficiaries could benefit along with the Medicare program. If prescribing patterns shift toward Part D drugs, beneficiary cost-sharing may increase or decrease depending upon the drugs they take, which phase of the Part D benefit such use occurs in, the beneficiary's eligibility for help with drug costs, and their plan choice. In addition, as a result of the MFN Model, we expect Medicare Part B premiums to decrease. Beneficiaries will benefit from 25 percent of any premium reduction that may result as this is the portion of annual premiums that beneficiaries pay.

If MFN participants choose not to provide MFN Model drugs or prescribe alternative therapies instead, beneficiaries may experience access to care impacts by having to find alternative care providers locally, having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment. There is significant uncertainty with these potential effects of the MFN Model. CMS will carefully monitor for evidence of these potential effects and conduct beneficiary surveys to assess impacts of the MFN Model on beneficiaries.

Given the uncertainty of these impacts, we are unable to quantify these potential effects of the MFN Model.

In section III.H. of this IFC, we describe our intention to include quality measures as part of the MFN Model, and our plan to collect one quality measure, focused on patient experience, to help better understand the impact of the MFN Model on beneficiary access and quality of care. This information collection will be one part of robust monitoring activities to ensure that MFN beneficiaries' access to medications and quality of care is preserved or enhanced. We will use a patient experience survey, which we will field to a sample of MFN beneficiaries, beginning in performance year 1. We will include additional items in the patient experience survey that focus on patient access, to the extent that valid and reliable items are available. The patient experience survey will be administered to these beneficiaries by a third party contractor throughout the model performance period. Beneficiaries will not be required to complete the survey.

The patient experience survey will be based on a standardized instrument, designed to assess patients' experiences with health care providers and staff in an ambulatory setting. We will use the most current version of the instrument plus additional survey questions as applicable to meet CMS's monitoring needs.

Based on drug claims analyses and the scope of the MFN Model, we assume the patient experience survey will be administered to 75,000 beneficiaries and be completed by 30,000 beneficiaries per year. The survey will take approximately 30 minutes to complete. Therefore, the annual total number of hours for this information collection will be 15,000 hours (30,000 beneficiaries times 0.5 hours per beneficiary responding).

To derive average costs for individuals we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates for our salary estimate (*www.bls.gov/oes/current/oes_nat.htm*). We believe that the burden will be addressed under All Occupations (occupation code 00–0000) at $25.72 per hour since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc. We are not adjusting this figure for fringe benefits and overhead since the individuals' activities will occur outside the scope of their employment. Therefore, the estimated cost for this information collection will be $385,800 (15,000 hours × $25.72). Beneficiaries will have annual costs associated with responding to the patient experience survey, which we estimate will be $385,800 annually during the model.

5. Estimated Effect and Burden on MFN Participants and Manufacturers

MFN participants and drug manufacturers will have administrative costs related to adjusting to and complying with the regulations. These costs may include adjusting purchasing arrangements, which for some affected businesses may mean substantially changing their pricing models and engaging in negotiations with other businesses; tracking units of MFN Model drugs that are paid under the MFN Model and excluded from manufacturers' ASPs; recordkeeping requirements, which may require acquisition of new tools and information sharing; and adjusting to any spillover effects. Additionally, MFN participants may be subject to site visits for the purposes of monitoring the MFN Model.

During the model performance period, MFN participants must participate in MFN Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), as the Secretary determines is necessary to monitor and evaluate the MFN Model, including without limitation collecting and reporting of information, including ''protected health information'' as that term is defined at 45 CFR 160.103. These monitoring activities may include a sample of site visits to verify any monitoring concerns. We anticipate that these monitoring and compliance requirements will not diverge from general monitoring requirements for Medicare Part B providers. We believe that these requirements do not add additional burden or impose regulatory impact on participants. The MFN Model monitoring will likely include beneficiaries and eligible providers and suppliers completing surveys. Burden for the patient survey is described previously, and burden for any provider and supplier survey will depend on the length, complexity, and frequency of surveys administered as needed to ensure confidence in the survey findings. We will make an effort to minimize the length, complexity, and frequency of any provider and supplier surveys. A typical survey on average requires about 20 minutes of the respondent's time. In other evaluations of models where a survey is required, the frequency of surveys varies from a minimum of one round of surveys to annual surveys. We estimate the burden for annual surveys from clinicians, assuming one per eligible provider and supplier, will be 7 surveys [annual] times ⅓ hour [20 min.] times $200 [median physician/surgeon hourly rate plus fringe benefits] times 22,888 [eligible providers and suppliers] = $10,702,429.

Finally, MFN participants may choose to apply for a financial hardship exemption that requires the submission of a timely, complete request for a financial hardship exemption. We think that approximately 900 MFN participants will submit a request for a financial hardship exemption each performance year of the model. We expect that a medical health service manager will need approximately 15 hours to compile the necessary supporting documentation and submit a complete financial hardship exemption request. We estimate the burden for applying for the financial hardship exemption per year for all performance year of the model will be 900 [number of MFN participants that submit

hardship exemption requests in each performance year] times 15 hours times $111 [medical health service manager hourly rate plus fringe benefits] = $1,498,500. Note, the financial hardship exemption requests for performance year 1 (2021) will be submitted in 2022, and the requests for performance year 7 will occur in 2028.

We expect that manufacturers will need to update their ASP reporting. However, we expect the burden to be de minimis compared to existing ASP reporting requirements and can likely be automated based on existing processes.

6. Regulatory Review Cost Estimation

In order to comply with the regulatory changes in this IFC, affected businesses will need to review the rule and MFN participants will need to review MFN-specific billing guidance on how to bill for the alternative add-on payment. We expect that a medical health service manager reading 250 words per minutes could review the rule in approximately 6 hours [(approximately 300 pages * 300 words/per page)/250 words per minute)/ 60 minutes)]. We estimate 1 hour to review the relevant MLN matters publication and 2 hours to read MFN Model billing guidance for a total of 3 hours of billing specific training. Since all MFN participants have experience billing HCPCS codes to Medicare, we do not expect any additional specific burden related to the alternative add-on payment M code during model implementation after the MFN-specific billing guidance is reviewed. We estimate the salary of a medical and health service manager is $111 per hour, using the wage information from the 2019 BLS including overhead and fringe benefits (BLS occupation code 11–9110). For each provider or supplier that reviews the rule and MFN-specific billing guidance, the estimated cost based on the expected time and salary of the person reviewing the rule is $999 ($111 * 9 [6 hours for reviewing the rule and 3 hours for billing training). We estimate that the cost for providers and suppliers to review this IFC and MFN-specific billing guidance will be approximately $117.9 million (118,101 entities times $999).

7. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief for small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *http://www.sba.gov/content/table-smallbusiness-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity. The RFA requires that CMS analyze regulatory options for small businesses and other entities unless CMS certifies that a rule will not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities. The vast majority of MFN participants are considered to be small entities, based upon the SBA standards. There are over twenty thousand MFN model participants that will be included or affected by the MFN Model. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this IFC is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

The RFA requires that a Regulatory Flexibility Analysis (RFA) be prepared if an IFC will have a ''significant impact on a substantial number'' of small entities. HHS interprets the statute as mandating this analysis only if the impact is adverse, though there are differing interpretations. For purposes of the RFA, most practitioners, hospitals, and other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards (having revenues of less than $7.5 million to $38.5 million in any 1 year). For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *https://www.sba.gov/document/support—table-size-standards.* The rule of thumb used by HHS for determining whether an impact is ''significant'' is an adverse effect equal to 3 percent or more of total annual revenues. Because the majority of providers/suppliers in the U.S. qualify as ''small,'' and this model includes all eligible providers/suppliers that submit claims for separately payable Medicare Part B drugs, we expect the majority of MFN participants to be small entities. However, some of these small entities may not administer Medicare Part B drugs and will not be MFN participants.

There are a number of providers and suppliers, including various physician specialties, that will see reduced drug component payments of 3 percent or more in performance year 1. Please refer to Table 3 to see the number of entities impacted, as well as the types of providers and suppliers that will be most likely impacted by the rule. Lower MFN Model drug payments will likely be a fraction of these entities' total revenues, taking into account non-Medicare patients and all other services provided. Moreover, the alternative add-on payments could offset such reductions to some extent, as described in section III.F. of this IFC. We considered potential impacts on small entities; we expect that the model's impact on an MFN participant's revenue will be driven by the proportion of Medicare payments to the MFN participant that is related to administering Medicare Part B drugs rather than its size. Further, to provide financial protection for MFN participants, we are including a financial hardship exemption for MFN participants (regardless of size) that experience significant financial hardship as a result of the model test, as described in section III.I.2. of this IFC. It is likely that many, if not all, included providers and suppliers will see an overall decrease in revenue for MFN Model drugs of 3 percent or more over the course of the model. Accordingly, we have determined that a Regulatory Flexibility Analysis (RFA) is required. This RIA, together with the preamble, constitutes the required analysis.

As a result of the model, we expect total allowed charges for Medicare Part B drugs for small entities to go down commensurate with the phase-in of the MFN Price in the calculation of the MFN Drug Payment Amount (Year 1: 75 percent applicable ASP and 25 percent MFN Price; Year 2: 50 percent applicable ASP and 50 percent MFN Price; etc.). Although the alternative add-on payment was designed to hold MFN participants harmless based on current revenue to the greatest extent possible, as shown in Table 8, some specialties will benefit from a higher aggregate add-on payment amount, while for other specialties some portion of such specialties will have a decrease in aggregate add-on payment. We estimate that MFN participants, on average, will see an approximate 40 percent increase in historical revenue related to the alternative add-on portion of the MFN Model payments, which will total approximately $4.4 billion in

the OACT estimate and $2.2 billion in the ASPE estimate over the 7-year model. In these estimates, the total Medicare FFS impact, as indicated in Tables 12 and 16, would be a reduction of approximately $85.5 billion in Medicare FFS spending in the OACT estimate and a majority of the $52.1 billion in reduced federal spending in the ASPE estimate over the 7-year model, and will apply mainly to urban and non-340B MFN participants. We note that there is much uncertainty around the assumptions for these estimates. Finally, we have and will continue to take steps to minimize the impact of this IFC on administrative and reporting burdens for small businesses. We welcome comments on our estimate of significantly affected providers and suppliers and the magnitude of estimated effects. We also welcome comments on adjustments to the MFN Model that could be considered for future rulemaking while preserving the innovative approach to payment in the MFN Model.

8. Effects on Small Rural Hospitals

Section 1102(b) of the Act requires CMS to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this IFC will have a significant impact on small rural hospitals.

As described in section III.C. of this IFC, we will exclude CAHs from the types of providers and suppliers that will be MFN participants. Slightly less than 10 percent ($3.35 billion) of total Medicare Part B drug allowed charges in 2019 are associated with rural providers and suppliers (other than CAHs) based on claims with ZIP codes associated with areas that are not assigned to metropolitan core based statistical areas (CBSA) identified by the Office of Management and Budget; of that amount, less than 0.015 percent ($4.87 million) is for drugs furnished in the U.S. territories outside of the metropolitan areas of Puerto Rico. These rural entities will experience drug payment reductions and overall payment reductions similar to urban entities under the MFN Model.

9. Unfunded Mandates Reform

Section 202 of the Unfunded Mandates Reform Act of 1995 (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 2020, that threshold is approximately $156 million. This IFC does not mandate any spending by State, local, or tribal governments, or by the private sector, and hence an UMRA analysis is not required.

10. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on State and local governments, preempts state law, or otherwise has Federalism implications. We have examined the provisions in the MFN Model included in this IFC in accordance with Executive Order 13132, and have determined that they will not have a direct effect on state, local or tribal governments, preempt state law, or otherwise have a Federalism implication.

D. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017, and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This IFC is considered an E.O. 13771 regulatory action. Details on the estimated costs of this IFC can be found in the preceding and subsequent analyses.

E. Alternatives Considered

This IFC contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the final policies, and presents rationales for our policies and, where relevant, alternatives that we considered in section III of this IFC.

Several alternatives we considered included: (1) The parameters included in this IFC; (2) variations of certain parameters included in this IFC, such as lengthening the phase-in of the MFN Price (described in section III.E.8. of this IFC) to occur over 5–7 performance years, limiting the model performance period to 5 performance years, expanding or limiting the Medicare Part B drugs that would be eligible for inclusion in the MFN Model and a different geographic area; (3) the parameters in the October 2018 ANPRM for a potential IPI Model for Medicare Part B Drugs; [89] and (4) not implementing the model. In addition, when developing the parameters for the October 2018 ANPRM and this IFC, we noted that there are a range of methods to implement external reference pricing, and these different approaches would affect the impact of the model.[90] [91] In examining potential variations of certain parameters included in this IFC, we considered potential differences such variations would have on the impacts presented in sections VI.C.1. and VI.C.2. of this IFC. We note that a potential model design with a longer MFN Price phase-in would have a lower estimate of overall Medicare savings; for example, a 7-year phase-in of the MFN Price over a 7-year model performance period would reduce estimates of Medicare savings in the OACT estimate by approximately 25 percent. As noted in section III.E.5. of this IFC, our policy is to phase-in the MFN Price more quickly during the initial years to allow CMS to test the full phase-in of the MFN Price. In considering the scope of the model, we actively assessed whether to pursue a smaller geographic scope. As we discuss in section III.C.3. of this IFC, we reviewed the comments that we received on the October 2018 ANPRM, where we considered 50 percent of the country in a model. We weighed whether the ability to have a research design where we would compare changes in drug spending and utilization relative to a comparison group, a design that CMS uses frequently in its models, would outweigh the concerns we highlight in section III.C.3. of this IFC. We ultimately concluded that operational concerns such as administrative complexity as well as the risk to model integrity associated with a limited geographic scope, as described in section III.C.3. of this IFC, necessitate a test with a nationwide scope using a different evaluation design.

The estimates for the impact of this IFC show a substantial reduction in Medicare Part B spending over a 7-year model.

[89] *https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs.*

[90] *https://jasmin.goeg.at/432/1/EURIPID_GuidanceDocument_V8.1_310718.pdf.*

[91] *https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/pharmaproductpricing_frep_en.pdf.*

In comparison, the parameters considered in the October 2018 ANPRM were estimated to result in a less substantial reduction in Medicare Part B spending over a 5-year model.[92] The alternative of not implementing the model would not have an impact compared to existing policy.

F. Accounting Statements and Tables

As required by OMB Circular A–4 under Executive Order 12866 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*) in Tables 17 and 18 we have prepared two accounting statements, based on the OACT and ASPE estimates respectively, showing the classification of transfers, benefits, and costs associated with the provisions in this IFC. The transfer from beneficiaries to providers and MA plans represents the premium change attributable to the drug price, *i.e.,* the difference between the gross impact and the net impact in the drug price section of Table 12. The accounting statement in Table 17 is based on estimates provided in this regulatory impact analysis in Table 12 and the accounting statement in Table 18 is based on estimates in Table 16. Tables 17 and 18 include the estimated effect and burden estimates on beneficiaries outlined in section VI.C.4. of this IFC and on participants and manufacturers in section VI.C.5. of this IFC. The costs shown in Table C18 reflect additional medical expenses incurred as a result of the potential loss of access to certain drugs for some beneficiaries in the ASPE estimate.

TABLE 17: ACCOUNTING STATEMENT: ESTIMATED IMPACTS FROM CY 2021 TO CY 2027 AS A RESULT OF CHANGES IN THIS IFC BASED ON THE OACT ESTIMATE

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Costs				
Annualized Monetized ($million/year)	29.4	2018	7%	January 2021 – December 2028
	27.1	2018	3%	January 2021 – December 2028
From Whom to Whom	Hospital/physicians			
Annualized Monetized ($million/year)	0.4	2018	7%	January 2021 – December 2027
	0.4	2018	3%	January 2021 – December 2027
Transfers				
Annualized Monetized ($million/year)	-11, 502.5	2018	7%	January 2021 – December 2027
	-11, 906.3	2018	3%	January 2021 – December 2027
From Whom to Whom	Federal Government to hospitals/physicians and MA plans.			
Annualized Monetized ($million/year)	-4,087.2	2018	7%	January 2021 – December 2027
	-4, 228.3	2018	3%	January 2021 – December 2027
From Whom to Whom	Beneficiaries to hospitals/physicians and MA plans.			
Annualized Monetized ($million/year)	-577.5	2018	7%	January 2021 – December 2027
	-596.5	2018	3%	January 2021 – December 2027
From Whom to Whom	States to hospitals/physicians and MA plans			
Notes	Price discrimination hinges upon producers being able to separate consumers according to their (and, in the pharmaceutical context, their payers') willingness-to-pay. Because the policy reduces the feasibility of that separation, prices would decrease for the consumers previously paying more (a subset of U.S. patients with the federal government as their payer); prices would increase for the consumers previously paying less (international patients and their payers); and producer surplus would decrease.			

[92] *https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs.*

TABLE 18: ACCOUNTING STATEMENT: ESTIMATED IMPACTS FROM CY 2021 TO CY 2027 AS A RESULT OF CHANGES IN THIS IFC BASED ON THE ASPE ESTIMATE

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Costs				
Annualized Monetized ($million/year)	29.4	2018	7%	January 2021 – December 2028
	27.1	2018	3%	January 2021 – December 2028
From Whom to Whom	Hospital/physicians			
Annualized Monetized ($million/year)	0.4	2018	7%	January 2021 – December 2027
	0.4	2018	3%	January 2021 – December 2027
Transfers				
Annualized Monetized ($million/year)	-7,058.3	2018	7%	January 2021 – December 2027
	-7,276.5	2018	3%	January 2021 – December 2027
From Whom to Whom	From Federal Government to hospitals/physicians and MA plans.			
Annualized Monetized ($million/year)	-4, 504.9	2018	7%	January 2021 – December 2027
	-4, 638.6	2018	3%	January 2021 – December 2027
From Whom to Whom	Beneficiaries to hospitals/physicians and MA plans			
Annualized Monetized ($million/year)	-342.4	2018	7%	January 2021 – December 2027
	-351.6	2018	3%	January 2021 – December 2027
From Whom to Whom	From states to hospitals/physicians and MA plans			
Notes	Price discrimination hinges upon producers being able to separate consumers according to their (and, in the pharmaceutical context, their payers') willingness-to-pay. Because the policy reduces the feasibility of that separation, prices would decrease for the consumers previously paying more (a subset of U.S. patients with the federal government as their payer); prices would increase for the consumers previously paying less (international patients and their payers); and producer surplus would decrease.			

G. Conclusion

The changes in this IFC will affect providers and suppliers that furnish separately payable Medicare Part B drugs in the outpatient setting for which annual Medicare FFS spending is high. These providers and suppliers are mostly physicians (including physician practices), non-physician practitioners, supplier groups, HOPDs (including on- and off-campus outpatient provider-based departments, but excluding cancer hospitals, children's hospitals and CAHs), and ASCs. We estimate that the effect of the MFN Model on providers and suppliers willvary, depending on their type, location, what drugs they furnish, their clinical patterns, and the alternative add-on payment for the MFN Model. We estimate that eligible providers and suppliers will experience a decrease in overall payment related to the MFN Model. We estimate that beneficiaries who receive included drugs from MFN participants will experience a decrease in cost-sharing, however, some beneficiaries' providers and suppliers may choose not to offer access to the MFN Model drugs, causing these beneficiaries to seek alternative providers, treatment alternatives, or forgo access. The financial hardship exemption is designed to mitigate this risk.

The changes in this IFC will also affect MA organizations, drug manufacturers, primary and secondary payers, and potentially non-Medicare patients. MA organizations will experience lower payments as a result of the MFN Model because the MA ratebook calculations will reflect changes in actual FFS spending due to the impact of the model. Drug manufacturers may have lower revenue, depending upon their behavioral response to the MFN Model. Other payers, including State Medicaid Programs, and patients who take prescription drugs may experience direct or indirect spillover effects that may increase or decrease their costs. In addition, as shown in Tables 12 and 16, the changes we are adopting in this IFC will reduce state and federal Medicaid spending and beneficiary spending on Medicare premiums.

In accordance with the provisions of E.O. 12866, this IFC was reviewed by the Office of Management and Budget.

VII. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. Section 553(b)(B) of the APA provides for exceptions from the notice and comment requirements; in cases in which these exceptions apply, section 1871(b)(2)(C) of the Act provides for exceptions from the notice and 60-day comment period requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with

normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

High drug prices in the U.S. have serious economic and health consequences for beneficiaries in need of treatment. Increasing premiums, out-of-pocket costs in both Part B and Part D, and increases in drug prices are causing beneficiaries to divert scarce resources to pharmaceutical treatments and away from other needs, or prompting them to skip doses of their medications, take less than the recommended doses, or abandon treatment altogether.[93] [94] In Medicare Part B, drug spending increased by over 9 percent between 2009 and 2017. Over two thirds of that increase in spending was based on increases in drug prices alone, and only one third due to increases in utilization.[95] Prices of certain drugs have increased by double-digit percentages over time.[96] These dramatic increases are on prices where the U.S. already pays significantly more than other countries.[97] When CMS announced the 2020 Part B Premiums and Deductibles, we noted that the increases in Part B premiums and deductibles was largely due to rising spending on physician-administered drugs.[98]

With more than 25 million Medicare beneficiaries living at or below 200 percent of the Federal Poverty Line (FPL),[99] high drug prices could lead to improper medication adherence or skipped treatment. The consequences of these behaviors can result in poor clinical outcomes for chronic disease management.[100] The COVID–19 pandemic has rapidly exacerbated these problems. The risk of severe illness from COVID–19 increases with age and the presence of chronic illnesses, putting many older adults at the highest risk levels.[101] [102] This is of particular concern given that 84 percent of individuals over the age of 65 having at least one chronic health condition, and more than 53 million adults over the age of 65 are enrolled in Medicare.[103] [104] With adults 65 and older comprising 8 out of 10 COVID–19 deaths reported in the U.S., COVID–19 has disproportionately impacted Americans 65 or older.[105]

Furthermore, the COVID–19 pandemic has led to historic levels of unemployment in the U. S., with both the unemployment rate and number of unemployed persons remaining nearly twice their Feburary (pre-pandemic) numbers.[106] The COVID–19 pandemic has also led to an increase in food prices, straining budgets for many of America's seniors, particularly those who live on fixed incomes,[107] such as the 6 million Medicare fee-for-service beneficiaries without supplemental coverage and over 12 million beneficiaries dually eligible for Medicare and Medicaid.[108] [109] [110] Already facing increased financial burden, this population is in need of urgent relief from high drug prices in order to prevent stinting on care and alleviate general financial instability worsened by the COVID–19 pandemic. This need is exacerbated in communities of color and among women, wherein Black, Latino, and Hispanic adults face higher economic insecurity than their white counterparts.[111] The economic disruptions caused by the COVID–19 pandemic have increased the burdens placed on America's seniors and other Medicare Part B beneficiaries and given rise to an urgent need for swift action to reduce drug prices. Though we have seen some positive economic and employment trends since the initial peak in April,[112] we are currently seeing a new surge in COVID–19 cases that may lead to additional hardship and requires immediate action.[113] As such, we find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID–19 pandemic. Implementation of this model will provide immediate relief to Medicare beneficiaries through reduced copays for MFN drugs due to lower drug payments and no beneficiary cost-sharing on the alternative add-on payment.

We also usually provide for a delay in effective date under section 553(d) of the APA and section 1871(e)(1)(B) of the Act. However, such delay in effective date may be waived for good cause,

[93] Kirzinger A, Neuman T, Cubanski J, Brodie M. Data Note: Prescription Drugs and Older Adults, Aug 09, 2019, Kaiser Family Foundation *https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/.*

[94] Kirzinger A, Lopes L, Wu B, Brodie M. KFF Health Tracking Poll—February 2019: Prescription Drugs, Kaiser Family Foundation, Mar 01, 2019, *https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/.*

[95] Medicare Payment Advisory Commission, Report to Congress ''Chapter 3: Medicare payment strategies to improve price competition and value for Part B drugs,'' June 2019, *http://www.medpac.gov/docs/default-source/reports/jun19_ch3_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

[96] Hernandez I, San-Juan-Rodriguez A, Good CB, Gellad WF. Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007–2018. *JAMA.* 2020;323(9):854–862. doi:10.1001/jama.2020.1012.

[97] Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures.*

[98] CMS Newsroom. 2020 Medicare Parts A & B Premiums and Deductibles. *https://www.cms.gov/newsroom/fact-sheets/2020-medicare-parts-b-premiums-and-deductibles.*

[99] Schoen C, Davis K, Willink A, Medicare Beneficiaries' High Out of Pocket Costs: Cost Burdens by Income and Health Status, Commonwealth Fund, May 12, 2017, *https://www.commonwealthfund.org/publications/issue-briefs/2017/may/medicare-beneficiaries-high-out-pocket-costs-cost-burdens-income?redirect_source=/publications/issue-briefs/2017/may/medicare-out-of-pocket-cost-burdens.*

[100] *https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm.*

[101] *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html#:~:text=Risk%20for%20Severe%20Illness%20Increases%20with%20Age&text=The%20greatest%20risk%20for%20severe%2cas%20having%20underlying%20medical%20conditions.*

[102] *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.*

[103] National Council on Aging, *https://www.ncoa.org/economic-security/money-management/debt/senior-debt-facts/.*

[104] MMCO Statistical & Analytic Reports, Managed Care Enrollment Trends (2006–2018 Data), *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Analytics.*

[105] *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html#:~:text=Risk%20for%20Severe%20Illness%20Increases%20with%20Age&text=The%20greatest%20risk%20for%20severe%2cas%20having%20underlying%20medical%20conditions.*

[106] U.S. Bureau of Labor Statistics. Economic News Release.The Employment Situation—October 2020. November 06, 2020. *https://www.bls.gov/news.release/empsit.nr0.htm.*

[107] 54 million people in America face food insecurity during the pandemic. It could have dire consequences for their health. AAMC. October 15, 2020. *https://www.aamc.org/news-insights/54-million-people-america-face-food-insecurity-during-pandemic-it-could-have-dire-consequences-their.*

[108] MMCO Statistical & Analytic Reports, Managed Care Enrollment Trends (2006–2018 Data), *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Analytics.*

[109] An Overview of Medicare, Kaiser Family Foundation, Feb 12, 2019, *https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/.*

[110] Note: The number of Medicare beneficiaries without supplemental insurance is from 2016 while the dual eligible numbers are from 2018.

[111] Center on Budget and Policy Priorities, Tracking the COVID–19 Recession's Effects on Food, Housing, and Employment Hardships. November 9, 2020. *https://www.cbpp.org/research/poverty-and-inequality/tracking-the-covid-19-recessions-effects-on-food-housing-and.*

[112] U.S. Bureau of Labor Statistics. Economic News Release.The Employment Situation- October 2020. November 06, 2020. *https://www.bls.gov/news.release/empsit.nr0.htm.*

[113] Center for Disease Control. COVID–19 Forecasts: Cases. *https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/forecasts-cases.html.*

when such delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the finding and a brief statement of the reasons therefore in the notice. We find that delaying implementation of this IFC is contrary to the public interest for the same reasons that we find good cause to waive prior notice and comment.

List of Subjects in 42 CFR Part 513

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble and under the authority at 5 U.S.C. 301, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV by adding part 513 to read as follows:

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE AND MODEL PROGRAMS

PART 513—Most Favored Nation (MFN) MODEL

Sec.

Authority: 42 U.S.C. 1302, 1315(a), and 1395hh.

Subpart A—General Provisions

§ 513.1 Basis, scope, and duration.

(a) *Basis.* This part implements the test of the Most Favored Nation (MFN) Model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part do not affect payment, coverage, program integrity, or any other requirements that otherwise apply to providers of services and suppliers under this chapter.

(b) *Scope.* This part sets forth the following:

(1) The types of providers and suppliers required to participate in the MFN Model and applicable requirements.

(2) The beneficiaries included in the MFN Model.

(3) The drugs included in the MFN Model.

(4) The methodologies for establishing Medicare payment amounts for and making payments for MFN Model drugs, including an alternative add-on payment.

(5) Beneficiary protections.

(6) Beneficiary cost-sharing.

(c) *Duration.* The MFN Model has a performance period of 7 performance years. The first performance year (performance year 1) begins on January 1, 2021, and the final performance year ends on December 31, 2027, unless sooner terminated in accordance with § 513.1000.

§ 513.2 Definitions.

For the purpose of this part the following definitions are applicable unless otherwise stated:

Add-on percentage means the percentage above 100 percent.

Alternative add-on payment means the payment described in § 513.220.

Applicable ASP means the payment amount determined in accordance with section 1847A of the Act for a quarter minus the applicable add-on percentage.

ASP stands for average sales price.

ASP calendar quarter means the period that is two calendar quarters prior to the calendar quarter to which the MFN Drug Payment Amount will apply.

CCN stands for CMS Certification Number.

Country-level price means the unadjusted country-level price for an MFN Model drug at the HCPCS code level as calculated in accordance with § 513.210(b)(2).

CPI–U stands for Consumer Price Index for All Urban Consumers based on all items in U.S. city average and not seasonally adjusted.

Days means calendar days.

DME stands for Durable Medical Equipment.

FDA stands for Food and Drug Administration.

GDP stands for gross domestic product.

GDP-adjusted country-level price means the country-level price adjusted by the GDP adjuster as calculated in accordance with § 513.210(b)(4).

GDP adjuster means the country-specific adjuster as calculated in accordance with § 513.210(b)(3).

HCPCS stands for Healthcare Common Procedure Coding System.

HCPCS code level means the specified drug and amount described in the HCPCS code long descriptor.

MAC stands for Medicare Administrative Contractor.

Manufacturer's average sales price has the same meaning as under 42 CFR Subpart J.

MFN stands for most favored nation.

MFN beneficiary means an individual who is furnished an MFN Model drug by an MFN participant and who, on the date of service, is enrolled in Medicare Part B, has Medicare as his or her primary payer, and is not covered under Medicare Advantage or any other group health plan, including a United Mine Workers of America health plan.

MFN Drug Payment Amount means the portion of the total allowed payment amount for an MFN Model drug determined in accordance with § 513.210.

MFN Model drug means a separately payable Medicare Part B drug or biological described by a HCPCS code included on the MFN Model Drug HCPCS Codes List.

MFN Model Drug HCPCS Codes List means the list of drugs included in the MFN Model for a given calendar quarter of a performance year established under § 513.130.

MFN participant means a Medicare participating provider or supplier, identified by its CCN or TIN, that is required to participate in the MFN Model in accordance with § 513.100(b).

MFN Model Payment means the total payment to an MFN participant for an MFN Model drug in accordance with subpart C of this part, inclusive of the MFN Drug Payment Amount and the Alternative Add-on Payment.

MFN Price means the lowest GDP-adjusted country-level price of the countries specified in § 513.140(b) for an MFN Model drug.

Model performance period means the 7-year period of time beginning on January 1, 2021, through December 31, 2027.

NOC stands for not otherwise classified.

OIG stands for the Department of Health and Human Services Office of Inspector General.

Outpatient prospective payment system (OPPS) means the payment system for designated hospital outpatient items and services and certain Medicare Part B services furnished to hospital inpatients when Part A payment cannot be made as defined by section 1833(t) of the Act.

Performance year means each 12-month period beginning on January 1 and ending on December 31 during the performance period for the MFN Model specified in § 513.1(c).

Provider means a ''provider of services'' as defined under section 1861(u) of the Act and codified at § 400.202 of this chapter.

Supplier means a supplier as defined in section 1861(d) of the Act and codified at § 400.202 of this chapter.

TIN stands for taxpayer identification number.

WAC means wholesale acquisition cost as defined at section 1847A(c)(6)(B) of the Act.

Subpart B—Inclusion in the Model

§ 513.100 MFN Model payments and MFN participants.

(a) *General.* Subject to the exceptions specified in paragraph (d) of this section, the MFN Model payments specified under this part apply only to claims for an MFN Model drug furnished to an MFN beneficiary by an MFN participant.

(b) *MFN participants.* Subject to the exclusions specified in paragraph (c) of this section, the MFN Model requires participation by each Medicare participating provider and supplier that submits a claim (except for claims specified in paragraph (d) of this section) for a separately payable drug that is an MFN Model drug furnished to an MFN beneficiary.

(c) *Excluded providers and suppliers.* The following are excluded from participation in the MFN Model:

(1) Children's hospitals (defined under section 1886(d)(1)(B)(iii) of the Act).

(2) PPS-exempt cancer hospitals (defined under section 1886(d)(1)(B)(v) of the Act).

(3) Critical access hospitals (CAHs) (defined under section 1820 of the Act).

(4) Indian Health Service (IHS) facilities (as described in section 1880 of the Act)), except when MFN Model drugs are furnished and such service is described in section 1880(e)(2)(B) of the Act.

(5) Federally Qualified Health Centers (FQHCs) (defined under section 1861(aa)(4) of the Act).

(6) Rural Health Clinics (RHCs) (defined under section 1861(aa)(2) of the Act).

(7) Hospitals that are not subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act) and are paid on the basis of reasonable costs subject to a ceiling under section 1886(b) of the Act.

(8) Extended neoplastic disease care hospitals (defined in section 1886(d)(1)(B)(vi) of the Act).

(9) For the first quarter and second quarter of performance year 1, acute care hospitals that participate in any model authorized under section 1115A of Act for which payment for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis under a waiver of section 1833(t) of the Act.

(10) Beginning with the third quarter of performance year 1, acute care hospitals that participate in any model authorized under section 1115A of Act for which payment for outpatient hospital services furnished to Medicare FFS beneficiaries, including MFN Model drugs, is made under such model on a fully capitated or global budget basis under a waiver of section 1833(t) of the Act, where the parameters of such model adjust for the difference in payment for MFN Model drugs between the MFN Model and non-MFN Model drug payments such that savings under the MFN Model are incorporated into the other CMS Innovation Center model's parameters (for example, the annual global budget) for the duration of the MFN Model.

(d) *Exceptions.* The MFN Model payments specified under this part do not apply to any of the following:

(1) Claims for MFN Model drugs furnished in the inpatient hospital setting under those circumstances where Part A would not pay for hospital services.

(2) Claims for MFN Model drugs administered during an inpatient hospital stay or included on an inpatient hospital claim.

(3) Claims administered by the DME MACs as described in § 421.404(c)(2) of this chapter.

(4) Claims paid under the End-Stage Renal Disease Prospective Payment System, including claims paid using the transitional drug add-on payment adjustment.

(e) *MFN participant requirements during the MFN Model.* During the model performance period described in § 513.1(c), MFN participants must do all of the following:

(1) Adhere to the beneficiary protections requirements under § 513.410.

(2) Adhere to the MFN Model-specific billing instructions requirements established by CMS and the MAC responsible for processing the MFN participant's claims, including without limitation those described in § 513.200.

(3) Participate in MFN Model monitoring and evaluation activities in accordance with § 403.1110(b) of this chapter, including collecting and reporting information as the Secretary determines is necessary to monitor and evaluate the MFN Model, including without limitation ''protected health information'' as that term is defined at 45 CFR 160.103.

(f) *MFN participant requirements after the MFN Model.* For 2 years after termination of the MFN Model, MFN participants must participate in MFN Model monitoring activities as described in § 513.420.

§ 513.120 MFN Model geographic area.

The MFN Model geographic area is all states and U.S. territories.

§ 513.130 MFN Model drugs, updates, categories and excluded drugs.

(a) *MFN Model drugs.* CMS creates and periodically updates the MFN Model Drug HCPCS Codes List as described in this section. The MFN Model Drug HCPCS Codes List designates the MFN Model drugs, which are subject to the MFN Model payments specified in subpart C of this part.

(1) *Initial MFN Model Drug HCPCS Codes List.* For the beginning of performance year 1, CMS identifies the top 50 drugs by HCPCS code with the highest aggregate 2019 Medicare Part B total allowed charges after making the exclusions specified in paragraphs (b)(1) and (b)(2) of this section, and adds the remaining HCPCS codes, after updating such HCPCS codes for any applicable changes, to the MFN Model Drug HCPCS Codes List. Final action claims with dates of service within calendar year 2019 and allowed charges greater than $0 are used to determine aggregate 2019 Medicare Part B total allowed charges.

(2) *Annual Update of the MFN Model Drug HCPCS Codes List.* For the start of each subsequent performance year, using Medicare Part B total allowed charge from the next subsequent calendar year, CMS identifies the top 50 drugs by HCPCS code with the highest aggregate Medicare Part B total allowed charges, after making the exclusions specified in paragraphs (b)(1) and (b)(2) of this section, for the most recent full calendar year, and adds any remaining

HCPCS codes not already on the MFN Model Drug HCPCS Codes List to the MFN Model Drug HCPCS Codes List, after updating such HCPCS codes for any applicable changes, effective on the first day of the performance year.

(3) *Removal.* No more frequently than quarterly, CMS removes HCPCS codes from the MFN Model Drug HCPCS Codes List when CMS becomes aware that all of the National Drug Codes assigned to the HCPCS code have been permanently withdrawn from the U.S. market and the drug has been permanently withdrawn from the U.S. market, the specific HCPCS code included on the MFN Model Drug HCPCS Codes List is terminated with no replacement code available or planned, or an exclusion in paragraph (b)(1) of this section applies.

(4) *Maintenance.* No more frequently than quarterly, CMS revises HCPCS codes on the MFN Model Drug HCPCS Codes List as necessary to reflect quarterly HCPCS code updates that are applicable to the HCPCS codes on the MFN Model Drug HCPCS Codes List, including adding replacement codes for HCPCS codes that were terminated.

(b) *Exclusions.* (1) The following are excluded from the MFN Model:

(i) Vaccines specified in section 1861(s)(10) of the Act (influenza, pneumococcal pneumonia, coronavirus disease 2019 (COVID–19), and Hepatitis B vaccines).

(ii) Radiopharmaceuticals.

(iii) Oral anticancer chemotherapeutic agents described in section 1861(s)(2)(Q) of the Act.

(iv) Oral anti-emetic drugs described in 1861(s)(2)(T) of the Act.

(v) Oral immunosuppressive drugs described in section 1861(s)(2)(J) of the Act.

(vi) Compounded drugs.

(vii) Intravenous immune globulin products.

(viii) Drugs billed with HCPCS codes that describe a drug product that was approved under an abbreviated new drug application under section 505(j) of the Federal Food, Drug, and Cosmetic Act;

(ix) Drugs for which there is an Emergency Use Authorization (EUA) from FDA, or FDA approval, to treat patients with suspected or confirmed COVID–19; or

(x) Drugs billed using a not otherwise classified (NOC) or not otherwise specified (NOS) billing and payment code.

(2) The following claims are excluded from the determination of whether a drug is to be included on the MFN Model Drug HCPCS Codes List:

(i) Professional claims with a place of service code indicating a home setting, including home, homeless shelter, assisted living facility, group home, temporary lodging, and custodial care facilities.

(ii) Claims administered by the DME MACs as described in § 421.404(c)(2) of this chapter.

§ 513.140 Included international data.

(a) *General.* (1) CMS uses drug pricing information from international data sources, available to CMS at least 20 business days prior to the start of a calendar quarter, meeting the requirements in paragraph (c) of this section for MFN Model drugs from countries included in paragraph (b) of this section.

(2) For purposes of selecting a data source for each MFN Model drug for a calendar quarter, CMS identifies available international drug pricing information data sources for the MFN Model drug, by aligning the MFN Model drug's HCPCS code long description (including dosage form) with the data sources' standardized method for identifying scientific names or nonproprietary names and dosage formulations, as applicable.

(b) *Non-U.S. member countries of the Organisation for Economic Co-operation and Development (OECD).* (1) CMS uses available international sales, volume, and pricing data for countries that were non-U.S. OECD member countries as of October 1, 2020 with a GDP per capita that is at least 60 percent of the U.S. GDP per capita as determined by CMS in accordance with this paragraph (b).

(2) Each country's GDP per capita is assessed using data available at the end of the applicable ASP calendar quarter.

(3) Subject to the limitation specified in paragraph (b)(4) of this section, the GDP per capita for a country is the the most recent estimate of GDP per capita based on purchasing power parity for that country available in the U.S. Central Intelligence Agency (CIA) World Factbook.

(4) The country's GDP per capita and U.S. GDP per capita selected from the CIA World Factbook must be for the same year.

(5) CMS identifies countries with a GDP per capita that is at least 60 percent of the U.S. GDP per capita by dividing the GDP per capita for a country by the U.S. GDP per capita and assessing the results.

(c) *Identification of international data sources.* (1) CMS obtains data from one or more international drug pricing information data sources for purposes of identifying available international drug pricing information for the countries specified in paragraph (b) of this section.

(2) Such data sources must, as determined by CMS—

(i) Utilize a standardized method for identifying drugs across countries within that data source, such as using internationally recognized scientific and nonproprietary product names;

(ii) Utilize a standard method for identifying drug forms that at a minimum distinguishes among injectable, oral, and other forms of a drug; and

(iii) Be maintained by an organization that seeks to limit the lag inherent in data to no more than 180 days from the end of the calendar quarter for which drug pricing information is compiled to the time that the organization makes such updates available to users of the database.

(iv) Contains international drug pricing information stated in U.S. currency, such as the following:

(A) Sales data, which may be based on ex-manufacturer prices (sometimes called ex-factory prices) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, or retail prices that represent actual or calculated sales for retail purchasers, or prices paid by other purchasers in the distribution channels.

(B) Volume data (for example, number of packages or units sold).

(C) List prices.

(v) Have mechanisms in place to maintain, update, and correct, if necessary, the information on international drug pricing in the data source on at least a quarterly basis.

(3) For each MFN Model drug for a calendar quarter, CMS selects a data source using the following hierarchy.

(i) The data source contains sales and volume data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(ii) The data source does not have sales and volume data for the applicable ASP calendar quarter, but contains sales and volume data for any prior ASP calendar quarter beginning on or after October 1, 2019 from at least one country described in paragraph (b) of this section. If sales and volume data from a prior ASP calendar quarter are used, CMS uses sales and volume data from the most recent ASP calendar quarter for which both sales and volume data are available.

(iii) The extracted data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website.

(iv) The data source contains ex-manufacturer price data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(v) The data source contains list price data for the applicable ASP calendar quarter from at least one country described in paragraph (b) of this section.

(vi) If there is more than one data source for an ASP calendar quarter, for each MFN Model drug, CMS selects the data source at the highest level of the hierarchy that contains information from the highest number of countries described in paragraph (b) of this section and, if available, incorporates discounts and rebates into its drug pricing information, and uses this data source to calculate the MFN Price as described in § 513.210(b).

Subpart C—Payment Process and Methodology

§ 513.200 Payment process and beneficiary cost-sharing.

(a) *General.* For purposes of the MFN Model, the allowed MFN Drug Payment Amount does not exceed the billed amount on the claim for the MFN Model drug.

(b) *Model-specific billing instructions.* MFN participants submit claims for MFN Model drugs to the applicable MAC in the form and manner specified by CMS in model-specific billing instructions.

(c) *Beneficiary cost-sharing.* Beneficiary coinsurance does not apply to the portion of the allowed payment amount for an MFN Model drug that is determined under § 513.220.

§ 513.210 Model payment methodology for MFN Model drugs.

(a) *Payment amount.* The total allowed payment amount for an MFN Model drug furnished to an MFN beneficiary by an MFN participant on a given date of service within a calendar quarter is determined in accordance with this section. The total allowed payment equals—

(1) For each billing unit in the HCPCS code descriptor of the MFN Model drug, the MFN Drug Payment Amount determined in accordance with paragraphs (b), (c) and (d) of this section, as applicable, where the allowed MFN Drug Payment Amount does not exceed the billed amount on the claim for the MFN Model drug as described in § 513.200(a); and

(2) The alternative add-on payment determined under § 513.220.

(b) *Calculation of the MFN Drug Payment Amount with Available International Drug Pricing Data.* CMS selects an available international drug pricing information data source described in § 513.140(c) for at least one country specified in § 513.140(b) for an MFN Model drug, and calculates, in advance of each calendar quarter for a performance year, the applicable MFN Drug Payment Amount for one billing unit of an MFN Model drug using the following steps:

(1) *Available international drug pricing data.* (i) For the MFN Model drug, using the data source selected in accordance with § 513.140(c)(3) (except for a data source described in § 513.140(c)(3)(iii)), CMS identifies available international drug pricing data for the MFN Model drug, by aligning the MFN Model drug's HCPCS code long description (including dosage form) with the data sources' standardized method for identifying scientific names or nonproprietary names and dosage formulations, as applicable. CMS extracts available drug pricing data for the countries specified in § 513.140(b) from the selected international drug pricing information data source. CMS uses the extracted data that have complete package size information and only for dosage formulations that could be described by the MFN Model drug's HCPCS code descriptor, as determined by CMS. If a data source described in § 513.140(c)(3)(iii) is selected, CMS uses such extracted data.

(ii) When international drug pricing data with sales and volume data are available, CMS excludes from the calculation of the unadjusted country-level price under paragraph (b)(2) of this section international drug pricing data without both sales and volume data, with less than $1,000 in quarterly sales (expressed as U.S. currency), or with less than 1,000 units in quarterly volume.

(iii) CMS converts the extracted volume data to the MFN Model drug's HCPCS code billing unit level, as applicable.

(iv) CMS adjusts the extracted volume data, as applicable, before converting the extracted volume data to the MFN Model drug's HCPCS code billing unit level when the data source shows the package size of a drug product that is inconsistent with the manufacturer's information about that product, as determined by CMS.

(v) CMS limits the number of HCPCS code billing units when—

(A) The package labeling indicates a limited amount of drug is to be used from the package; and

(B) The HCPCS code dosage is per dose.

(2) *Calculate the unadjusted country-level price for the MFN Model drug by country.*

(i) Using the drug pricing data extracted and adjusted in accordance with paragraph (b)(1) of this section, CMS calculates the unadjusted country-level price for the MFN Model drug by country, using the calculation that is applicable.

(ii) If an international drug pricing information data source with sales and volume data is used, the applicable calculation is as follows:

(A) CMS sums the adjusted volume data (as specified in paragraph (b)(1)(iii) of this section) for the drug.

(B) CMS sums the total sales for the drug (that remain after performing the exclusions in paragraph (b)(1)(ii) of this section).

(C) CMS divides the sum determined in paragraph (b)(2)(ii)(B) of the section by the sum determined in paragraph (b)(2)(ii)(A) of this section, resulting in an average price per unit of drug, where the unit of drug is the same as the HCPCS code billing unit.

(iii) If an international drug pricing information data source with ex-manufacturer or list prices is used, the applicable calculation is as follows:

(A) For each extracted ex-manufacturer or list price, CMS calculates the number of HCPCS billing units in the package by dividing the amount of drug in the package by the amount of drug represented in one HCPCS billing unit.

(B) CMS divides the ex-manufacturer or list price, as applicable, by the number of HCPCS billing units in the package, resulting in a price per unit of drug where the unit of drug is the same as the HCPCS code billing unit.

(C) CMS sums the price per unit of drug calculated in paragraph (c)(3)(iii)(B) of this section.

(D) CMS divides the sum calculated in paragraph (c)(3)(iii)(C) of this section by the number of ex-manufacturer or list prices that were summed in paragraph (c)(3)(iii)(C) of this section, resulting in an average price per unit of drug where the unit of drug is the same as the HCPCS code billing unit.

(iv) CMS performs the applicable calculation for each country specified in § 513.140(b) for which international drug pricing information is available in the selected data source.

(3) *Calculate the GDP adjuster for each country.* (i) CMS calculates the GDP adjuster by dividing the country's GDP per capita by the U.S. GDP per capita for the same year.

(ii) In cases where the resulting ratio exceeds 1.0, the GDP adjuster is set to 1.0.

(iii) Subject to the limitations specified in paragraph (b)(3)(iv) of this section, the GDP per capita for a country is the most recent estimate of GDP per capita based on purchasing power parity for that country available in the CIA World Factbook at the end of the applicable ASP calendar quarter.

(iv) *Limitations.* (A) The country's GDP per capita and U.S. GDP per capita must be for the same year.

(B) The GDP per capita used must be for the same year as the data used to calculate the unadjusted country-level price, if available, or the most recent earlier year available.

(4) *Apply the GDP adjuster to calculate the GDP-adjusted country-level price.* CMS applies the applicable GDP adjuster identified in paragraph (b)(3) of this section to each unadjusted country-level price identified in paragraph (b)(2) of this section to calculate the GDP-adjusted country-level price by dividing each unadjusted country-level price by the applicable GDP adjuster.

(5) *Identify the lowest GDP-adjusted country-level price.* CMS identifies the lowest GDP-adjusted country-level price for the MFN Model drug. Except as provided in paragraph (b)(7) of this section, the price identified is the MFN Model drug's MFN Price.

(6) *Identify Applicable ASP.* CMS identifies the applicable ASP for the applicable quarter.

(7) *Compare the MFN Price to the applicable ASP.* CMS compares the price determined in paragraph (b)(5) of this section to the applicable ASP identified in paragraph (b)(6) of this section. The MFN Price equals the applicable ASP if the applicable ASP is less than the price determined in paragraph (b)(5) of this section.

(8) *Phase-in.* CMS identifies the applicable phase-in formula based on the applicable performance year as follows:

(i) Performance year 1: 75 percent applicable ASP and 25 percent MFN Price.

(ii) Performance year 2: 50 percent applicable ASP and 50 percent MFN Price.

(iii) Performance year 3: 25 percent applicable ASP and 75 percent MFN Price.

(iv) Performance year 4: 100 percent MFN Price.

(v) Performance year 5: 100 percent MFN Price.

(vi) Performance year 6: 100 percent MFN Price.

(vii) Performance year 7: 100 percent MFN Price.

(9) *Final calculation steps.* (i) CMS applies the applicable phase-in formula to the applicable ASP and the MFN Price. Subject to any applicable adjustments as provided in paragraph (d) of this section, the amount determined in this paragraph is the MFN Drug Payment Amount.

(ii) Subject to the limitation in paragraph (b)(iii) in this section, CMS recalculates the MFN Drug Payment Amounts for prior quarters when revised international drug pricing information is available in the data source that was used to calculate the MFN Price and applicable ASP updates are available from CMS. CMS prospectively applies the recalculations in the quarterly update following the availability of revised international drug pricing information and ASP updates.

(iii) MFN Drug Payment Amounts may be recalculated for the prior four calendar quarters of the model.

(c) *Frequency of MFN Drug Payment Amount updates.* CMS updates the MFN Drug Payment Amounts on a calendar quarter basis. CMS publishes the quarterly MFN Drug Payment Amounts on the MFN Model website in advance of the calendar quarter in which the MFN Drug Payment Amounts apply, along with any recalculated MFN Drug Payment Amounts for prior quarters.

(d) *Exceptions.* (1) *Payment for MFN Model drugs for which no international drug pricing data are available.* If, as of the first calendar quarter during which an MFN Model drug has been included in the MFN Model Drug HCPCS Codes List in accordance with § 513.130, no international sales, volume or pricing information meeting the requirements described in § 513.140(c)—including data used by CMS to determine the most recent MFN Price used to calculate an MFN Drug Payment Amount posted on the MFN Model website—is available from any country described in § 513.120(b) for any calendar quarter beginning on or after October 1, 2019 through the applicable quarter, the MFN Drug Payment Amount is the applicable ASP.

(2) *Payment for MFN Model drugs that are in short supply.* If an MFN Model drug is reported as ''Currently in Shortage'' by FDA, beginning with the first day of the next calendar quarter after the date on which it is reported in shortage, the MFN Drug Payment Amount is the applicable ASP. CMS calculates payment in accordance with paragraph (b) of this section as of the first day of the calendar quarter after the date upon which the drug is no longer reported as ''Currently in Shortage'' by FDA.

(3) *Adjustment to phase-in formula.* (i) CMS accelerates the phase-in of the MFN Price by 5 percentage points at the next quarterly update to calculate the MFN Drug Payment Amount for the MFN Model drug where both of the following conditions are met:

(A) There is a greater cumulative percentage increase in either the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the CPI–U.

(B) There is a greater cumulative percentage increase in either the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the MFN Price.

(C) For purposes of paragraphs (d)(3)(i)(A) and (B) of this section, the cumulative percentage increase means the cumulative percentage change from the end of the baseline to the end of the applicable ASP calendar quarter.

(D) The baseline in paragraph (d)(3)(i)(C) of this section for an MFN Model drug is the ASP calendar quarter for the applicable ASP for the first quarter of performance year 1. If there is not an applicable ASP for the first quarter of performance year 1 for an MFN Model drug, the baseline for that MFN Model drug is the ASP calendar quarter for the first applicable ASP based on the manufacturer's average sales price for that MFN Model drug that occurs after the ASP calendar quarter for the applicable ASP for the first quarter of performance year 1.

(ii) For purposes of paragraph (d)(3)(i) of this section, if the cumulative percentage increase in CPI–U or MFN Price is negative, CMS uses zero as the cumulative percentage increase in CPI–U or MFN Price, as applicable.

(iii) The application of an acceleration of the phase-in formula continues for the duration of the model performance period.

(iv) CMS applies an additional acceleration of the phase-in formula for each calendar quarter where the conditions specified in paragraph (i) are met.

(4) *Adjustment for rapid increases in the applicable ASP or any monthly U.S. list prices beyond inflation and MFN Price after the full phase-in of the MFN Price.* If the conditions described in paragraphs (d)(3)(i)(A) and (B) of this section are met after the full phase-in of the MFN Price for an MFN Model drug, for each calendar quarter thereafter, CMS decreases the MFN Drug Payment Amount equal to largest difference in the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices for the NDCs

assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the CPI–U and in the MFN Price, respectively, determined quarterly.

(5) *Limitation on MFN Drug Payment Amount.* The MFN Drug Payment Amount cannot exceed the non-model drug payment amount for claim lines submitted with the JG modifier (or any successor modifier used to identify drugs purchased under the 340B program) after removing any add-on amount, if applicable.

(e) *Blood clotting factor furnishing fee.* When applicable, the blood clotting furnishing fee under § 410.63(c) of this chapter is payable along with the MFN Drug Payment Amount.

§ 513.220 Model alternative add-on payment.

(a) *Payment amount.* (1) The total allowed alternative add-on payment amount for a separately payable dose of an MFN Model drug furnished to an MFN beneficiary by an MFN participant on a given date of service within a calendar quarter is determined in accordance with this section.

(2) The total allowed alternative add-on payment amount for a claim line does not exceed the billed amount on that claim line.

(b) *Calculation of the per-dose alternative add-on payment amount.* CMS calculates the per-dose alternative add-on payment for performance year 1, quarter 1 for MFN Model drugs using the following steps:

(1) CMS identifies available Medicare Part B fee-for-service final action claims lines, with dates of service in 2019, for drugs on the initial MFN Model HCPCS Codes List described in § 513.130(a)(1), excluding claims for providers and suppliers specified in § 513.100(c), and claims specified in § 513.100(d), that were furnished by Medicare-participating providers and suppliers, have a separately paid allowed charge greater than $0, and for which Medicare Part B was the primary payer. If a HCPCS code on the initial MFN Model HCPCS Codes List was not in use during any calendar quarter in 2019, CMS uses the HCPCS code that was applicable for the MFN Model drug during 2019.

(2) CMS identifies the applicable ASP for each calendar quarter of 2019 for the drugs (by HCPCS code as specified in paragraph (b)(1) of this section) included on the initial MFN Model HCPCS Codes List. In the case of a biosimilar biological product, the applicable ASP for the reference biological product is identified and used in paragraph (b)(3) of this section.

(3) CMS multiplies the number of units billed for each claim line described in paragraph (b)(1) of this section by 6.1224 percent of the applicable ASP identified in paragraph (b)(2) of this section for the HCPCS code on the claim line and date of service.

(4) CMS sums the products calculated in paragraph (b)(3) of this section for all claim lines for each MFN Model drug to calculate the total add-on spending amount for each MFN Model drug.

(5) CMS sums the amounts calculated in paragraph (b)(4) of this section to calculate the total pooled add-on spending amount for all MFN Model drugs.

(6) CMS divides the amount calculated in paragraph (b)(5) of this section by the total number of claim lines retained in paragraph (b)(1) of this section, excluding claim lines billed with the JW modifier.

(7) CMS trends the amount calculated in paragraph (b)(6) of this section forward to the applicable ASP calendar quarter for quarter 1 of performance year 1 using the percentage change in CPI–U from July 2019 through October 2020.

(c) *Frequency of alternative add-on payment amount updates.* For each calendar quarter after quarter 1 of performance year 1, CMS updates the alternative add-on payment by applying a cumulative inflation factor based on the cumulative percentage change in CPI–U from October 2020 through the first month of the prior calendar quarter. If the cumulative percentage change in the CPI–U is negative, CMS uses an inflation factor of 1.

(d) *Limitation on the alternative add-on payment.* The alternate add-on payment is not payable for claim lines billed—

(1) With the JW modifier; or

(2) By MFN participants that receive an alternative add-on payment for an MFN Model drug under any other model authorized by section 1115A of the Act that tests an alternative approach to the add-on portion of payment for Medicare Part B drugs.

§ 513.230 Financial hardship exemptions, request process, and reconciliation payment.

(a) *General.* For purposes of the MFN Model, a financial hardship exemption for a performance year may be granted to an MFN participant by CMS, in its sole discretion and not subject to appeal, when the provisions in this section are met.

(b) *Request for financial hardship exemption.* To be eligible for a financial hardship exemption, the MFN participant must submit a request for financial hardship exemption in the form and manner and with the content specified by CMS, including without limitation the requirements of this paragraph (b).

(1) *Timing and form of request.* The MFN participant must submit its request for a financial hardship exemption to CMS in accordance the submission process posted on the MFN Model website and such request must be submitted within 60 calendar days following the end of the performance year for which the MFN participant seeks a financial hardship exemption.

(2) *Request content.* The MFN participant's request a financial hardship exemption must include, at a minimum, all of the following:

(i) Evidence of methods used to obtain each MFN Model drug that was furnished by the MFN participant during the performance year to any patient.

(ii) Average net acquisition cost for each MFN Model drug (inclusive of all on- and off-invoice discounts or adjustments, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to MFN beneficiaries.

(iii) Average net acquisition cost for each MFN Model drug (inclusive of all on- and off-invoice discounts and adjustments, and any other price concessions related to the purchase of the MFN Model drug) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries.

(iv) Statement of any remuneration received by the MFN participant from manufacturers of MFN Model drugs, wholesalers, and distributors that is not reflected in the MFN participant's average net acquisition costs with a justification of why such remuneration should not be treated as a price concession related to the purchase of an MFN Model drug.

(v) Administrative information, including: MFN participant's name, TIN or CCN (as applicable), contact name, phone number, and email address.

(vi) The MFN participant's attestation that:

(A) The MFN participant experienced a reduction in Medicare Part B FFS payments for separately payable drugs on a per beneficiary basis during the performance year as compared to the prior year (that is, the four calendar quarters immediately preceding the performance year) due to its inability to obtain one or more of the MFN Model drugs at or below the MFN Model Payments for such drugs during the performance year;

(B) The MFN participant has not received and will not receive any remuneration from manufacturers of MFN Model drugs, wholesalers, and distributors related to the purchase of an MFN Model drug that was furnished by the MFN participant during the performance year that is not reflected in the MFN participant's submission; and

(C) The MFN participant submission is true, accurate and complete.

(c) *Standard of review.* (1) Incomplete requests for a financial hardship exemption, as determined by CMS, are not reviewed.

(2) CMS grants a financial hardship exemption to an MFN participant for a performance year, if the agency in its sole discretion determines the following requirements have been met:

(i) The MFN participant submits a timely, complete request for financial hardship exemption in accordance with the requirements of this section which in the sole discretion of CMS demonstrates all of the following:

(A) The MFN participant exhausted all reasonable methods to obtain MFN Model drugs at or below the MFN Model Payment for such drugs during the performance year.

(B) The MFN participant's average net acquisition cost for each MFN Model drug (including invoices and off-invoice discounts or adjustments) that was furnished by the MFN participant during the performance year to patients who were not MFN beneficiaries was not less than the MFN participant's average net acquisition costs for such MFN Model drug (including invoices and off-invoice discounts or adjustments) that was furnished by the MFN participant during the performance year to MFN beneficiaries.

(C) Any remuneration the MFN participant received from manufacturers of MFN Model drugs, wholesalers, and distributors that was not reflected in the MFN participant's average net acquisition costs was not a price concession related to the purchase of an MFN Model drug.

(ii) The MFN participant's excess reduction amount per beneficiary (as determined in paragraph (d)(6) of this section), is greater than zero.

(d) *Excess reduction amount per beneficiary.* CMS calculates the MFN participant's excess reduction amount per beneficiary using available final action claims data where Medicare was the primary payer that is estimated to be more than 90 percent complete in accordance with the following steps:

(1) CMS calculates, separately for dates of service within the performance year and prior year, the MFN participant's total allowed charges for separately payable Medicare Part B drugs, and the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than $0.

(2) CMS divides the MFN participant's total allowed charges for separately payable Medicare Part B drugs for dates of service within the performance year by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than $0 with a service date within the performance year, to calculate the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the performance year.

(3) CMS divides the MFN participant's total allowed charges for separately payable Medicare Part B drugs for dates of service within the prior year by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than $0 with a service date within the prior year, to calculate the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the prior year.

(4) CMS subtracts the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the performance year (as calculated in paragraph (d)(2) of this section) from the MFN participant's average per beneficiary total allowed charges for separately payable Medicare Part B drugs for the prior year (as calculated in paragraph (d)(3) of this section).

(5) CMS calculates 25 percent of the MFN participant's total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year and divides that amount by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than $0 with a service date within the prior year, to calculate 25 percent of the MFN participant's average per beneficiary total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year.

(6) CMS subtracts 25 percent of the MFN participant's average per beneficiary total allowed charges for all Medicare Part A and Part B claims with dates of service within the prior year (as calculated in paragraph (d)(5) of this section) from the difference calculated in paragraph (d)(4) of this section, to calculate the MFN participant's excess reduction amount per beneficiary.

(e) *Reconciliation payment.* (1) If CMS in its sole discretion grants a financial hardship exemption to an MFN participant for a performance year, CMS provides such MFN participant a reconciliation payment for the performance year that equals the amount calculated by multiplying the excess reduction amount per beneficiary specified in paragraph (d)(6) of this section by the total number of beneficiaries that had at least one claim for a service furnished by the MFN participant with a Medicare Part A or Medicare Part B allowed charge greater than $0 with a service date within the performance year.

(2) The amount of a reconciliation payment provided in accordance with this section is—

(i) Not subject to appeal;

(ii) Not subject to beneficiary cost-sharing, including any deductible or coinsurance; and

(iii) Made by CMS (or a CMS contractor) as soon as practical.

Subpart D—[Reserved]

Subpart E—Quality Strategy, Beneficiary Protections, and Compliance Activities

§ 513.400 Quality measures.

(a) *General.* Quality measures do not adjust model payments to MFN participants and are used for monitoring purposes.

(b) *Collection of quality measures.* (1) CMS administers a patient experience survey to a sample of beneficiaries who receive an MFN Model drug. A sample of non-MFN beneficiaries may also be surveyed.

(2) If during the MFN Model CMS determines that the quality measures specified in paragraph (b) of this section are not sufficient to adequately monitor the quality of care that MFN beneficiaries are receiving from MFN participants or that MFN participants are providing, CMS may specify additional measures. CMS applies the following criteria when specifying additional quality measures:

(i) Additional measures are among one or more of the following categories:

(A) Patient experience of care.

(B) Patient activation

(C) Shared decision making.

(D) Adherence.

(E) Utilization.

(F) Process measures.

(ii) Additional measures will not add significant burden to MFN participants or beneficiaries.

(iii) Additional measures utilize an instrument that CMS has used previously in a model to adjust payment or for monitoring or evaluation.

§ 513.410 Beneficiary protections.

(a) *Beneficiary choice.*

(1) MFN participants must not restrict beneficiaries' ability to choose to receive care from any Medicare participating provider or supplier or any provider or supplier who has opted out of Medicare.

(2) The MFN participant must not commit any act or omission, nor adopt any policy that inhibits a beneficiary from exercising his or her freedom to choose to receive care from any Medicare participating provider or supplier or any provider or supplier who has opted out of Medicare. Notwithstanding the foregoing, MFN participants may communicate to beneficiaries the benefits of receiving care from an MFN participant, if otherwise consistent with the requirements of this part and applicable law.

(b) *Appeals.* An MFN beneficiary and his or her assignees retain their right to appeal claims in accordance with part 405 subpart I of this chapter.

(c) *Availability of services.* MFN participants must not take any action to select or avoid treating beneficiaries based on their diagnoses, care needs, income levels or other factors that would render the beneficiary an ''at-risk beneficiary'' as defined at § 425.20 of this chapter.

§ 513.420 Monitoring and compliance activities.

(a) *Compliance with laws.* (1) *Agreement to comply.* The MFN participant must comply with all applicable laws and regulations.

(2) *Notification.* The MFN participant must notify CMS within 15 days after becoming aware that the MFN participant is under investigation or has been sanctioned by the federal, state, or local government, or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing privileges).

(b) *CMS monitoring and compliance activities.* (1) CMS conducts monitoring activities to ensure compliance by MFN participants with the terms of the MFN Model, to obtain timely information about the effects of the MFN Model on MFN beneficiaries, providers, suppliers, and on the Medicare program and to facilitate real time identification and response to potential issues. Such monitoring activities may include, without limitation, the following:

(i) Documentation requests sent to the MFN participant including, without limitation, surveys and questionnaires.

(ii) Audits of claims data, medical records, and other data from the MFN participant.

(iii) Interviews with any individual or entity participating in the MFN Model including members of the MFN participant's leadership, management, and staff.

(iv) Interviews with beneficiaries and their caregivers.

(v) Site visits to the MFN participants, performed in a manner consistent with § 513.420(c).

(vi) Tracking patient complaints and appeals.

(2) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation, all Medicare claims submitted for items or services furnished to beneficiaries in the MFN Model.

(3) The MFN participant must cooperate with evaluation and monitoring activities as may be necessary to enable CMS to evaluate the MFN Model in accordance with section 1115A(b)(4) of the Act and to conduct monitoring activities under this section.

(c) *Site visits.* (1) To the extent practicable, CMS or its designee provides the MFN participant with no less than 15 days advance notice of any site visit. To the extent practicable, CMS attempts to accommodate a request for particular dates in scheduling site visits. However, the MFN participant may not request a date that is more than 60 days after the date of the initial site visit notice from CMS.

(2) The MFN participant must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(3) Notwithstanding the foregoing, CMS may perform unannounced site visits at all physical locations of the MFN participant at any time to investigate concerns about the health or safety of beneficiaries or other patients or other program integrity issues.

(4) Nothing in this part must be construed to limit or otherwise prevent CMS from performing site visits permitted or required by applicable law.

(d) *Right to correct.* If CMS discovers that it has made or received an incorrect model-specific payment under the terms of the MFN Model, CMS may make payment to, or demand payment from, the MFN participant.

§ 513.430 Audits and record retention.

(a) *Right to audit.* The Federal Government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of the MFN Model.

(b) *Access to records.* MFN participants must maintain and give the Federal Government, including CMS, HHS, and the Comptroller General, or their designees, access to all such documents and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the implementation of the MFN Model, including without limitation, documents and other evidence regarding the following:

(1) The MFN participant's compliance with the terms of the MFN Model, including this subpart.

(2) Quality measure information and the quality of services performed under the terms of the MFN Model, including this subpart.

(3) Patient safety.

(4) The accuracy of model-specific payments made under the MFN Model.

(5) Utilization of items and services furnished under the MFN Model.

(6) Other program integrity issues.

(c) *Record retention.* The MFN participant must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of 6 years from the last payment received by the MFN participant under the MFN Model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(1) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MFN participant at least 30 days before the normal disposition date; or

(2) There has been a termination, dispute, or allegation of fraud or similar fault against the MFN participant, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

§ 513.440 Enforcement authority.

(a) *Remedial action*—(1) *Grounds for remedial action.* In addition to any other grounds for remedial action that are permitted under the terms of this part, CMS may take one or more of the remedial actions set forth in paragraph (a)(2) of this section if CMS determines,

in CMS' sole discretion, that an MFN participant:

(i) Has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(ii) Has failed to comply with any of the terms of the MFN Model, including applicable requirements of this part.

(iii) Has systematically engaged in the under delivery or over delivery of an MFN Model drug.

(iv) Has taken any action that threatens the health or safety of an MFN beneficiary or other patient.

(v) Has undergone a change of control that presents a program integrity risk.

(vi) Has submitted false data or made false representations, warranties, certifications or attestations in connection with any aspect of the MFN Model.

(vii) Has avoided at-risk beneficiaries, as this term is defined in § 425.20 of this chapter.

(viii) Has avoided patients on the basis of payer status.

(ix) Is subject to sanctions or final actions of an accrediting organization or Federal, State, or local government agency.

(x) Takes any action that CMS determines for program integrity reasons is not in the best interests of the MFN Model or the Medicare program, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the MFN Model or Medicare program.

(xi) Is subject to investigation by HHS (including the HHS Office of Inspector General (OIG)) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act *qui tam* matter in which the Federal Government has intervened, or similar action;

(xii) Is the subject of administration enforcement action imposed by CMS; or

(xiii) Has failed to demonstrate improved performance following any remedial action imposed under this section.

(2) *Taking remedial actions.* If CMS determines that one or more grounds for remedial action described in paragraph (a)(1) of this section exist, CMS make take one or more of the following remedial actions:

(i) Notifying the MFN participant of the violation.

(ii) Requiring the MFN participant to provide additional information to CMS or its designees.

(iii) Requiring the MFN participant to develop and implement a corrective action plan in a form and manner and by a deadline specified by CMS.

(iv) Subjecting the MFN participant to additional monitoring, auditing, or both.

(v) Removing the MFN participant from the MFN Model.

(vi) Recouping model-specific payments.

(vii) Other action as may be permitted under the terms of this part.

(b) *OIG authority.* Nothing contained in the terms of the MFN Model or this part limits or restricts the authority of the HHS Office of Inspector General or any other Federal Government authority or agency, including its authority to audit, evaluate, investigate, or inspect model participant for violations of any statutes, rules, or regulations administered by the Federal Government.

§ 513.450 Limitations on review.

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for any of the following:

(a) The selection of models for testing or expansion under section 1115A of the Act.

(b) The selection of organizations, sites, or participants, including MFN participants, to test the MFN Model, including a decision by CMS to remove an MFN participant from the MFN Model.

(c) The elements, parameters, scope, and duration of such MFN Model for testing or dissemination, including without limitation all of the following:

(1) The selection of the model geographic area for the MFN Model by CMS.

(2) The selection of MFN Model drugs by CMS.

(3) The selection of included international data, including selection of countries, international drug pricing databases, and international drug pricing data.

(d) Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.

(e) The termination or modification of the design and implementation of an MFN Model under section 1115A(b)(3)(B) of the Act.

(f) Determinations about expansion of the duration and scope of the MFN Model under section 1115A(c) of the Act, including the determination that the MFN Model is not expected to meet criteria described in paragraphs (c)(1) or (2) of such section.

Subpart F—Waivers

§ 513.500 Waivers of Medicare program requirements for purposes of testing the MFN Model.

CMS waives the Medicare program requirements in the following provisions that are necessary solely for purposes of testing the MFN Model:

(a) Sections 1833(t)(6) and 1833(t)(14) of the Act and §§ 419.62 and 419.64 of this chapter related to Medicare payment amounts for drugs and biologicals under the hospital outpatient prospective payment system (OPPS) as necessary to permit testing of an alternative payment amount for MFN Model drugs.

(b) Section 1833(i)(2)(D) of the Act related to Medicare payment to ASCs for drugs and biologicals as necessary to permit testing of an alternative payment amount for MFN Model drugs.

(c) Sections 1847A(b) and 1847A(c) of the Act and §§ 414.904 and 414.802 of this chapter related to use of the ASP-based, WAC-based, or other applicable payment methodology and calculation of manufacturers' ASP as necessary to permit testing of an alternative payment for MFN Model drugs and to exclude certain units of MFN Model drugs from manufacturers' ASPs.

(d) Section 1833(a)(1) of the Act related to Medicare payment portion of the allowed payment amount for an included MFN Model drug that is determined under § 513.220 as necessary to permit testing of an innovative payment approach for the alternative add-on payment amount.

(e) Section 1833(a)(1)(S) of the Act related to Medicare payment for drugs and biologicals is 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o) of the Act as necessary to permit testing of an innovative payment approach for the total allowable MFN Model payment as determined under subpart C.

(f) Section 1833(a)(1)(G) of the Act related to the amounts paid with respect to facility services furnished in connection with certain surgical procedures and with respect to services furnished to an individual in an ASC must be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system as necessary to permit testing of an innovative payment approach for the total allowable MFN Model payment as determined under subpart C.

(g) Section 1833(t) of the Act related to how beneficiary copayment is calculated under the OPPS as necessary to permit testing of an innovative

payment approach for the total allowable MFN Model payment as determined under subpart C of this part.

(h) Section 1833(t)(9)(B) of the Act related to the requirement that Medicare account for adjustments to ensure that the amount of expenditures under the OPPS for the year does not increase or decrease from the estimated amount of expenditures under the OPPS that would have been made if the adjustments had not been made.

Subparts G through J—[Reserved]

Subpart K—Model Termination

§ 513.1000 Termination of the MFN Model.

(a) CMS may terminate the MFN Model for reasons including, but not limited to, the following:

(1) CMS determines that it no longer has the funds to support the MFN Model.

(2) CMS terminates the model in accordance with section 1115A(b)(3)(B) of the Act.

(b) As specified in section 1115A(d)(2) of the Act, termination of the model in accordance with section 1115A(b)(3)(B) of the Act is not subject to administrative or judicial review.

Dated: November 18, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 18, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–26037 Filed 11–20–20; 4:15 pm]

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Part III

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 226

Endangered and Threatened Species; Critical Habitat for the Threatened Indo-Pacific Corals; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 223 and 226

[Docket No: 200918–0249]

RIN 0648–BJ52

Endangered and Threatened Species; Critical Habitat for the Threatened Indo-Pacific Corals

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

ACTION: Proposed rule; request for comments.

SUMMARY: We, the National Marine Fisheries Service (NMFS), propose to designate critical habitat for the seven threatened corals in U.S. waters in the Indo-Pacific (*Acropora globiceps, Acropora jacquelineae, Acropora retusa, Acropora speciosa, Euphyllia paradivisa, Isopora crateriformis,* and *Seriatopora aculeata*) pursuant to section 4 of the Endangered Species Act (ESA). Seventeen specific occupied areas containing physical features essential to the conservation of these coral species are being proposed for designation as critical habitat; these areas contain approximately 600 square kilometers (km^2; 230 square miles) of marine habitat. We have considered positive and negative economic, national security, and other relevant impacts of the proposed designations, and we propose to exclude two areas from the critical habitat designations due to anticipated impacts on national security. We are soliciting comments from the public on all aspects of the proposal, including our identification of the geographical area and depths occupied by the species, the physical and biological feature essential to the coral species' conservation and identification, areas not included and excluded, and consideration of impacts of the proposed action.

DATES: Comments on this proposal must be received by January 26, 2021.

Public hearings: If requested, we will hold at least one public hearing on this proposed rule.

ADDRESSES: You may submit comments, identified by the docket number NOAA–NMFS–2016–0131, by any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2016-0131* click the ''Comment Now'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Lance Smith, Protected Resources Division, NMFS, Pacific Islands Regional Office, NOAA Inouye Regional Center, 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

Instructions: You must submit comments by one of the previously described methods to ensure that we receive, document, and consider them. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Lance Smith, NMFS, Pacific Islands Regional Office, 808–725–5131, *lance.smith@noaa.gov;* or, Celeste Stout, NMFS, Office of Protected Resources, 301–427–8436, *celeste.stout@noaa.gov.*

SUPPLEMENTARY INFORMATION: In accordance with section 4(b) of the ESA (16 U.S.C. 1533) and our implementing regulations (50 CFR 424.12), this proposed rule is based on the best scientific information available concerning the range, biology, habitat, threats to the habitat, and conservation objectives for the seven threatened corals in U.S. waters of the Indo-Pacific (*Acropora globiceps, A. jacquelineae, A. retusa, A. speciosa, Euphyllia paradivisa, Isopora crateriformis,* and *Seriatopora aculeata*). We reviewed the available information and have used it to identify physical and biological features essential to the conservation of each coral, the specific areas within the occupied areas that contain the essential physical and biological features that may require special management considerations or protections, the Federal activities that may impact the physical or biological features or areas, and the potential impacts of designating critical habitat for these seven Indo-Pacific corals. The economic, national security, and other relevant impacts of the proposed critical habitat designations for these coral species are described in the draft document titled, ''Endangered Species Act Critical Habitat Information Report: Basis and Impact Considerations of Critical Habitat Designations for Threatened Indo-Pacific Corals,'' hereafter referred to as the Draft Information Report (NMFS, 2019). This supporting document is available at *https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-indo-pacific-corals,* at *www.regulations.gov,* or upon request (see **FOR FURTHER INFORMATION CONTACT**).

Background

We listed 20 coral species as threatened under the ESA on September 10, 2014 (79 FR 53851). Although 15 of the listed species occur in the Indo-Pacific, only 7 of the listed coral species have been found in U.S. waters: *A. globiceps, A. jacquelineae, A. retusa, A. speciosa, E. paradivisa, I. crateriformis,* and *S. aculeata.* These seven species have been found in the U.S. jurisdictions of American Samoa, Guam, the Commonwealth of the Northern Mariana Islands (CNMI), and the Pacific Remote Island Area (PRIA). The final listing determinations were based on the best available information on a suite of demographic, spatial, and susceptibility components that influence the species' vulnerability to extinction in the face of continuing threats over the foreseeable future. All 20 listed species have undergone some level of population decline and are susceptible to multiple threats, including: Ocean warming, diseases, ocean acidification, ecological effects of fishing, and land-based sources of pollution. We found that aspects of the species' demography and distribution buffer the effects of these threats. Although we have no information that indicates that these species are currently in danger of extinction, we determined that they all are likely to become endangered throughout all of their ranges within the foreseeable future as a result of a combination of threats, the most severe of which are related to climate change. As such, we listed them as threatened. The following proposed rule is based on our Draft Information Report and peer review comments on the report. All of the information that we used to make our determinations in this proposed rule is contained in that report. The Draft Information Report is available at *https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-indo-pacific-corals,* at *www.regulations.gov,* or upon request (see **FOR FURTHER INFORMATION CONTACT**).

Natural History

This section summarizes life history and biological characteristics of Indo-

Pacific reef-building corals to provide context for the identification of the physical and biological feature essential for the conservation of these species. In this section, we cover several topic areas including an introduction to reef-building corals, as well as reproduction, settlement and growth, coral habitat types, and coral reef ecosystems. There is little species-specific information available on the life history, reproductive biology, and ecology for the seven corals that occur in U.S. waters of the Indo-Pacific, because many of the several hundred Indo-Pacific reef-building corals resemble one another, thus most investigations to date have been at the genus level. We provide specific information for each species where possible. In addition, we provide general information on the biology and ecology of the Indo-Pacific corals, highlighting traits that these seven corals share. The information below is largely summarized from the final listing rule (79 FR 53851; September 10, 2014), and it has been updated with the best available scientific information to date. The seven ESA-listed Indo-Pacific corals are reef-building corals. Reef-building corals, in the phylum Cnidaria, are marine invertebrates that occur as polyps. The Cnidaria include true stony corals (class Anthozoa, order Scleractinia), the blue coral (class Anthozoa, order Helioporacea), and fire corals (class Hydrozoa, order Milleporina). These species secrete massive calcium carbonate skeletons that form the physical structure of coral reefs. Reef-building coral species collectively produce coral reefs over time in high-growth conditions, but they also occur in non-reef habitats. That is, they are reef-building, but not reef-dependent. About 90 percent of the world's approximately 800 reef-building coral species occur in the Indo-Pacific (Veron, 2000). These unique animals contain symbiotic algae within their cells, they produce clones of themselves by different means, and most of them occur as colonies of polyps. Polyps are the building blocks of colonies, and colony growth occurs both by increasing the number of polyps, as well as extending the supporting skeleton under each polyp.

Reef-building corals are able to grow and thrive in the characteristically nutrient-poor environments of tropical and subtropical regions due to their ability to form mutually beneficial symbioses with unicellular photosynthetic algae (zooxanthellae) living within the host coral's tissues. Zooxanthellae belong to the dinoflagellate genus *Symbiodinium* and provide nutrition to the host coral by translocating fixed organic carbon and other nutrients. In return, they receive inorganic waste metabolites from host respiration as well as protection from grazing. This exchange of nutrients allows both partners to flourish and helps the coral secrete the calcium carbonate that forms the skeletal structure of the coral colony, which in turn contributes to the formation of the reef. Thus, reef-building corals are also known as zooxanthellate corals. Some corals do not contain zooxanthellae, and these species form much smaller skeletons, and therefore are not considered reef-building. The seven ESA-listed Indo-Pacific corals discussed in this proposed rule are zooxanthellate species, and thus are reef-building, because they contain symbiotic algae in their cells, enabling them to grow large skeletons that contribute to the physical structure of coral reefs.

Coral polyps can occur as free-living, solitary polyps (*e.g.,* fungiids) or as colonies of polyps, depending on the species. Most reef-building coral species are colonial, producing colonies made up of dozens to thousands of polyps that are connected seamlessly through tissue and skeleton. In a colonial species, a single larva will develop into a discrete unit (the primary polyp) that then produces modular units of itself (*i.e.,* genetically-identical copies, or clones, of the primary polyp, otherwise known as clones). Each polyp consists of a column with mouth and tentacles on the upper side growing on top of a calcium carbonate skeleton, which the polyps produce through the process of calcification. Colony growth is achieved mainly through the addition of more cloned polyps. The colony can continue to exist even if numerous polyps die, or if the colony is broken apart or otherwise damaged. The seven listed Indo-Pacific corals are all colonial species, although polyp size, colony size, and colony morphology vary considerably by species and also based on environmental variables in different habitats. Colonies themselves can produce clones, most commonly through fragmentation or budding (described in more detail below). Clones can also be produced in some species by asexual larvae or polyp bail-out (a rare case when an individual polyp breaks away from the colony due to poor environmental conditions and re-settles elsewhere). The seven listed Indo-Pacific corals are all clonal species, both as colonies of cloned polyps, and with the ability to produce clones of individual colonies. The way they produce colony-level clones varies by species. For example, branching species are much more likely than encrusting species to produce clones via fragmentation; Brainard *et al.,* 2011).

Corals use a number of diverse reproductive strategies that have been researched extensively; however, many individual species' reproductive modes remain poorly described. Most coral species use both sexual and asexual propagation. Sexual reproduction in corals is primarily through gametogenesis (*i.e.,* development of eggs and sperm within the polyps). Some coral species have separate sexes (gonochoric), while others are hermaphroditic. Strategies for fertilization are either by brooding (internal fertilization) or broadcast spawning (external fertilization). Asexual reproduction in coral species most commonly involves fragmentation, by which colony pieces or fragments are dislodged from larger colonies and establish new colonies, although the budding of new polyps within a colony can also be considered asexual reproduction. In many species of branching corals, fragmentation is a common and sometimes dominant means of propagation (79 FR 53852, September 10, 2014).

Of the seven listed Indo-Pacific species, *A. retusa, A. globiceps,* and *A. jacquelineae* are all hermaphroditic spawners. The reproductive characteristics of *A. speciosa* have not yet been determined, but most other *Acropora* species are also hermaphroditic spawners. *Euphyllia paradivisa*'s reproductive mode is unknown and other *Euphyllia* species exhibit a variety of reproductive characteristics, so it is unclear which is most probable for the species. The reproductive characteristics of *I. crateriformis* and *S. aculeata* have also not been determined, but other similar species of both *Isopora* and *Seriatopora* are simultaneous hermaphroditic brooders. As for skeletal growth, there is no species-specific information available, but branching *Acropora* species such as the four listed *Acropora* species are typically relatively fast-growing (Brainard *et al.,* 2011).

Coral larvae presumably experience considerable mortality from predation or other factors prior to settlement and metamorphosis. Such mortality cannot be directly observed, but is inferred from the large number of eggs and sperm spawned versus the much smaller number of recruits observed later. Little is known concerning the settlement patterns of planulae (free-swimming larvae) of the listed Indo-Pacific corals. In general, upon proper

stimulation, coral larvae, whether released from parental colonies or developed in the water column external to the parental colonies (like *Acropora* spp.), settle and metamorphose on appropriate substrates. Biological and physical factors that have been shown to affect spatial and temporal patterns of coral recruitment include substrate availability and community structure, grazing pressure, fecundity, mode and timing of reproduction, behavior of larvae, hurricane disturbance, physical oceanography, the structure of established coral assemblages, and chemical cues. Like most corals, the listed Indo-Pacific corals require hard, consolidated substrate, including attached, dead coral skeleton, for their larvae to settle. Algal growth limits the amount of hard substrate available to coral settlement, and a low nutrient environment is less conducive to algal growth. Once larvae are able to settle onto appropriate hard substrate, metabolic energy is diverted to colony growth and maintenance.

Reef-building corals combine calcium and carbonate ions derived from seawater into crystals that form their skeletons. Skeletal expansion rates vary greatly by taxa, morphology, location, habitat and other factors. For example, in general, branching species (*e.g.,* most *Acropora* species) have much higher skeletal extension rates than massive species (*e.g.,* massive *Porites* species). The energy required to produce new polyps and build calcium carbonate skeleton is provided by the symbiotic relationship corals have with photosynthetic zooxanthellae. The zooxanthellae require light to photosynthesize, thus lower water clarity (*i.e.,* poor transparency) reduces the host coral's energy, growth and survival by limiting the amount of light that penetrates the water. Lower water clarity sharply reduces photosynthesis in zooxanthellae with moderate reductions in adult colony survival and calcification. The skeletons of coral colonies are bound together by cementation, resulting in the formation of coral reefs. Species with high recruitment rates or fast growth rates may have the ability to recover more quickly from disturbances. Additionally, long-lived species with large colony size can sustain partial mortality (fission) and still have the potential for persistence and regrowth (79 FR 53852, September 10, 2014). Additional information on the biological requirements for reproduction, settlement, and growth is provided below in the *Physical and Biological Features Essential for Conservation* section.

Shallow coral reefs are fragile ecosystems that exist in a narrow band of environmental conditions that allow the skeletons of reef-building coral species to grow quickly enough for reef accretion to outpace reef erosion. High-growth conditions for reef-building corals include clear, warm waters with abundant light, and low levels of nutrients, sediments, and freshwater. The three broad categories of coral reefs are fringing reefs, barrier reefs, and atolls. Fringing reefs are mostly close to coastlines, and usually have a high component of non-carbonate sediment. Barrier reefs are offshore and are composed of wave-resistant consolidated limestone. Atolls are usually a wall of reefs partially or completely enclosing a central lagoon. There are not sharp differences that clearly mark boundaries between reef types. For example, fringing reefs gradually become barrier reefs with increasing distance from shore. Also, the shape of both barrier reefs and atolls is largely determined by the bathymetry of the substratum, producing many irregularly shaped reefs that are intermediary between the two types. Isolated reefs that do not fit any of these descriptions are referred to as platform reefs. Despite the differences between the reef categories, most fringing reefs, barrier reefs, atolls, and platform reefs consist of a reef slope, a reef crest, and a back-reef, which in turn are typically characterized by distinctive habitats. The characteristics of coral reef habitat vary greatly by reef categories, locations, latitudes, frequency of disturbance, etc., and there is also much variability within each habitat type. Temporal variability in coral habitat conditions is also very high, both cyclically (*e.g.,* from tidal, seasonal, annual, and decadal cycles) and episodically (*e.g.,* storms, temperature anomalies, etc.). Together, all these factors contribute to the habitat heterogeneity of coral reefs across the Indo-Pacific, as described in more detail in the final listing rule (79 FR 53852; September 10, 2014).

As described previously, reef-building corals are not dependent on coral reefs, and many of these species can thrive in low-growth conditions where skeletal growth is inadequate to result in accretion of coral reefs. ''Non-reef habitat'' refers to hard substrates where reef-building corals can grow, including marginal habitats where conditions prevent reef development (*e.g.,* turbid or high-latitude or upwelling-influenced areas) and recently available habitat (*e.g.,* lava flows). All the listed species can occur in both shallow coral reef and non-reef habitats, provided that hard substrate and suitable water quality are present. The term ''mesophotic habitat'' refers to hard substrates deeper than 30 m. Shallow coral reefs, non-reef habitats, and mesophotic habitats are not necessarily sharply delineated from one another, thus one may gradually blend into another. The total area of non-reef and mesophotic habitats is likely greater than the total area of shallow coral reef habitats within the ranges of the listed corals (79 FR 53852; September 10, 2014). Despite the large amount of variability in habitats occupied by corals, they have several characteristics in common that provide the fundamental support necessary for coral settlement and growth, including hard substrate and low-nutrient, clear water with good light penetration.

The seven listed Indo-Pacific species within U.S. waters vary in their recorded depth ranges and habitat types. *Acropora globiceps* occurs on upper reef slopes, reef flats, and adjacent habitats. In the final listing rule, the best available information indicated this species occurs in depths ranging from 0 to 8 meters (m). However, in 2015, we learned that *A. globiceps* has been observed in American Samoa at 11 m (Asili, Tutuila) and 18 m in the National Park of American Samoa on the north side of Tutuila (D. Fenner, pers. comm., 2015). Based on the new information, we consider the rangewide depth distributions of *A. globiceps* to be 0 to 20 m. *Acropora jacquelineae* is found in numerous subtidal reef slope and back-reef habitats, including but not limited to, lower reef slopes, walls and ledges, mid-slopes, and upper reef slopes protected from wave action, and its depth range is 10 to 35 m (D. Fenner, pers. comm. 2015). *Acropora retusa* occurs in shallow reef slope and back-reef areas, such as upper reef slopes, reef flats, and shallow lagoons. In the final listing rule, the best available information indicated its depth range to be 0 to 5 m. In 2015, we learned that *A. retusa* has been observed in American Samoa at 10 m near Asili on Tutuila Island (D. Fenner, pers. comm. 2015). Based on the previously described new information combined with the fact that it's almost always found in shallower waters, we consider the rangewide depth distribution of *A. retusa* to be 0 to 10 m in this rule. *Acropora speciosa* occurs on lower reef slopes and walls, especially those characterized by clear water and high *Acropora* diversity, in a depth range of 12 to 40 m (Veron, 2014). *Euphyllia paradivisa* is found in environments protected from wave action on at least upper reef slopes, mid-

slope terraces, and lagoons at a depth range of 2 to 25 m (Veron, 2014). *Isopora crateriformis'*s predominant habitat is shallow, high-wave energy environments, including reef flats and reef crests, and it also occurs in adjacent habitats such as upper reef slopes. It has a depth distribution of 0 to 12 m, and has been reported as common at 5 to 10 m (D. Fenner, pers. comm. 2015). *Seriatopora aculeata* occurs in a broad range of habitats on the reef slope and back reef, including but not limited to upper reef slopes, mid-slope terraces, lower reef slopes, reef flats, and lagoons in a depth range of 3 to 40 m (Veron, 2014).

In summary, based on the best currently available information, we consider the rangewide depth distributions of the seven listed species as follows: *A. globiceps,* 0 to 20 m; *A. jacquelineae,* 10 to 35 m; *A. retusa,* 0 to 10 m; *A. speciosa,* 12 to 40 m; *E. paradivisa,* 2 to 25 m; *I. crateriformis,* 0 to 12 m; and *S. aculeata,* 3 to 40 m (Table 1).

TABLE 1—CONFIRMED GEOGRAPHIC AND DEPTH DISTRIBUTIONS OF THREATENED INDO-PACIFIC CORALS IN THE U.S.

Jurisdiction	Am Samoa				Mariana Islands (Guam and CNMI)									Pacific Remote Island Area					
Unit [1]	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
A. globiceps, (0–20 m)	X	X	X	X	X	X	X	X	X	X	X	X	X	.....	X	X	.....	X	.....
A. jacquelineae, (10–35 m)	X	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
A. retusa, (0–10 m)	X	X	X	X	X	.....	.....	X	.....	.....	.....	.....	.....	X	.....	X	X	X	X
A. speciosa, (12–40 m)	X	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	X	.....	.....	.....
E. paradivisa, (2–40 m)	X	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
I. crateriformis, (0–12 m)	X	X	X	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
S. aculeata, (3–40 m)	.....	.....	.....	.....	X	.....	.....	.....	X	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....
Depths of all listed spp.[2]	a	b	b	b	a	b	b	b	a	b	b	b	b	c	B	a	c	b	c

[1] *Unit Key:* (1) Tutuila & Offshore Banks; (2) Ofu & Olosega; (3) Ta'u; (4) Rose Atoll; (5) Guam & Offshore Banks; (6) Rota; (7) Aguijan; (8) Tinian and Tatsumi Reef; (9) Saipan and Garapan Bank; (10) Farallon de Medinilla; (11) Anatahan; (12) Pagan; (13) Maug Islands & Supply Reef; (14) Howland Island; (15) Palmyra Atoll; (16) Kingman Reef; (17) Johnston Atoll; (18) Wake Atoll; and (19) Jarvis Island.
[2] *Depth Key:* (a) 0–40 m; (b) 0–20 m; (c) 0–10 m.

Species identification of many Indo-Pacific reef-building corals is challenging, even for experts who have worked in the field for decades. There are a multitude of reasons for this, including: Poor quality type specimens; lack of samples to verify photos; inter-specific and intra-specific morphological plasticity and variability; inherent human subjectivity; and unreliable published information. For the seven listed species considered here, current species identification uncertainty is rated as moderate or high for six species (all but *E. paradivisa*). In addition, because traditional coral identification is based on colony morphological characteristics, and recent genetics results often contradict morphological identifications, species identification uncertainty is predicted to increase for most of these species (Fenner, 2015).

Critical Habitat Identification and Designation

The purpose of designating critical habitat is to identify the areas that are essential to the species' recovery. Once critical habitat is designated, it can contribute to the conservation of listed species in several ways, including by identifying areas where Federal agencies can focus their section 7(a)(1) conservation programs, and helping focus the efforts of other conservation partners, such as States and local governments, nongovernmental organizations, and individuals (81 FR 7414, February 11, 2016). Designating critical habitat also provides a significant regulatory protection by ensuring that the Federal government considers the effects of its actions in accordance with section 7(a)(2) of the ESA and avoids or modifies those actions that are likely to destroy or adversely modify critical habitat. This requirement is in addition to the section 7 requirement that Federal agencies ensure that their actions are not likely to jeopardize the continued existence of ESA-listed species. Critical habitat requirements do not apply to citizens engaged in activities on private land that do not involve a Federal agency.

Section 3(5)(A) of the ESA defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the provisions of section 4 of the ESA, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed in accordance with the provisions of section 4 of the ESA, upon a determination by the Secretary that such areas are essential for the conservation of the species (16 U.S.C. 1532(5)(A)). Conservation is defined in section 3 of the ESA as the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to this chapter are no longer necessary (16 U.S.C. 1532(3)). Therefore, critical habitat is the habitat essential for the species' recovery. However, section 3(5)(C) of the ESA clarifies that, except in those circumstances determined by the Secretary, critical habitat shall not include the entire geographical area which can be occupied by the threatened or endangered species.

To identify and designate critical habitat, we considered information on the distribution of the seven threatened Indo-Pacific corals, their major life stages, habitat requirements of those life stages, threats to the species, and conservation objectives that can be supported by identifiable essential physical or biological features (hereafter also referred to as ''PBFs'' or ''essential features''). In the final listing rule, ocean warming, diseases, ocean acidification, trophic effects of reef fishing, nutrient enrichment, sedimentation, and inadequacy of regulatory mechanisms were found to be the main threats contributing to the threatened status of all seven corals. Several other threats also contributed to the species' statuses, but were considered to be relatively lower in importance as compared to the main threats. Therefore, we evaluated physical and biological features of their habitats to determine what features are essential to the conservation of each coral.

Accordingly, our step-wise approach for identifying potential critical habitat areas for the threatened corals was to determine: (1) The geographical area occupied by each coral at the time of listing; (2) the physical or biological

features essential to the conservation of the corals; (3) whether those features may require special management considerations or protection; (4) the specific areas of the occupied geographical area where these features occur; and, (5) whether any unoccupied areas are essential to the conservation of any of the corals.

Geographical Area Occupied by the Species

''Geographical area occupied'' in the definition of critical habitat is interpreted to mean the entire range of the species at the time it was listed, inclusive of all areas they use and move through seasonally (81 FR 7413; February 11, 2016). We did not consider geographical areas outside of the United States because we cannot designate critical habitat areas outside of U.S. jurisdiction (50 CFR 424.12(g)). As noted previously, seven of the listed species have been confirmed within U.S. Pacific Islands waters (Table 1), and only these seven are currently being considered for critical habitat designation. We first identified the U.S. jurisdictional areas where observations of listed coral species have been confirmed. In summary, six listed species are confirmed in American Samoa (*A. globiceps, A. jacquelineae, A. speciosa, A. retusa, I. crateriformis,* and *E. paradivisa*); three listed species are confirmed in Guam and CNMI (*A. globiceps, A. retusa,* and *S. aculeata*); and three listed species are confirmed in PRIA (*A. globiceps, A. retusa,* and *A. speciosa*). We further broke down the areas under consideration for critical habitat designation into 19 units based on information on the confirmed locations of each species within these jurisdictions, in order to better describe the geographic areas occupied by each species. The units generally consist of individual islands or atolls and nearby shoals or banks. Table 1 shows the distributions of the seven listed species by both jurisdiction and critical habitat unit. The proposed units are shown in the figures at the end of this rule. More detailed information on the distributions of the seven listed species in these units is provided in the Draft Information Report (NMFS, 2019).

Physical or Biological Features Essential for Conservation

Within the geographical area occupied, critical habitat consists of specific areas on which are found those PBFs essential to the conservation of the species and that may require special management considerations or protection. PBFs essential to the conservation of the species are defined as the features that occur in specific areas and that are essential to support the life-history needs of the species, including water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic, or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity (50 CFR 424.02).

In the final listing rule, we determined that the seven corals were threatened under the ESA. This means that while the species are not in danger of extinction currently, they are likely to become so within the next several decades based on their current abundances and trends in abundance, distributions, and threats they experience now and in the future. The goal of an ESA listing is to first prevent extinction, and then to recover the species so they no longer meet the definition of a threatened species and no longer need the protections of the ESA. One of the first steps in recovery planning we completed after listing these coral species was to develop a Recovery Outline that contains a Recovery Vision, which describes what the state of full recovery looks like for the species. We identified the following Recovery Vision for the 15 Indo-Pacific corals listed in 2014, including the 7 species covered by this critical habitat rule: Populations of the 15 listed Indo-Pacific corals should be present throughout as much of their historical ranges as future environmental changes will allow, and may expand their ranges into new locations with more favorable habitat conditions in the future (*https://www.fisheries.noaa.gov/resource/document/15-indo-pacific-coral-species-recovery-outline*). Recovery of these species will require conservation of the coral reef ecosystem through threats abatement to ensure a high probability of survival into the future (NMFS, 2015). The key conservation objective that facilitates this Recovery Vision, and that can be assisted through these critical habitat designations, is supporting successful reproduction and recruitment, and survival and growth of all life stages, by abating threats to the corals' habitats. In the final listing rule, we identified the major threats contributing to the seven corals' extinction risk: Ocean warming, disease, ocean acidification, trophic effects of reef fishing, nutrient enrichment, and sedimentation. Five of the six major threats (*i.e.,* all but disease) impact corals in part by changing the corals' habitat, making it unsuitable for them to carry out the essential functions at all life stages. Although it was not considered to be posing a major threat at the time of listing, we also identified contaminants as a potential threat to each of these corals (79 FR 53852, September 10, 2014). Thus, we identify ocean warming, ocean acidification, trophic effects of reef fishing, nutrient enrichment, sedimentation, and contaminants as the threats to the seven corals' habitat that are impeding their recovery. Protecting essential features of the corals' habitat from these threats will facilitate the Recovery Vision.

We then turned to determining the physical or biological features essential to this conservation objective of supporting successful reproduction and recruitment, and survival and growth of all life stages. Specifically, we evaluated whether particular habitat features will facilitate recovery through enhancing population growth. There are many physical and biological features that are important in supporting the corals' habitat; therefore, we focused on a composite habitat feature that supports the conservation objective through its relevance to the major threats and threats impeding recovery. The essential feature we ultimately identified is sites with a complex combination of substrate and water column characteristics that support normal functions of all life stages of the corals. Due to corals being sessile for almost their entire life cycle, they carry out most of their demographic functions in one location. Thus, we have identified sites with a combination of certain substrate and water column characteristics as the essential feature. A detailed discussion of how this feature was determined will follow. Specifically, these sites have attributes that determine the quality of the appropriate attachment substrate, in association with warm, aragonite-supersaturated, oligotrophic, clear marine water, which are essential to reproduction and recruitment, survival, and growth of all life stages of all seven species of coral. These sites can be impacted by ocean acidification and ocean warming, trophic effects of reef fishing, nutrient enrichment, sedimentation, and contamination.

Based on the best scientific information available we identify the following physical feature essential to the conservation of the seven corals. Our proposed definition for the essential feature is:

Reproductive, recruitment, growth, and maturation habitat. Sites that support the normal function of all life stages of the corals are natural, consolidated hard substrate or dead coral skeleton free of algae and sediment at the appropriate scale at the point of larval settlement or fragment reattachment, and the associated water column. Several attributes of these sites determine the quality of the area and influence the value of the associated feature to the conservation of the species:

(1) Substrate with presence of crevices and holes that provide cryptic habitat, the presence of microbial biofilms, or presence of crustose coralline algae;

(2) Reefscape (all the visible features of an area of reef) with no more than a thin veneer of sediment and low occupancy by fleshy and turf macroalgae;

(3) Marine water with levels of temperature, aragonite saturation, nutrients, and water clarity that have been observed to support any demographic function; and

(4) Marine water with levels of anthropogenically-introduced (from humans) chemical contaminants that do not preclude or inhibit any demographic function.

As described in detail in the Draft Information Report (NMFS, 2019), all corals require exposed natural consolidated hard substrate for the settlement and recruitment of larvae or asexual fragments. Substrate provides the physical surface and space necessary for settlement of coral larvae, a stable environment for metamorphosis of the larvae into the primary polyp, growth of juvenile and adult colonies, and re-attachment of fragments. Larvae can settle and attach to dead coral skeleton (Brainard *et al.,* 2011). A number of attributes have been shown to influence coral larval settlement. Positive cues include the presence of crustose coralline algae (Heyward and Negri, 1999), biofilms (Webster *et al.,* 2004), and cryptic habitat such as crevices and holes (Nozawa, 2008). Attributes that negatively affect settlement include presence of sediment and algae (Vermeij *et al.,* 2009). Coral recruitment tends to be greater when macroalgal biomass is low (Birrell *et al.,* 2005). In addition to preempting space for coral larvae settlement, many fleshy macroalgae produce substances that may inhibit larval settlement, recruitment, and survival (Jompa and McCook, 2003). Furthermore, algal turfs can trap sediments (Purcell and Bellwood, 2001), which then create the potential for algal turfs and sediments to act in combination to hinder coral settlement (Birrell *et al.,* 2005).

Presence and amount of sediment is a particularly important determinant of the quality of substrate for reef-building coral habitat. Sediments enter the reef environment through many processes that are natural or anthropogenic in origin, including erosion of the coastline, resuspension of bottom sediments, terrestrial run-off, and nearshore dredging for coastal construction projects and navigation purposes. The rate of sedimentation affects reef distribution, community structure, growth rates, and coral recruitment (Dutra *et al.,* 2006). Sediment accumulation on dead coral skeletons and exposed hard substrate reduces the amount of available substrate for coral larvae settlement and fragment reattachment (Rogers, 1990). Sediment impedes settlement of coral larvae (Babcock and Smith, 2002). The deeper the sediment, the longer it may take for natural waves and currents to remove the sediment from the settlement substrate. Sediment texture also affects the severity of impacts to corals and recruitment substrate. Fine grain sediments have greater negative effects to live coral tissue and to recruitment substrate (Erftemeijer *et al.,* 2012). Accumulation of sediments is also a major cause of mortality in coral recruits (Fabricius *et al.,* 2003). In some instances, if mortality of coral recruits does not occur under heavy sediment conditions, then settled coral planulae may undergo reverse metamorphosis and die in the water column (Te, 1992). Accumulation of sediment can smother living corals, cover dead coral skeleton, and exposed hard substrate (Erftemeijer *et al.,* 2012; Fabricius, 2005). Sedimentation, therefore, impacts the health and survivorship of all life stages of corals (*i.e.,* adults, fragments, larvae, and recruits).

The literature provides several recommendations on maximum sediment levels for coral reefs (*i.e.,* levels that managers should strive to stay under). De'ath and Fabricius (2008) and the Great Barrier Reef Marine Park Authority (GBRMPA 2010) recommend that sediment levels on the Great Barrier Reef (GBR) be less than a mean annual sedimentation rate of 3 mg/cm^2/day, and less than a daily maximum of 15 mg/cm^2/day. Rogers (1990) recommends that sediment levels on coral reefs globally be less than a mean maximum of 10 mg/cm^2/day to maintain healthy corals, and also notes that moderate to severe effects on corals are generally expected at mean maximum sedimentation rates of 10 to 50 mg/cm^2/day, and severe to catastrophic effects at >50 mg/cm^2/day. Similarly, Erftemeijer *et al.* (2012) suggests that moderate to severe effects to corals are expected at mean maximum sediment levels of >10 mg/cm^2/day, and catastrophic effects at >50 mg/cm^2/day. Nelson *et al.* (2016) suggests that sediment depths of >0.5 cm result in substantial stress to most coral species, and that sediment depths of >1.0 cm are lethal to most coral species. The previously described generalizations are for coral reef communities and ecosystems, rather than individual species.

Sublethal effects of sediment to corals potentially occur at much lower levels than mortality. Sublethal effects include reduced growth, lower calcification rates and reduced productivity, bleaching, increased susceptibility to diseases, physical damage to coral tissue and reef structures (breaking, abrasion), and reduced regeneration from tissue damage (see reviews by Fabricius *et al.,* 2005; Erftemeijer *et al.,* 2012; Browne *et al.,* 2015; and Rogers, 1990). Erftemeijer *et al.* (2012) states that sublethal effects for coral species that are sensitive, intermediate, or tolerant to sediment (*i.e.,* most reef-building coral species) occur at mean maximum sedimentation rates of between <10 and 200 mg/cm^2/day, depending on species, exposure duration, and other factors.

Finally, artificial substrates and frequently disturbed ''managed areas'' are not essential to coral conservation. Only natural substrates provide the quality and quantity of recruitment habitat necessary for the conservation of threatened corals. Artificial substrates are generally less functional than natural substrates in terms of supporting healthy and diverse coral reef ecosystems (Edwards and Gomez, 2007; USFWS, 2004). Artificial substrates are typically man-made or introduced substrates that are not naturally occurring to the area. Examples include, but are not necessarily limited to, fixed and floating structures, such as aids-to-navigation (AToNs), jetties, groins, breakwaters, seawalls, wharves, boat ramps, fishpond walls, pipes, wrecks, mooring balls, docks, aquaculture cages, and other artificial substrates. Our definition of recruitment substrate does not include any artificial substrate. In addition, there are some natural substrates that, because of their consistently disturbed nature, also do not provide the quality of substrate necessary for the conservation of threatened corals. While these areas may provide hard substrate for coral settlement and growth over short periods, the periodic nature of direct human disturbance renders them poor environments for coral growth and

survival over time (*e.g.,* they can become covered with sediment). Therefore, they are not essential to the conservation of the species. Specific areas that may contain these disturbed natural substrates are described in the *Specific Areas Containing the Essential Features within the Geographical Areas Occupied by the Species* section of this proposed rule.

The substrate characterized previously must be associated with water that also supports all life functions of corals that are carried out at the site. Water quality conditions fluctuate greatly over various spatial and temporal scales in natural reef environments (Kleypas *et al.,* 1999). However, certain levels of particular parameters (*e.g.,* water clarity, water temperature, aragonite saturation) must exist on average to provide the conditions conducive to coral growth, reproduction, and recruitment. Corals may tolerate and survive in conditions outside these levels, depending on the local conditions to which they have acclimatized and the intensity and duration of any deviations from conditions conducive to a particular coral's growth, reproduction and recruitment. Deviations from tolerance levels of certain parameters result in direct negative effects on all life stages.

As described in the Draft Information Report, corals thrive in warm, clear, nutrient-poor marine waters with calcium carbonate concentrations that allow for symbiont photosynthesis, coral physiological processes and skeleton formation. This water must also have low to no levels of contaminants (*e.g.,* heavy metals, chemicals) that would interfere with normal functions of all life stages. Water quality that supports normal functions of corals is adversely affected by ocean warming, ocean acidification, nutrient enrichment, sedimentation, and contamination.

Seawater temperature is a particularly important limiting factor of coral habitat, and consequently ocean warming is one of the most important threats to reef-building corals. Corals occur in a wide temperature range across geographic locations (15.7°C–35.5°C weekly average and 21.7–29.6°C annual average; Guan *et al.,* 2015), but only thrive in areas with mean temperatures in a narrow range (typically 25°C–29°C) as indicated by the global distribution of coral reefs (Brainard *et al.,* 2011; Kleypas *et al.,* 1999). Short-term exposures (days) to temperature increases of a few degrees (*i.e.,* 3°C–4°C increase above mean maximum summer temperature) or long-term exposures (several weeks) to minor temperature increases (*i.e.,* 1°C–2°C above mean maximum summer temperature) can cause significant thermal stress and mortality to most coral species (Berkelmans and Willis, 1999; Jokiel and Coles, 1990). In addition to coral bleaching, elevated seawater temperatures impair coral fertilization and settlement (Nozawa and Harrison, 2007) and cause increases in coral disease (Miller *et al.,* 2009).

Effects of elevated seawater temperatures are well-studied for reef-building corals, and many approaches have been used to estimate temperature thresholds for coral bleaching and mortality (see reviews by Brown, 1997; Berkelmans, 2002; Coles and Brown, 2003; Jokiel, 2004; Baker *et al.,* 2007; Jones, 2008; Coles and Riegl, 2013). The tolerance of corals to temperature is species-specific (van Woesik *et al.,* 2011; Vega-Rodriguez, 2016) and depends on suites of other variables that include acclimation temperature, aragonite saturation state, dissolved inorganic nitrogen (Cunning and Baker, 2012; Fabricius, 2005; Wooldridge, 2013); and physical, physiological, and chemical stressors, including suspended sediments and turbidity (Anthony *et al.,* 2007; Woods *et al.,* 2016); trace metals such as copper (Negri and Hoogenboom, 2011; Woods *et al.,* 2016); ultraviolet radiation (Anthony *et al.,* 2007); and salinity, nitrates, and phosphates (Negri and Hoogenboom, 2011).

Ocean warming is one of the most significant threats to the seven ESA-listed Indo-Pacific corals. Mean seawater temperatures in reef-building coral habitat in the Indo-Pacific have increased during the past few decades, and are predicted to continue to rise between now and 2100 (IPCC, 2013). The primary observable coral response to ocean warming is bleaching of adult coral colonies, wherein corals expel their symbiotic zooxanthellae in response to stress (Brown, 1997). Even so, evaluating the effects that changes in water temperatures have on the conservation value of coral habitat is very complex and contextually-driven, and simple numeric effect thresholds are not easily assigned to listed corals to establish when stress responses occur. For many corals, an episodic increase of only 1°C–2°C above the normal local seasonal maximum ocean temperature can induce bleaching (Hoegh-Guldberg *et al.,* 2007; Jones, 2008). Corals can withstand mild to moderate bleaching; however, severe, repeated, or prolonged bleaching can lead to colony death (Brown, 1997). In addition to coral bleaching, other effects of ocean warming detrimentally affect virtually every life-history stage in reef-building corals. Impaired fertilization and developmental abnormalities (Negri and Heyward, 2000), mortality, and impaired settlement success (Nozawa and Harrison, 2007) have all been documented. Increased seawater temperature also may act synergistically with coral diseases to reduce coral health and survivorship (Bruno and Selig, 2007). Coral disease outbreaks often have either accompanied or immediately followed bleaching events (Jones *et al.,* 2004; Miller *et al.,* 2009). Outbreaks also follow seasonal patterns of high seawater temperatures (Willis *et al.,* 2004).

Coles and Brown (2003) defined a general bleaching threshold for reef-building corals as increases in seawater temperatures of 1–3°C above maximum annual mean temperatures at a given location. GBRMPA (2010) defined a general ''trigger value'' for bleaching in reef-building corals as increases in seawater temperatures of no more than 1°C above maximum annual mean temperatures at a given location. Because duration of exposure to elevated temperatures determines the extent of bleaching, several methods have been developed to integrate duration into bleaching thresholds, including the number of days, weeks, or months of the elevated temperatures (Berkelmans, 2002; Eakin *et al.,* 2009). NOAA's Coral Reef Watch Program utilizes the Degree Heating Week method (Glynn and D'Croz, 1990; Eakin *et al.* 2009), which defines a general bleaching threshold for reef-building corals as seawater temperatures of 1°C above maximum monthly mean at a given location for four consecutive weeks (*https://coralreefwatch.noaa.gov/*).

These general thresholds were developed for coral reef communities and ecosystems, rather than individual species. Many of these studies are community or ecosystem-focused and do not account for species-specific responses to changes in seawater temperatures, and instead are focused on long-term climatic changes and large scale impacts (*e.g.,* coral reef distribution, persistence).

In summary, temperature deviations from local averages prevent or impede successful completion of all life history stages of the listed coral species. Identifying temperatures at which the conservation value of habitat for listed corals may be affected is inherently complex and influenced by taxa, exposure duration, and other factors.

Carbonate ions (CO_3^{2-}) are used by many marine organisms, including corals, to build calcium carbonate skeletons. For corals, the mineral form

of calcium carbonate in their skeletons is called ''aragonite.'' The more carbonate ions there are dissolved in seawater, the easier it is for corals to build their aragonite skeletons. The metric used to express the relative availability of calcium and carbonate ions is the aragonite saturation state (Ω_{arg}). Thus, the lower the Ω_{arg} of seawater, the lower the abundance of carbonate ions, and the more energy corals have to expend for skeletal calcification, and vice versa (Cohen and Holcomb, 2009). At saturation states between 1 and 20, marine organisms can create calcium carbonate shells or skeletons using a physiological calcifying mechanism and the expenditure of energy. The aragonite saturation state varies greatly within and across coral reefs and through daily cycles with temperature, salinity, pressure, and localized biological processes such as photosynthesis, respiration, and calcification by marine organisms (Gray *et al.,* 2012; McMahon *et al.,* 2013; Shaw *et al.,* 2012b).

Coral reefs form in an annually-averaged saturation state of 4.0 or greater for optimal calcification, and an annually-averaged saturation state below 3.3 will result in reduced calcification at rates insufficient to maintain net positive reef accretion, resulting in loss of reef structure (Guinotte *et al.,* 2003; Hoegh-Guldberg *et al.,* 2007). Guinotte *et al.* (2003) classified the range of aragonite saturation states between 3.5–4.0 as ''adequate'' and < 3 as ''extremely marginal.'' Thus, aragonite saturation state between 3 and 4 is likely necessary for coral calcification. But, generally, seawater Ω_{arg} should be 3.5 or greater to enable maximum calcification of reef-building corals, and average Ω_{arg} in most coral reef areas is currently in that range (Guinotte *et al.,* 2003). Further, (Kleypas *et al.,* 1999) concluded that a general threshold for Ω_{arg} occurs near 3.4, because only a few reefs occur where saturation is less than this. Guan *et al.* (2015) found that the minimum aragonite saturation observed where coral reefs currently occur is 2.82; however, it is not known if those locations hosted live accreting corals. These general characterizations and thresholds were identified for coral reef communities and ecosystems, rather than individual species.

Ocean acidification is a term referring to changes in ocean carbonate chemistry, including a drop in the pH of ocean waters, that is occurring in response to the rise in the quantity of atmospheric CO_2 and the partial pressure of CO_2 (pCO_2) absorbed in oceanic waters (Caldeira and Wickett, 2003). As pCO_2 rises, oceanic pH declines through the formation of carbonic acid and subsequent reaction with water resulting in an increase of free hydrogen ions. The free hydrogen ions react with carbonate ions to produce bicarbonate, reducing the amount of carbonate ions available, and thus reducing the aragonite saturation state. Ocean acidification is one of the most significant threats to reef-building corals (Brainard *et al.,* 2011; Jokiel, 2015).

A variety of laboratory studies conducted on corals and coral reef organisms (*e.g.,* Langdon and Atkinson, 2005) consistently show declines in the rate of coral calcification and growth with rising pCO_2, declining pH, and declining carbonate saturation state. Laboratory experiments have also shown that skeletal deposition and initiation of calcification in newly settled corals is reduced by declining aragonite saturation state (Albright *et al.,* 2008; Cohen *et al.,* 2009). Field studies from a variety of coral locations in the Caribbean, Indo-Pacific, and Red Sea have shown a decline in linear extension rates of coral skeleton under decreasing aragonite saturation state (Bak *et al.,* 2009; De'ath *et al.,* 2009; Schneider and Erez, 2006; Tanzil *et al.,* 2009). Reduced calcification and slower growth will mean slower recovery from breakage, whether natural (hurricanes and storms) or human (breakage from vessel groundings, anchors, fishing gear, etc.), or mortality from a variety of disturbances. Slower growth also implies even higher rates of mortality for newly settled corals due to the longer time it will take to reach a colony size that is no longer vulnerable to overgrowth competition, sediment smothering, and incidental predation. Reduced calcification and slower growth means more time to reach reproductive size and reduces sexual and asexual reproductive potential. Increased pCO_2 coupled with increased sea surface temperature can lead to even lower rates of calcification, as found in the meta-analysis by Kornder *et al.* (2018).

In summary, aragonite saturation reductions prevent or impede successful completion of all life history stages of the listed coral species. Identifying the declining aragonite saturation state at which the conservation value of habitat for listed corals may be affected is inherently complex and influenced by taxa, exposure duration, acclimatization to localized nutrient regimes, and other factors.

Nitrogen and phosphorous are two of the main nutrients that affect the suitability of coral habitat (Fabricius *et al.,* 2005; Fabricius, 2005). These two nutrients occur as different compounds in coral reef habitats and are necessary in low levels for normal reef function. Dissolved inorganic nitrogen and dissolved inorganic phosphorus in the forms of nitrate (NO_3) and phosphate ($PO4_3$) are particularly important for photosynthesis, with dissolved organic nitrogen also providing an important source of nitrogen, and are the dominant forms of nitrogen and phosphorous in coral reef waters. Nutrients are a major component of land-based sources of pollution (LBSP), one of the most important threats to reef-building corals (Brainard *et al.,* 2011). Excessive nutrients affect corals through two main mechanisms: direct impacts on coral physiology such as reduced fertilization and growth (Harrison and Ward, 2001; Ferrier-Pages *et al.,* 2000), and indirect effects through nutrient-stimulation of other community components (*e.g.,* macroalgae seaweeds, turfs/filamentous algae, cyanobacteria, and filter feeders) that compete with corals for space on the reef (79 FR 53851, September 10, 2014). As discussed previously, the latter also affects the quality of recruitment substrate. The physiological response a coral exhibits to an increase in nutrients mainly depends on concentration and duration. A short duration of a large increase in a nutrient may result in a severe adverse response, just as a chronic, lower concentration might.

Most coral reefs occur where annual mean nutrient levels are low. Kleypas *et al.* (1999) analyzed dissolved nutrient data from nearly 1,000 coral reef sites, finding mean values of 0.25 micromoles per liter (µmol/l) for NO_3, and 0.13 µmol/l for PO_4. Over 90 percent of the sites had mean NO_3 values of <0.6 µmol/l, and mean PO_4 values of <0.2 µmol/l (Kleypas *et al.,* 1999). Several authors, including Bell and Elmetri (1995) and Lapointe (1997) have proposed threshold values of 1.0 µmol/l for NO_3, and 0.1–0.2 µmol/l for PO_4, above which NO_3 and PO_4 are excessive (eutrophic). However, concentrations of dissolved nutrients are poor indicators of coral reef status, and the concept of a simple threshold concentration that indicates eutrophication has little validity (McCook *et al.,* 1999). One reason for that is because corals are exposed to nutrients in a variety of forms, including dissolved nitrogen (*e.g.,* NO_3), dissolved phosphorus (*e.g.,* $PO4_3$), particulate nitrogen (PN), and particulate phosphate (PP). Since the dissolved forms are assimilated rapidly by phytoplankton, and the majority of nitrogen and phosphorus discharged in

terrestrial runoff is in the particulate forms, PN and PP are the most common bio-available forms of nutrients for corals on coastal zone reefs (Cooper and Fabricius, 2007). Thus, De'ath and Fabricius (2008) and GBRMPA (2010) provide general recommendations on maximum annual mean values for PN and PP of 1.5 µmol/l PN and 0.09 µmol/l PP for coastal zone reefs. These generalizations are for coral reef communities and ecosystems, rather than individual species.

As noted previously, identifying nutrient concentrations at which the conservation value of habitat for listed corals may be affected is inherently complex and influenced by taxa, exposure duration, and acclimatization to localized nutrient regimes, and other factors.

Water clarity or transparency is a key factor for marine ecosystems and it is the best explanatory variable for a range of bioindicators of reef health (Fabricius *et al.,* 2012). Water clarity affects the light availability for photosynthetic organisms and food availability for filter feeders. Corals depend upon their symbiotic algae for nutrition and thus depend on light availability for algal photosynthesis. Reduced water clarity is determined by the presence of particles of sediment, organic matter, and/or plankton in the water, and so is often associated with elevated sedimentation and/or nutrients. Water clarity can be measured in multiple ways, including percent of solar irradiance at depth, Secchi depth (the depth in the water column at which a black and white disk is no longer visible), and Nephelometric Turbidity Unit (NTU) (measure of light scatter based on particles in the water column). Reef-building corals naturally occur across a broad range of water clarity levels from very turbid waters on enclosed reefs near river mouths (Browne *et al.,* 2012) to very clear waters on offshore barrier reefs, and many intermediate habitats such as open coastal and mid-shelf reefs (GBRMPA, 2010). Coral reefs appear to thrive in extremely clear areas where Secchi depth is ≥ 15 m or light scatter is < 1 NTU (De'ath and Fabricius, 2010). Typical levels of total suspended solids (TSS) in reef environments are less than 10 mg/L (Rogers, 1990). The minimum light level for reef development is about 6–8 percent of surface irradiance (Fabricius *et al.,* 2014).

For a particular coral colony, tolerated water clarity levels likely depend on several factors, including species, life history stage, spatial variability, and temporal variability. For example, colonies of a species occurring on fringing reefs around high volcanic islands with extensive groundwater inputs are likely to be better acclimatized or adapted to higher turbidity than colonies of the same species occurring on offshore barrier reefs or around atolls with very little or no groundwater inputs. In some cases, corals occupy naturally turbid habitats (Anthony and Larcombe, 2000; McClanahan and Obura, 1997; Te, 2001) where they may benefit from the reduced amount of UV radiation to which they are exposed (Zepp *et al.,* 2008). Reductions in water clarity affect light availability for corals. As turbidity and nutrients increase, thus decreasing water clarity, reef community composition shifts from coral-dominated to macroalgae-dominated, and ultimately to heterotrophic animals (Fabricius *et al.,* 2012). Light penetration is diminished by suspended abiotic and biotic particulate matter (especially clay and silt-sized particles) and some dissolved substances (Fabricius *et al.,* 2014). The availability of light decreases directly as a function of particle concentration and water depth, but also depends on the nature of the suspended particles. Fine clays and organic particles are easily suspended from the sea floor, reducing light for prolonged periods, while undergoing cycles of deposition and resuspension. Suspended fine particles also carry nutrients and other contaminants (Fabricius *et al.,* 2013). Increased nutrient runoff into semi-enclosed seas accelerates phytoplankton production to the point that it also increases turbidity and reduces light penetration, and can also settle on colony surfaces (Fabricius, 2005). In areas of nutrient enrichment, light for benthic organisms can be additionally severely reduced by dense stands of large fleshy macroalgae shading adjacent corals (Fabricius, 2005).

The literature provides several recommendations on maximum turbidity levels for coral reefs (*i.e.,* levels that managers should strive to stay under). GBRMPA (2010) recommends minimum mean annual water clarity, or ''trigger values'', in Secchi distances for the GBR depending on habitat type: For enclosed coastal reefs, 1.0–1.5 m; for open coastal reefs and mid-shelf reefs, 10 m; and for offshore reefs, 17 m. De'ath and Fabricius (2008) recommend a minimum mean annual water clarity trigger value in Secchi distance averaged across all GBR habitats of 10 m. Bell and Elmetri (1995) recommend a maximum value of 3.3 mg/L TSS across all GBR habitats. Thomas *et al.* (2003) recommend a maximum value of 10 mg/L averaged across all Papua New Guinea coral reef habitats. Larcombe *et al.* (2001) recommend a maximum value of 40 mg/L TSS for GBR ''marginal reefs'', *i.e.,* reefs close to shore with high natural turbidity levels. Guan *et al.* (2015) recommend a minimum light intensity (µmol photons second/m2) of 450 µmol photons second/m2 globally for coral reefs. The previously described generalizations are for coral reef communities and ecosystems, rather than individual species.

A coral's response to a reduction in water clarity is dependent on intensity and duration. For example, corals exhibited partial mortality when exposed to 476 mg/L TSS (Bengtsson *et al.,* 1996) for 96 hours, but had total mortality when exposed to 1000 mg/L TSS for 65 hours (Thompson and Bright, 1980). Depending on the duration of exposure, most coral species exhibited sublethal effects when exposed to turbidity levels between 7 and 40 NTU (Erftemeijer *et al.,* 2012). The most tolerant coral species exhibited decreased growth rates when exposed to 165 mg/L TSS for 10 days (Rice and Hunter, 1992). Turbidity reduces water clarity and so reduces the maximum depth at which corals can live, making deeper habitat unsuitable (Fabricius, 2005). Existing data suggest that coral reproduction and settlement are more highly sensitive to changes in water clarity than adult survival, and these functions are dependent on clear water. Suspended particulate matter reduces fertilization and sperm function (Ricardo *et al.,* 2015), and strongly inhibits larvae survival, settlement, recruitment, and juvenile survival (Fabricius, 2005).

In summary, water clarity deviations from local averages prevent or impede successful completion of all life history stages of the listed coral species. Identifying turbidity levels at which the conservation value of habitat for listed corals may be affected is inherently complex and influenced by taxa, exposure duration, and acclimatization to localized nutrient regimes, and other factors.

The water column may include levels of anthropogenically-introduced chemical contaminants that prevent or impede successful completion of all life history stages of the listed coral species. For the purposes of this rule, ''contaminants'' is a collective term to describe a suite of anthropogenically-introduced chemical substances in water or sediments that may adversely affect corals. The study of the effects of contaminants on corals is a relatively new field and information on sources and ecotoxicology is incomplete. The

major groups of contaminants that have been studied for effects to corals include heavy metals (also called trace metals), pesticides, and hydrocarbons. Other organic contaminants, such as chemicals in personal care products, polychlorinated biphenyl, and surfactants, have also been studied. Contaminants may be delivered to coral reefs via point or non-point sources. Specifically, contaminants enter the marine environment through wastewater discharge, shipping, industrial activities, and agricultural and urban runoff. These contaminants can cause negative effects to coral reproduction, development, growth, photosynthesis, and survival.

Heavy metals (*e.g.,* copper, cadmium, manganese, nickel, cobalt, lead, zinc, and iron) can be toxic at concentrations above naturally-occurring levels. Heavy metals are persistent in the environment and can bioaccumulate. Metals are adsorbed to sediment particles, which can result in their long distance transport away from sources of pollution. Corals incorporate metals in their skeleton and accumulate them in their soft tissue (Al-Rousan *et al.,* 2012; Barakat *et al.,* 2015). Although heavy metals can occur in the marine environment from natural processes, in nearshore waters they are mostly a result of anthropogenic sources (*e.g.,* wastewater, antifouling and anticorrosive paints from marine vessels and structures, land filling and dredging for coastal expansion, maritime activities, inorganic and organic pollutants, crude oil pollution, shipping processes, industrial discharge, agricultural activities), and are found near cities, ports, and industrial developments.

The effects of copper on corals include physiological impairment, impaired photosynthesis, bleaching, reduced growth, and DNA damage (Bielmyer *et al.,* 2010; Schwarz *et al.,* 2013). Effects to fertilization, larval development, larval swimming behavior, metamorphosis, and larval survival have also been documented (Kwok and Ang, 2013; Negri and Hoogenboom, 2011; Puisay *et al.,* 2015; Reichelt-Brushett and Hudspith, 2016; Rumbold and Snedaker, 1997). Toxicity of copper was found to be higher when temperatures are elevated (Negri and Hoogenboom, 2011). Nickel and cobalt can also have negative effects on corals, such as reduced growth and photosynthetic rates (Biscere *et al.,* 2015), and reduced fertilization success (Reichelt-Brushett and Hudspith, 2016). Chronic exposure of corals to higher levels of iron may significantly reduce growth rates Ferrier-Pages *et al.* (2001). Further, iron chloride has been found to cause oxidative DNA damage to coral larvae (Vijayavel *et al.,* 2012).

Polycyclic aromatic hydrocarbons (PAHs) are found in fossil fuels such as oil and coal and can be produced by the incomplete combustion of organic matter. PAHs disperse through non-point sources such as road run-off, sewage, and deposition of particulate air pollution. PAHs can also disperse from point sources such as oil spills and industrial sites. Studies have found effects of oil pollution on corals include growth impairments, mucus production, and decreased reproduction, especially at increased temperature (Kegler *et al.,* 2015). Hydrocarbons have also been found to affect early life stages of corals. Oil-contaminated seawater reduced settlement of *Orbicella faveolata* and of *Agaricia humilis* and was more severe than any direct or latent effects on survival (Hartmann *et al.,* 2015). Natural gas (water accommodated fraction) exposure resulted in abortion of larvae during early embryogenesis and early release of larvae during late embryogenesis, with higher concentrations of natural gas yielding higher adverse effects (Villanueva *et al.,* 2011). Oil, dispersant, and a combination of oil and dispersant on significantly decreased settlement and survival of *Porites astreoides* and *O. faveolata* larvae (Goodbody-Gringley *et al.,* 2013).

Anthracene (a PAH used in dyes, wood preservatives, insecticides, and coating materials) exposure to apparently healthy and diseased (Caribbean yellow band disease) fragments of *O. faveolata* reduced activity of enzymes important for protection against environmental stressors in the diseased colonies (Montilla *et al.,* 2016). The results indicated that diseased tissues might be more vulnerable to the exposure to PAHs such as anthracene than apparently healthy corals. PAH concentrations similar to those present after an oil spill inhibited metamorphosis of *Acropora tenuis* larvae, and sensitivity increased when larvae were co-exposed to PAHs and ''shallow reef'' UV light levels (Negri *et al.,* 2016).

Pesticides include herbicides, insecticides, and antifoulants used on vessels and other marine structures. Pesticides can affect non-target marine organisms like corals and their zooxanthellae. Diuron, an herbicide, decreased photosynthesis isolated zooxanthellae (Shaw *et al.,* 2012b). Irgarol, an additive in copper-based antifouling paints, significantly reduced settlement in *Porites hawaiiensis* (Knutson *et al.,* 2012). *Porites astreoides* larvae exposed to two major mosquito pesticide ingredients, naled and permethrin, for 18–24 hours showed differential responses. Concentrations of 2.96 µg/L or greater of naled significantly reduced larval survivorship. However, reduced larval survivorship was not detected in exposure of up to 6.0 µg/L of permethrin. Larval settlement, post-settlement survival, and zooxanthellae density were not impacted by any treatment (Ross *et al.,* 2015).

Benzophenone-2 (BP-2) is a chemical additive to personal care products (*e.g.,* shampoo, body lotions, soap, detergents), product coatings (oil-based paints, polyurethanes), acrylic adhesives, and plastics that protects against damage from ultraviolet light. It is released into the ocean through municipal and boat/ship wastewater discharges, landfill leachates, residential septic fields, and unmanaged cesspits. BP-2 is a known endocrine disruptor and a DNA mutagen, and its effects are worse in the light. It caused deformation of *Stylophora pistillata* larvae changing them from a motile planktonic state to a deformed sessile condition at low concentrations. It also caused increasing larval bleaching with increasing concentration (Downs *et al.,* 2014). Benzophenone-3 (BP-3; oxybenzone) is an ingredient in sunscreen and personal care products (*e.g.,* hair cleaning and styling products, cosmetics, insect repellent, soaps) that protects against damage from ultraviolet light. It enters the marine environment through swimmers and municipal, residential, and boat/ship wastewater discharges and can cause DNA mutations. Oxybenzone is a skeletal endocrine disruptor, and it caused larvae of *S. pistillata* to encase themselves in their own skeleton. Exposure to oxybenzone transformed *S. pistillata* larvae from a motile state to a deformed, sessile condition. Larvae exhibited an increasing rate of coral bleaching in response to increasing concentrations of oxybenzone (Downs *et al.,* 2016).

Polychlorinated biphenyls (PCBs) are environmentally stable, persistent organic pollutants that have been used as heat exchange fluids in electrical transformers and capacitors, and as additives in paint, carbonless copy paper, and plastics. They can be transported globally through the atmosphere, water, and food web. A study of the effects of the PCB Aroclor 1254 on the scleractinian coral *S. pistillata* found no effects on coral survival, photosynthesis, or growth; however, the exposure concentration

and duration may alter the expression of certain genes involved in important cellular functions (Chen *et al.,* 2012).

Surfactants are used as detergents and soaps, wetting agents, emulsifiers, foaming agents, and dispersants. Linear alkylbenzene sulfonate (LAS) is one of the most common surfactants in use. Biodegradation of surfactants can occur within a few hours to several days, but significant proportions of surfactants attach to suspended solids and remain in the environment. This sorption of surfactants onto suspended solids depends on environmental factors such as temperature, salinity, or pH. Exposure of *Pocillopora verrucosa* to LAS resulted in tissue loss on fragments. The combined effects of LAS exposure with increased temperature (+3°C to 31°C) resulted in greater tissue loss than LAS exposure alone (Kegler *et al.,* 2015).

In summary, there are multiple chemical contaminants that prevent or impede successful completion of all life history stages of the listed coral species. Identifying contaminant levels at which the conservation value of habitat for listed corals may be affected is inherently complex and influenced by taxa, exposure duration, and other factors.

As described previously, the best-available information shows coral reefs form on solid substrate but only within a narrow range of water column conditions that on average allow the deposition rates of corals to exceed the rates of physical, chemical, and biological erosion (*i.e.,* conducive conditions, Brainard *et al.,* 2005). However, as with all ecosystems, water column conditions are dynamic and vary over space and time. Therefore, we also describe environmental conditions in which coral reefs currently exist globally, thus indicating the conditions that may be tolerated by corals and allow at least for survival. To the extent tolerance conditions deviate in duration and intensity from conducive conditions, they may not support coral reproduction and recruitment, and reef growth, and thus would impair recovery of the species. Further, annually and spatially averaged-tolerance ranges provide the limits of the environmental conditions in which coral reefs exist globally (Guan *et al.,* 2015), but these conditions do not necessarily represent the conditions that may be tolerated by individual coral species. Individual species may or may not be able to withstand conditions within or exceeding the globally-averaged tolerance ranges for coral reefs, depending on the individual species' biology, local average conditions to which the species are acclimatized, and intensity and duration of exposure to adverse conditions. In other words, changes in the water column parameters discussed previously that exceed the tolerance ranges may induce adverse effects in a particular species. Thus, the concept of individual species' tolerance limits is a different aspect of water quality conditions compared to conditions that are conducive for formation and growth of reef structures.

These values presented in the previous summaries constitute the best available information at the time of this rulemaking. It is possible that future scientific research will identify species-specific values for some of these parameters that become more applicable to the seven listed coral species, though it is also possible that future species-specific research will document that conducive or tolerance ranges for the seven corals fall within these ranges. Because the ESA requires us to use the best scientific information available in conducting consultations under section 7, we will incorporate any such new scientific information into consultations when evaluating potential impacts to the critical habitat.

Need for Special Management Considerations or Protection

Specific areas within the geographical area occupied by a species may be designated as critical habitat only if they contain essential features that may require special management considerations or protection (16 U.S.C. 1532(5)(A)(i)(II). Special management considerations or protection are any methods or procedures useful in protecting physical or biological features for the conservation of listed species (50 CFR 424.02).

The proposed essential feature is particularly susceptible to impacts from human activity because of the relatively shallow water depth ranges of the seven listed corals (less than 40 m). The proximity of this habitat to coastal areas subject this feature to impacts from multiple activities, including, but not limited to, coastal and in-water construction, dredging and disposal activities, beach nourishment, stormwater run-off, wastewater and sewage outflow discharges, point and non-point source pollutant discharges, and fishery management. Further, the global oceans are being impacted by climate change from greenhouse gas emissions, particularly the tropical oceans in which the Indo-Pacific corals occur (van Hooidonk *et al.,* 2014). The impacts from these activities, combined with those from natural factors (*e.g.,* major storm events), significantly affect habitat for all life stages for these threatened corals. We conclude that the essential feature is currently and will likely continue to be negatively impacted by some or all of these factors.

Greenhouse gas emissions (*e.g.,* fossil fuel combustion) lead to global climate change and ocean acidification. These activities adversely affect the essential feature by increasing sea surface temperature and decreasing the aragonite saturation state. Coastal and in-water construction, channel dredging, and beach nourishment activities can directly remove the essential feature by dredging it or by depositing sediments on it, making it unavailable for settlement and recruitment of coral larvae or fragments. These same activities can impact the essential feature by creating turbidity during operations. Stormwater run-off, wastewater and sewage outflow discharges, and point and non-point source contaminant discharges can adversely impact the essential feature by allowing nutrients and sediments, as well as contaminants, from point and non-point sources, including sewage, stormwater and agricultural runoff, river discharge, and groundwater, to alter the natural levels in the water column. The same activities can also adversely affect the essential feature by increasing the growth rates of macroalgae, allowing them to preempt available recruitment habitat. Fishery management can adversely affect the essential feature if it allows for the reduction in the number of herbivorous fishes available to control the growth of macroalgae on the substrate.

Given these ongoing threats throughout the corals' habitat, we find that the essential feature may require special management considerations.

Specific Areas Containing the Essential Features Within the Geographical Areas Occupied by the Species

Our regulations state that each critical habitat area will be shown on a map, with more-detailed information discussed in the preamble of the rulemaking documents published in the **Federal Register** defined by specific limits using reference points and lines on standard topographic maps of the area, and referencing each area by the State, county, or other local governmental unit in which it is located (50 CFR 424.12(c)). Our regulations also state that when several habitats, each satisfying requirements for designation as critical habitat, are located in proximity to one another, an inclusive area may be designated as critical habitat (50 CFR 424.12(d)).

We identified 19 units within the geographical area occupied by the seven listed Indo-Pacific species confirmed in U.S. waters, at the time of listing, that contain the essential feature (Table 1): Four in American Samoa (Tutuila and Offshore Banks, Ofu and Olosega, Ta'u, and Rose Atoll); one in Guam (Guam and Offshore Banks); eight in CNMI (Rota, Aguijian, Tinian and Tatsumi Reef, Saipan and Garapan Bank, Farallon de Medinilla, Anatahan, Pagan, and Maug Islands and Supply Reef); and six in PRIA (Howland Island, Palmyra Atoll, Kingman Reef, Johnston Atoll, Wake Atoll, and Jarvis Island).

Within each of these 19 units, we delineated more specific areas that contain the essential feature using a 3-step process: (1) We reviewed available information on substrate and water quality parameters to determine where the essential feature occurs; (2) we established upper and lower depth limits for these areas depending on the species present; and (3) within the depth limits, we identified areas that may have the essential feature but are not necessary for the conservation of the listed species because they are artificial substrates or natural substrates that are consistently disturbed, and therefore do not qualify as critical habitat.

For step 1, determining specific areas that contain the essential feature, we reviewed available substrate and water quality data for each unit. For substrate, we used data and maps from two benthic habitat mapping programs that collect benthic data for coral reef ecosystems throughout the United States (these programs are also available to the public on their websites): (1) For habitat <20 m depth, the National Centers for Coastal Ocean Science's (NCCOS; *https://coastalscience.noaa.gov/*) provides data and maps (except for some of the PRIA); and (2) for habitat >20 m depth, the Pacific Islands Benthic Habitat Mapping Center (PIBHMC; *https://www.soest.hawaii.edu/pibhmc/cms/*) provides data and maps. These two complementary programs provide nearly complete, large-scale coverage of reef-building coral substrate in the U.S. Pacific Islands, except for some of the PRIA areas which are not included in the NCCOS database. For substrate and water quality information, we also used coral reef monitoring and status reports from the Pacific Islands Fisheries Science Center (PIFSC, *https://www.fisheries.noaa.gov/region/pacific-islands#science*) for the Mariana Islands (Brainard *et al.,* 2012; except for Farallon de Medinilla (FDM)) and American Samoa (Brainard *et al.,* 2008). For the PRIA, we used Miller *et al.* (2008). In contrast to substrate, data for water quality parameters are limited to a few of the parameters over a small overall portion of reef-building coral habitat within the area under consideration for critical habitat.

We applied step 2, establishing upper and lower depth limits for these areas, by using depth distribution information for the listed coral species that occur in each unit to delineate upper and lower depth limits for each unit. Because at least some, if not all, listed corals in each unit occur in shallow habitats (*e.g.,* reef flats), the upper depth limit for all units is mean low water, referred to here as zero (0) m depth. The lower depth limit for each unit is based on the deepest observed record of any listed species in that unit. As previously described in more detail in the Background section, based on the best currently available information, we consider the rangewide depth distributions of the seven listed species as follows: *A. globiceps,* 0 to 20 m; *A. jacquelineae,* 10 to 35 m; *A. retusa,* 0 to 10 m; *A. speciosa,* 12 to 40 m; *E. paradivisa,* 2 to 25; *I. crateriformis,* 0 to 12 m; and *S. aculeata,* 3 to 40 m. We used depth distributions for all listed Indo-Pacific species within U.S. waters combined as a comprehensive approach to establish a lower limit because most listed species have overlapping depth distributions, and depth distributions of these species are still not well known for many of the critical habitat units.

We next applied step 3 for each unit by identifying areas that may contain the essential feature, but are not necessary for the conservation of the listed species. There are two types of areas that may contain hard consolidated substrate and suitable water quality parameters, but are not considered necessary for the conservation of the species, and none, one, or both may occur in each unit: (1) artificial substrates; and (2) ''managed areas.'' Artificial substrates include any human-made structure, regardless of age or level of active management. Examples include, but are not limited to, fixed and floating structures, such as: Jetties, groins, breakwaters, fixed or floating AToNs, seawalls, wharves, boat ramps, fishpond walls, pipes, wrecks, mooring balls, docks, aquaculture cages, and other artificial substrates. Managed areas are areas where the substrate has been disturbed by management and will continue to be periodically disturbed by such management. Examples include, but are not limited to, dredged navigation channels, shipping basins, vessel berths, and AToN chain scour areas around anchor blocks. As noted previously, protecting artificial substrates and managed areas would not facilitate meeting our conservation goal of maintaining functional natural reef ecosystems on which the listed species depend. They do not provide stable natural environments for coral growth and settlement and therefore are not necessary for the conservation of the species.

NMFS is aware that dredging may result in sedimentation impacts beyond the actual dredge channel. To the extent that these impacts are persistent, are expected to recur whenever the channel is dredged and are of such a level that the areas in question have already been made unsuitable for coral, then NMFS expects that the federal action agency can assess and identify such areas during their pre-dredging planning and provide their rationale and information supporting this conclusion. To the extent that the federal action agency does so, NMFS proposes that these persistently impacted areas be considered part of the managed areas and excluded from critical habitat.

The application of the 3-step process to each of the 19 specific areas is described in more detail in the Draft Information Report. The resulting delineations of the specific areas are described in Appendix A of the report, and 17 of the 19 are described and shown in the maps at the end of this rule. The entireties of the other two specific areas (Wake and FDM) were determined to be ineligible by the 4(a)(3) analyses summarized below, and described and shown in the Draft Information Report (NMFS, 2019). These are the 19 specific areas to which the ESA section 4(a)(3) and 4(b)(2) analyses were applied. The essential feature is unevenly distributed throughout these 19 specific areas. Within these areas there exists a mosaic of habitats at relatively small spatial scales, some of which naturally contain the essential feature and some that do not. Further, within these large areas, specific managed areas as described previously also exist. If a location within one of these areas does not meet the definition of critical habitat (such as an area of soft substrate or a continuously managed area), it is not included in the designations. Due to the spatial scale at which the essential feature exists interspersed with these other habitats and disturbed areas, and the fact that the precise locations of the essential feature change over time (*e.g.,* seasonally, in response to storms, etc.), we are not able to more finely delineate the essential feature.

Unoccupied Critical Habitat Areas

We have not identified any unoccupied areas for designation of critical habitat. ESA section 3(5)(A)(ii) defines critical habitat to include specific areas outside the geographical area occupied by the species at the time of listing if the areas are determined by the Secretary to be essential for the conservation of the species. Regulations at 50 CFR 424.12(b)(2) specify that we will identify, at a scale determined to be appropriate, specific areas outside the geographical area occupied by the species that are essential for its conservation, considering the life history, status, and conservation needs of the species based on the best available scientific data.

The threats to these seven corals include ocean warming, ocean acidification, and other threats that are primarily caused by global climate change (Brainard *et al.,* 2011). We issued guidance in June 2016 on the treatment of climate change uncertainty in ESA decisions, which addresses critical habitat specifically (NMFS 2016). The guidance states that, when designating critical habitat, NMFS will consider proactive designation of unoccupied habitat as critical habitat when there is adequate data to support a reasonable inference that the habitat is essential for the conservation of the species because of the function(s) it is likely to serve as climate changes.

All seven of these species occur in the Coral Triangle, an area predicted to have rapid and severe impacts from climate change. As a response to changing conditions, these species may shift into previously unoccupied habitats as they become more suitable and as other parts of their range become less suitable in the future. However, the best information available currently does not support a reasonable inference that listed Indo-Pacific corals may expand into unoccupied areas within U.S. waters in the future due to changing climate conditions. In addition, coral reef areas within U.S. jurisdiction provide no more than about 2 percent of each listed species' total range. Without further information, we cannot support the notion that such a small area of unoccupied habitat at the range margin is essential to the conservation of the species.

Application of ESA Section 4(a)(3)(B)(i) (Military Lands)

Section 4(a)(3)(B)(i) of the ESA prohibits designating as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (DoD), or designated for its use, that are subject to an Integrated Natural Resources Management Plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary of Commerce determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.

Two INRMPs are applicable to proposed coral critical habitat: (1) The Navy's Joint Region Marianas INRMP (JRM INRMP), finalized and signed in 2019 (DoN, 2019); and (2) the Air Force's INRMP for Wake Island Air Field, Wake Atoll, Kokee Air Force Station, Kauai, Hawaii, and Mt. Kaala Air Force Station, Oahu, Hawaii (Wake INRMP), finalized and signed in 2017 (USAF, 2017). The JRM INRMP is a composite of management plans for many distinct DoD controlled areas in the Mariana Islands, including in Guam and CNMI (DoN, 2019).

Summaries of the analyses of whether these two INRMPs are likely to benefit the ESA-listed corals or their habitat in Guam and CNMI (JRM INRMP) and Wake (Wake INRMP) are provided below, following the four considerations outlined in the 2016 guidance for the 4(a)(3) and 4(b)(2) portions of critical habitat designations (81 FR 7413; February 11, 2016). These four considerations are: (1) The extent of the area and essential feature present in the area; (2) The type and frequency of use of the area by the listed species; (3) The relevant elements of the INRMP in terms of management objectives, activities covered, and best management practices, and the certainty that the relevant elements will be implemented; and (4) The degree to which the relevant elements of the INRMP will protect the habitat (essential feature) from the types of effects that would be addressed through a destruction-or-adverse-modification analysis.

JRM INRMP—Guam

In Guam, the JRM INRMP encompasses three marine areas that overlap with areas proposed for coral critical habitat (hereafter ''INRMP marine areas''): (1) Naval Base Guam—Main Base (NBG Main Base) Submerged Lands; (2) Naval Base Guam—Telecommunications Site (NBG TS) Submerged Lands; and (3) Andersen Air Force Base (AAFB) Submerged Lands. A summary of the analyses of whether the INRMP is likely to benefit the habitat of ESA-listed corals in each of these three INRMP marine areas is provided below, summarized from the full analyses in the Draft Information Report (NMFS, 2019).

With regard to the extent of the area and essential feature present: (1) The NBG Main Base Submerged Lands cover approximately 30,000 acres along the coastline from Orote Peninsula to Asan (described in the JRM INRMP, Section 5.3, DoN, 2019); (2) the NBG TS Submerged Lands cover approximately 19,500 acres on the northwestern side of Guam (described in the JRM INRMP, Section 8.3, DoN, 2019); and (3) AAFB Submerged Lands cover approximately 26,500 acres of Submerged Lands on the northern side of Guam (described in the JRM INRMP, Section 9.3, DoN, 2019). Each of the three INRMP marine areas includes extensive potential proposed critical habitat, as shown in Fig. 21 in the Draft Information Report (NMFS, 2019). Most or all of the potential proposed critical habitat within the three INRMP marine areas includes both the substrate and water quality components of the essential feature of coral critical habitat (*i.e.,* characteristics of substrate and water quality support coral life history, including reproduction, recruitment, growth, and maturation), based on information provided previously in the Guam section of the Draft Information Report (NMFS, 2019), the Guam chapter of PIFSC's coral reef monitoring report for the Mariana archipelago (Brainard *et al.,* 2012), and the INRMP (DoN, 2019).

With regard to use of the area by the listed species, the listed coral *Acropora globiceps* occurs within each of the three INRMP marine areas. Two other listed coral species, *Acropora retusa* and *Seriatopora aculeata,* have been recorded on Guam at one or two sites, and thus may also occur in one or more of the three INRMP marine areas (DoN, 2019).

With regard to the relevant elements of the INRMP, and certainty that the relevant elements will be implemented, the two parts of this step are addressed separately below. The relevant elements of the JRM INRMP for each INRMP marine area include: (1) For the NBG Main Base Submerged Lands, the INRMP includes a Coral Habitat Enhancement plan (Section 5.4.2.1), consisting of eight specific actions in three categories: (1) Monitoring and adaptive management (3 actions), (2) collaboration with local partners (3 actions), and (3) reduction of vessel impacts (2 actions); (2) for NBG TS Submerged Lands, the INRMP includes a Coral Habitat Enhancement plan (Section 8.4.2.1), consisting of a similar set of eight specific actions as for NBG Main Base; and (3) for AAFB Submerged Lands, the INRMP includes a Coral Habitat Enhancement plan (Section 9.4.2.1), consisting of a similar set of seven specific actions as for NBG Main Base, except that there is less focus on

reduction in vessel impacts because of the much lower vessel traffic there.

NMFS concludes that the Navy will implement the relevant elements of the JRM INRMP for the previously described three INRMP marine areas for three reasons:

(1) Clear and Recent Documentation—the 2019 JRM INRMP includes Coral Habitat Enhancement plans for INRMP marine areas in Guam, with clear strategies and actions that address the habitat conservation needs of ESA-listed corals within these areas. The JRM INRMP's Appendix D also includes annual reports describing how coral conservation efforts have been implemented in recent years. These new coral habitat conservation plans, as well as reports from recent years, clearly articulate how Navy is conserving coral habitat within the INRMP marine areas in Guam, and how it will do so in the future.

(2) Demonstration of Good Faith Efforts for Listed Corals—the Navy has already implemented coral habitat conservation projects that are beneficial to ESA-listed corals within some INRMP marine areas in Guam, as described in the INRMP annual reports in the JRM INRMP's Appendix D (DoN, 2019a), and listed in the Draft Information Report. Many of these projects have been ongoing for several years and are proactive, in that they were not required of the Navy by the ESA. For example, in Fiscal Year 2018 (Oct-18 to Sep-19, FY18), the following coral habitat conservation projects were carried out by the Navy within these waters: (1) 20 mooring buoys were installed within NBG Main Base submerged waters to prevent anchoring on its coral reefs; (2) monitoring of the impacts of coral bleaching and crown of thorns starfish on reef-building corals including listed species; (3) coral surveys of Apra Harbor including listed species; (4) translocation of corals from a dredging area within Apra Harbor (no listed corals); (5) water quality monitoring; and (6) environmental education and outreach (DoN, 2019a, Appendix D, FY18 Annual Report). Many of these projects have been ongoing for several years and are proactive, in that they were not required of the Navy by the ESA.

(3) History of Strong Conservation Work—the Navy has a long history of carrying out successful marine habitat conservation work on Guam, and often takes the initiative on conservation efforts whether requested by NMFS or FWS or not. For example, many of the coral habitat conservation projects in the 2019 JRM INRMP had already been started by the Navy before corals were listed in 2014, and were being done to improve conservation of marine resources on the island, regardless of whether they were required by Federal statute or not.

The coral habitat enhancement elements of the JRM INRMP described previously are expected to substantially reduce the types of effects within the three INRMP marine areas in Guam that would be addressed through the destruction-or-adverse-modification analysis. Navy would accomplish this primarily by using the results of its own monitoring program to develop and implement management actions to enhance coral habitat and measures to minimize the impacts of Navy's (and other DoD branches') actions in Guam on coral habitat within the INRMP marine areas, thereby benefiting listed corals and their habitat.

JRM INRMP—CNMI

In CNMI, the JRM INRMP encompasses two marine areas that overlap with areas considered for coral critical habitat: (1) The Tinian Marine Lease Area (Tinian MLA) Submerged Lands; and (2) the Farallon de Medinilla (FDM) Submerged Lands (DoN, 2019). A summary of the analyses of whether the INRMP is likely to benefit the habitat of ESA-listed corals in each of these two INRMP marine areas is provided below, summarized from the full analyses in the Draft Information Report (NMFS, 2019).

With regard to the extent of the area and essential feature present: (1) The Tinian MLA Submerged Lands cover approximately 47,500 acres surrounding the northern portion of Tinian (described in the JRM INRMP, Section 11.3, DoN, 2019); (2) the FDM Submerged Lands consists of approximately 25,000 acres surrounding FDM (described in the JRM INRMP, Section 12.3, DoN, 2019). Most or all of the potential proposed critical habitat within the two INRMP marine areas includes both the substrate and water quality components of the essential feature of coral critical habitat (*i.e.,* characteristics of substrate and water quality support coral life history, including reproduction, recruitment, growth, and maturation), based on information provided in the Tinian and FDM sections of the Draft Information Report (NMFS, 2019), the Tinian and FDM chapters of PIFSC's coral reef monitoring report for the Mariana archipelago (Brainard *et al.* 2012), and the INRMP (DoN, 2019).

With regard to use of the area by the listed species, the listed coral *Acropora globiceps* is distributed widely throughout the Tinian MLA Submerged Lands, and also occurs in the FDM Submerged Lands. One other listed coral species, *Acropora retusa,* has been recorded in the Tinian MLA Submerged Lands, but not in the FDM Submerged Lands. No other listed corals have been reported from either INRMP marine area (DoN, 2019; NMFS, 2019).

With regard to the relevant elements of the INRMP, and certainty that the relevant elements will be implemented, the two parts of this step are addressed separately below. The relevant elements of the JRM INRMP for each INRMP marine area include: (1) For the Tinian MLA Submerged Lands, the INRMP includes a Coral Habitat Enhancement plan, consisting three specific actions to enhance coral habitat by monitoring health and acute impacts (Section 11.4.2.1; DoN, 2019); and (2) for the FDM Submerged Lands, the INRMP includes marine habitat management actions, consisting of surveys and mapping of ESA-listed corals, coral reef, and other marine habitats within the area (Section 12.4.2; DoN, 2019). The INRMP also includes assessment of ESA-listed corals, as required by the 2015 biological opinion on the Navy's Mariana Islands Testing and Training program (Section 12.4.2.2; DoN, 2019).

NMFS concludes that the Navy will implement these relevant elements of the JRM INRMP for three reasons:

(1) Clear and Recent Documentation—the 2019 JRM INRMP includes Coral Habitat Enhancement plans for INRMP marine areas in CNMI (Tinian MLA, FDM Submerged Lands), with clear strategies and actions that address the habitat conservation needs of ESA-listed corals within these areas. The JRM INRMP's Appendix D also includes annual reports describing how coral conservation efforts have been implemented in recent years in INRMP marine areas in CNMI. These new coral habitat conservation plans, as well as reports from recent years, clearly articulate how Navy is conserving coral habitat within the INRMP marine areas in CNMI, and how it will do so in the future.

(2) Demonstration of Good Faith Efforts for Listed Corals—the Navy has already implemented coral projects that have the potential to benefit the habitat of ESA-listed corals within INRMP marina areas in CNMI (Tinian MLA, FDM Submerged Lands). For example, coral species presence and abundance surveys were conducted within the Tinian MLA in 2013 (DoN, 2014) and 2017 (DoN, 2017), and around FDM in 2012 (Smith and Marx, 2016) and 2017 (Carilli *et al.,* 2018). These surveys were not required by the ESA, and have the potential to benefit the habitat of ESA-

listed corals by providing information needed to better protect these areas in the future.

(3) History of Strong Conservation Work—the Navy has a long history of carrying out successful marine habitat conservation work in the Mariana Islands, and often takes the initiative on conservation efforts whether requested by NMFS or FWS or not. For example, many of the coral habitat conservation projects in the 2019 JRM INRMP had already been started by the Navy before corals were listed in 2014, and were being done to improve conservation of marine resources on the island, regardless of whether they were required by Federal statute or not. While the great majority of these projects have been implemented in Guam rather than CNMI, the JRM INRMP includes many plans for CNMI (as noted previously), and the same Navy office (Navy Facilities Marianas) is responsible for carrying out such work in both Guam and CNMI.

The coral habitat enhancement elements of the JRM INRMP described previously are expected to substantially reduce the types of effects within the two INRMP marine areas in CNMI that would be addressed through the destruction-or-adverse-modification analysis. Navy would accomplish this primarily by using the results of its own monitoring program to develop and implement management measures to minimize the impacts of Navy's (and other DoD branches') actions in CNMI on coral habitat within the INRMP marine areas, thereby benefiting listed corals and their habitat.

Wake INRMP

On Wake Atoll, the Wake INRMP (USAF, 2017) encompasses the entire area considered for coral critical habitat, as described and shown in the Draft Information Report (NMFS, 2019). A summary of the analyses of whether the INRMP is likely to benefit the habitat of ESA-listed corals in this INRMP marine area is provided below, summarized from the full analyses in the Draft Information Report (NMFS, 2019).

With regard to the extent of the area and essential feature present, the Wake INRMP marine area includes nearly 500,000 acres of Submerged Lands and waters within the lagoon and surrounding the atoll out to 12 nautical miles from the mean low water line (USAF 2017), and thus includes all reef-building corals and coral reefs associated with the atoll. Most or all of the potential proposed critical habitat within the INRMP marine area includes both the substrate and water quality components of the essential feature of coral critical habitat (*i.e.,* characteristics of substrate and water quality support coral life history, including reproduction, recruitment, growth, and maturation), based on information provided in the Wake section of the Draft Information Report (NMFS, 2019) and the INRMP (USAF, 2017).

With regard to use of the area by the listed species, the USFWS coral survey at Wake Atoll in August 2016 recorded colonies of both *Acropora globiceps* and *A. retusa* on the south side of Wake in the vicinity of the three sites (USFWS, 2017; USAF, 2017). Thus, we assume that at least these two listed species occur throughout much of this INRMP marine area. No other listed corals have been reported from Wake (USAF, 2017; NMFS, 2019).

With regard to the relevant elements of the INRMP, and certainty that the relevant elements will be implemented, the two parts of this step are addressed separately below. The relevant element of the Wake INRMP is the coral conservation component that was added to the INMRP in 2017 (Appendix S, Coral Conservation Actions at Wake Atoll; USAF, 2017), which is made up of four groups of actions, each of which include multiple projects: Water quality improvements (six projects), education and outreach (two projects), fisheries management (four projects), and physical DoD presence on Wake Atoll (three projects; USAF, 2017). The actions and projects are described in detail in the Draft Information Report (NMFS, 2019).

NMFS concludes that the Air Force will implement these relevant elements of the Wake INRMP for three reasons:

(1) Clear and Recent Documentation—the Wake INRMP includes a coral conservation plan (Appendix S) with a 4-pronged strategy (water quality improvement, outreach and education for Wake-based staff, fisheries management, and physical DoD presence on Wake Atoll *i.e.,* restriction of access and overall natural resource management) that comprehensively addresses the conservation needs of ESA-listed corals on Wake Atoll. This new official coral conservation plan clearly articulates how USAF is conserving corals on Wake, and how it will do so in the future.

(2) Demonstration of Good Faith Efforts for Listed Corals: USAF has already implemented projects on Wake for each of its 4-pronged coral conservation strategy, as explained in Appendix S of the Wake INRMP. For water quality improvement, in 2016 USAF began implementation of both the stormwater pollution prevention and invasive plant control projects. For outreach and education, in 2016 USAF revised the Wake Island Dive Club Charter to further reduce the potential impacts of recreational activities on corals. For fisheries management, in 2017 USAF updated its fishing rules, which are part of the Wake Island Operating Guidance (PSRC 2017) to prohibit the use of (1) cast nets on the exterior of the atoll, (2) anchoring on coral reef habitat, and (3) and trolling over coral reef habitat. For physical DoD presence on Wake Atoll, in 2016 USAF funded and provided logistical support for a FWS coral survey that documented two ESA-listed corals on the atoll for the first time.

(3) History of Strong Conservation Work—USAF has a long history of carrying out successful conservation work on Wake, and often takes the initiative on conservation efforts whether requested by NMFS or FWS or not. For example, many of the projects in the new INRMP's coral conservation strategy had already been started by USAF before corals were listed in 2014, and were being done to improve conservation of marine and terrestrial resources on the atoll, regardless of whether they were required by Federal statute or not. Likewise, in 2016, USAF funded and supported the FWS coral survey of the atoll, leading to the discovery of two ESA-listed corals. In addition, USAF has historically been an excellent conservation partner with NMFS and FWS, supporting a wide variety of marine and terrestrial conservation projects, and actively engaging both agencies in the INRMP planning and implementation process.

The coral conservation component of the Wake INRMP (Appendix S, Coral Conservation Actions at Wake Atoll; USAF, 2017) is expected to reduce both direct and indirect impacts to listed corals via minimization or avoidance of recreational impacts (fishing, diving, anchoring), and terrestrial impacts (*i.e.,* run-off from land-based activities; USAF, 2017). Thus, implementation of the Wake INRMP is likely to provide substantial protection to the essential feature of coral critical habitat (reproductive, recruitment, growth, and maturation habitat) within the INRMP marine area from the types of effects that would be addressed through critical habitat consultation, thereby benefiting listed corals and their habitat.

4(a)(3) Conclusion

Based on the analyses summarized previously and provided in the Draft Information Report (NMFS, 2019), implementation of the JRM INRMP (DoN, 2019) and the Wake INRMP (USAF, 2017) both are likely to benefit

the habitats of ESA-listed coral species within all INRMP marine areas on Guam, CNMI, and Wake. Thus, the potential proposed coral critical habitat within the INRMP marine areas on Guam, Tinian, FDM, and Wake are ineligible for coral critical habitat. The partial overlap of these INRMP marine areas with potential proposed coral critical habitat are shown in Figures 21 (Guam) and 22 (Tinian) of the Draft Information Report (NMFS, 2019). On FDM and Wake, the INRMP marine areas completely encompass all the potential proposed coral critical habitat, as shown in Figures 11 (FDM) and 19 (Wake) of the Draft Information Report (NMFS, 2019).

Application of ESA Section 4(b)(2)

Section 4(b)(2) of the ESA requires that we consider the economic impact, impact on national security, and any other relevant impact, of designating any particular area as critical habitat. Additionally, the Secretary has the discretion to consider excluding any area from critical habitat if (s)he determines that the benefits of exclusion (that is, avoiding some or all of the impacts that would result from designation) outweigh the benefits of designation based upon the best scientific and commercial data available. The Secretary may not exclude an area from designation if exclusion will result in the extinction of the species. Because the authority to exclude is discretionary, exclusion is not required for any particular area under any circumstances.

The ESA provides the U.S. Fish and Wildlife Service (USFWS) and NMFS (the Services) with broad discretion in how to consider impacts. (See, H.R. Rep. No. 95–1625, at 17, reprinted in 1978 U.S.C.C.A.N. 9453, 9467 (1978). Economics and any other relevant impact shall be considered by the Secretary in setting the limits of critical habitat for such a species. The Secretary is not required to give economics or any other relevant impact predominant consideration in his specification of critical habitat. The consideration and weight given to any particular impact is completely within the Secretary's discretion.). Courts have noted the ESA does not contain requirements for any particular methods or approaches. (See, *e.g., Bldg. Indus. Ass'n of the Bay Area et al.* v. *U.S. Dept. of Commerce et al.,* No. 13–15132 (9th Cir., July 7, 2015), upholding district court's ruling that the ESA does not require the agency to follow a specific methodology when designating critical habitat under section 4(b)(2)). For this proposed rule, we followed the same basic approach to describing and evaluating impacts as we have for several recent critical habitat rulemakings, as informed by our Policy Regarding Implementation of Section 4(b)(2) of the ESA (81 FR 7226, February 11, 2016).

The following sub-sections describe the economic, national security, and other relevant impacts that we projected would result from including the specific areas described previously in these proposed critical habitat designations. We considered these impacts when deciding whether to exercise our discretion to propose excluding particular areas from the designation. Both positive and negative impacts were identified and considered (these terms are used interchangeably with benefits and costs, respectively). Impacts were evaluated in quantitative terms where feasible, but qualitative appraisals were used where that is more appropriate.

The primary impacts of a critical habitat designation result from the ESA section 7(a)(2) requirement that Federal agencies ensure that their actions are not likely to result in the destruction or adverse modification of critical habitat, and that they consult with NMFS in fulfilling this requirement. Determining these impacts is complicated by the fact that section 7(a)(2) also requires that Federal agencies ensure their actions are not likely to jeopardize the species' continued existence. One incremental impact of designation is the extent to which Federal agencies modify their proposed actions to ensure that they are not likely to destroy or adversely modify the critical habitat beyond any modifications they would make because of listing and the jeopardy requirement. When the same modification would be required due to impacts to both the species and critical habitat, the impact of the designation is co-extensive with the ESA listing of the species (*i.e.,* attributable to both the listing of the species and the designation critical habitat). To the extent possible, our analysis identified impacts that were incremental to the proposed designations of critical habitat, meaning those impacts that are over and above impacts attributable to the species' listing or any other existing regulatory protections. Relevant, existing regulatory protections (including the species' listing) are referred to as the ''baseline'' and are also discussed in the following sections.

The following economic and national security impact analyses describe projected future Federal activities that would trigger section 7 consultation requirements because they may affect the essential feature, and consequently may result in economic or national security impacts. Additionally, these analyses describe broad categories of project modifications that may reduce impacts to the essential feature, and state whether the modifications are likely to be solely a result of the critical habitat designation or co-extensive with another regulation, including the ESA listing of the species. These analyses incorporate recent guidance provided in the final rule on 4(b)(2) analyses (81 FR 7413 February 11, 2016).

Economic Impacts

Economic impacts of the critical habitat designations result through implementation of section 7 of the ESA in consultations with Federal agencies to ensure their proposed actions are not likely to destroy or adversely modify critical habitat. These economic impacts may include both administrative and project modification costs. Economic impacts that may be associated with the conservation benefits of the designations are described later.

An economic impact analysis was conducted in 2016 on the proposed coral critical habitat that projected annual economic impacts during the 10-year period 2016–2025, as described in section 5.1 of the Draft Information Report. Due to a large number of uncertainties, low-end and high-end estimates of economic impacts were developed in terms of the incremental cost of implementing coral critical habitat in addition to the cost of section 7 consultations without critical habitat. A key uncertainty in estimating the economic impacts of coral critical habitat is the lack of critical habitat for any marine species in the affected areas, which means that the historic record of section 7 consultations in these areas does not provide a good predictor of either the future number of total consultations, or the proportion of formal vs. informal consultations resulting from coral critical habitat. Consequently, there is a very large difference between the low-end and high-end economic impact estimates. Low-end total incremental costs resulting from the listed corals' critical habitat are estimated at just under $350,000 over ten years, with an annualized cost of approximately $50,000. High-end total incremental costs are estimated at more than $13 million over 10 years, with an annualized cost of approximately $1.9 million, although this number is unrealistic, as explained below (Draft Information Report, section 5.1).

The high-end estimate is 40 times higher than the low-end estimate primarily because of the assumption that critical habitat would result in all

future coral consultations being formal, and that the resulting biological opinions would require modifications to all activities that would not be required in the absence of critical habitat. Critical habitat could only have a high-end level of economic impact if (1) all managed areas such as navigation channels, harbors, and marinas are included in critical habitat, as this is where the action areas for most activities requiring consultation would be located; and (2) the action areas contain the essential feature but not the listed corals, so formal consultation would be required solely because of critical habitat. However, managed areas are not included in the proposed critical habitat, as explained in the Specific Areas Containing the Essential Features Within the Geographical Areas Occupied by the Species section (although they were included in the economic impact analysis because that analysis began in 2015 before managed areas were excluded), thereby minimizing incremental impacts. In addition, a comparison of the projected annual Section 7 formal consultations in 2016–2025 vs. the actual formal consultations that occurred in 2016–2019 found that projected consultations were three times higher than actual consultations (NMFS, 2019, section 5.1). Thus, the likely economic impact of coral critical habitat is likely to be much closer to the low-end estimate than the high-end estimate.

Many studies describe the economic benefits of corals and coral reefs, such as fisheries, recreation, protection of coastal areas by reefs, and many others, as described in Appendix B of the Draft Information Report (NMFS, 2019). By furthering the conservation of the habitat of the listed coral species and associated coral reef species, the critical habitat designations has the potential to contribute to such economic benefits. The extent of the potential economic benefits of coral critical habitat depends on the level of additional protection provided. For example, certain activities such as dredging of navigation channels permitted by the U.S. Army Corps of Engineers (USACE) may be subject to project modifications to avoid adverse modification of critical habitat. These modifications would provide better protection of corals and coral reefs that may then provide economic benefits. Although the proportion of USACE-permitted activities that would be subject to modifications ranges from zero (low-end scenario) to approximately 85 percent (high-end scenario), as described previously, we anticipate the actual economic impacts to be much closer to the low-end than the high-end scenario, with corresponding reduction of potential economic benefits. However, we cannot quantify the anticipated level of economic benefits.

National Security Impacts

When a 4(b)(2) exclusion analysis is undertaken, the Secretaries are to determine if the benefits of exclusion outweigh the benefits of inclusion for a particular area. If so, they may exclude that area, unless they determine that the exclusion will result in the extinction of the species concerned. When DoD, DHS, or another Federal agency requests exclusion from critical habitat on the basis of national-security or homeland security impacts, it must provide a reasonably specific justification of an incremental impact on national security that would result from the designation of that specific area as critical habitat. That justification could include demonstration of probable impacts, such as impacts to ongoing border security, patrols and surveillance activities, or a delay in training or facility construction, as a result of compliance with section 7(a)(2) of the Act.

If the agency provides a reasonably specific justification, we will defer to the expert judgment of DoD, DHS, another Federal agency as to: (1) Whether activities on its lands or waters, or its activities on other lands or waters, have national security or homeland security implications; (2) the importance of those implications; and (3) the degree to which the cited implications would be adversely affected in the absence of an exclusion. In that circumstance, in conducting a discretionary 4(b)(2) exclusion analysis, we will give great weight to national-security and homeland-security concerns in analyzing the benefits of exclusion.

Outside of the JRM and Wake INRMP marine areas described in the 4(a)(3) section, four sites were requested for exclusion by DoD or USCG based on national security impacts, one in Guam and three in CNMI: The portion of the Navy's Ritidian Point Surface Danger Zone Complex outside of DoD Submerged Lands on Guam, two USCG anchorages on Tinian, and a system of six Navy anchorage berths on Saipan. For each of these four sites, the impacts to national security of designating the site as critical habitat were weighed against the benefits to the conservation of listed corals of designating the site as critical habitat. If impacts to national security outweigh benefits to conservation of the listed species, the site is excluded from critical habitat. If benefits to the conservation of the listed species outweigh impacts to national security, the site is not excluded from critical habitat. The full analysis of impacts vs. benefits is provided in the Draft Information Report (NMFS, 2019), and summarized below. The decision to exclude any sites from a designation of critical habitat is always at the discretion of NMFS. In no circumstances is an exclusion of any site required by the ESA (81 FR 7226, February 11, 2016).

For the Navy's Ritidian Point Surface Danger Zone complex, we conclude that the impacts to national security of including this area within critical habitat outweigh the conservation benefits of designation, thus we propose to exclude the site from coral critical habitat designation. The full rationale for excluding this site is provided in the Draft Information Report, section 5.2.1. The most important factors supporting this exclusion are that this area is a unique and important place for DoD activities, and the consultation requirements for critical habitat would place new demands on DoD both in terms of the consultation process as well as potential modifications to the DoD activities. The benefits of designating this low-use and remote habitat is reduced somewhat by the protections already afforded to some of the characteristics of the essential feature, and because DoD use of this area is likely to discourage other Federal activities that may otherwise require consultation. While DoD must still ensure that activities in this area are not likely to jeopardize the continued existence of listed corals, the exclusion of this area means DoD will not be required to consult to insure that its activities are not likely to adversely modify habitat or essential features within this area. Based on our best scientific judgment and acknowledging the small size of this area, and other safeguards that are in place (*e.g.,* protections already afforded listed corals under its listing and other regulatory mechanism), we conclude that exclusion of this area will not result in the extinction of the species.

For the USCG's Tinian anchorages (*i.e.,* Explosives Anchorages A and B on Tinian), we conclude that the conservation benefits of designation outweigh the impacts to national security of including this area within critical habitat, and therefore the anchorages are not excluded from coral critical habitat designation. The full rationale for not excluding this site is provided in the Draft Information Report, section 5.2.2. The factors

supporting denial of this exclusion request are that: (1) Coral critical habitat would not create a new consultation requirement for USCG at these sites in addition what is already required by the fact that some corals on Tinian are listed as threatened under the ESA; (2) even if coral critical habitat would create a new consultation requirement for USCG at these site, USCG did not provide enough information to demonstrate how national security would be impacted if critical habitat is designated in these areas; (3) the majority of the areas within the Tinian anchorages are already ineligible for critical habitat due to overlap with the Tinian Marine Lease Area, and most of the remaining areas of the two anchorages are shallow nearshore areas that provide no anchorage; (4) the portions of the anchorages that lie outside of the Tinian Marine Lease Area (*i.e.,* those areas that are still eligible for coral critical habitat) have no protection other than EFH; and (5) the portions of the anchorages that lie outside of the Tinian Marine Lease contain high quality coral habitat.

For the six Navy anchorage berths (L–19, L–32, L–44, L–47, L–62, and M–16) within the Saipan Military Prepositioned Squadron Anchorages site, we conclude that the impacts to national security of including these sites within critical habitat outweigh the conservation benefits of designation, and thus the six berths are proposed for exclusion from coral critical habitat designation. The full rationale for proposing to exclude this site is provided in the Draft Information Report, section 5.2.3. The most important factor supporting this exclusion is that coral critical habitat would create a new consultation requirement for the Navy at these sites in addition to what is already required by the fact that some corals on Saipan are listed as threatened under the ESA. The subsequent formal consultation would cause project delays and modifications that would impact the Military Sealift Command's mission, which is to provide logistics support to distant Navy, USMC, Army, and Air Force military forces for a wide range of national security related activities. The circumstances range from a rise in military tensions with other nations to the ability of the U.S. Government to respond to attacks on U.S. forces, the territory and people of the United States, and U.S. allies. The ability of the prepositioning fleet to provide a response to a threat to the U.S. requires quick transport and delivery of weapons, fuel, and supplies to U.S. military forces; thus delays and modifications at this site would result in substantial national security impacts. Conservation benefits of including the site in critical habitat could be substantial because the site has high quality and quantity of the essential feature with high potential to aid in the conservation of listed corals, for which critical habitat consultation could provide significant protection. However, no listed corals have been recorded within any of the six anchorage berths. While DoD must still insure that activities in this area are not likely to jeopardize the continued existence of listed corals, the exclusion of this area means DoD will not be required to consult to insure that its activities are not likely to adversely modify habitat or essential features within this area. Based on our best scientific judgment and acknowledging the small size of this area, and other safeguards that are in place (*e.g.,* protections already afforded listed corals under its listing and other regulatory mechanism), we conclude that exclusion of this area will not result in the extinction of the species.

Other Relevant Impacts

We identified three broad categories of other relevant impacts of this proposed critical habitat: Conservation benefits, both to the species and to society; impacts on governmental or private entities that are implementing existing management plans that provide benefits to the listed species; and educational and awareness benefits.

Conservation Benefits

The primary benefit of critical habitat designation is the contribution to the conservation and recovery of the seven corals. That is, in protecting the features essential to the conservation of the species, critical habitat directly contributes to the conservation and recovery of the species. This analysis contemplates three broad categories of benefits of critical habitat designation:

(1) Increased probability of conservation and recovery of the seven corals: The most direct benefits of the critical habitat designations stem from the enhanced probability of conservation and recovery of the seven corals. From an economics perspective, the appropriate measure of the value of this benefit is people's ''willingness-to-pay'' for the incremental change. While the existing economics literature is insufficient to provide a quantitative estimate of the extent to which people value incremental changes in recovery potential, the literature does provide evidence that people have a positive preference for listed species conservation, even beyond any direct (*e.g.,* recreation, such as viewing the species while snorkeling or diving) or indirect (*e.g.,* reef fishing that is supported by the presence of healthy reef ecosystems) use for the species.

(2) Ecosystem service benefits of coral reef conservation, in general: Overall, coral reef ecosystems, including those comprising populations of the seven corals, provide important ecosystem services of value to individuals, communities, and economies. These include recreational opportunities (and associated tourism spending in the regional economy), habitat and nursery functions for recreationally and commercially valuable fish species, shoreline protection in the form of wave attenuation and reduced beach erosion, and climate stabilization via carbon sequestration. The total annual economic value of coral reefs in U.S. Pacific Islands jurisdictions in 2012 has been summarized as: (1) American Samoa—$12 million/year, (2) Guam—$155 million/year, and (3) CNMI—$72 million/year (Brander and Van Beukering, 2013). Efforts to conserve the seven corals also benefit the broader reef ecosystems, thereby preserving or improving these ecosystem services and values.

Conservation benefits to each coral in all their specific areas are expected to result from the designations. Critical habitat most directly influences the recovery potential of the species and protects coral reef ecosystem services through its implementation under section 7 of the ESA. That is, these benefits stem from the implementation of project modifications undertaken to avoid destruction and adverse modification of critical habitat. Accordingly, critical habitat designation is most likely to generate the benefits discussed in those areas expected to be subject to additional recommendations for project modifications (above and beyond any conservation measures that may be implemented in the baseline due to the listing status of the species or for other reasons). In addition, critical habitat designation may generate ancillary environmental improvements and associated ecosystem service benefits (*i.e.,* to commercial fishing and recreational activities) in areas subject to incremental project modifications. While neither benefit can be directly monetized, existing information on the value of coral reefs provides an indication of the value placed on those ecosystems.

(3) Education and Awareness Benefits that May Result from the Designations: There is the potential for education and awareness benefits arising from the critical habitat designations. This

potential stems from two sources: (1) Entities that engage in section 7 consultation and (2) members of the general public interested in coral conservation. The former potential exists from parties who alter their activities to benefit the species or essential feature because they were made aware of the critical habitat designation through the section 7 consultation process. The latter may engage in similar efforts because they learned of the critical habitat designations through outreach materials. For example, NMFS has been contacted by diver groups in the Florida Keys who are specifically seeking the two ESA-listed Caribbean *Acropora* corals on dives and report those locations to NMFS, thus assisting us in planning and implementing coral conservation and management activities for those listed species. In our experience, designation raises the public's awareness that there are special considerations to be taken within the area.

Similarly, state and local governments may be prompted to enact laws or rules to complement the critical habitat designations and benefit the listed corals. Those laws would likely result in additional impacts of the designations. However, we are unable to quantify the beneficial effects of the awareness gained through, or the secondary impacts from state and local regulations resulting from the critical habitat designation.

Impacts to Governmental and Private Entities With Existing Management Plans Benefitting the Essential Features

Many previous critical habitat impact analyses evaluated the impacts of the designation on relationships with, or the efforts of, private and public entities involved in management or conservation efforts benefiting listed species. These analyses found that the additional regulatory layer of a designation could negatively impact the conservation benefits provided to the listed species by existing or proposed management or conservation plans.

There are a large number of Federal marine protected areas in American Samoa, Guam, CNMI, and the PRIA where coral critical habitat is being considered (Draft Information Report, Appendix B). Impacts of critical habitat designation on the agencies responsible for natural resource management planning of these areas depend on the type and number of Section 7 consultations that may result from the designation in the areas covered by those plans, as well as any potential project modifications recommended by these consultations. Negative impacts to these entities could result if the critical habitat designation interferes with these agencies' ability to provide for the conservation of the species, or otherwise hampers management of these areas. Existing or proposed management plans in the marine protected areas and their associated regulations protect existing coral reef resources, but they may not specifically protect the substrate and water quality feature for purposes of increasing listed coral abundance and eventual recovery.

However, most of these Federal marine protected areas are still developing management plans, especially the larger ones that include the most potential coral critical habitat (*e.g.,* the National Marine Monuments), thus it is not possible to determine at this time if and how they would be subject to Section 7 consultation due to potential effects on coral critical habitat. Therefore, it is not possible to determine at this time if and how the management of Federal marine protected areas in the Pacific Islands would be impacted by coral critical habitat.

Discretionary Exclusions Under Section 4(b)(2)

We are not exercising our discretion to consider exclusions based on economic impacts. As summarized in the Economic Impacts section, low-end total incremental costs resulting from the listed corals' critical habitats are estimated at just under $350,000 over 10 years, with an annualized cost of approximately $50,000. High-end total incremental costs are estimated at more than $13 million over 10 years, with an annualized cost of approximately $1.9 million. However, the likely economic impact of coral critical habitat is likely to be much closer to the low-end estimate than the high-end estimate.

We are proposing to exclude two particular areas from critical habitat on the basis of national security impacts: The Navy's Ritidian Point Surface Danger Zone complex in Guam, and the Navy's six anchorage berths within the Saipan Military Prepositioned Squadron Anchorages. For the Ritidian Point Surface Danger Zone complex, as summarized in the National Security Impacts section, substantial national security impacts would be expected because consultation requirements for critical habitat would place new demands on DoD both in terms of the consultation process as well as potential modifications to the DoD activities. Conservation benefits are expected to be low because very few Federal activities are likely to be proposed within this site. Thus, we conclude that impacts outweigh benefits, and the site is excluded from proposed critical habitat.

For the Saipan anchorage berths, as summarized in the National Security Impacts section, substantial national security impacts would be expected because formal consultation on anchoring would result in delays or changes to critical DoD activities at the site. Conservation benefits are expected to be substantial because the site has high quality and quantity of the essential feature with high potential to aid in the conservation of listed corals, for which critical habitat consultation could provide significant protection. In addition, non-DoD Federal actions may be proposed within the site, and critical habitat would address a unique management challenge for listed corals at the site. However, because of the substantial national security impacts, we conclude that impacts outweigh benefits, thus the site is excluded from proposed critical habitat.

While at this time we are not proposing to exclude the USCG's Tinian anchorages (*i.e.,* Explosives Anchorages A and B on Tinian) due to a lack of information demonstrating how national security would be impacted if critical habitat is designated in these areas. NMFS will take comments on and reconsider its decision as it pertains to this area consistent with the weighing factors, and provide final exclusion determinations for this request in the final rule.

We are not proposing to exclude any particular area based on other relevant impacts. Other relevant impacts include conservation benefits of the designations, both to the species and to society. Because the feature that forms the basis of the critical habitat designations is essential to the conservation of the seven threatened corals, the protection of critical habitat from destruction or adverse modification may at minimum prevent loss of the benefits currently provided by the species and their habitat, and may contribute to an increase in the benefits of these species to society in the future. While we cannot quantify nor monetize the benefits, we believe they are not negligible and would be an incremental benefit of these designations.

Proposed Critical Habitat Designations

Critical habitat must be defined by specific limits using reference points and lines as found on standard topographic maps of the area, and cannot use ephemeral reference points (50 CFR 424.12(c)). When several habitats, each satisfying the requirements for designation as critical

habitat, are located in proximity to one another, an inclusive area may be designated as critical habitat (50 CFR 424.12(d)).

The habitat containing the physical or biological feature that is essential to the conservation of the seven threatened Indo-Pacific corals and that may require special management considerations or protection, is marine habitat of particular depths for each species in American Samoa, Guam, CNMI, and PRIA. The boundaries of each of the 19 specific areas that were considered for proposed coral critical habitat were determined by the process described in the Specific Areas section of the Draft Information Report (NMFS, 2019) and summarized previously. Each specific area provides critical habitat for the one to six listed species known to occur in that area (see Table 1). After applying the 4(a)(3) analysis, the entireties of the FDM and Wake Units were found to be ineligible for critical habitat, leaving the 17 specific areas described below. Of those, portions of the Guam and Tinian Units were also found to be ineligible after applying the 4(a)(3) analysis. In addition, after applying the 4(b)(2) analysis, one site in the Guam Unit (the Navy's Ritidian Point Surface Danger Zone complex), and one site in the Saipan Unit (a group of six Navy berths: L–19, L–32, L–44, L–47, L–62, and M–16)) were excluded from critical habitat.

Occupied Critical Habitat Unit Descriptions

The 17 units of proposed coral critical habitat are briefly described below. Detailed descriptions and maps are provided in the regulatory text:

(1) Tutuila and Offshore Banks: All waters from 0–40 m depth around Tutuila and Offshore Banks, except the areas specified in section (d) of the regulatory text below.

(2) Ofu and Olosega: All waters 0–20 m depth around Ofu and Olosega Islands, except the areas specified in section (d) of the regulatory text below.

(3) Ta'u: All waters 0–20 m depth around Ta'u Island, except the areas specified in section (d) of the regulatory text below.

(4) Rose Atoll: All waters 0–20 m depth around Rose Atoll, except the areas specified in section (d) of the regulatory text below.

(5) Guam: All waters from 0–40 m depth around Guam and Offshore Banks, except the areas specified in section (d) of the regulatory text below, and the national security exclusion (Ritidian Point Surface Danger Zone complex) specified in section (e) of the regulatory text below.

(6) Rota: All waters 0–20 m depth around Rota Island, except the areas specified in section (d) of the regulatory text below.

(7) Aguijian: All waters 0–20 m depth around Aguijian Island, except as specified in section (d) of the regulatory text below.

(8) Tinian and Tatsumi Reef: All waters 0–20 m depth around Tinian and Tatsumi Reef, except the areas specified in section (d) of the regulatory text below.

(9) Saipan and Garapan Bank: All waters 0–40 m depth around Saipan and Garapan Bank, except the areas specified in section (d) of the regulatory text below, and the national security exclusion (six Navy berths) specified in section (e) of the regulatory text below.

(10) Anatahan: All waters 0–20 m depth around Anatahan Island, except as specified in section (d) of the regulatory text below.

(11) Pagan: All waters 0–20 m depth around Pagan Island, except as specified in section (d) of the regulatory text below.

(12) Maug Islands and Supply Reef: All waters 0–20 m depth around Maug Islands and Supply Reef, except as specified in section (d) of the regulatory text below.

(13) Howland Island: All waters 0–10 m depth around Howland Island, except as specified in section (d) of the regulatory text below.

(14) Palmyra Atoll: All waters 0–20 m depth around Palmyra Atoll, except the areas specified in section (d) of the regulatory text below.

(15) Kingman Reef: All waters 0–40 m depth around Kingman Reef, except as specified in section (d) of the regulatory text below.

(16) Johnston Atoll: All waters 0–10 m depth around Johnston Atoll, except the areas specified in section (d) of the regulatory text below.

(17) Jarvis Island: All waters 0–10 m depth around Jarvis Island, except as specified in section (d) of the regulatory text below.

Effects of Critical Habitat Designations

Section 7(a)(2) of the ESA requires Federal agencies, including NMFS, to ensure that any action authorized, funded, or carried out by the agency does not jeopardize the continued existence of any threatened or endangered species or destroy or adversely modify designated critical habitat. When a species is listed or critical habitat is designated, Federal agencies must consult with NMFS on any agency actions to be conducted in an area where the species is present and that may affect the species or its critical habitat. During the consultation, NMFS would evaluate the agency action to determine whether the action may adversely affect listed species or critical habitat and issue its findings in a biological opinion. If NMFS concludes in the biological opinion that the agency action would likely result in the destruction or adverse modification of critical habitat, NMFS would also recommend any reasonable and prudent alternatives to the action. Reasonable and prudent alternatives are defined in 50 CFR 402.02 as alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that would avoid the destruction or adverse modification of critical habitat.

Regulations at 50 CFR 402.16 require Federal agencies that have retained discretionary involvement or control over an action, or where such discretionary involvement or control is authorized by law, to reinitiate consultation on previously reviewed actions in instances in which (1) critical habitat is subsequently designated, or (2) new information or changes to the action may result in effects to critical habitat not previously considered in the biological opinion. Consequently, some Federal agencies may request reinitiation of consultation or conference with NMFS on actions for which formal consultation has been completed, if those actions may adversely modify or destroy designated critical habitat or adversely modify or destroy proposed critical habitat, respectively.

Activities subject to the ESA section 7 consultation process include activities on Federal lands or conducted by a Federal agency, and activities requiring a permit from a Federal agency or some other Federal action, including funding. In the marine and aquatic environments, activities subject to the ESA section 7 consultation process include activities in Federal waters and in state waters that (1) have the potential to affect listed species or critical habitat, and (2) are carried out by a Federal agency, need a permit or license from a Federal agency, or receive funding from a Federal agency. ESA section 7 consultation would not be required for Federal actions that do not affect listed species or critical habitat and for actions that are not federally funded, authorized, or carried out.

Activities That May Be Affected

Section 4(b)(8) of the ESA requires that we describe briefly, and evaluate in any proposed or final regulation to designate critical habitat, those activities that may adversely modify such habitat or that may be affected by such designation. As described in our Draft Information Report, a wide variety of Federal activities may require ESA section 7 consultation because they may affect the essential feature of critical habitat. Specific future activities will need to be evaluated with respect to their potential to destroy or adversely modify critical habitat, in addition to their potential to affect and jeopardize the continued existence of listed species. For example, activities may adversely modify the essential feature by removing or altering the substrate or reducing water clarity through turbidity. These activities would require ESA section 7 consultation when they are authorized, funded, or carried out by a Federal agency. Private entities may also be affected by these proposed critical habitat designations if they are undertaking a project that requires a Federal permit or receives Federal funding.

Categories of activities that may be affected by the designations include coastal and in-water construction, channel dredging, beach nourishment and shoreline protection, water quality management, protected area management, fishery management, aquaculture, military activities, shipwreck removal, scientific research and monitoring, and contaminants regulation. Further information is provided in our Draft Information Report (NMFS, 2019). Questions regarding whether specific activities will constitute destruction or adverse modification of critical habitat should be directed to us (see **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT**).

Public Comments Solicited

We request that interested persons submit comments, information, and suggestions concerning this proposed rule during the comment period (see **DATES**). We are soliciting comments or suggestions from the public, other concerned governments and agencies, the scientific community, industry, or any other interested party concerning this proposed rule, including any foreseeable economic, national security, or other relevant impact resulting from the proposed designations. We specifically are seeking comments on: Areas we are proposing for exclusion, including but not limited to the types of areas that qualify as managed area (*e.g.,* areas adjacent to dredged channels, nearshore placement areas); other areas not included and excluded; the identified geographic areas and depths occupied by the species; the physical and biological feature essential to the coral species' conservation and identification; and the Economic Impact Analysis and Initial Regulatory Flexibility Analysis (Appendices B and C of the Draft Information Report; NMFS, 2019) related to the low and high end estimates and any other costs that may be borne by small businesses directly. You may submit your comments and materials concerning this proposal by any one of several methods (see **ADDRESSES**). Copies of the proposed rule and supporting documentation are available at *https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-indo-pacific-corals,* at *www.regulations.gov,* or upon request (see **FOR FURTHER INFORMATION CONTACT**). We will consider all comments pertaining to this designation received during the comment period in preparing the final rule. Accordingly, the final designation may differ from this proposal.

Information Quality Act and Peer Review

The data and analyses supporting this proposed action have undergone a pre-dissemination review and have been determined to be in compliance with applicable information quality guidelines implementing the Information Quality Act (section 515 of Pub. L. 106–554). On July 1, 1994, a joint USFWS/NMFS policy for peer review was issued stating that the Services would solicit independent peer review to ensure the best biological and commercial data is used in the development of rulemaking actions and recovery plans under the ESA (59 FR 34270). In addition, on December 16, 2004, the Office of Management and Budget (OMB) issued its Final Information Quality Bulletin for Peer Review (Bulletin). The Bulletin was published in the **Federal Register** on January 14, 2005 (70 FR 2664), and went into effect on June 16, 2005. The primary purpose of the Bulletin is to improve the quality and credibility of scientific information disseminated by the Federal government by requiring peer review of ''influential scientific information'' and ''highly influential scientific information'' prior to public dissemination. ''Influential scientific information'' is defined as ''information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.'' The Bulletin provides agencies broad discretion in determining the appropriate process and level of peer review. Stricter standards were established for the peer review of ''highly influential scientific information,'' defined as information whose ''dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest.''

The information in the Draft Information Report (NMFS, 2019) supporting this proposed critical habitat rule is considered influential scientific information and is subject to peer review. To satisfy our requirements under the OMB Bulletin, we obtained independent peer review of the information used to draft this document and incorporated the peer review comments into this draft prior to dissemination of this proposed rulemaking. For this action, compliance with the OMB Peer Review Bulletin satisfies any peer review requirements under the 1994 joint peer review policy. Comments received from peer reviewers are available at *https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-indo-pacific-corals,* at *www.regulations.gov,* or upon request (see **FOR FURTHER INFORMATION CONTACT**).

Classification

Takings (Executive Order 12630)

Under E.O. 12630, Federal agencies must consider the effects of their actions on constitutionally protected private property rights and avoid unnecessary takings of property. A taking of property includes actions that result in physical invasion or occupancy of private property, and regulations imposed on private property that substantially affect its value or use. In accordance with E.O. 12630, this proposed rule would not have significant takings implications. A takings implication assessment is not required.

Executive Order 12866, Regulatory Planning and Review, and Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This rule has been determined to be significant for purposes of E.O. 12866 review. This proposed rulemaking is expected to be considered ''regulatory'' under E.O. 13771.

Low-end total incremental costs resulting from the listed corals' critical habitat are estimated at just under

$350,000 over ten years, with an annualized cost of approximately $50,000. High-end total incremental costs are estimated at more than $13 million over 10 years, with an annualized cost of approximately $1.9 million (Appendix B of the Draft Information Report; NMFS, 2019). The high-end estimate is 40 times higher than the low-end estimate primarily because of the assumption that critical habitat would result in all future coral consultations being formal, and that the resulting biological opinions would require modifications to all activities that would not be required in the absence of critical habitat. Critical habitat could only have a high-end level of economic impact if (1) all managed areas such as navigation channels, harbors, and marinas are included in critical habitat, as this is where the action areas for most activities requiring consultation would be located; and (2) the action areas contain the essential feature but not the listed corals, so formal consultation would be required solely because of critical habitat. However, managed areas are not included in the proposed critical habitat, as explained in the Specific Areas Containing the Essential Features Within the Geographical Areas Occupied by the Species section, thereby minimizing incremental impacts. In addition, a comparison of the projected annual Section 7 formal consultations in 2016–2025 vs. the actual formal consultations that occurred in 2016–2019 found that projected consultations were three times higher than actual consultations (NMFS, 2019, section 5.1). Thus, the likely economic impact of coral critical habitat is likely to be much closer to the low-end estimate than the high-end estimate.

A Draft Economic Report (Appendix B of the Draft Information Report; NMFS, 2019) and Draft ESA Section 4(b)(2) Report (the 4(b)(2) section of the Draft Information Report; NMFS, 2019) have been prepared to support the exclusion process under section 4(b)(2) of the ESA and our consideration of alternatives to this rulemaking. These supporting documents are available at *https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-indo-pacific-corals,* at *www.regulations.gov,* or upon request (see **FOR FURTHER INFORMATION CONTACT**).

Federalism (Executive Order 13132)

Pursuant to the Executive Order on Federalism, E.O. 13132, we determined that this proposed rule does not have significant federalism effects and that a federalism assessment is not required. However, in keeping with Department of Commerce policies and consistent with ESA regulations at 50 CFR 424.16(c)(1)(ii), we will request information for this proposed rule from Territorial resource agencies in American Samoa, Guam, and the CNMI. The proposed designations may have some benefit to state and local resource agencies in that the proposed rule more clearly defines the physical and biological feature essential to the conservation of the species and the areas on which that feature is found.

Energy Supply, Distribution, and Use (Executive Order 13211)

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking an action expected to lead to the promulgation of a final rule or regulation that is a significant regulatory action under E.O. 12866 and is likely to have a significant adverse effect on the supply, distribution, or use of energy. OMB Guidance on Implementing E.O. 13211 (July 13, 2001) states that significant adverse effects could include any of the following outcomes compared to a world without the regulatory action under consideration: (1) Reductions in crude oil supply in excess of 10,000 barrels per day; (2) reductions in fuel production in excess of 4,000 barrels per day; (3) reductions in coal production in excess of 5 million tons per year; (4) reductions in natural gas production in excess of 25 million cubic feet per year; (5) reductions in electricity production in excess of 1 billion kilowatt-hours per year or in excess of 500 megawatts of installed capacity; (6) increases in energy use required by the regulatory action that exceed any of the thresholds previously described; (7) increases in the cost of energy production in excess of one percent; (8) increases in the cost of energy distribution in excess of one percent; or (9) other similarly adverse outcomes. A regulatory action could also have significant adverse effects if it (1) adversely affects in a material way the productivity, competition, or prices in the energy sector; (2) adversely affects in a material way productivity, competition or prices within a region; (3) creates a serious inconsistency or otherwise interferes with an action taken or planned by another agency regarding energy; or (4) raises novel legal or policy issues adversely affecting the supply, distribution or use of energy arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866 and 13211.

This rule, if finalized, will not have a significant adverse effect on the supply, distribution, or use of energy. Therefore, we have not prepared a Statement of Energy Effects.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

We prepared an Initial Regulatory Flexibility Analysis (IRFA) pursuant to section 603 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601, *et seq.*). The IRFA analyzes the impacts to those areas where critical habitat is proposed, and is included as Appendix C of the Draft Information Report (NMFS, 2019), which is available at *https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-indo-pacific-corals,* at *www.regulations.gov,* or upon request (see **FOR FURTHER INFORMATION CONTACT**). The IRFA is summarized below, as required by section 603 of the RFA. The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities.

Consultations on in-water and coastal construction and dredging and disposal (as determined by the 4(b)(2) economic impact analysis in Appendix B of the draft Information Report) all have the potential to involve third parties, such as recipients of Clean Water Act section 404 permits. These activities were combined into one broad industry category that may experience impacts to small entities: In-Water and Coastal Construction and Dredging. This IRFA relies on the estimated incremental impacts resulting from the proposed critical habitat designation, as described in the 4(b)(2) economic impact analysis in Appendix B of the Draft Information Report (NMFS, 2019). To be consistent with this analysis, the IRFA provides low-end and high-end estimates of the impacts to small entities.

The low-end estimate assumes no incremental project modifications occur because baseline permit conditions and regulations would provide sufficient protection to avoid adverse modification of critical habitat. Impacts to small entities would be due solely to the additional administrative costs of considering the potential for adverse effects to critical habitat during section 7 consultations. In addition, the low-end estimate assumes that trends in the frequency of informal consultations over the next ten years will resemble those of the past ten years. The high-end estimate of the impacts to small entities assumes that there will be incremental project modification costs for future projects related to in-water and coastal construction and dredging and that all projected future actions will require formal consultations (Section 6.0 of Appendix B of Draft Information Report; NMFS, 2019).

For some projects related to in-water and coastal construction and dredging most of the administrative costs and project modification costs will likely either be borne directly by, or passed onto, Federal agencies. However, in order to present a conservative estimate of the impacts to small entities, this IRFA assumes that all administrative and project modification costs are borne by third parties rather than Federal agencies.

The low-end and high-end estimated impacts to small entities are summarized in Tables 1 and 2 in Appendix B of Draft Information Report (NMFS, 2019). Assuming all small entities bear an equal share of costs, the low-end estimated impacts per small entity per year ranges from $2,273 to $2,816, and the high-end estimated impacts per small entity per year ranges from $115,625 to $117,580 in CNMI, Guam, and American Samoa.

The low-end estimate of the total annualized incremental impacts of critical habitat designation to small entities across the three areas is about $39,000. These costs are distributed evenly among the approximate 16 entities expected to be subject to section 7 consultations each year. Per entity annualized impacts of critical habitat designation across the three areas are estimated to make up only 0.05 percent of the average annual revenues for a business engaged in in-water and coastal construction or dredging. The high-end estimate of the annualized impacts to small entities across the three areas is $1,819,000. Per entity annualized impacts of critical habitat designation across the three areas are estimated to make up 2.4 percent of annual revenues for each affected small entity.

The high-end estimate is almost certainly an overstatement of the costs borne by small entities. It is not likely that all projected future actions will require formal consultations, nor is it likely that one small entity would bear all the consultation costs. Moreover, the IRFA conservatively assumes that all administrative and project modification costs are borne by third parties rather than Federal agencies. On other hand, the low-end estimate likely overstates the number of small entities affected and possibly understates the costs borne by these entities. In other words, the scenarios in the IRFA present broad ranges of the number of potentially affected entities and associated revenue effects. The actual number of small entities affected and revenue effects are not expected to fall at either extreme end of the continuum. NMFS seeks comments on its analysis presented in the IRFA related to the low and high end estimates and any other costs that may be borne by small businesses directly.

Coastal Zone Management Act

We have determined that this action will have no reasonably foreseeable effects on the enforceable policies of American Samoa, Guam, and CNMI. Upon publication of this proposed rule, these determinations will be submitted for review by the responsible Territorial agencies under section 307 of the Coastal Zone Management Act [16 U.S.C. 1456].

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This proposed rule does not contain any new or revised collection of information. This rule, if adopted, would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

This proposed rule will not produce a Federal mandate. The designation of critical habitat does not impose a legally-binding duty on non-Federal government entities or private parties. The only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7 of the ESA. Non-Federal entities which receive Federal funding, assistance, permits or otherwise require approval or authorization from a Federal agency for an action may be indirectly affected by the designation of critical habitat, but the Federal agency has the legally binding duty to avoid destruction or adverse modification of critical habitat.

We do not anticipate that this rule, if finalized, will significantly or uniquely affect small governments. Therefore, a Small Government Action Plan is not required.

Consultation and Coordination With Indian Tribal Governments (Executive Order 13175)

The longstanding and distinctive relationship between the Federal and tribal governments is defined by treaties, statutes, executive orders, judicial decisions, and agreements, which differentiate tribal governments from the other entities that deal with, or are affected by, the Federal Government.

This relationship has given rise to a special Federal trust responsibility involving the legal responsibilities and obligations of the United States toward Indian Tribes and with respect to Indian lands, tribal trust resources, and the exercise of tribal rights. Pursuant to these authorities, lands have been retained by Indian Tribes or have been set aside for tribal use. These lands are managed by Indian Tribes in accordance with tribal goals and objectives within the framework of applicable treaties and laws. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, outlines the responsibilities of the Federal Government in matters affecting tribal interests. The proposed critical habitat designations for threatened Indo-Pacific corals are located in U.S. territories and therefore do not have tribal implications in accordance with Executive Order 13175.

References Cited

A complete list of all references cited in this rulemaking is available at *https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-indo-pacific-corals,* at *www.regulations.gov,* or upon request (see **FOR FURTHER INFORMATION CONTACT**). In addition, pdf copies of all cited documents are available upon request from the NMFS Pacific Islands Regional Office in Honolulu, HI (see **ADDRESSES**).

List of Subjects

50 CFR Part 23

Endangered and threatened species, Exports, Imports, Transportation.

50 CFR Part 226

Endangered and threatened species.

Dated: September 22, 2020.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, we propose to amend 50 CFR parts 223 and 226 as follows:

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

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

Authority: 16 U.S.C. 1531–1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

■ 2. In § 223.102(e), in the table, under the heading ''Corals'' revise the entries for ''*Acropora globiceps*'', ''*Acropora jacquelineae*'', ''*Acropora retusa*'', ''*Acropora speciosa*'', ''*Euphyllia paradivisa*'', ''*Isopora crateriformis*'', and ''*Seriatopora aculeata*''.

§ 223.102 Enumeration of threatened marine and anadromous species.

* * * * *

(e) * * *

Species [1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
*	*	*	*	*	*
Corals					
Coral, [no common name]	*Acropora globiceps*	Entire species	79 FR 53852, Sept. 10, 2014.	*226.228*	NA.
Coral, [no common name]	*Acropora jacquelineae*	Entire species	79 FR 53852, Sept. 10, 2014	*226.228*	NA.
*	*	*	*	*	*
Coral, [no common name]	*Acropora retusa*	Entire species	79 FR 53852, Sept. 10, 2014	*226.228*	NA.
Coral, [no common name]	*Acropora speciosa*	Entire species.	79 FR 53852, Sept. 10, 2014	*226.228*	NA.
Coral, [no common name]	*Euphyllia paradivisa*	Entire species	79 FR 53852, Sept. 10, 2014	*226.228*	NA.
Coral, [no common name]	*Isopora crateriformis*	Entire species.	79 FR 53852, Sept. 10, 2014	*226.228*	NA.
*	*	*	*	*	*
Coral, [no common name]	*Seriatopora aculeata*	Entire species	79 FR 53852, Sept. 10, 2014	*226.228*	NA.
*	*	*	*	*	*

[1] Species includes taxonomic species, subspecies, distinct population segments (DPSs) (for a policy statement, see 61 FR 4722; February 7, 1996), and evolutionarily significant units (ESUs) (for a policy statement, see 56 FR 58612; November 20, 1991).

PART 226—DESIGNATED CRITICAL HABITAT

■ 3. The authority citation for part 226 continues to read as follows:

Authority: 16 U.S.C. 1533.

■ 4. Add § 226.228 to read as follows:

§ 226.228 Critical habitat for *Acropora globiceps, Acropora jacquelineae, Acropora retusa, Acropora speciosa, Euphyllia paradivisa, Isopora crateriformis,* and *Seriatopora aculeata.*

Critical habitat is designated in the following jurisdictions for the following species as depicted in the maps below and described in paragraphs (a) through (e) of this section. The maps can be viewed or obtained with greater resolution (available at *https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-indo-pacific-corals*) to enable a more precise inspection of proposed critical habitat for *A. globiceps, A. jacquelineae, A. retusa, A. speciosa, E. paradivisa, I. crateriformis,* and *S. aculeata.*

(a) *Critical habitat locations.* Critical habitat is designated for the following species in the following jurisdictions:

TABLE 1 TO PARAGRAPH (a)

Species	State—counties (or other jurisdiction)
Acropora globiceps	American Samoa (AS), Guam (Gu), Commonwealth of the Northern Mariana Islands (CNMI), Pacific Remote Island Area (PRIA).
Acropora jacquelineae	AS.
Acropora retusa	AS, Gu, CNMI, PRIA.
Acropora speciosa	AS, PRIA.
Euphyllia paradivisa	AS.
Isopora crateriformis	AS.
Seriatopora aculeata	Gu, CNMI.

(b) *Critical habitat boundaries.* Except as noted in paragraphs (d) and (e) of this section, critical habitat for the seven species in the 17 units includes the following areas:

(1) Tutuila and Offshore Banks: All waters from 0–40 m depth around Tutuila and Offshore Banks, except the areas specified in paragraph (d) of this section.

(2) Ofu and Olosega: All waters 0–20 m depth around Ofu and Olosega Islands, except the areas specified in paragraph (d) of this section.

(3) Ta'u: All waters 0–20 m depth around Ta'u Island, except the areas specified in paragraph (d) of this section.

(4) Rose Atoll: All waters 0–20 m depth around Rose Atoll, except the areas specified in paragraph (d) of this section.

(5) Guam: All waters from 0–40 m depth around Guam and Offshore Banks, except the areas specified in paragraph (d) of this section, and the national security exclusion (the Navy's Ritidian Point Surface Danger Zone complex) specified in paragraph (e) of this section.

(6) Rota: All waters 0–20 m depth around Rota Island, except the areas specified in paragraph (d) of this section.

(7) Aguijian: All waters 0–20 m depth around Aguijian Island, except as specified in paragraph (d) of this section.

(8) Tinian and Tatsumi Reef: All waters 0–20 m depth around Tinian and Tatsumi Reef, except the areas specified in paragraph (d) of this section.

(9) Saipan and Garapan Bank: All waters 0–40 m depth around Saipan and Garapan Bank, except the areas specified in paragraph (d) of this section, and the national security exclusion (six Navy berths) specified in paragraph (e) of this section.

(10) Anatahan: All waters 0–20 m depth around Anatahan Island, except as specified in paragraph (d) of this section.

(11) Pagan: All waters 0–20 m depth around Pagan Island, except as specified in paragraph (d) of this section.

(12) Maug Islands and Supply Reef: All waters 0–20 m depth around Maug Islands and Supply Reef, except as specified in paragraph (d) of this section.

(13) Howland Island: All waters 0–10 m depth around Howland Island, except as specified in paragraph (d) of this section.

(14) Palmyra Atoll: All waters 0–20 m depth around Palmyra Atoll, except the areas specified in paragraph (d) of this section.

(15) Kingman Reef: All waters 0–40 m depth around Kingman Reef, except as specified in paragraph (d) of this section.

(16) Johnston Atoll: All waters 0–10 m depth around Johnston Atoll, except the areas specified in paragraph (d) of this section.

(17) Jarvis Island: All waters 0–10 m depth around Jarvis Island, except as specified in paragraph (d) of this section.

(18) Maps of the 17 units where critical habitat is proposed are provided below (all of Wake Atoll and Farallon de Medinilla are ineligible for critical habitat because of 4(a)(3)).

(c) *Essential feature.* The feature essential to the conservation of *A. globiceps, A. jacquelineae, A. retusa, A. speciosa, E. paradivisa, I. crateriformis,* and *S. aculeata* is: Reproductive, recruitment, growth, and maturation habitat. Sites that support the normal function of all life stages of the corals are natural, consolidated hard substrate or dead coral skeleton free of algae and sediment at the appropriate scale at the point of larval settlement or fragment reattachment, and the associated water column. Several attributes of these sites determine the quality of the area and influence the value of the associated feature to the conservation of the species:

(1) Substrate with presence of crevices and holes that provide cryptic habitat, the presence of microbial biofilms, or presence of crustose coralline algae;

(2) Reefscape with no more than a thin veneer of sediment and low occupancy by fleshy and turf macroalgae;

(3) Marine water with levels of temperature, aragonite saturation, nutrients, and water clarity that have been observed to support any demographic function; and

(4) Marine water with levels of anthropogenically-introduced (from humans) chemical contaminants that do not preclude or inhibit any demographic function.

(d) *Areas not included in critical habitat.* Critical habitat does not include the following particular areas where they overlap with the areas described in paragraphs (a) through (c) of this section:

(1) Pursuant to ESA section 4(a)(3)(B), all areas subject to the 2017 Wake Island and 2019 Joint Region Marianas Integrated Natural Resources Management Plans.

(2) Pursuant to ESA section 3(5)(A)(i)(I), areas where the essential feature does not occur;

(3) Pursuant to ESA section 3(5)(A)(i)(I), all managed areas that may contain natural hard substrate but do not provide the quality of substrate essential for the conservation of threatened corals. Managed areas that do not provide the quality of substrate essential for the conservation of the seven Indo-Pacific corals are defined as particular areas whose consistently disturbed nature renders them poor habitat for coral growth and survival over time. These managed areas include specific areas where the substrate has been disturbed by planned management authorized by local, territorial, state, or Federal governmental entities at the time of critical habitat designation, and will continue to be periodically disturbed by such management. Examples include, but are not necessarily limited to, dredged navigation channels, shipping basins, vessel berths, and active anchorages;

(4) Pursuant to ESA section 3(5)(A)(i), artificial substrates including but not limited to: Fixed and floating structures, such as aids-to-navigation (AToNs), seawalls, wharves, boat ramps, fishpond walls, pipes, submarine cables, wrecks, mooring balls, docks, aquaculture cages;

(5) Areas not included in critical habitat on Tutuila.

(i) Critical habitat does not include two areas where the essential feature does not occur: Inner Pago Pago Harbor: West of line between Nuutatai Point (−14.276621, −170.680441) and Trading Point (−14.270756, −170.684961) on Map 10 of NOAA Chart 83484; and Pala Lagoon: West of line between Coconut Point (−14.322021, −170.702835) and the airport tarmac (−14.324714, −170.699535).

(ii) Critical habitat does not include managed areas, including but not limited to: USACE-managed small boat harbors, basins, and navigation channels (areas within ''Federal Project Limits'' indicated in Hydrographic Surveys for Aunu'u and Auasi Small Boat Harbors on USACE Honolulu District Civil Works' website); the seawall breakwaters, and areas lying between the ''Federal Project Limits'' and seawall breakwaters; all other harbors, navigation channels, turning basins, and berthing areas that are periodically dredged or maintained; all seawall breakwaters, areas lying between the managed areas and seawall breakwaters, and a 25 m radius of substrate around each of the AToN bases.

(iii) Critical habitat does not include artificial substrates, including but not limited to: The 11 USCG-managed fixed and floating AToNs, USACE-managed seawalls (Afono, Aoa, Lepua, Masefau, Matafao, Paloa, Vatia, Pago Pago to Nuuuli, and Pago Pago Airport Shore Protection and Beach Erosion Control Projects, as described on USACE Honolulu District Civil Works' website); and all other AToNs, seawalls, wharves, docks, boat ramps, moorings, pipes, wrecks, and other artificial structures.

(6) Areas not included in critical habitat on Ofu and Oloseg.

(i) Critical habitat does not include managed areas, including but not limited to: The USACE-managed Ofu Small Boat Harbor and navigation channel (areas within ''Federal Project Limits'' indicated in Hydrographic Surveys for the Ofu Small Boat Harbor on USACE Honolulu District Civil Works' website); the seawall breakwaters, areas lying between the Federal Project Limits and seawall breakwaters, and a 25 m radius of substrate around each of the AToN bases.

(ii) Critical habitat does not include artificial substrates, including but not limited to: The two USCG-managed fixed and floating AToNs, USACE-managed Ofu Airstrip Shore Protection Project, as described on USACE Honolulu District Civil Works' website; and all other AToNs, seawalls, wharves, docks, boat ramps, moorings, pipes, wrecks, and other artificial structures.

(7) Areas not included in critical habitat on Ta‘u.

(i) Critical habitat does not include managed areas, including but not limited to: The USACE-managed Ta'u Small Boat Harbor and navigation channel (areas within ''Federal Project Limits'' indicated in Hydrographic Surveys for Ta'u Small Boat Harbor on USACE Honolulu District Civil Works' website); the seawall breakwaters, areas lying between the Federal Project Limits and seawall breakwaters, and a 25 m radius of substrate around each of the AToN bases.

(ii) Critical habitat does not include artificial substrates including but not limited to: The four USCG-managed fixed and floating AToNs, all other AToNs, seawalls, wharves, docks, boat

ramps, moorings, pipes, wrecks, and other artificial structures.

(8) Areas not included in critical habitat on Rose Atoll.

(i) Critical habitat does not include the lagoon because it lacks the essential feature.

(ii) Critical habitat does not include any managed areas or artificial substrates.

(9) Areas not included in critical habitat on Guam.

(i) Critical habitat does not include three INRMP marine areas:

(A) NBG Main Base Submerged Lands;

(B) NBG TS Submerged Lands; and

(C) AAFB Submerged Lands.

(ii) Critical habitat does not include managed areas, including but not limited to: The Guam Port Authority harbors, basins, and navigation channels; Navy-managed Apra Harbor basins, and navigation channels, and the seawall breakwaters; USACE-managed small boat harbors, basins, and navigation channels (areas within ''Federal Project Limits'' indicated in Hydrographic Surveys for Agat and Agana Small Boat Harbors on USACE Honolulu District Civil Works' website); the seawall breakwaters, and areas lying between the Federal Project Limits and seawall breakwaters; all other channels, turning basins, and berthing areas that are periodically dredged or maintained, and 25 m radius of substrate around each of the AToN bases.

(iii) Critical habitat does not include artificial substrates, including but not limited to: The USCG-managed 32 fixed and floating AToNs; USACE-managed seawalls (Asquiroga Bay Shoreline Protection Project and marine components of the Namo River Flood Control project, as described on USACE Honolulu District Civil Works' website); Territory-managed boat ramps, including at Agana, Merizo, Seaplane Ramp in Apra Harbor, Umatac, and Agat; all other AToNs, seawalls, wharves, docks, boat ramps, moorings, pipes, wrecks, and other artificial structures.

(10) Areas not included in critical habitat on Rota.

(i) Critical habitat does not include managed areas, including but not limited to: The USACE-managed Rota Harbor and navigation channel (areas within ''Federal Project Limits'' indicated in Hydrographic Surveys for the Rota Harbor on USACE Honolulu District Civil Works' website); the seawall breakwaters, areas lying between the Federal Project Limits and seawall breakwaters, and a 25 m radius of substrate around each of the AToN bases.

(ii) Critical habitat does not include artificial substrates, including but not limited to: The two USCG-managed fixed AToNs; the Territory-managed boat ramp at Rota Harbor; all other AToNs, seawalls, wharves, docks, boat ramps, moorings, pipes, wrecks, and other artificial structures.

(11) Critical habitat does not include any managed areas or artificial substrates on Aguijian.

(12) Areas not included in critical habitat on Tinian and Tatsumi Reef.

(i) Critical habitat does not include the Tinian MLA Submerged Lands.

(ii) Critical habitat does not include managed areas, including but not limited to: Tinian Harbor and navigation channel as shown on NOAA Navigation Chart 81067, the seawall breakwater, and a 25 m radius of substrate around each of the AToN bases.

(iii) Critical habitat does not include artificial substrates, including but not limited to: The six USCG-managed fixed AToNs, the Territory-managed boat ramp at Tinian Harbor, all other AToNs, seawalls, wharves, docks, boat ramps, moorings, pipes, wrecks, and other artificial structures.

(13) Areas not included in critical habitat on Saipan and Garapan Bank.

(i) Critical habitat does not include the Commonwealth Ports Authority harbors, basins, and navigation channels, their seawall breakwaters; all other channels, turning basins, berthing areas that are periodically dredged or maintained, and a 25 m radius of substrate around each of the AToN bases.

(ii) Critical habitat does not include artificial substrates, including but not limited to: The 15 USCG-managed fixed AToNs, Territory-managed boat ramps at Smiling Cove (Garapan), Sugar Dock (Chalan Kanoa), Tanapag, Fishing Base (Garapan), and Lower Base (Tanapag); and all other AToNs, seawalls, wharves, docks, boat ramps, moorings, pipes, wrecks, and other artificial structures.

(14) Critical habitat does not include any managed areas or artificial substrates on Anatahan, Pagan, Maug Islands and Supply Reef, or Howland Island.

(18) Areas not included in critical habitat on Palmyra Atoll.

(i) Critical habitat does not include managed areas, including but not limited to: The main channel into the lagoon, dredged area in the central lagoon, and other channels and areas that are periodically dredged or maintained.

(ii) Critical habitat does not include artificial substrates, including but not limited to: Seawalls, wharves, docks, boat ramps, moorings, pipes, wrecks, and other artificial structures.

(16) Critical habitat does not include any managed areas or artificial substrates on Kingman Reef.

(17) Areas not included in critical habitat on Johnston Atoll.

(i) Critical habitat does not include managed areas, including but not limited to: The main channel around Johnston Island, and other dredged channels and areas.

(ii) Critical habitat does not include artificial substrates, including but not limited to: Seawalls, wharves, docks, boat ramps, moorings, pipes, wrecks, and other structures.

(18) Critical habitat does not include managed areas or artificial substrates Jarvis Island.

(e) *Areas excluded from critical habitat.* Pursuant to ESA section 4(b)(2), the following areas are excluded from critical habitat:

(1) On Guam, the marine component of the Navy's complex of overlying Surface Danger Zones off of Ritidian Point, delineated from point 144°51′18″ W, 13°39′5″ S on the shoreline to point 144°51′27″ W, 13°39′34″ S at 40 m depth, then along the 40 m depth contour to point 144°53′1″ W, 13°39′8″ S, then to point 144°52′49″ W, 13°38′38″ S on the shoreline, then along the shoreline back to the original point of 144°51′18″ W, 13°39′5″ S on the shoreline.

(2) On Saipan, Naval anchorage berths off the west coast known as L–62 (circle with radius approximately 366 m around center point 15°11′4.9194″ N 145°39′41.7594″ E), L–32 (circle with radius approximately 366 m around center point 15°12′13.6794″ N 145°41′33.3594″ E), L–44 (circle with radius approximately 366 m around center point 15°11′40.1994″ N 145°40′37.5594″ E), L–47 (circle with radius approximately 366 m around center point 15°11′27.2394″ N 145°41′30.1194″ E), L–19 (circle with radius approximately 366 m around center point 15°12′53.64″ N 145°40′53.3994″ E), and M–16 (circle with radius approximately 488 m around center point 15°12′36″ N 145°39′34.9194″ E).

(f) *Critical habitat maps.* Maps of the 17 units of proposed Indo-Pacific coral critical habitat.

BILLING CODE 3510–22–P

Figure 1 to paragraph (f) – Tutuila and Offshore Banks.

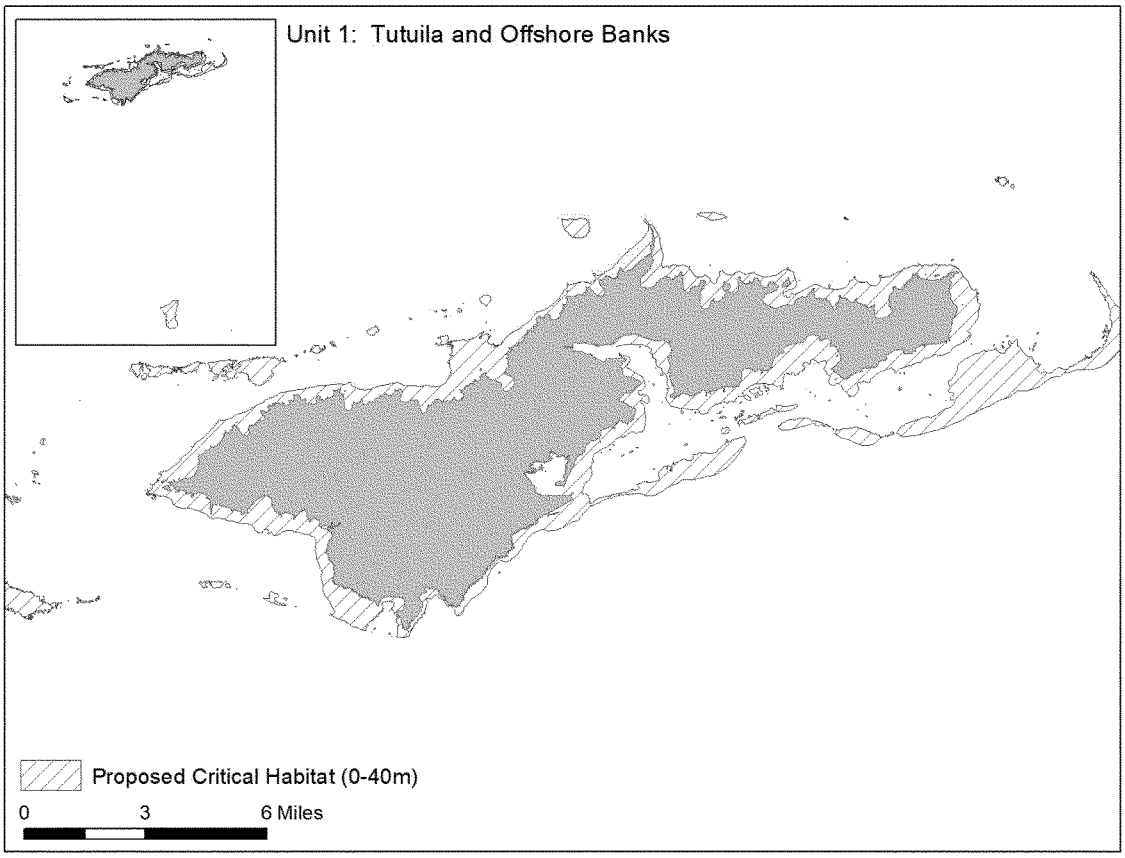

Figure 2 to paragraph (f) – Ofu and Olosega

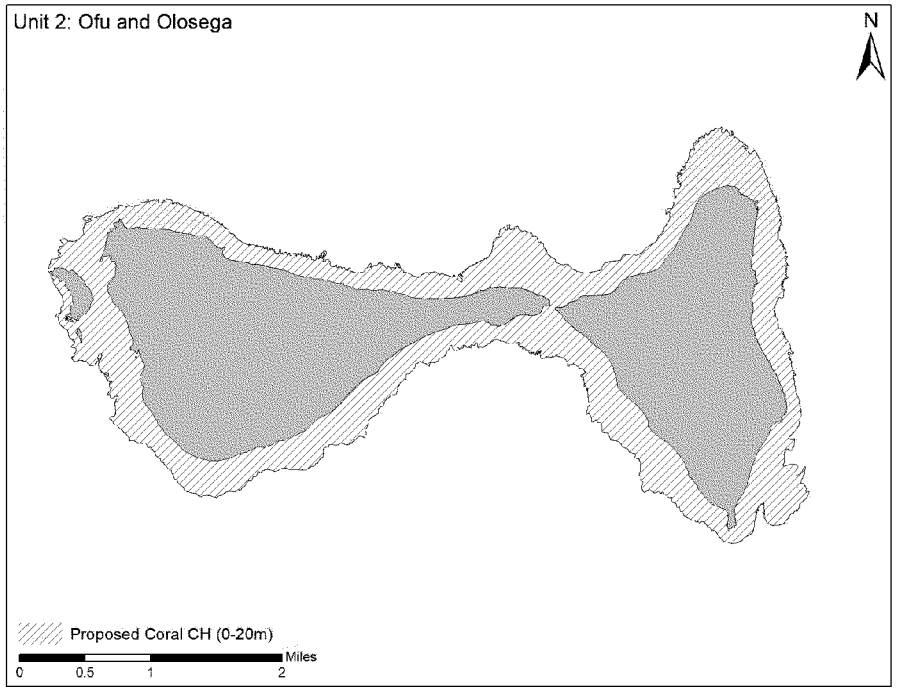

Figure 3 to paragraph (f) – Ta`u

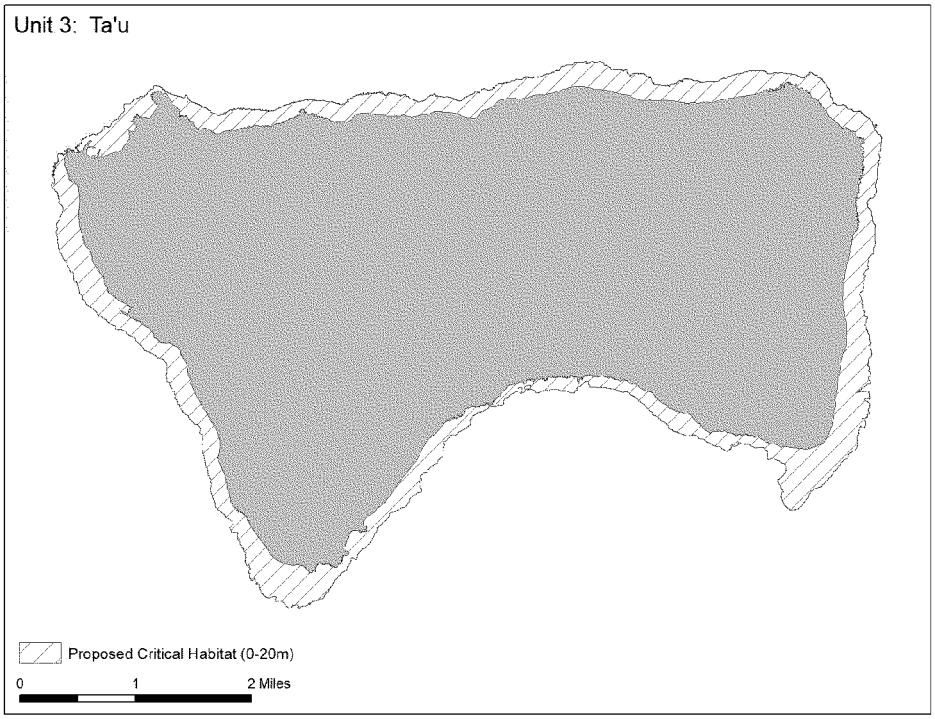

Figure 4 to paragraph (f) – Rose Atoll

Figure 5 to paragraph (f) – Guam

Figure 6 to paragraph (f) – Rota

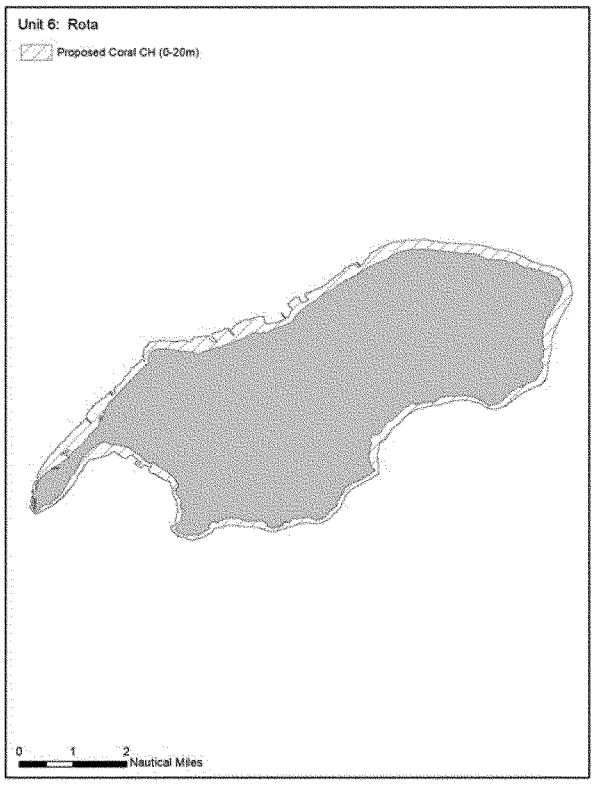

Figure 7 to paragraph (f) – Aguijan

Figure 8 to paragraph (f) – Tinian and Tatsumi Reef

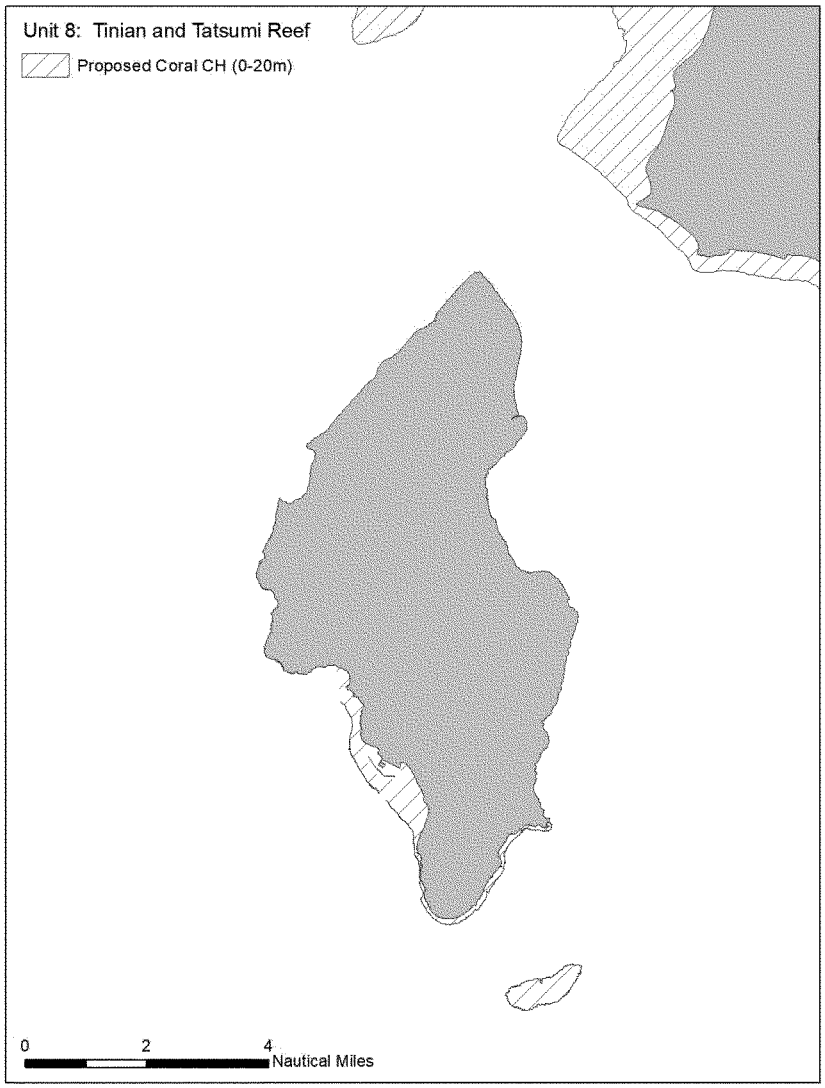

Figure 9 to paragraph (f) – Saipan and Garapan Bank

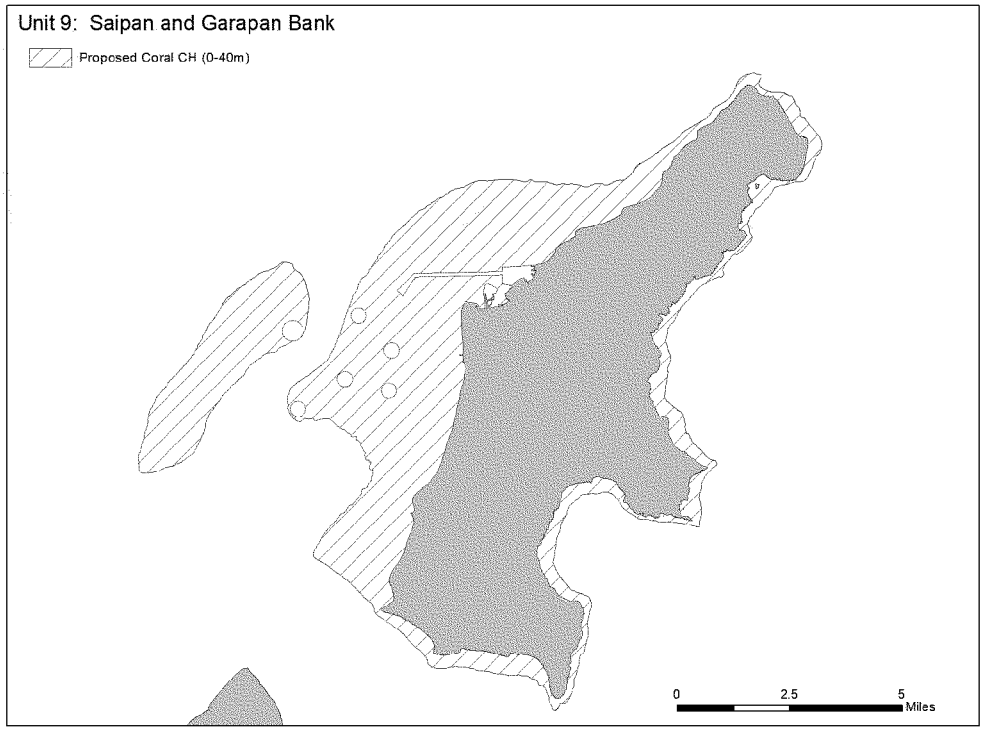

Figure 10 to paragraph (f) – Anatahan

Figure 11 to paragraph (f) – Pagan

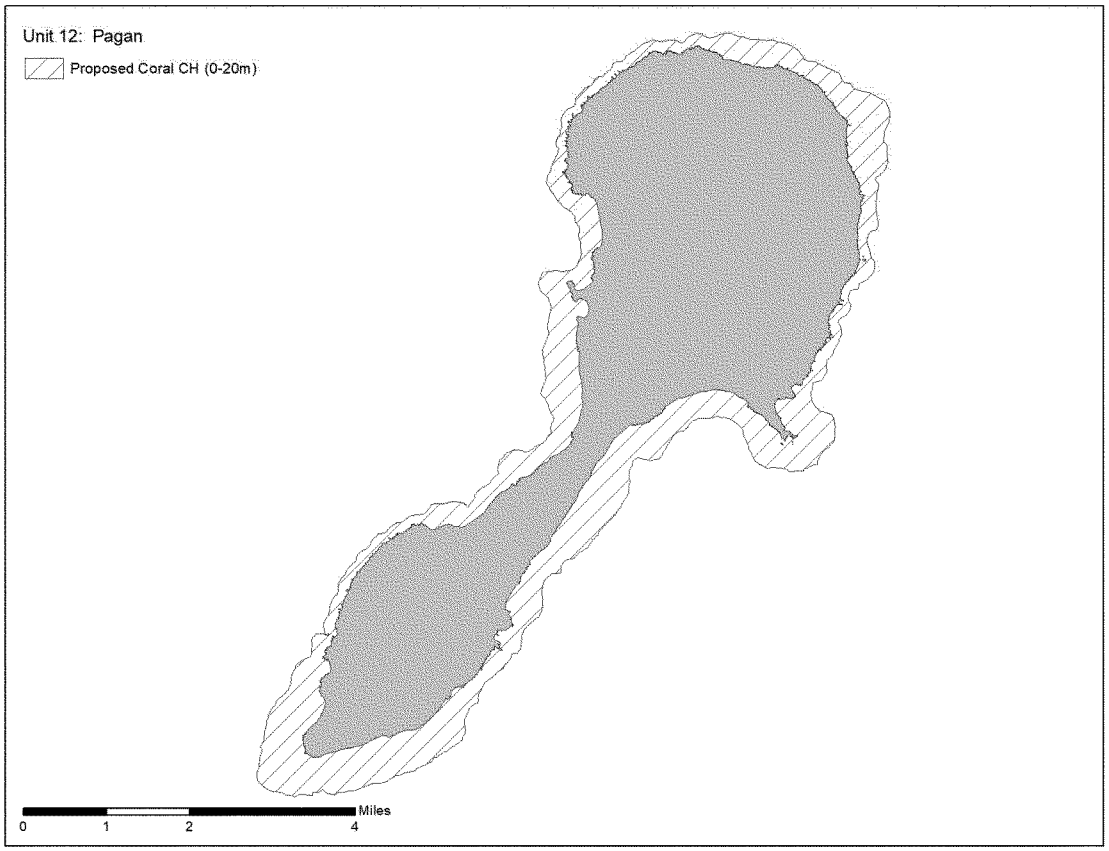

Figure 12 to paragraph (f) – Maug Islands and Supply Reef

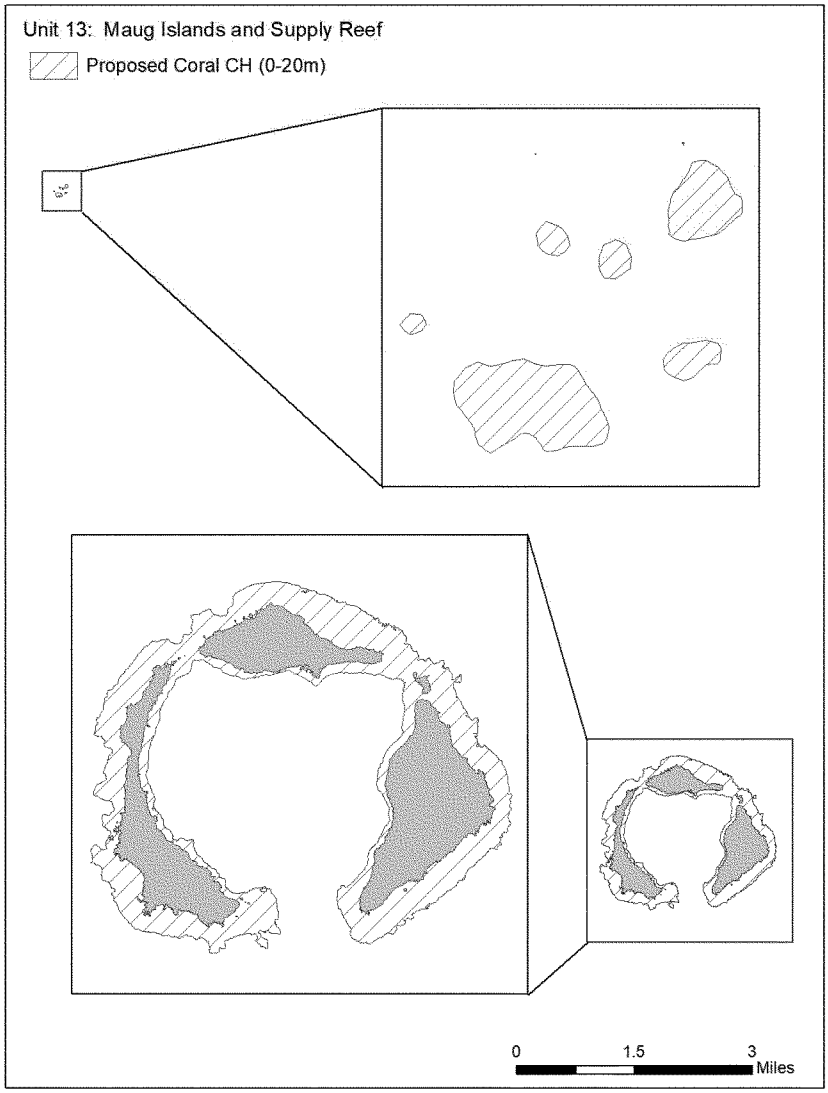

Figure 13 to paragraph (f) – Howland Island

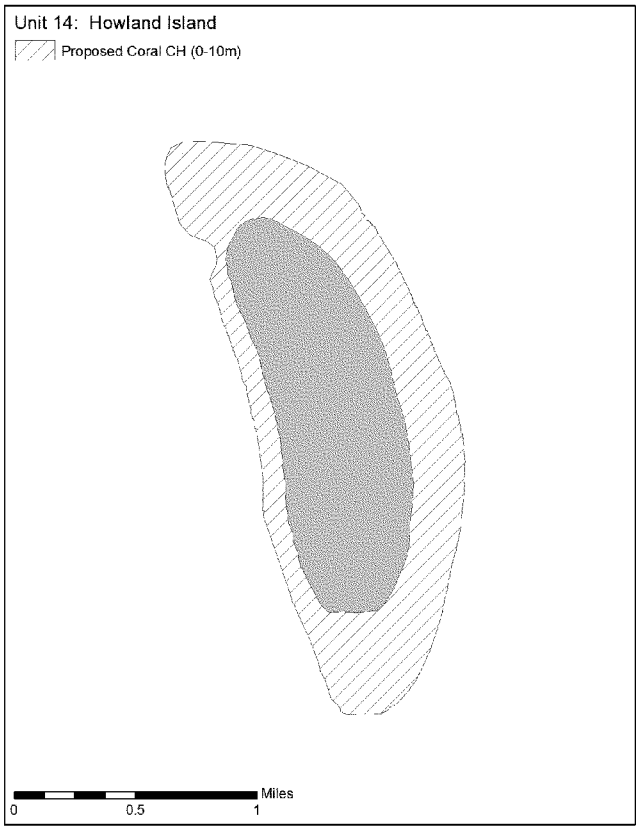

Figure 14 to paragraph (f) – Palmyra Atoll

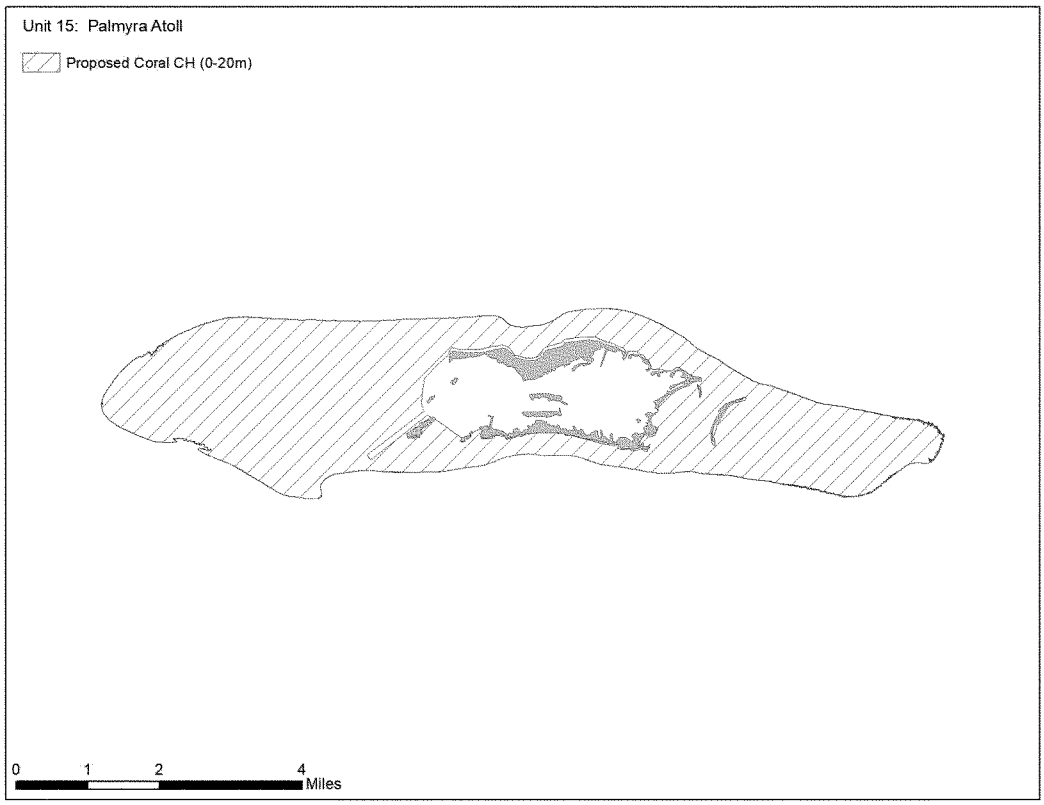

Figure 15 to paragraph (f) – Kingman Reef

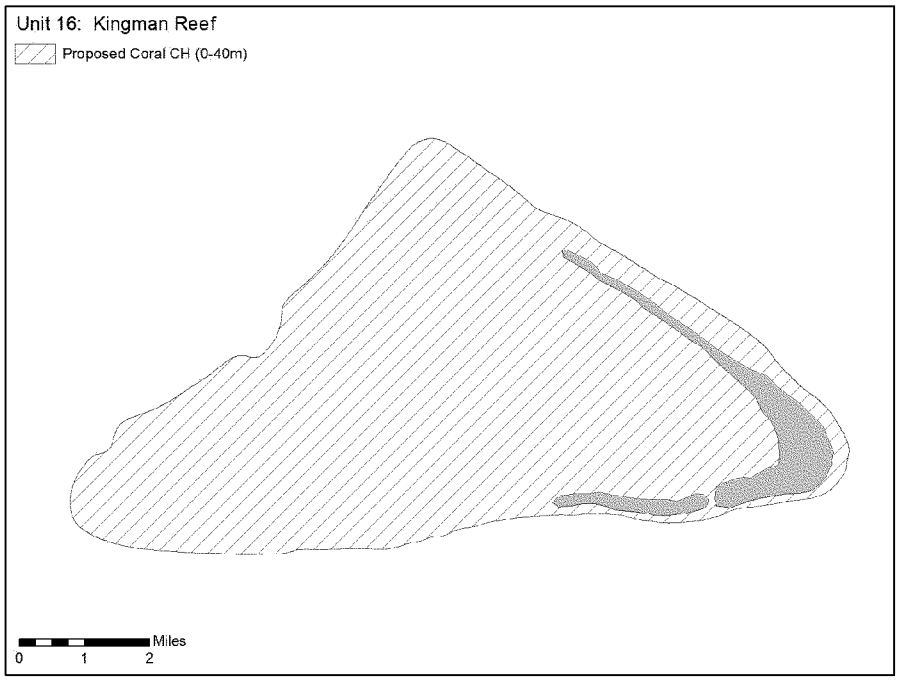

Figure 16 to paragraph (f) – Johnston Atoll

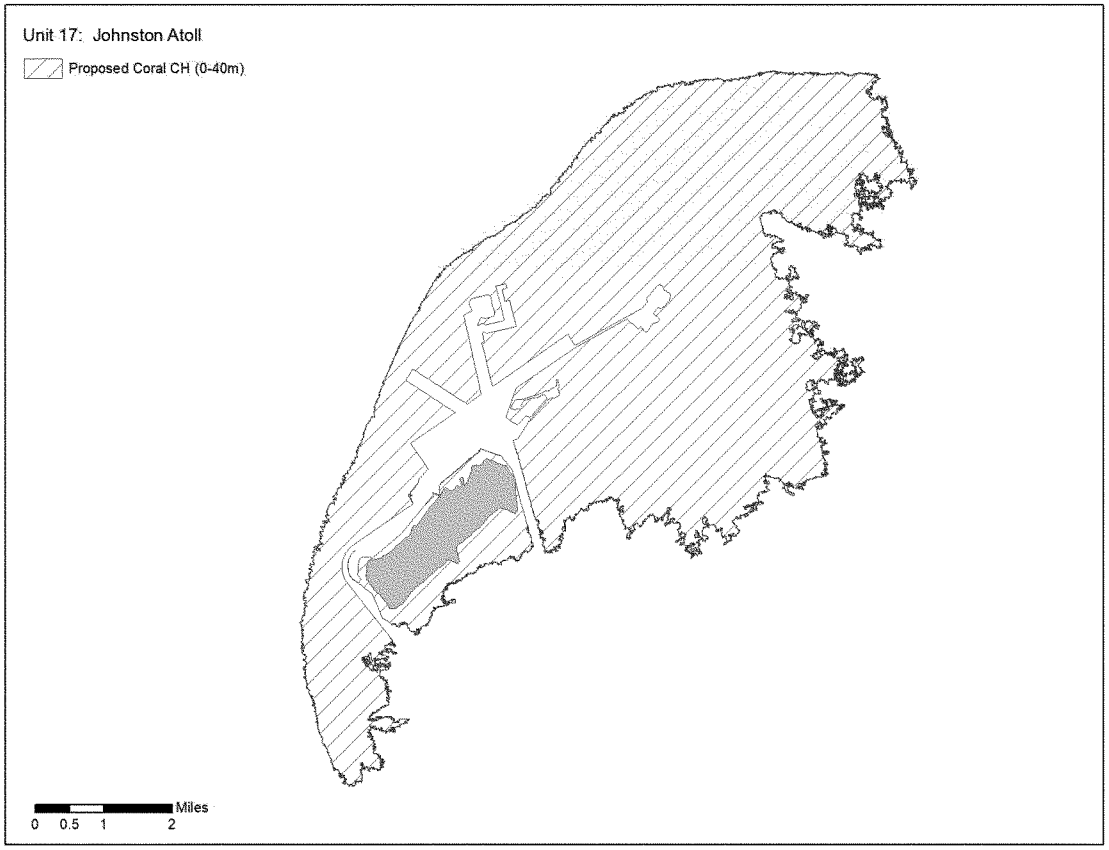

Figure 17 to paragraph (f) – Jarvis Island.

[FR Doc. 2020–21226 Filed 11–25–20; 8:45 am]
BILLING CODE 3510–22–C

FEDERAL REGISTER

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Part IV

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 226
Endangered and Threatened Species; Critical Habitat for the Threatened Caribbean Corals; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 226

[Docket No. 200918–0250]

RIN 0648–BG26

Endangered and Threatened Species; Critical Habitat for the Threatened Caribbean Corals

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

ACTION: Proposed rule; request for comments.

SUMMARY: We, NMFS, propose to designate critical habitat for the threatened Caribbean corals: *Orbicella annularis, O. faveolata, O. franksi, Dendrogyra cylindrus,* and *Mycetophyllia ferox* pursuant to section 4 of the Endangered Species Act (ESA). Twenty-eight mostly overlapping specific occupied areas containing physical features essential to the conservation of all these coral species are being proposed for designation as critical habitat; these areas contain approximately 15,000 square kilometers (km^2; 5,900 square miles (mi^2)) of marine habitat. We have considered positive and negative economic, national security, and other relevant impacts of the proposed designations, and we propose to exclude one area from the critical habitat designations due to anticipated impacts on national security. We are soliciting comments from the public on all aspects of the proposal, including our identification of the geographical area and depths occupied by the species, the physical and biological feature essential to the coral species' conservation and identification, areas not included and excluded, and consideration of impacts of the proposed action.

DATES: Comments on this proposal must be received by January 26, 2021.

Public hearings: If requested, we will hold at least one public hearing on this proposed rule.

ADDRESSES: You may submit comments, identified by the docket number NOAA–NMFS–2020–0131, by any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0131* click the ''Comment Now'' icon, complete the required fields, and enter or attach your comments.

Instructions: You must submit comments by the above to ensure that we receive, document, and consider them. Comments sent by any other method or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Jennifer Moore, NMFS, SERO, 727–824–5312, *Jennifer.Moore@noaa.gov;* Celeste Stout, NMFS, Office of Protected Resources, 301–427–8436, *Celeste.Stout@noaa.gov.*

SUPPLEMENTARY INFORMATION: In accordance with section 4(b) of the ESA and our implementing regulations (50 CFR 424.12), this proposed rule is based on the best scientific information available concerning the range, biology, habitat, threats to the habitat, and conservation objectives for the threatened Caribbean boulder star coral (*Orbicella franksi*), lobed star coral (*O. annularis*), mountainous star coral (*O. faveolata*), pillar coral (*Dendrogyra cylindrus*), and rough cactus coral (*Mycetophyllia ferox*). We have reviewed the available information and have used it to identify a composite physical feature essential to the conservation of each coral, the specific areas within the occupied geographical areas that contain the physical essential feature that may require special management considerations or protections, the Federal activities that may impact the proposed critical habitat, and the potential impacts of designating critical habitat for the corals. The economic, national security, and other relevant impacts of the proposed critical habitat designations are described in the draft document titled, Draft Information Basis and Impact Considerations of Critical Habitat Designations for Threatened Caribbean Corals (Draft Information Report). This supporting document is available at *www.regulations.gov* or upon request (see **ADDRESSES**).

Background

We listed twenty coral species as threatened under the ESA effective October 10, 2014 (79 FR 53851, September 10, 2014). Five of the corals occur in the Caribbean: *Orbicella annularis, O. faveolata, O. franksi, Dendrogyra cylindrus,* and *Mycetophyllia ferox.* The final listing determinations were all based on the best scientific and commercial information available on a suite of demographic, spatial, and susceptibility components that influence the species' vulnerability to extinction in the face of continuing threats over the foreseeable future. All of the species had undergone population declines and are susceptible to multiple threats, including: Ocean warming, diseases, ocean acidification, ecological effects of fishing, and land-based sources of pollution. However, aspects of the species' demography and distribution buffer the effects of the threats. We determined that all the Caribbean coral species are likely to become endangered throughout all of their ranges within a foreseeable future of the next several decades as a result of a combination of threats, of which the most severe are related to climate change, and we listed them as threatened.

This proposed rule is based on our Draft Information Report and peer review comments on the report. All of the information that we used to make our determinations in this proposed rule is contained in that report. The Draft Information Report is available on NMFS's Southeast Regional Office website at [*https://www.fisheries.noaa.gov/resource/document/5-caribbean-coral-proposed-CH-Information-Report* and at *www.regulations.gov,* see **ADDRESSES**].

Natural History

This section summarizes life history and biological characteristics of the five corals to provide context for the identification of the physical and biological feature essential for the conservation of these species. In this section, we cover several topic areas, including an introduction to reef-building corals, reproduction, settlement and growth, coral habitat types, and coral reef ecosystems. The amount of information available on the life history, reproductive biology, and ecology varies for each of the five corals that occur in U.S. waters of the Caribbean. We provide specific information for each species where possible. In addition, we provide information on the biology and ecology of Caribbean corals in general,

highlighting traits that these five corals share. The information below is largely summarized from the final listing rule (79 FR 53852, September 10, 2014), and updated with the best scientific information available to date.

Reef-building corals, in the phylum Cnidaria, are marine invertebrates that occur as polyps. The Cnidaria include true stony corals (class Anthozoa, order Scleractinia), the blue coral (class Anthozoa, order Helioporacea), and fire corals (class Hydrozoa, order Milleporina). These species secrete massive calcium carbonate skeletons that form the physical structure of coral reefs. Reef-building coral species collectively produce coral reefs over time when growth outpaces erosion. Corals may also occur on hard substrate that is interspersed among other benthic features (*e.g.,* seagrass beds in the back reef lagoon) in the coral reef ecosystem, but not on the physical structure of coral reefs. Corals also contain symbiotic algae within their cells. As described below, corals produce clones of themselves by several different means, and most corals occur as colonies of polyps.

Reef-building corals are able to grow and thrive in the characteristically nutrient-poor environments of tropical and subtropical regions due to their ability to form mutually beneficial symbioses with unicellular photosynthetic algae (zooxanthellae) belonging to the dinoflagellate genus *Symbiodinium* living within the host coral's tissues. Zooxanthellae provide a food source for their host by translocating fixed organic carbon and other nutrients. In return, the algae receive shelter and nutrients in the form of inorganic waste metabolites from host respiration. This exchange of energy, nutrients, and inorganic metabolites allows the symbiosis to flourish and helps the coral secrete the calcium carbonate that forms the skeletal structure of the coral colony, which in turn contributes to the formation of the reef. Thus, reef-building corals are also known as zooxanthellate corals. Some corals, which do not contain zooxanthellae, form skeletons much more slowly, and therefore are not considered reef-building. The five corals discussed in this proposed rule are zooxanthellate species, and thus are reef-building species that can grow large skeletons that contribute to the physical structure of coral reefs.

Only about 10 percent of the world's approximately 800 reef-building coral species occur in the Caribbean. The acroporids were once the most abundant and most important species on Caribbean coral reefs in terms of accretion of reef structure, characterizing the ''palmata'' and ''cervicornis'' zones in the classical descriptions of Caribbean reefs (Goreau, 1959). The three species (*O. annularis, O. faveolata,* and *O. franski*) in the *Orbicella* star coral species complex have also been dominant components on Caribbean coral reefs, characterizing the ''buttress zone'' and ''annularis zone.'' After the die-off of *Acropora* spp., the star coral species complex became the major reef-builder in the greater Caribbean due to their large size.

Most reef-building coral species are colonial, producing colonies made up of polyps that are connected through tissue and skeleton. In a colonial species, a single larva will develop into a discrete unit (the primary polyp) that then produces modular units of itself (*i.e.,* genetically-identical copies, or clones, of the primary polyp). Each polyp consists of a column with mouth and tentacles on the upper side growing on top of a calcium carbonate skeleton that the polyps produced through the process of calcification. Colony growth is achieved mainly through the addition of more cloned polyps. The colony can continue to exist even if numerous polyps die or if the colony is broken apart or otherwise damaged. The five corals are all colonial species, although polyp size, colony size, and colony morphology vary considerably by species, and can also vary based on environmental variables in different habitats. Colonies can produce clones, most commonly through fragmentation or budding (described in more detail below). The five corals are all clonal species with the ability to produce colonies of cloned polyps as well as clones of entire colonies. The way they produce colony-level clones varies by species. For example, branching species are much more likely than encrusting species to produce clones via fragmentation.

Corals use a number of reproductive strategies that have been researched extensively; however, many individual species' reproductive modes remain poorly described. Most coral species use both sexual and asexual propagation. Sexual reproduction in corals is primarily through gametogenesis (*i.e.,* development of eggs and sperm within the polyps near the base). Some coral species have separate sexes (gonochoric), while others are hermaphroditic (individuals simultaneously containing both sexes), and others are a combination of both (Richmond, 1997). Strategies for fertilization are either by brooding (internal fertilization) or broadcast spawning (external fertilization). Asexual reproduction in coral species usually occurs by fragmentation, when colony pieces or fragments are dislodged from larger colonies to establish new colonies, or by the budding of new polyps within a colony.

Depending on the mode of fertilization, coral larvae (called planulae) undergo development either mostly within the mother colony (brooders) or outside of the mother colony, adrift in the ocean (broadcast spawners). In either mode of larval development, larvae presumably experience considerable mortality (up to 90 percent or more) from predation or other factors prior to settlement and metamorphosis (Goreau *et al.,* 1981). Such mortality cannot be directly observed, but is inferred from the large number of eggs and sperm spawned versus the much smaller number of recruits observed later. Coral larvae are relatively poor swimmers; therefore, their dispersal distances largely depend on the duration of the pelagic phase and the speed and direction of water currents transporting the larvae.

All three species of the *Orbicella* star coral species complex are hermaphroditic broadcast spawners, spawning over a 3-night period, 6 to 8 nights following the full moon in late August, September, or early October (Levitan *et al.,* 2004). Fertilization success measured in the field was generally below 15 percent for all three species and correlated to the number of colonies concurrently spawning (Levitan *et al.,* 2004). The minimum colony size at first reproduction for the *Orbicella* species complex is 83 cm^2 (Szmant-Froelich, 1985). Successful recruitment by the *Orbicella* species has seemingly always been rare with many studies throughout the Caribbean reporting negligible to no recruitment (Bak and Engel, 1979; Hughes and Tanner, 2000; Rogers *et al.,* 1984; Smith and Aronson, 2006).

Dendrogyra cylindrus is a gonochoric (having separate sexes) broadcast spawning species with relatively low annual egg production for its size. The combination of gonochoric spawning with persistently low population densities is expected to yield low rates of successful fertilization and low larval supply. Spawning has been observed several nights after the full moon of August in the Florida Keys (Neely *et al.,* 2013; Waddell and Clarke, 2008). In Curaçao, *D. cylindrus* was observed to spawn over a 3-night period, 2–5 nights after the full moons in August and September (Marhaver *et al.,* 2015). Lab-reared embryos developed into swimming planulae larvae within 16 hours after spawning and were

competent to settle relatively soon afterward (Marhaver *et al.,* 2015). Despite short duration from spawn to settlement competency in the lab, sexual recruitment of this species is low, and there are no reported juvenile colonies in the Caribbean (Bak and Engel, 1979; Chiappone, 2010; Rogers *et al.,* 1984). *Dendrogyra cylindrus* can propagate by fragmentation following storms or other physical disturbance (Hudson and Goodwin, 1997). Recent investigations determined that there is no genetic differentiation along the Florida Reef Tract, meaning that all colonies belong to a single mixed population (Baums *et al.,* 2016). The same study found that all sampled colonies from Curaçao belonged to a single population that was distinct from the Florida population. Similar studies have not been conducted elsewhere in the species' range.

Mycetophyllia ferox is a hermaphroditic brooding species producing larvae during the winter months (Szmant, 1986). Brooded larvae are typically larger than broadcast spawned larvae and are expected to have higher rates of survival once settled. However, recruitment of *M. ferox* appears to be very low, even in studies from the 1970s (Dustan, 1977; Rogers and Garrison, 2001).

Spatial and temporal patterns of coral recruitment are affected by substrate availability and community structure, grazing pressure, fecundity, mode and timing of reproduction, behavior of larvae, hurricane disturbance, physical oceanography, the structure of established coral assemblages, and chemical cues. Additionally, several other factors may influence reproductive success and reproductive isolation, including external cues, genetic precision, and conspecific signaling.

Like most corals, the threatened Caribbean corals require hard, consolidated substrate, including attached, dead coral skeleton, for their larvae to settle. The settlement location on the substrate must be free of macroalgae, turf algae, or sediment for larvae to attach and begin growing a colony. Further, the substrate must provide a habitat where burial by sediment or overgrowth by competing organisms (*i.e.,* algae) will not occur. In general, on proper stimulation, coral larvae settle and metamorphose on appropriate hard substrates. Some evidence indicates that chemical cues from crustose coralline algae (CCA), microbial films, and/or other reef organisms or acoustic cues from reef environments stimulate planulae's settlement behaviors. Calcification of the newly-settled larva begins with the forming of the basal plate. Buds formed on the initial corallite develop into daughter corallites. Once larvae have metamorphosed onto appropriate hard substrate, metabolic energy is diverted to colony growth and maintenance. Because newly settled corals barely protrude above the substrate, juveniles need to reach a certain size to limit damage or mortality from threats such as grazing, sediment burial, and algal overgrowth. In some species, it appears there is virtually no limit to colony size beyond structural integrity of the colony skeleton, as polyps apparently can bud indefinitely.

Polyps are the building blocks of colonies, and colony growth occurs both by increasing the number of polyps, as well as extending the supporting skeleton under each polyp. Reef-building corals combine calcium and carbonate ions derived from seawater into crystals that form their skeletons. Skeletal expansion rates vary greatly by taxa, morphology, location, habitat and other factors. For example, in general, branching species (*e.g.,* most *Acropora* species) have much higher skeletal extension rates than massive species (*e.g., Orbicella* species). The energy required to produce new polyps and build calcium carbonate skeleton is provided by the symbiotic relationship corals have with photosynthetic zooxanthellae. Therefore, corals need light for their zooxanthellae to photosynthesize and provide the coral with food, and thus also require low turbidity for energy, growth, and survival. Lower water clarity sharply reduces photosynthesis in zooxanthellae and results in reductions in adult colony calcification and survival (79 FR 53852, September 10, 2014). Some additional information on the biological requirements for reproduction, settlement, and growth is provided below in the *Physical or Biological Features Essential to Conservation* section.

Coral reefs are fragile ecosystems that exist in a narrow band of environmental conditions that allow the skeletons of reef-building coral species to grow quickly enough for reef accretion to outpace reef erosion. High-growth conditions for reef-building corals include clear, warm waters with abundant light, and low levels of nutrients, sediments, and freshwater.

There are several categories of coral reefs: Fringing reefs, barrier reefs, patch reefs, platform reefs, and atolls. Despite the differences between the reef categories, most fringing reefs, barrier reefs, atolls, and platform reefs consist of a reef slope, a reef crest, and a back-reef, which in turn are typically characterized by distinctive habitats. The characteristics of these habitat types vary greatly by reef categories, locations, latitudes, frequency of disturbance, etc., and there is also much habitat variability within each habitat type. Temporal variability in coral habitat conditions is also very high, both cyclically (*e.g.,* from tidal, seasonal, annual, and decadal cycles) and episodically (*e.g.,* storms, temperature anomalies, etc.). Together, all these factors contribute to the habitat heterogeneity of coral reefs.

The five corals vary in their recorded depth ranges and habitat types (Table 1). All five corals generally have overlapping ranges and occur throughout the wider-Caribbean. The major variance in their distributions occurs at the northern-most extent of their ranges in Florida or the Flower Garden Banks (FGB) in the northwest Gulf of Mexico. As described below, critical habitat can be designated only in areas under U.S. jurisdiction, thus we provide the species' distribution in U.S. waters (Table 1).

TABLE 1—DISTRIBUTIONS OF THREATENED CARIBBEAN CORALS IN THE UNITED STATES

Species	Depth distribution	U.S. geographic distribution
Dendrogyra cylindrus	1 to 25 m	Southeast Florida from Lake Worth Inlet in Palm Beach County to the Dry Tortugas; Puerto Rico; USVI; Navassa Island.
Mycetophyllia ferox	5 to 90 m	Southeast Florida from Broward County to the Dry Tortugas; Puerto Rico; USVI; Navassa Island.
Orbicella annularis	0.5 to 20 m	Southeast Florida from Lake Worth Inlet in Palm Beach County to the Dry Tortugas; FGB; Puerto Rico; USVI; Navassa Island.
Orbicella faveolata	0.5 to 90 m	Southeast Florida from St. Lucie Inlet in Martin County to the Dry Tortugas; FGB; Puerto Rico; USVI; Navassa Island.

TABLE 1—DISTRIBUTIONS OF THREATENED CARIBBEAN CORALS IN THE UNITED STATES—Continued

Species	Depth distribution	U.S. geographic distribution
Orbicella franksi	0.5 to 90 m	Southeast Florida from Lake Worth Inlet in Palm Beach County to the Dry Tortugas; FGB; Puerto Rico; USVI; Navassa Island.

The depth ranges in Table 1 are the typical ranges and do not apply to the depths in which the species occur at FGB, which are much deeper due to the unique setting and conditions at that site.

Critical Habitat Identification and Designations

The purpose of designating critical habitat is to identify the areas that are essential to the species' recovery. Once critical habitat is designated, it can contribute to the conservation of listed species in several ways, including by identifying areas where Federal agencies can focus their section 7(a)(1) conservation programs, and helping focus the efforts of other conservation partners, such as States and local governments, nongovernmental organizations, and individuals (81 FR 7414, February 11, 2016). Designating critical habitat also provides a significant regulatory protection by ensuring that the Federal government considers the effects of its actions in accordance with section 7(a)(2) of the ESA and avoids or modifies those actions that are likely to destroy or adversely modify critical habitat. This requirement is in addition to the section 7 requirement that Federal agencies ensure that their actions are not likely to jeopardize the continued existence of ESA-listed species. Critical habitat requirements do not apply to citizens engaged in activities on private land that do not involve a Federal agency.

Section 3(5)(A) of the ESA defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the provisions of section 4 of the ESA, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed in accordance with the provisions of section 4 of the ESA, upon a determination by the Secretary that such areas are essential for the conservation of the species (16 U.S.C. 1532(5)(A)). Conservation is defined in section 3 of the ESA as the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to this chapter are no longer necessary (16 U.S.C. 1532(3)). Therefore, critical habitat is the habitat essential for the species' recovery. However, section 3(5)(C) of the ESA clarifies that, except in those circumstances determined by the Secretary, critical habitat shall not include the entire geographical area which can be occupied by the threatened or endangered species.

To identify and designate critical habitat, we considered information on the distribution of the five threatened Caribbean corals, their major life stages, habitat requirements of those life stages, threats to the species, and conservation objectives that can be supported by identifiable essential physical or biological features (hereafter also referred to as ''PBFs'' or ''essential features''). In the final listing rule, ocean warming, diseases, ocean acidification, trophic effects of reef fishing, nutrient enrichment, sedimentation, and inadequacy of regulatory mechanisms were found to be the main threats contributing to the threatened status of all five corals. Several other threats also contributed to the species' statuses, but were considered to be relatively lower in importance as compared to the main threats. Therefore, we evaluated physical and biological features of their habitats to determine what features are essential to the conservation of each coral.

Accordingly, our step-wise approach for identifying potential critical habitat areas for the threatened corals was to determine: (1) The geographical area occupied by each coral at the time of listing; (2) the physical or biological features essential to the conservation of the corals; (3) whether those features may require special management considerations or protection; (4) the specific areas of the occupied geographical area where these features occur; and, (5) whether any unoccupied areas are essential to the conservation of any of the corals.

Geographical Area Occupied by the Species

''Geographical area occupied'' in the definition of critical habitat is interpreted to mean the entire range of the species at the time it was listed, inclusive of all areas they use and move through seasonally (50 CFR 424.02; 81 FR 7413, February 11, 2016). The ranges of the five threatened corals span the wider-Caribbean, and specifically Florida, Puerto Rico, and USVI in the United States (79 FR 53851, September 10, 2014). We did not consider geographical areas outside of the United States, because we cannot designate critical habitat areas outside of U.S. jurisdiction (50 CFR 424.12(g)).

Physical or Biological Features Essential to Conservation

Within the geographical area occupied, critical habitat consists of specific areas on which are found those PBFs essential to the conservation of the species and that may require special management considerations or protection. PBFs essential to the conservation of the species are defined as the features that occur in specific areas and that are essential to support the life-history needs of the species, including water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic, or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity (50 CFR 424.02).

In the final listing rule, we determined that the five corals were threatened under the ESA. This means that while the species are not in danger of extinction currently, they are likely to become so within the next several decades based on their current abundances and trends in abundance, distributions, and threats they experience now and in the future. Further, the reproductive strategies of the three Caribbean *Orbicella* spp. and *Dendrogyra cylindrus* present a challenge to repopulation after mortality events they have experienced and will likely experience in the future. The goal of an ESA listing is to first prevent extinction, and then to recover the species so they no longer meet the definition of a threatened species and no longer need the protections of the

ESA. One of the first steps in recovery planning we completed after listing these coral species was to develop a Recovery Outline that contains a Recovery Vision, which describes what the state of full recovery looks like for the species. We identified the following Recovery Vision for the five corals listed in 2014: Populations of the five threatened Caribbean corals should be present across their historical ranges, with populations large enough and genetically diverse enough to support successful reproduction and recovery from mortality events and dense enough to maintain ecosystem function (*https://www.fisheries.noaa.gov/resource/document/5-caribbean-coral-species-recovery-outline*). Recovery of these species will require conservation of the coral reef ecosystem through threats abatement to ensure a high probability of survival into the future (NMFS, 2015). The key conservation objective that facilitates this Recovery Vision, and that can be assisted through these critical habitat designations, is supporting successful reproduction and recruitment, and survival and growth of all life stages, by abating threats to the corals' habitats. In the final listing rule, we identified the major threats contributing to the five corals' extinction risk: Ocean warming, disease, ocean acidification, trophic effects of reef fishing, nutrient enrichment, and sedimentation. Five of the six major threats (*i.e.,* all but disease) impact corals in part by changing the corals' habitat, making it unsuitable for them to carry out the essential functions at all life stages. Although it was not considered to be posing a major threat at the time of listing, we also identified contaminants as a potential threat to each of these corals (79 FR 53852, September 10, 2014). Thus, we identify ocean warming, ocean acidification, trophic effects of reef fishing, nutrient enrichment, sedimentation, and contaminants as the threats to the five corals' habitat that are impeding their recovery. Protecting essential features of the corals' habitat from these threats will facilitate the recovery of these threatened species.

We then turned to determining the physical or biological features essential to this conservation objective of supporting successful reproduction and recruitment, and survival and growth of all life stages. There are many physical and biological features that are important in supporting the corals' habitat; therefore, we focused on a composite habitat feature that supports the conservation objective through its relevance to the major threats and threats impeding recovery. The essential feature we ultimately identified is sites with a complex combination of substrate and water column characteristics that support normal functions of all life stages of the corals. Due to corals being sessile for almost their entire life cycle, they carry out most of their demographic functions in one location. Thus, we have identified sites with a combination of certain substrate and water column characteristics as the essential feature. A detailed discussion of how this feature was determined will follow. Specifically, these sites have attributes that determine the quality of the appropriate attachment substrate, in association with warm, aragonite-supersaturated, oligotrophic, clear marine water, which are essential to reproduction and recruitment, survival, and growth of all life stages of all five species of coral. These sites can be impacted by ocean acidification and ocean warming, trophic effects of reef fishing, nutrient enrichment, sedimentation, and contamination.

Based on the best scientific information available we propose the following essential physical feature for the five corals:

Reproductive, recruitment, growth, and maturation habitat. Sites that support the normal function of all life stages of the corals are natural, consolidated hard substrate or dead coral skeleton free of algae and sediment at the appropriate scale at the point of larval settlement or fragment reattachment, and the associated water column. Several attributes of these sites determine the quality of the area and influence the value of the associated feature to the conservation of the species:

(1) Substrate with presence of crevices and holes that provide cryptic habitat, the presence of microbial biofilms, or presence of crustose coralline algae;

(2) Reefscape (all the visible features of an area of reef) with no more than a thin veneer of sediment and low occupancy by fleshy and turf macroalgae;

(3) Marine water with levels of temperature, aragonite saturation, nutrients, and water clarity that have been observed to support any demographic function; and

(4) Marine water with levels of anthropogenically-introduced (from humans) chemical contaminants that do not preclude or inhibit any demographic function.

As described in detail in the Draft Information Report, all corals require exposed natural consolidated hard substrate for the settlement and recruitment of larvae or asexual fragments. Recruitment substrate provides the physical surface and space necessary for settlement of coral larvae, and a stable environment for metamorphosis of the larvae into the primary polyp, growth of juvenile and adult colonies, and re-attachment of fragments. The substrate must be available at appropriate physical and temporal scales for attachment to occur. In other words, the attachment location must be available at the physical scale of the larva or fragment, and at the temporal scale of when the larva or fragment is ''seeking'' recruitment. Larvae can also settle and attach to dead coral skeleton (Grober-Dunsmore *et al.,* 2006; Jordán-Dahlgren, 1992).

A number of features have been shown to influence coral larval settlement. Positive cues include the presence of particular species of crustose coralline algae (Morse and Morse, 1996; Ritson-Williams *et al.,* 2010), microbial biofilms (Sneed *et al.,* 2014; Webster *et al.,* 2004), and cryptic habitat such as crevices and holes (Edmunds *et al.,* 2004; Edwards *et al.,* 2014; Nozawa, 2012). Features that negatively affect settlement include presence of sediment, turf algae, sediment bound in turf algae, and macroalgae (Birrell *et al.,* 2005; Kuffner *et al.,* 2006; Richmond *et al.,* 2018; Speare *et al.,* 2019; Vermeij *et al.,* 2009). While sediment, turf algae, and macroalgae are all natural features of the coral reef ecosystem, it is the relative proportion of free space versus occupied space that influences recruitment; recruitment rate is positively correlated with free space (Connell *et al.,* 1997). The recruitment substrate feature is adversely affected by four of the major threats to the five corals: Ocean acidification, trophic effects of reef fishing, nutrient enrichment, and sedimentation.

The dominance of fleshy macroalgae as major space-occupiers on many Caribbean coral reefs impedes the recruitment of new corals. A shift in benthic community structure over recent decades from the dominance of stony corals to fleshy algae on Caribbean coral reefs is generally attributed to the greater persistence of fleshy macroalgae under reduced grazing regimes due to human overexploitation of herbivorous fishes (Edwards *et al.,* 2014; Hughes, 1994; Jackson *et al.,* 2014) and the regional mass mortality of the herbivorous long-spined sea urchin in 1983–84 (Hughes *et al.,* 1987). As overall coral cover has declined, the absolute area occupied by macroalgae has increased and herbivore grazing capacity is spread more thinly across a

larger relative amount of space (Williams *et al.,* 2001). Further, impacts to water quality (principally nutrient input) coupled with low herbivore grazing are also believed to enhance fleshy macroalgal productivity. Fleshy macroalgae are able to colonize dead coral skeleton and other available substrate, preempting space available for coral recruitment (McCook *et al.,* 2001; Pastorok and Bilyard, 1985). The increasing frequency of coral mortality events, such as the 2014–2016 global bleaching event, continues to increase the amount of dead skeleton available to be colonized by algae.

The persistence of fleshy macroalgae under reduced grazing regimes also negatively impacts CCA growth, potentially reducing settlement cues which may reduce settlement of coral larvae (Sharp *et al.,* 2010). Most CCA are susceptible to fouling by fleshy algae, particularly when herbivores are absent (Steneck, 1986). Patterns observed in St. Croix, USVI, also indicate a strong positive correlation between CCA abundance and herbivory (Steneck and Testa, 1997). Both turf and macroalgal cover increases and CCA cover decreases with reductions in herbivory, which may last for a period of time even when herbivores are reintroduced (de Ruyter van Steveninck and Bak, 1986; Liddell and Ohlhorst, 1986; Miller *et al.,* 1999). The ability of fleshy macroalgae to affect growth and survival of CCA has indirect, yet important, impacts on the ability of coral larvae to successfully settle and recruit.

In addition to the direct impacts of ocean acidification on the corals from reduced aragonite saturation state (discussed later in this section), significant impacts to recruitment habitat are also expected. Kuffner *et al.* (2007) and Jokiel *et al.* (2008) showed dramatic declines in the growth rate of CCA and other reef organisms, and an increase in the growth of fleshy algae at atmospheric CO_2 levels expected later this century. The decrease in CCA growth, coupled with rapid growth of fleshy algae, will result in less available habitat and more competition for settlement and recruitment of new coral colonies.

Several studies show that coral recruitment tends to be greater when macroalgal biomass is low (Birrell *et al.,* 2008a; Birrell *et al.,* 2005; Birrell *et al.,* 2008b; Connell *et al.,* 1997; Edmunds *et al.,* 2004; Hughes, 1985; Kuffner *et al.,* 2006; Rogers *et al.,* 1984; Vermeij, 2006). In addition to preempting space for coral larvae settlement, many fleshy macroalgae produce secondary metabolites with generalized toxicity that also may inhibit larval settlement, recruitment, and survival (Kuffner and Paul, 2004; Kuffner *et al.,* 2006; Paul *et al.,* 2011). Furthermore, algal turfs can trap sediments (Kendrick, 1991; Nugues and Roberts, 2003a; Purcell and Bellwood, 2001; Purcell, 2000; Steneck and Testa, 1997; Wilson and Harrison, 2003), which then creates the potential for algal turfs and sediments to act in combination to hinder coral settlement (Birrell *et al.,* 2005; Nugues and Roberts, 2003a). These turf algae-sediment mats also can suppress coral growth under high sediment conditions (Nugues and Roberts, 2003b) and may gradually kill the marginal tissues of stony corals with which they come into contact (Dustan, 1977).

Coral recruitment habitat is also adversely impacted by sediment cover. Sediments enter the reef environment through many processes that are natural or anthropogenic in origin, including coastal erosion, coastal development, resuspension of bottom sediments, terrestrial erosion and run-off, in-water construction, dredging for coastal construction projects and navigation purposes, and in-water and beach placement of dredge spoils. The rate of sedimentation affects reef distribution, community structure, growth rates, and coral recruitment (Dutra *et al.,* 2006). Accumulation of sediment can smother living corals, cover dead coral skeleton, and exposed hard substrate (Erftemeijer *et al.,* 2012; Fabricius, 2005). Sediment accumulation on dead coral skeletons and exposed hard substrate reduces the amount of available substrate for coral larvae settlement and fragment reattachment (Rogers, 1990). The location of larval settlement must be free of sediment for attachment to occur (Harrington *et al.,* 2004; Mundy and Babcock, 1998).

The depth of sediments over hard substrate affects the duration that the substrate may be unavailable for settlement. The deeper the sediment, the longer it may take for natural waves and currents to remove the sediment from the settlement substrate. Lirman *et al.* (2003) found sediment depth next to live coral colonies was approximately 1 cm deep and significantly lower than mean sediment depth collected haphazardly on the reef. Sediment deposition threshold criteria have recently been proposed for classifying sediment impacts to reef habitats based on threshold values in peer-reviewed studies and new modeling approaches (Nelson *et al.,* 2016). Nelson *et al.* (2016) suggest that sediment depth greater than 1 cm represents a significant impact to corals, while sediment between 0.5 and 1 cm depth represents a moderate impact, with the ability to recover. Nelson *et al.* (2016) identify sediment depth less than 0.5 cm as posing minimal stress to corals and settlement habitat.

Sediment texture also affects the severity of impacts to corals and recruitment substrate. Fine grain sediments have greater negative effects to live coral tissue and to recruitment substrate (Erftemeijer *et al.,* 2012). Accumulation of sediments is also a major cause of mortality in coral recruits (Fabricius *et al.,* 2003). In some instances, if mortality of coral recruits does not occur under heavy sediment conditions, then settled coral planulae may undergo reverse metamorphosis and die in the water column (Te, 1992). Sedimentation, therefore, impacts the health and survivorship of all life stages (*i.e.,* adults, fragments, larvae, and recruits) of corals, in addition to adversely affecting recruitment habitat.

The literature provides several recommendations on maximum sedimentation rates for coral reefs (*i.e.,* levels that managers should strive to stay under). De'ath and Fabricius (2008) and The Great Barrier Reef Marine Park Authority (2010) recommend that sediment levels on the Great Barrier Reef (GBR) be less than a mean annual sedimentation rate of 3 mg/cm^2/day, and less than a daily maximum of 15 mg/cm^2/day. Rogers (1990) recommends that sediment levels on coral reefs globally be less than a mean maximum of 10 mg/cm^2/day to maintain healthy corals, and also notes that moderate to severe effects on corals are generally expected at mean maximum sedimentation rates of 10 to 50 mg/cm^2/day, and severe to catastrophic effects at >50 mg/cm^2/day. Similarly, Erftemeijer *et al.* (2012) suggest that moderate to severe effects to corals are expected at mean maximum sediment levels of >10 mg/cm^2/day, and catastrophic effects at >50 mg/cm^2/day. Nelson *et al.* (2016) suggest that sediment depths of >0.5 cm result in substantial stress to most coral species, and that sediment depths of >1.0 cm are lethal to most coral species. The above generalizations are for coral reef communities and ecosystems, rather than individual species.

Sublethal effects of sediment to corals potentially occur at much lower levels than mortality. Sublethal effects include reduced growth, lower calcification rates and reduced productivity, bleaching, increased susceptibility to diseases, physical damage to coral tissue and reef structures (breaking, abrasion), and reduced regeneration from tissue damage (see reviews by Fabricius *et al.,* 2005; Erftemeijer *et al.,* 2012; Browne *et al.,* 2015; and Rogers, 1990). Erftemeijer *et al.* (2012) states that sublethal effects

for coral species that are sensitive, intermediate, or tolerant to sediment (*i.e.,* most reef-building coral species) occur at mean maximum sedimentation rates of between <10 and 200 mg/cm^2/day, depending on species, exposure duration, and other factors.

Artificial substrates and frequently disturbed ''managed areas'' are not essential to coral conservation. Only natural substrates provide the quality and quantity of recruitment habitat necessary for the conservation of threatened corals. Artificial substrates are generally less functional than natural substrates in terms of supporting healthy and diverse coral reef ecosystems (Edwards and Gomez, 2007; USFWS, 2004). Artificial substrates are man-made or introduced substrates that are not naturally occurring to the area. Examples include, but are not necessarily limited to, fixed and floating structures, such as aids-to-navigation (AToNs), jetties, groins, breakwaters, seawalls, wharves, boat ramps, fishpond walls, pipes, wrecks, mooring balls, docks, aquaculture cages, and other artificial structures. The proposed essential feature does not include any artificial substrate. In addition, there are some natural substrates that, because of their consistently disturbed nature, also do not provide the quality of substrate necessary for the conservation of threatened corals. While these areas may provide hard substrate for coral settlement and growth over short periods, the periodic nature of direct human disturbance renders them poor environments for coral growth and survival over time (*e.g.,* they can become covered with sediment). Therefore, they are not essential to the conservation of the species. Specific areas that may contain these disturbed natural substrates are described in the *Specific Areas Containing the Essential Features within the Geographical Area Occupied by the Species* section of this proposed rule.

The substrate characterized previously must be associated with water that also supports all life functions of corals that are carried out at the site. Water quality conditions fluctuate greatly over various spatial and temporal scales in natural reef environments (Kleypas *et al.,* 1999). However, certain levels of particular parameters (*e.g.,* water clarity, water temperature, aragonite saturation) must occur on average to provide the conditions conducive to coral growth, reproduction, and recruitment. Corals may tolerate and survive in conditions outside these levels, depending on the local conditions to which they have acclimatized and the intensity and duration of any deviations from conditions conducive to a particular coral's growth, reproduction and recruitment. Deviations from tolerance levels of certain parameters result in direct negative effects on all life stages.

As described in the Draft Information Report, corals thrive in warm, clear, nutrient-poor marine waters with calcium carbonate concentrations that allow for symbiont photosynthesis, coral physiological processes, and skeleton formation. The water must also have low to no levels of contaminants (*e.g.,* heavy metals, chemicals) that would interfere with normal functions of all life stages. Water quality that supports normal functions of corals is adversely affected by ocean warming, ocean acidification, nutrient enrichment, sedimentation, and contamination.

Temperature is a particularly important limiting factor of coral habitat. Corals occur in a fairly-wide temperature range across geographic locations (15.7 °C–35.5 °C weekly average and 21.7–29.6 °C annual average; Guan *et al.,* 2015), but only thrive in areas with mean temperatures in a fairly-narrow range (typically 25 °C–29 °C) as indicated by the formation of coral reefs (Brainard *et al.,* 2011; Kleypas *et al.,* 1999; Stoddart, 1969; Vaughan, 1919). Short-term exposures (days) to temperature increases of a few degrees (*i.e.,* 3 °C–4 °C increase above climatological mean maximum summer temperature) or long-term exposures (several weeks) to minor temperature increases (*i.e.,* 1 °C–2 °C above mean maximum summer temperature) can cause significant thermal stress and mortality to most coral species (Berkelmans and Willis, 1999; Jokiel and Coles, 1990). In addition to coral bleaching, elevated seawater temperatures impair coral fertilization and settlement (Negri and Heyward, 2000; Nozawa and Harrison, 2007) and cause increases in coral disease (Jones *et al.,* 2004b; Miller *et al.,* 2009). Effects of elevated seawater temperatures are well-studied for reef-building corals, and many approaches have been used to estimate temperature thresholds for coral bleaching and mortality (see reviews by (Baker *et al.,* 2008; Berkelmans, 2002; Brown, 1997; Coles and Brown, 2003; Coles and Riegl; Jokiel, 2004; Jones, 2008)). The tolerance of corals to temperature is species-specific (Barker, 2018; Bruno *et al.,* 2007; Eakin *et al.,* 2010; Heron *et al.,* 2010; Ruzicka *et al.,* 2013; Smith and Buddemeier, 1992; van Woesik *et al.,* 2011; Vega-Rodriguez *et al.,* 2015) and depends on suites of other variables that include acclimation temperature, aragonite saturation state, dissolved inorganic nitrogen (Barker, 2018; Cunning and Baker, 2013; Fabricius, 2005; Wooldridge, 2013); suspended sediments and turbidity (Anthony *et al.;* Devlin-Durante *et al.*); trace metals such as copper (Kwok *et al.,* 2016; Negri and Hoogenboom, 2011; Woods *et al.,* 2016); ultraviolet radiation (Anthony *et al.,* 2007); and salinity, nitrates, and phosphates (Negri and Hoogenboom, 2011), among other physical, physiological, and chemical stressors (Barker, 2018).

Ocean warming is one of the most significant threats to the five ESA-listed Caribbean corals (Brainard *et al.,* 2011). Mean seawater temperatures in reef-building coral habitat in both the Caribbean and Indo-Pacific have increased during the past few decades, and are predicted to continue to rise between now and 2100 (IPCC, 2013). The primary observable coral response to ocean warming is bleaching of adult coral colonies, wherein corals expel their symbiotic zooxanthellae in response to stress (Brown, 1997). For many corals, an episodic increase of only 1 °C–2 °C above the normal local seasonal maximum ocean temperature can induce bleaching (Hoegh-Guldberg *et al.,* 2007; Jones, 2008; Whelan *et al.,* 2007). Corals can withstand mild to moderate bleaching; however, severe, repeated, or prolonged bleaching can lead to colony death (Brown, 1997; Whelan *et al.,* 2007). Increased sea surface temperatures are occurring more frequently and leading to multiple mass bleaching events (Hughes *et al.,* 2017), which are reoccurring too rapidly for coral populations to rebound in between (Hughes *et al.,* 2018).

In addition to coral bleaching, other effects of ocean warming detrimentally affect virtually every life-history stage in reef-building corals. Impaired fertilization and developmental abnormalities (Negri and Heyward, 2000), mortality, and impaired settlement success (Nozawa and Harrison, 2007; Putnam *et al.,* 2008; Randall and Szmant, 2009) have all been documented. Increased seawater temperature also may act synergistically with coral diseases to reduce coral health and survivorship (Bruno and Selig, 2007). Coral disease outbreaks often have either accompanied or immediately followed bleaching events (Brandt and McManus, 2009; Jones *et al.,* 2004a; Lafferty *et al.,* 2004; Miller *et al.,* 2009; Muller *et al.,* 2008). Outbreaks also follow seasonal patterns of high seawater temperatures (Sato *et al.,* 2009; Willis *et al.,* 2004).

Coles and Brown (2003) defined a general bleaching threshold for reef-

building corals as increases in seawater temperatures of 1–3 °C above maximum annual mean temperatures at a given location. GBRMPA (2010) defined a general ''trigger value'' for bleaching in reef-building corals as increases in seawater temperatures of no more than 1 °C above maximum annual mean temperatures at a given location. Because duration of exposure to elevated temperatures determines the extent of bleaching, several methods have been developed to integrate duration into bleaching thresholds, including the number of days, weeks, or months of the elevated temperatures (Berkelmans, 2002; Eakin *et al.,* 2009; Goreau and Hayes, 1994; Podesta and Glynn, 1997). NOAA's Coral Reef Watch Program utilizes the Degree Heating Week method (Glynn & D'Croz, 1990; Eakin *et al.* 2009), which defines a general bleaching threshold for reef-building corals as seawater temperatures of 1 °C above maximum monthly mean at a given location for 4 consecutive weeks (*https://coralreefwatch.noaa.gov/*).

These general thresholds were developed for coral reef communities and ecosystems, rather than individual species. Many of these studies are community or ecosystem-focused and do not account for species-specific responses to changes in seawater temperatures, and instead are focused on long-term climatic changes and large-scale impacts (*e.g.,* coral reef distribution, persistence).

In summary, temperature deviations from local averages prevent or impede successful completion of all life history stages of the listed coral species. Identifying temperatures at which the conservation value of habitat for listed corals may be affected is inherently complex and influenced by taxa, exposure duration, and other factors.

Carbonate ions (CO_3^{2-}) are used by many marine organisms, including corals, to build calcium carbonate skeletons. The mineral form of calcium carbonate used by corals to form their skeletons is aragonite. The more carbonate ions dissolved in seawater, the easier it is for corals to build their aragonite skeletons. The metric used to express the relative availability of calcium and carbonate ions is the aragonite saturation state (Ω_{arg}). Thus, the lower the Ωarg of seawater, the lower the abundance of carbonate ions, and the more energy corals have to expend for skeletal calcification, and vice versa (Cohen and Holcomb, 2009). At saturation states between 1 and 20, marine organisms can create calcium carbonate shells or skeletons using a physiological calcifying mechanism and the expenditure of energy. The aragonite saturation state varies greatly within and across coral reefs and through daily cycles with temperature, salinity, pressure, and localized biological processes such as photosynthesis, respiration, and calcification by marine organisms (Gray *et al.,* 2012; McMahon *et al.,* 2013; Shaw *et al.,* 2012b)). Coral reefs form in an annually-averaged saturation state of 4.0 or greater for optimal calcification, and an annually-averaged saturation state below 3.3 will result in reduced calcification at rates insufficient to maintain net positive reef accretion, resulting in loss of reef structure (Guinotte *et al.,* 2003; Hoegh-Guldberg *et al.,* 2007). Guinotte *et al.* (2003) classified the range of aragonite saturation states between 3.5–4.0 as ''adequate'' and < 3 as ''extremely marginal.'' Thus, aragonite saturation state between 3 and 4 is likely necessary for coral calcification. But, generally, seawater Ωarg should be 3.5 or greater to enable maximum calcification of reef-building corals, and average Ωarg in most coral reef areas is currently in that range (Guinotte *et al.,* 2003). Further, (Kleypas *et al.,* 1999) concluded that a general threshold for Ωarg occurs near 3.4, because only a few reefs occur where saturation is below this level. Guan *et al.* (2015) found that the minimum aragonite saturation observed where coral reefs currently occur is 2.82; however, it is not known if those locations hosted live, accreting corals. These general characterizations and thresholds were identified for coral reef communities and ecosystems, rather than individual species.

Ocean acidification is a term referring to changes in ocean carbonate chemistry, including a drop in the pH of ocean waters, that is occurring in response to the rise in the quantity of atmospheric CO_2 and the partial pressure of CO_2 (pCO_2) absorbed in oceanic waters (Caldeira and Wickett, 2003). As pCO_2 rises, oceanic pH declines through the formation of carbonic acid and subsequent reaction with water resulting in an increase of free hydrogen ions. The free hydrogen ions react with carbonate ions to produce bicarbonate, reducing the amount of carbonate ions available, and thus reducing the aragonite saturation state. Ocean acidification is one of the most significant threats to reef-building corals (Brainard *et al.,* 2011; Jokiel, 2015).

A variety of laboratory studies conducted on corals and coral reef organisms (Langdon and Atkinson, 2005) consistently show declines in the rate of coral calcification and growth with rising pCO2, declining pH, and declining carbonate saturation state. Laboratory experiments have also shown that skeletal deposition and initiation of calcification in newly settled corals is reduced by declining aragonite saturation state (Albright *et al.,* 2008; Cohen *et al.,* 2009). Field studies from a variety of coral locations in the Caribbean, Indo-Pacific, and Red Sea have shown a decline in linear extension rates of coral skeleton under decreasing aragonite saturation state (Bak *et al.,* 2009; De'ath *et al.,* 2009; Schneider and Erez, 2006; Tanzil *et al.,* 2009). In addition to effects on growth and calcification, recent laboratory experiments have shown that increased CO_2 also substantially impairs fertilization and settlement success in *Acropora palmata* (Albright *et al.,* 2010). Reduced calcification and slower growth will mean slower recovery from breakage, whether natural (hurricanes and storms) or human (breakage from vessel groundings, anchors, fishing gear, etc.), or mortality from a variety of disturbances. Slower growth also implies even higher rates of mortality for newly settled corals due to the longer time it will take to reach a colony size that is no longer vulnerable to overgrowth competition, sediment smothering, and incidental predation. Reduced calcification and slower growth means more time to reach reproductive size and reduces sexual and asexual reproductive potential. Increased pCO_2 coupled with increased sea surface temperature can lead to even lower rates of calcification, as found in the meta-analysis by Kornder *et al.* (2018).

In summary, aragonite saturation reductions prevent or impede successful completion of all life history stages of the listed coral species. Identifying the declining aragonite saturation state at which the conservation value of habitat for listed corals may be affected is inherently complex and influenced by taxa, exposure duration, acclimatization to localized nutrient regimes, and other factors.

Nitrogen and phosphorous are two of the main nutrients that affect the suitability of the water column in coral reef habitats (Fabricius *et al.,* 2005; Fabricius, 2005). These two nutrients occur as different compounds in coral reef habitats and are necessary in low levels for normal reef function. Dissolved inorganic nitrogen and dissolved inorganic phosphorus in the forms of nitrate (NO_3^-) and phosphate (PO_4^{3-}) are particularly important for photosynthesis, with dissolved organic nitrogen also providing an important source of nitrogen, and are the dominant forms of nitrogen and phosphorous in

coral reef waters. Nutrients are a major component of land-based sources of pollution (LBSP), which is one of the most significant threats to reef-building corals (Brainard *et al.,* 2011). Excessive nutrients affect corals through two main mechanisms: Direct impacts on coral physiology, such as reduced fertilization and growth (Harrison and Ward, 2001; Ferrier-Pages *et al.,* 2000), and indirect effects through nutrient-stimulation of other community components (*e.g.,* macroalgae seaweeds, turfs/filamentous algae, cyanobacteria, and filter feeders) that compete with corals for space on the reef (79 FR 53851, September 10, 2014). As discussed previously, the latter also affects the quality of recruitment substrate. The physiological response a coral exhibits to an increase in nutrients mainly depends on concentration and duration. A short duration of a high increase in a nutrient may result in a severe adverse response, just as a chronic, lower concentration might. Increased nutrients can result in adverse responses in all life stages and affect most physiological processes, resulting in reduced number and size of gametes (Ward and Harrison, 2000), reduced fertilization (Harrison and Ward, 2001), reduced growth, mortality (Ferrier-Pages *et al.,* 2000; Koop *et al.,* 2001), increased disease progression (Vega Thurber *et al.,* 2013; Voss and Richardson, 2006), tissue loss (Bruno *et al.,* 2003), and bleaching (Kuntz *et al.,* 2005; Wiedenmann *et al.,* 2012).

Most coral reefs occur where annual mean nutrient levels are low. Kleypas *et al.* (1999) analyzed dissolved nutrient data from nearly 1,000 coral reef sites, finding mean values of 0.25 micromoles per liter (µmol/l) for NO_3, and 0.13 µmol/l for PO_4. Over 90 percent of the sites had mean NO_3 values of <0.6 µmol/l, and mean PO_4 values of <0.2 µmol/l (Kleypas *et al.,* 1999). Several authors, including Bell and Elmetri (1995) and Lapointe (1997) have proposed threshold values of 1.0 µmol/l for NO_3, and 0.1–0.2 µmol/l for PO_4, beyond which reefs are assumed to be eutrophic. However, concentrations of dissolved nutrients are poor indicators of coral reef status, and the concept of a simple threshold concentration that indicates eutrophication has little validity (McCook, 1999). One reason for that is because corals are exposed to nutrients in a variety of forms, including dissolved nitrogen (*e.g.,* NO_3), dissolved phosphorus (*e.g.,* $PO4_3$), particulate nitrogen (PN), and particulate phosphate (PP). Since the dissolved forms are assimilated rapidly by phytoplankton, and the majority of nitrogen and phosphorus discharged in terrestrial runoff is in the particulate forms, PN and PP are the most common bio-available forms of nutrients for corals on coastal zone reefs (Cooper *et al.,* 2008). De'ath and Fabricius (2008) and GBRMPA (2010) provide general recommendations on maximum annual mean values for PN and PP of 1.5 µmol/l PN and 0.09 µmol/l PP for coastal zone reefs. These generalizations are for coral reef communities and ecosystems, rather than individual species.

As noted above, identifying nutrient concentrations at which the conservation value of habitat for listed corals may be affected is inherently complex and influenced by taxa, exposure duration, and acclimatization to localized nutrient regimes, and other factors.

Water clarity or transparency is a key factor for marine ecosystems and it is the best explanatory variable for a range of bioindicators of reef health (Fabricius *et al.,* 2012). Water clarity affects the light availability for photosynthetic organisms and food availability for filter feeders. Corals depend upon their symbiotic algae for nutrition and thus depend on light availability for algal photosynthesis. Reduced water clarity is determined by the presence of particles of sediment, organic matter, and/or plankton in the water, and so is often associated with elevated sedimentation and/or nutrients. Water clarity can be measured in multiple ways, including percent of solar irradiance at depth, Secchi depth (the depth in the water column at which a black and white disk is no longer visible), and Nephelometric Turbidity Unit (NTU) (measure of light scatter based on particles in the water column). Reef-building corals naturally occur across a broad range of water clarity levels from very turbid waters on enclosed reefs near river mouths (Browne *et al.,* 2012) to very clear waters on offshore barrier reefs, and many intermediate habitats such as open coastal and mid-shelf reefs (GBRMPA, 2010). Coral reefs appear to thrive in extremely clear areas where Secchi depth is ≥ 15 m or light scatter is < 1 NTU (De'ath and Fabricius, 2010). Typical levels of total suspended solids (TSS) in reef environments are less than 10 mg/L (Rogers, 1990). The minimum light level for reef development is about 6–8 percent of surface irradiance (Fabricius *et al.,* 2014).

For a particular coral colony, tolerated water clarity levels likely depend on several factors, including species, life history stage, spatial variability, and temporal variability. For example, colonies of a species occurring on fringing reefs around high volcanic islands with extensive groundwater inputs are likely to be better acclimatized or adapted to higher turbidity than colonies of the same species occurring on offshore barrier reefs or around atolls with very little or no groundwater inputs. In some cases, corals occupy naturally turbid habitats (Anthony and Larcombe, 2000; McClanahan and Obura, 1997; Te, 2001) where they may benefit from the reduced amount of UV radiation to which they are exposed (Zepp *et al.,* 2008). As turbidity and nutrients increase, thus decreasing water clarity, reef community composition shifts from coral-dominated to macroalgae-dominated, and ultimately to heterotrophic animals (Fabricius *et al.,* 2012). Light penetration is diminished by suspended abiotic and biotic particulate matter (esp. clay and silt-sized particles) and some dissolved substances (Fabricius *et al.,* 2014). The availability of light decreases directly as a function of particle concentration and water depth, but also depends on the nature of the suspended particles. Fine clays and organic particles are easily suspended from the sea floor, reducing light for prolonged periods, while undergoing cycles of deposition and resuspension. Suspended fine particles also carry nutrients and other contaminants (Fabricius *et al.,* 2013). Increased nutrient runoff into semi-enclosed seas accelerates phytoplankton production to the point that it also increases turbidity and reduces light penetration, and can also settle on colony surfaces (Fabricius, 2005). In areas of nutrient enrichment, light for benthic organisms can be additionally severely reduced by dense stands of large fleshy macroalgae shading adjacent corals (Fabricius, 2005).

The literature provides several recommendations on maximum turbidity levels for coral reefs (*i.e.,* levels that managers should strive to stay under). GBRMPA (2010) recommends minimum mean annual water clarity, or ''trigger values'', in Secchi distances for the GBR depending on habitat type: For enclosed coastal reefs, 1.0–1.5 m; for open coastal reefs and mid-shelf reefs, 10 m; and for offshore reefs, 17 m. De'ath and Fabricius (2008) recommend a minimum mean annual water clarity trigger value in Secchi distance averaged across all GBR habitats of 10 m. Bell and Elmetri (1995) recommend a maximum value of 3.3 mg/L TSS across all GBR habitats. Thomas *et al.* (2003) recommend a maximum value of 10 mg/L averaged across all Papua New Guinea coral reef habitats. Larcombe *et al.* (2001) recommend a maximum value

of 40 mg/L TSS for GBR ''marginal reefs'', *i.e.,* reefs close to shore with high natural turbidity levels. Guan *et al.* (2015) recommend a minimum light intensity (µmol photons second/m^2) of 450 µmol photons second/m^2 globally for coral reefs. The above generalizations are for coral reef communities and ecosystems, rather than individual species.

A coral's response to a reduction in water clarity is dependent on the intensity and duration of the particular conditions. For example, corals exhibited partial mortality when exposed to 476 mg/L TSS (Bengtsson *et al.,* 1996) for 96 hours, but had total mortality when exposed to 1000 mg/L TSS for 65 hours (Thompson and Bright, 1980). Depending on the duration of exposure, most coral species exhibited sublethal effects when exposed to turbidity levels between 7 and 40 NTU (Erftemeijer *et al.,* 2012). The most tolerant coral species exhibited decreased growth rates when exposed to 165 mg/L TSS for 10 days (Rice and Hunter, 1992). By reducing water clarity, turbidity also reduces the maximum depth at which corals can live, making deeper habitat unsuitable (Fabricius, 2005). Existing data suggest that coral reproduction and settlement are more highly sensitive to changes in water clarity than adult survival, and these functions are dependent on clear water. Suspended particulate matter reduces fertilization and sperm function (Ricardo *et al.,* 2015), and strongly inhibits larvae survival, settlement, recruitment, and juvenile survival (Fabricius, 2005).

In summary, water clarity deviations from local averages prevent or impede successful completion of all life history stages of the listed coral species. Identifying turbidity levels at which the conservation value of habitat for listed corals may be affected is inherently complex and influenced by taxa, exposure duration, and acclimatization to localized nutrient regimes, and other factors.

The water column may include levels of anthropogenically-introduced chemical contaminants that prevent or impede successful completion of all life history stages of the listed coral species. For the purposes of this rule, ''contaminants'' is a collective term to describe a suite of anthropogenically-introduced chemical substances in water or sediments that may adversely affect corals. The study of the effects of contaminants on corals is a relatively new field and information on sources and ecotoxicology is incomplete. The major groups of contaminants that have been studied for effects to corals include heavy metals (also called trace metals), pesticides, and hydrocarbons. Other organic contaminants, such as chemicals in personal care products, polychlorinated biphenyl, and surfactants, have also been studied. Contaminants may be delivered to coral reefs via point or non-point sources. Specifically, contaminants enter the marine environment through wastewater discharge, shipping, industrial activities, and agricultural and urban runoff. These contaminants can cause negative effects to coral reproduction, development, growth, photosynthesis, and survival.

Heavy metals (*e.g.,* copper, cadmium, manganese, nickel, cobalt, lead, zinc, and iron) can be toxic at concentrations above naturally-occurring levels. Heavy metals are persistent in the environment and can bioaccumulate. Metals are adsorbed to sediment particles, which can result in their long distance transport away from sources of pollution. Corals incorporate metals in their skeleton and accumulate them in their soft tissue (Al-Rousan *et al.,* 2012; Barakat *et al.,* 2015). Although heavy metals can occur in the marine environment from natural processes, in nearshore waters they are mostly a result of anthropogenic sources (*e.g.,* wastewater, antifouling and anticorrosive paints from marine vessels and structures, land filling and dredging for coastal expansion, maritime activities, inorganic and organic pollutants, crude oil pollution, shipping processes, industrial discharge, agricultural activities), and are found near cities, ports, and industrial developments.

The effects of copper on corals include physiological impairment, impaired photosynthesis, bleaching, reduced growth, and DNA damage (Bielmyer *et al.,* 2010; Schwarz *et al.,* 2013). Adverse effects to fertilization, larval development, larval swimming behavior, metamorphosis, and larval survival have also been documented (Kwok and Ang, 2013; Negri and Hoogenboom, 2011; Puisay *et al.,* 2015; Reichelt-Brushett and Hudspith, 2016; Rumbold and Snedaker, 1997). Toxicity of copper was found to be higher when temperatures are elevated (Negri and Hoogenboom, 2011). Nickel and cobalt can also have negative effects on corals, such as reduced growth and photosynthetic rates (Biscere *et al.,* 2015), and reduced fertilization success (Reichelt-Brushett and Hudspith, 2016). Chronic exposure of corals to higher levels of iron may significantly reduce growth rates (Ferrier-Pages *et al.,* 2001). Further, iron chloride has been found to cause oxidative DNA damage to coral larvae (Vijayavel *et al.,* 2012).

Polycyclic aromatic hydrocarbons (PAHs) are found in fossil fuels such as oil and coal and can be produced by the incomplete combustion of organic matter. PAHs disperse through non-point sources such as road run-off, sewage, and deposition of particulate air pollution. PAHs can also disperse from point sources such as oil spills and industrial sites. Studies have found adverse effects of oil pollution on corals that include growth impairments, mucus production, and decreased reproduction, especially at increased temperature (Kegler *et al.,* 2015). Hydrocarbons have also been found to affect early life stages of corals. Oil-contaminated seawater reduced settlement of *O. faveolata* and of *Agaricia humilis* and was more severe than any direct or latent effects on survival (Hartmann *et al.,* 2015). Natural gas (water accommodated fraction) exposure resulted in abortion of larvae during early embryogenesis and early release of larvae during late embryogenesis, with higher concentrations of natural gas yielding higher adverse effects (Villanueva *et al.,* 2011). Exposure to oil, dispersants, and a combination of oil and dispersant significantly decreased settlement and survival of *Porites astreoides* and *Orbicella faveolata* larvae (Goodbody-Gringley *et al.,* 2013).

Anthracene (a PAH that is used in dyes, wood preservatives, insecticides, and coating materials) exposure to apparently healthy fragments and diseased fragments (Caribbean yellow band disease) of *O. faveolata* reduced activity of enzymes important for protection against environmental stressors in the diseased colonies (Montilla *et al.,* 2016). The results indicated that diseased tissues might be more vulnerable to exposure to PAHs such as anthracene compared to healthy corals. PAH concentrations similar to those present after an oil spill inhibited metamorphosis of *Acropora tenuis* larvae, and sensitivity increased when larvae were co-exposed to PAHs and ''shallow reef'' ultraviolet (UV) light levels (Negri *et al.,* 2016).

Pesticides include herbicides, insecticides, and antifoulants used on vessels and other marine structures. Pesticides can affect non-target marine organisms like corals and their zooxanthellae. Diuron, an herbicide, decreased photosynthesis in zooxanthellae that had been isolated from the coral host and grown in culture (Shaw *et al.,* 2012a). Irgarol, an additive in copper-based antifouling paints, significantly reduced settlement in

Porites hawaiiensis (Knutson *et al.,* 2012). *Porites astreoides* larvae exposed to two major mosquito pesticide ingredients, naled and permethrin, for 18–24 hours showed differential responses. Concentrations of 2.96 µg/L or greater of naled significantly reduced larval survivorship, while exposure of up to 6.0 µg/L of permethrin did not result in reduced larval survivorship. Larval settlement, post-settlement survival, and zooxanthellae density were not impacted by any treatment (Ross *et al.,* 2015).

Benzophenone-2 (BP–2) is a chemical additive to personal care products (*e.g.,* sunscreen, shampoo, body lotions, soap, detergents), product coatings (oil-based paints, polyurethanes), acrylic adhesives, and plastics that protects against damage from UV light. It is released into the ocean through municipal and boat/ship wastewater discharges, landfill leachates, residential septic fields, and unmanaged cesspits (Downs *et al.,* 2014). BP–2 is a known endocrine disruptor and a DNA mutagen, and its effects are worse in the light. It caused deformation of scleractinian coral *Stylophora pistillata* larvae, changing them from a motile planktonic state to a deformed sessile condition at low concentrations (Downs *et al.,* 2014). It also caused increasing larval bleaching with increasing concentration (Downs *et al.,* 2014). Benzophenone-3 (BP–3; oxybenzone) is an ingredient in sunscreen and personal care products (*e.g.,* hair cleaning and styling products, cosmetics, insect repellent, soaps) that protects against damage from UV light. It enters the marine environment through swimmers and municipal, residential, and boat/ship wastewater discharges and can cause DNA mutations. Oxybenzone is a skeletal endocrine disruptor, and it caused larvae of *S. pistillata* to encase themselves in their own skeleton (Downs *et al.,* 2016). Exposure to oxybenzone transformed *S. pistillata* larvae from a motile state to a deformed, sessile condition (Downs *et al.,* 2016). Larvae exhibited an increasing rate of coral bleaching in response to increasing concentrations of oxybenzone (Downs *et al.,* 2016).

Polychlorinated biphenyls (PCBs) are environmentally stable, persistent organic contaminants that have been used as heat exchange fluids in electrical transformers and capacitors and as additives in paint, carbonless copy paper, and plastics. They can be transported globally through the atmosphere, water, and food chains. A study of the effects of the PCB, Aroclor 1254, on the *Stylophora pistillata* found no effects on coral survival, photosynthesis, or growth; however, the exposure concentration and duration may alter the expression of certain genes involved in various important cellular functions (Chen *et al.,* 2012).

Surfactants are used as detergents and soaps, wetting agents, emulsifiers, foaming agents, and dispersants. Linear alkylbenzene sulfonate (LAS) is one of the most common surfactants in use. Biodegradation of surfactants can occur within a few hours up to several days, but significant proportions of surfactants attach to suspended solids and remain in the environment. This sorption of surfactants onto suspended solids depends on environmental factors such as temperature, salinity, or pH. Exposure of *Pocillopora verrucosa* to LAS resulted in tissue loss on fragments (Kegler *et al.,* 2015). The combined effects of LAS exposure with increased temperature (+3 °C, from 28 to 31 °C) resulted in greater tissue loss than LAS exposure alone (Kegler *et al.,* 2015).

In summary, there are multiple chemical contaminants that prevent or impede successful completion of all life history stages of the listed coral species. Identifying contaminant levels at which the conservation value of habitat for listed corals may be affected is inherently complex and influenced by taxa, exposure duration, and other factors.

As described above, the best-available information shows coral reefs form on solid substrate but only within a narrow range of water column conditions that on average allow the deposition rates of corals to exceed the rates of physical, chemical, and biological erosion (*i.e.,* conducive conditions, Brainard *et al.,* 2005). However, as with all ecosystems, water column conditions are dynamic and vary over space and time. Therefore, we also describe environmental conditions in which coral reefs currently exist globally, thus indicating the conditions that may be tolerated by corals and allow at least for survival. To the extent tolerance conditions deviate in duration and intensity from conducive conditions, they may not support coral reproduction and recruitment, and reef growth, and thus would impair recovery of the species. Further, annually and spatially averaged-tolerance ranges provide the limits of the environmental conditions in which coral reefs exist globally (Guan *et al.,* 2015), but these conditions do not necessarily represent the conditions that may be tolerated by individual coral species. Individual species may or may not be able to withstand conditions within or exceeding the globally-averaged tolerance ranges for coral reefs, depending on the individual species' biology, local average conditions to which the species are acclimatized, and intensity and duration of exposure to adverse conditions. In other words, changes in the water column parameters discussed above that exceed the tolerance ranges may induce adverse effects in a particular species. Thus, the concept of individual species' tolerance limits is a different aspect of water quality conditions compared to conditions that are conducive for formation and growth of reef structures.

These values presented in the summaries above constitute the best available information at the time of this rulemaking. It is possible that future scientific research will identify species-specific values for some of these parameters that become more applicable to the five listed coral species, though it is also possible that future species-specific research will document that conducive or tolerance ranges for the five Caribbean corals fall within these ranges. Because the ESA requires us to use the best scientific information available in conducting consultations under section 7, we will incorporate any such new scientific information into consultations when evaluating potential impacts to the critical habitat.

Need for Special Management Considerations or Protection

Specific areas within the geographical area occupied by a species may be designated as critical habitat only if they contain essential features that may require special management considerations or protection (16 U.S.C. 1532(5)(A)(i)(II). Special management considerations or protection are any methods or procedures useful in protecting physical or biological features for the conservation of listed species (50 CFR 424.02).

The proposed essential feature is particularly susceptible to impacts from human activity because of the relatively shallow water depth range (less than 295 ft (90 m)) the corals inhabit. The proximity of this habitat to coastal areas subjects this feature to impacts from multiple activities, including, but not limited to, coastal and in-water construction, dredging and disposal activities, beach nourishment, stormwater run-off, wastewater and sewage outflow discharges, point and non-point source discharges of contaminants, and fishery management. Further, the global oceans are being impacted by climate change from greenhouse gas emissions, particularly the tropical oceans in which the Caribbean corals occur (van Hooidonk *et al.,* 2014). The impacts from these activities, combined with those from

natural factors (*e.g.,* major storm events), significantly affect habitat for all life stages for these threatened corals. We conclude that the essential feature is currently and will likely continue to be negatively impacted by some or all of these factors.

Greenhouse gas emissions (*e.g.,* fossil fuel combustion) lead to global climate change and ocean acidification. These activities adversely affect the essential feature by increasing sea surface temperature and decreasing the aragonite saturation state. Coastal and in-water construction, channel dredging, and beach nourishment activities can directly remove the essential feature by dredging it or by depositing sediments on it, making it unavailable for settlement and recruitment of coral larvae or fragments. These same activities can impact the essential feature by creating turbidity during operations. Stormwater run-off, wastewater and sewage outflow discharges, and point and non-point source contaminant discharges can adversely impact the essential feature by allowing nutrients and sediments, as well as contaminants, from point and non-point sources, including sewage, stormwater and agricultural runoff, river discharge, and groundwater, to alter the natural levels in the water column. The same activities can also adversely affect the essential feature by increasing the growth rates of macroalgae, allowing them to preempt available recruitment habitat. Fishery management can adversely affect the essential feature if it allows for the reduction in the number of herbivorous fishes available to control the growth of macroalgae on the substrate.

Given these ongoing threats throughout the corals' habitat, we find that the essential feature may require special management considerations.

Specific Areas Containing the Essential Features Within the Geographical Area Occupied by the Species

The definition of critical habitat requires us to identify specific areas on which are found the physical or biological features essential to the species' conservation that may require special management considerations or protection. Our regulations state that critical habitat will be shown on a map, with more-detailed information discussed in the preamble of the rulemaking documents in the **Federal Register**, which will reference each area by the State, county, or other local governmental unit in which it is located (50 CFR 424.12(c)). Our regulations also state that when several habitats, each satisfying requirements for designation as critical habitat, are located in proximity to one another, an inclusive area may be designated as critical habitat (50 CFR 424.12(d)).

Within the geographical areas occupied by each of the five corals in U.S. waters, at the time of listing, there are five or six broad areas in which the essential feature occurs. For each of the five corals, boundaries of specific areas were determined by each coral's commonly occupied minimum and maximum depth ranges within each coral's specific geographic distribution. Across all five coral species, a total of 28 specific areas were identified as being under consideration for critical habitat designation. There are five or six specific areas per species, depending on whether it occurs in FGB; one each in Florida, Puerto Rico, St. Thomas and St. John, USVI, St. Croix, USVI, FGB, and Navassa Island. Within each of these areas, the individual species' specific areas are largely-overlapping. For example, in Puerto Rico, there are five largely-overlapping specific areas, one for each species, that surround each of the islands. The difference between each of the areas is the particular depth contours that were used to create the boundaries. For example, *Dendrogyra cylindrus'* specific area in Puerto Rico extends from the 1-m contour to the 25-m contour, which mostly overlaps the *Orbicella annularis* specific area that extends from the 0.5-m contour to the 20-m contour. Overlaying all of the specific areas for each species results in the maximum geographic extent of the areas under consideration for designation, which covers 0.5–90 m (1.6 to 295-ft) water depth around all the islands of Puerto Rico, USVI, and Navassa, FGB, and from St. Lucie Inlet, Martin County to Dry Tortugas, Florida.

To these specific areas, we reviewed available species occurrence, bathymetric, substrate, and water quality data. We used the highest resolution bathymetric data available from multiple sources depending on the geographic location. In Florida and the FGB, we used contours created from National Ocean Service Hydrographic Survey Data and NOAA ENCDirect bathymetric point data (NPS) and contours created from NOAA's Coastal Relief Model. In Puerto Rico, contours were derived from the National Geophysical Data Center's (NGDC) 2005 U.S. Coastal Relief Model. In USVI, we used contours derived from NOAA's 2004–2015 Bathymetric Compilation. In Navassa, contours were derived from NOAA's NGDC 2006 bathymetric data. These bathymetric data (*i.e.,* depth contours) were used with other geographic or management boundaries to draw the boundaries of each specific area on the maps in the proposed critical habitat designations.

Within the areas bounded by depth and species occurrence, we evaluated available data on the essential feature. For substrate, we used information from the NCCOS Benthic Habitat Mapping program that provides data and maps at *http://products.coastalscience.noaa.gov/collections/benthic/default.aspx* and the Unified Florida Reef Tract Map found at *https://myfwc.com/research/gis/regional-projects/unified-reef-map/.* Using GIS software, we extracted all habitat classifications that could be considered potential recruitment habitat, including hardbottom and coral reef. The benthic habitat information assisted in identifying any major gaps in the distribution of the substrate essential feature. The data show that hard substrate is unevenly distributed throughout the ranges of the species. However, there are large areas where benthic habitat characterization data are still lacking, particularly deeper than 30 m (99 ft). Therefore, we made assumptions that the substrate feature does exist in those areas, though in unknown quantities, because the species occur there. The available data also represent a snapshot in time, while the exact location of the habitat feature may change over time (*e.g.,* natural sediment movement covering or exposing hard substrate).

There are areas within the geographical and depth ranges of the species that contain natural hard substrates that, due to their consistently disturbed nature, do not provide the quality of substrate essential for the conservation of threatened corals. These disturbances may be naturally occurring or caused by human activities. While these areas may provide hard substrate for coral settlement and growth over short periods, the periodic nature of direct human disturbance renders them poor habitat for coral growth and survival over time. These ''managed areas,'' for the purposes of this proposed rule, are specific areas where the substrate has been persistently disturbed by planned management activities authorized by local, state, or Federal governmental entities at the time of critical habitat designation, and expectations are that the areas will continue to be periodically disturbed by such management activities. Examples include, but are not necessarily limited to, dredged navigation channels, vessel berths, and active anchorages. These managed areas are not under consideration for critical habitat designation.

NMFS is aware that dredging may result in sedimentation impacts beyond the actual dredge channel. To the extent that these impacts are persistent, are expected to recur whenever the channel is dredged and are of such a level that the areas in question have already been made unsuitable for coral, then NMFS expects that the federal action agency can assess and identify such areas during their pre-dredging planning and provide their rationale and information supporting this conclusion. To the extent that the federal action agency does so, NMFS proposes that these persistently impacted areas be considered part of the managed areas and excluded from critical habitat.

GIS data of the locations of some managed areas were available and extracted from the maps of the specific areas being considered for critical habitat designation. These data were not available for every managed area; however, regardless of whether the managed area is extracted from the maps depicting the specific areas being proposed as critical habitat, no managed areas are part of the specific areas that contain the essential feature.

The nearshore surf zones of Martin, Palm Beach, Broward, and Miami-Dade Counties are also consistently disturbed by naturally-high sediment movement, suspension, and deposition levels. Hard substrate areas found within these nearshore surf zones are ephemeral in nature and are frequently covered by sand, and the threatened coral species have never been observed there. Thus, this area (water in depths from 0 ft to 6.5 ft [0 m to 2 m] offshore St. Lucie Inlet to Government Cut) does not contain the essential feature and is not considered part of the specific areas under consideration for critical habitat. The shallow depth limit (*i.e.,* inshore boundary) was identified based on the lack of these or any reef building corals occurring in this zone, indicating conditions are not suitable for their settlement and recruitment into the population. These conditions do not exist in the area south of Government Cut, nor in the nearshore zones around the islands of Puerto Rico and the U.S. Virgin Islands. In these areas the hydrodynamics allow for the growth of some (*e.g., Orbicella* spp.) of the threatened coral in the shallow depths.

Due to the ephemeral nature of conditions within the water column and the various scales at which water quality data are collected, this aspect of the essential feature is difficult to map at fine spatial or temporal scales. However, annually-averaged plots of temperature, aragonite saturation, nitrate, phosphate, and light, at relatively large spatial scale (*e.g.,* 1° X 1° grid) are available from Guan *et al.* (2015), using 2009 data for some parameters, and updated with newer data from the World Ocean Atlas (2013) for temperature and nutrients. Those maps indicate that conditions that support coral reef growth, and thus coral demographic functions, occur throughout the specific areas under consideration.

Based on the available data, we identified 28 mostly-overlapping specific areas that contain the essential feature. The units can generally be grouped as the: (1) Florida units, (2) Puerto Rico units, (3) St. Thomas/St. John units (STT/STJ), (4) St. Croix units, (5) Navassa units, and (6) FGB units. Within each group of units, each species has its own unique unit that is specific to its geographic and depth distributions. Therefore, within a group there are five mostly-overlapping units—one for each species. The exception is that there are only three completely-overlapping units in the FGB group, because only the three species of *Orbicella* occur there. The essential feature is unevenly distributed throughout these 28 specific areas. Within these areas there exists a mosaic of habitats at relatively small spatial scales, some of which naturally contain the essential features (*e.g.,* coral reefs) and some of which do not (*e.g.,* seagrass beds). Further, within these large areas, specific managed areas and naturally disturbed areas, as described above, also exist. Due to the spatial scale at which the essential feature exists interspersed with these other habitats and disturbed areas, we are not able to more discretely delineate the specific areas under consideration for critical habitat designation.

Unoccupied Critical Habitat Areas

ESA section 3(5)(A)(ii) defines critical habitat to include specific areas outside the geographical area occupied by the species at the time of listing if the areas are determined by the Secretary to be essential for the conservation of the species. Our regulations at 50 CFR 424.12(b)(2) further explain that unoccupied areas shall only be designated after determining that occupied areas are inadequate to ensure the conservation of the species, and the unoccupied areas are reasonably certain to contribute to the conservation of the species and contain one or more essential feature.

The threats to these five corals are generally the same threats affecting coral reefs throughout the world (climate change, fishing, and land-based sources of pollution) and are fully described in the final listing rule (79 FR 53852, September 10, 2014). Specifically, ocean warming, disease, and ocean acidification are the three most significant threats that will impact the potential for recovery of all the listed coral species. Because the primary threats are global in nature, adapting to changing conditions will be critical to the species' conservation and recovery.

We issued guidance in June 2016 on the treatment of climate change uncertainty in ESA decisions, which addresses critical habitat specifically (*https://www.fisheries.noaa.gov/national/endangered-species-conservation/endangered-species-act-guidance-policies-and-regulations*). The guidance states that, when designating critical habitat, NMFS will consider proactive designation of unoccupied habitat as critical habitat when there are adequate data to support a reasonable inference that the habitat is essential for the conservation of the species because of the function(s) it is likely to serve as climate changes. Further, we will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied would be inadequate to ensure the conservation of the species (50 CFR 424.12(b)(2). We specifically address this consideration for threatened Caribbean corals in this section.

All five corals occur in the Caribbean, an area predicted to have more rapid and severe impacts from climate change (van Hooidonk *et al.,* 2014). Shifting into previously unoccupied habitats that become more suitable as other parts of their range become less suitable may be a strategy these corals employ in the future to adapt to changing conditions. However, due to the nature of the Caribbean basin, there is little opportunity for range expansion. The only area of potential expansion is north up the Florida coast. Several of the five coral species have different northern limits to their current range, with *Orbicella faveolata's* limit at St. Lucie Inlet, Martin County, Florida, being the farthest north and at the limit of coral reef formation in Florida for these species. A northern range expansion along Florida's coast beyond this limit is unlikely due to lack of evidence of historical reef growth under warmer climates. Further, northern expansion is inhibited by hydrographic conditions (Walker and Gilliam, 2013). The other corals could theoretically expand into the area between their current northern extents to the limit of reef formation. However, temperature is not likely the factor limiting occupation of those areas, given the presence of other reef-

building corals. Thus, there are likely other non-climate-related factors limiting the northern extent of the corals' ranges.

Because the extent of the proposed critical habitat designations is the entire occupied areas of the species, we believe that the designations are adequate to provide for the conservation of the five corals. Further, no unoccupied areas exist that would add to the conservation of the five corals. Therefore, we are not considering any unoccupied areas for designation of critical habitat for the five corals.

Application of ESA Section 4(a)(3)(B)(i) (Military Lands)

Section 4(a)(3)(B)(i) of the ESA prohibits designating as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (DoD), or designated for its use, that are subject to an Integrated Natural Resources Management Plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation. Our regulations at 50 CFR 424.12(h) provide that, in determining whether an applicable benefit is provided, we will consider:

(1) The extent of the area and features present;

(2) The type and frequency of use of the area by the species;

(3) The relevant elements of the INRMP in terms of management objectives, activities covered, and best management practices, and the certainty that the relevant elements will be implemented; and

(4) The degree to which the relevant elements of the INRMP will protect the habitat from the types of effects that would be addressed through a destruction-or-adverse-modification analysis.

Naval Air Station Key West (NASKW) is the only installation controlled by the DoD, specifically the Department of the Navy (Navy), that coincides with any of the areas under consideration for critical habitat. On September 21, 2015, the Navy requested in writing that the areas covered by the 2014 INRMP for NASKW not be designated as critical habitat, pursuant to ESA section 4(a)(3)(B)(i), and provided the INRMP for our review.

The NASKW INRMP covers the lands and waters—generally out to 50 yards (45.7 m)—adjacent to NASKW, including several designated restricted areas (see INRMP figures C–1 through C–14). The total area of the waters covered by the INRMP that overlaps with areas considered for the proposed critical habitat is approximately 800 acres. Within this area, four of the threatened corals (*D. cylindrus, O. annularis, O. faveolata, and O. franksi*) and the proposed essential feature are present in densities and proportions similar to those throughout the rest of the nearshore habitat in the Florida Keys. The species use this area in the same way that they do all areas proposed for critical habitat—to carry out all life functions. As detailed in Chapter 4 and Appendix C of the INRMP, the plan provides benefits to the threatened corals and existing *Acropora* critical habitat through the following NASKW broad programs and activities: (1) Erosion control—which will prevent sediments from entering into the water; (2) Boca Chica Clean Marina Designation—which eliminates or significantly reduces the release of nutrients and contaminants; (3) stormwater quality improvements—which prevent or reduce the amount of nutrients, sediments, and contaminants; and (4) wastewater treatment—which reduces the release of nutrients and contaminants consistent with Florida Surface Water Quality Standards. Within these categories, there are 15 specific management activities and projects that provide benefit to the corals and their habitat (see Table 4–2 of the INRMP). These types of best management practices have been ongoing at NASKW since 1983; thus, they are likely to continue into the future. Further, the plan specifically provides assurances that all NASKW staff have the authority and funding (subject to appropriations) to implement the plan. The plan also provides assurances that the conservation efforts will be effective through annual reviews conducted by state and Federal natural resource agencies. These activities provide a benefit to the species and the identified essential feature in the proposed critical habitat designations by reducing sediment and nutrient discharges into nearshore waters, which addresses some of the particular conservation and protection needs that critical habitat would afford. These activities are similar to those that we describe below as project modifications for avoiding or reducing adverse effects to the proposed critical habitat. Therefore, were we to consult on the activities in the INRMP that may affect the proposed critical habitat, we would likely not require any project modifications based on best management practices in the INRMP. Further, the INRMP includes provisions for monitoring and evaluating conservation effectiveness, which will ensure continued benefits to the species. Annual reviews of the INRMP for 2011–2015 found that the INRMP executions, including actions that minimize or eliminate land-based sources of pollution, ''satisfied'' or ''more than satisfied'' conservation objectives. We believe the NASKW INRMP provides the types of benefits to the threatened corals described in our regulations (50 CFR 424.12(h)).

Four (*D. cylindrus, O. annularis, O. faveolata, and O. franksi*) of the five corals' specific areas overlap with NASKW, based on the depth in which the species occur and the distance from shore covered by NASKW's INRMP. Therefore, pursuant to section 4(a)(3)(B)(i) of the ESA, we determined that the INRMP provides a benefit to those threatened corals, and we are not designating critical habitat within the boundaries covered by the INRMP.

Application of ESA Section 4(b)(2)

Section 4(b)(2) of the ESA requires that we consider the economic impact, impact on national security, and any other relevant impact, of designating any particular area as critical habitat. Additionally, the Secretary has the discretion to consider excluding any area from critical habitat if (s)he determines, based upon the best scientific and commercial data available, the benefits of exclusion (that is, avoiding some or all of the impacts that would result from designation) outweigh the benefits of designation. The Secretary may not exclude an area from designation if exclusion will result in the extinction of the species. Because the authority to exclude is discretionary, exclusion is not required for any particular area under any circumstances.

The ESA provides the U.S. Fish and Wildlife Service (USFWS) and NMFS (the Services) with broad discretion in how to consider impacts. (*See,* H.R. Rep. No. 95–1625, at 17, reprinted in 1978 U.S.C.C.A.N. 9453, 9467 (1978). Economics and any other relevant impact shall be considered by the Secretary in setting the limits of critical habitat for such a species. The Secretary is not required to give economics or any other relevant impact predominant consideration in his specification of critical habitat. The consideration and weight given to any particular impact is completely within the Secretary's discretion.). Courts have noted the ESA does not contain requirements for any particular methods or approaches. (*See, e.g., Bldg. Indus. Ass'n of the Bay Area et al.* v. *U.S. Dept. of Commerce et al.,* No. 13–15132 (9th Cir., July 7, 2015),

upholding district court's ruling that the ESA does not require the agency to follow a specific methodology when designating critical habitat under section 4(b)(2)). For this proposed rule, we followed the same basic approach to describing and evaluating impacts as we have for several recent critical habitat rulemakings, as informed by our Policy Regarding Implementation of Section 4(b)(2) of the ESA (81 FR 7226, February 11, 2016).

The following discussion of impacts is summarized from our Draft Information Report, which identifies the economic, national security, and other relevant impacts that we projected would result from including each of the specific areas in the proposed critical habitat designations. We considered these impacts when deciding whether to exercise our discretion to propose excluding particular areas from the designations. Both positive and negative impacts were identified and considered (these terms are used interchangeably with benefits and costs, respectively). Impacts were evaluated in quantitative terms where feasible, but qualitative appraisals were used where that is more appropriate to particular impacts.

The primary impacts of a critical habitat designation result from the ESA section 7(a)(2) requirement that Federal agencies ensure their actions are not likely to result in the destruction or adverse modification of critical habitat, and that they consult with NMFS in fulfilling this requirement. Determining these impacts is complicated by the fact that section 7(a)(2) also requires that Federal agencies ensure their actions are not likely to jeopardize the species' continued existence. One incremental impact of designation is the extent to which Federal agencies modify their proposed actions to ensure they are not likely to destroy or adversely modify the critical habitat beyond any modifications they would make because of listing and the requirement to avoid jeopardy to listed corals. When the same modification would be required due to impacts to both the species and critical habitat, there would be no additional or incremental impact attributable to the critical habitat designation beyond the administrative impact associated with conducting the critical habitat analysis. Relevant, existing regulatory protections are referred to as the ''baseline'' for the analysis and are discussed in the Draft Information Report. In this case, notable baseline protections include the ESA listings of the threatened corals, and the existing critical habitat for elkhorn and staghorn corals (73 FR 72210; November 26, 2008).

The Draft Information Report describes the projected future Federal activities that would trigger section 7 consultation requirements if they are implemented in the future, because they may affect the essential feature and consequently may result in economic costs or negative impacts. The report also identifies the potential national security and other relevant impacts that may arise due to the proposed critical habitat designations, such as positive impacts that may arise from conservation of the species and its habitat, state and local protections that may be triggered as a result of designation, and education of the public to the importance of an area for species conservation.

Economic Impacts

Economic impacts of the critical habitat designations result through implementation of section 7 of the ESA in consultations with Federal agencies to ensure their proposed actions are not likely to destroy or adversely modify critical habitat. The economic impacts of consultation may include both administrative and project modification costs; economic impacts that may be associated with the conservation benefits resulting from consultation are described later.

In 2016, we examined the ESA section 7 consultation record for the period 2004–2014, as compiled in our Public Consultation Tracking System (PCTS) database, to identify the types of Federal activities that may affect the five threatened Caribbean corals' proposed critical habitat. We will also review more recent consultation information prior to the publication of any final rule. We requested that Federal action agencies provide us with information on any additional future consultations that may affect the proposed critical habitat, and therefore should be included in our analysis. Of the types of past consultations that may affect the essential feature in any unit of proposed critical habitat, we determined that none of the activities would solely affect the essential feature. That is, all categories of the activities identified have potential routes of effects to both the threatened corals and the critical habitat.

We identified the following 10 categories of activities implemented by six different Federal entities as having the potential to affect the essential feature of the five corals' critical habitat:

- Coastal and in-water construction (*e.g.* docks, seawalls, piers, marinas, port expansions, anchorages, pipelines/cables, bridge repairs, aids to navigation, etc.) conducted or authorized by U.S. Army Corps of Engineers (USACE);
- Channel dredging (maintenance dredging of existing channels and offshore disposal of dredged material) conducted or authorized by USACE;
- Beach nourishment/shoreline protection (placement of sand onto eroding beaches from onshore or offshore borrow sites) conducted or authorized by USACE;
- Water quality management (revision of state water quality standards, issuance of National Pollutant Discharge Elimination System (NPDES) permits and Total Maximum daily load (TMDL) standards under the CWA, and pesticide registrations under the Federal Insecticide, Fungicide and Rodenticide Act) authorized by the Environmental Protection Agency (EPA);
- Protected area management (development of management plans for national parks, marine sanctuaries, wildlife refuges, etc.) conducted by the National Park Service (NPS) and NOAA National Ocean Service (NOS);
- Fishery management (development of fishery management plans under the Magnuson-Stevens Fishery Conservation and Management Act) conducted by NMFS;
- Aquaculture (development of aquaculture facilities) authorized by EPA and USACE, and funded by NMFS; and
- Military activities (*e.g.,* training exercises) conducted by DoD.

By conducting interviews and querying the database for these categories of activities in the maximum geographic extent of the sum of the five corals' proposed critical habitat, we estimate that 5 programmatic, 39 formal, and 272 informal section 7 consultations (for a total of 307) are likely to occur over the next 10 years and will require analysis of impacts to the proposed critical habitat. Because we have data on past consultations for impacts to the acroporid corals as well as their critical habitat, we believe it is a reasonable assumption that the breakout of the type of past consultations (into informal, formal, and programmatic consultations) likely reflects the breakout of future consultations. In addition to the type of consultation, we also present the data across the geopolitical groups of units (*i.e.,* the scale at which economic data is collected) that overlap with the maximum geographic extent *(i.e.,* the area that is determined by the species with the widest geographic and depth ranges) of the proposed critical habitat designations. We are not able to display the data by individual species' specific areas due to the largely overlapping but

distinct nature of the specific areas for all the species within a geopolitical area, and the limitations on the way the historical consultation data are recorded (*i.e.,* by county or region, rather than specific location).

As discussed in more detail in our Draft Information Report, all categories of activities identified as having the potential to affect the proposed essential feature also have the potential to affect the threatened Caribbean corals. To estimate the economic impacts of critical habitat designation, our analysis compares the state of the world with and without the designation of critical habitat for the five corals. The ''without critical habitat'' scenario represents the baseline for the analysis, considering protections already afforded the proposed critical habitat as a result of the listing of the five corals as threatened species and as a result of other Federal, state, and local regulations or protections, notably the previous designation of critical habitat for the two Caribbean acroporids. The ''with critical habitat'' scenario describes the state of the world with the critical habitat designations. The incremental impacts that will be associated specifically with these critical habitat designations if finalized as proposed are the difference between the two scenarios. Baseline protections exist in large areas proposed for designation; however, there is uncertainty as to the degree of protection that these protections provide. In particular:

- The five corals are present in each of the areas proposed for them, and are already expected to receive significant protections related to the listing of the species under the ESA that may also protect the critical habitat. However, there is uncertainty on whether a particular species may be present within a particular project site, due to their patchy distribution throughout their habitat.
- The 2008 *Acropora* critical habitat designation overlaps significantly with the specific areas under consideration, and the overlap includes the areas where the vast majority of projects and activities potentially affected are projected to occur. The existing critical habitat designation shares the substrate aspect of the essential feature with this proposed designation for the five corals, but not the water quality components. The activities that may affect the proposed critical habitat water column feature are the same as those that would affect the *Acropora* critical habitat substrate feature, with the exception of activities that would increase water temperature.

Incremental impacts result from changes in the management of projects and activities, above and beyond those changes resulting from existing required or voluntary conservation efforts undertaken due to other Federal, state, and local regulations or guidelines (baseline requirements). The added administrative costs of considering critical habitat in section 7 consultation and the additional impacts of implementing conservation efforts (*i.e.,* reasonable and prudent alternatives in the case of an adverse modification finding) resulting from the designation of critical habitat are the direct, incremental compliance costs of designating critical habitat.

Designation of critical habitat for the five corals is unlikely to result in any new section 7 consultations. Given the listing of the five corals, and the fact that the proposed critical habitat overlaps, in part, with *Acropora* critical habitat, section 7 consultations are already likely to occur for activities with a Federal nexus throughout the proposed critical habitat areas. However, the need to address adverse modification of the proposed critical habitat in future consultations will add an incremental administrative burden, but only for those activities that would not have affected *Acropora* critical habitat (*i.e.,* the Federal action areas are outside the boundaries or the actions involve increases in water temperature that is not considered under existing *Acropora* critical habitat). Thus, some of the categories of activities identified above as having the potential to affect the proposed critical habitat will not result in incremental impacts due to these designations. We estimate that 1 programmatic, 19 formal and 34 informal, for a total of 54 consultations will result in incremental costs over the next 10 years. Table 2 shows the predicted number of consultations, by activity and Federal agency, that are projected to result in incremental costs.

TABLE 2—FORECAST INCREMENTAL SECTION 7 CONSULTATIONS BY ACTIVITY AND ACTION AGENCY (2016–2025)

Unit	Coastal & in-water construction (USACE)	Channel dredging (USACE)	Beach nourishment (USACE)	Water quality mgmt. (EPA)	Military (NAVY)	Total
Florida	24	5	4	2	2	37
Puerto Rico	4	0	0	7	0	11
STT/STJ	1	0	0	2	0	3
St. Croix	0	0	0	2	0	2
Navassa	0	0	0	0	0	0
FGB	0	0	0	0	0	0
Total	29	5	4	19	2	54
% of Total	43%	9%	7%	35%	4%	100%

The administrative effort required to address adverse effects to the proposed critical habitat is assumed to be the same, on average, across activities regardless of the type of activity (*e.g.,* beach nourishment versus channel dredging). Informal consultations are expected to require comparatively low levels of administrative effort, while formal and programmatic consultations are expected to require comparatively higher levels of administrative effort. For all formal and informal consultations, we anticipate that incremental administrative costs will be incurred by NMFS, a Federal action agency, and potentially a third party (*e.g.,* applicant, permittee). For programmatic consultations, we anticipate that costs will be incurred by NMFS and a Federal action agency. Incremental administrative costs per consultation effort are expected on average to be $9,200 for programmatic consultations, $5,100 for formal consultations, and $2,400 for informal consultations. The cost per consultation effort is multiplied by the number of each anticipated type of consultation (*i.e.,* programmatic, formal, and

informal) within each unit under consideration. Incremental administrative costs are expected to total approximately $140,000 over the next 10 years for an annualized cost of $20,000 (discounted at 7 percent as required by the Office of Management and Budget (OMB)).

To determine the incremental impact of the designations of critical habitat from project modifications triggered specifically to avoid potential destruction or adverse modification of critical habitat, we evaluated whether and where critical habitat designations may generate project modifications above and beyond those undertaken under the baseline, for example, to avoid jeopardy to the five corals or to avoid destruction or adverse modification of existing *Acropora* critical habitat. Depending on the circumstances, project modifications may be considered baseline (*e.g.,* would be required regardless of critical habitat designation) or incremental (*e.g.,* resulting from critical habitat designation). The types of project modifications that may be recommended to avoid adverse modification of the five corals critical habitat are the same as those that would be recommended to avoid adverse modification of the existing *Acropora* critical habitat (with the exception of modifications to address increases in water temperature), or to avoid jeopardy to the five corals. Whether projects will require modifications solely due to the proposed critical habitat will depend on: (1) Geographic location, (2) activity type, and (3) results of surveys to determine the potential presence of at least one of the five corals. Project modifications would be incremental only in cases where the five listed corals are all absent and thus would not be affected, and the project would also not affect existing *Acropora* critical habitat.

We conducted the following steps to quantify the incremental impacts of potential project modifications to the activities that we ultimately concluded would not affect one of the five corals and *Acropora* critical habitat: (1) Identified the types and occurrence of activities that are likely to be affected by the proposed critical habitat designations, (2) projected the likelihood that forecasted activities will in fact need to be modified, and (3) estimated the average costs of modifications needed to comply with the ESA's critical habitat provisions. Based on this analysis, incremental project modifications and associated costs are projected to result only from coastal and in-water construction, channel dredging, beach nourishment/shoreline protection, water quality management activities, and military activities.

We recognize that uncertainty exists regarding whether, where, and how frequently surveys will identify the presence of the five coral species. Should one of the listed corals be present within the area of a future project that may also affect proposed critical habitat, the costs of project modifications would not be incremental to the critical habitat. To reflect the uncertainty with respect to the likelihood that these consultations will require additional project modifications due to impacts to new critical habitat, we estimated a range of costs. The low-end estimate assumes that no incremental project modifications will occur because any project modifications would be required to address impacts to one of the five corals or to existing *Acropora* critical habitat in a project area. The high-end estimate assumes that all the project modifications would be incremental because none of the five corals are present and the action would not affect existing *Acropora* critical habitat. Taking into consideration the types and cost estimates of the project modifications that may be required for predicted consultations identified, we estimate the high-end incremental costs, which total $880,000 over 10 years for an annualized cost of $88,000 (discounted at 7 percent).

Total incremental costs resulting from the five corals critical habitat are estimated to range from $140,000 to $1.02 million over 10 years, an annualized cost of $20,000 to $140,000 (discounted at 7 percent). The low-end costs are a result of the increased administrative effort to analyze impacts to the proposed critical habitat in future consultations on activities that are not projected to affect *Acropora* critical habitat (*i.e.,* in areas outside the boundaries, projects with impacts to water temperature, or pesticide registrations). The high-end costs are a result of the increased administrative effort (*i.e.,* low-end costs) plus the incremental project modification costs that stem solely from the proposed critical habitat. Incremental project modification costs are a result of future consultations that are not projected to have effects on *Acropora* critical habitat. The high-end costs also assume that the project modifications will be solely a result of the proposed critical habitat, and not the presence of the species. However, the high-end estimate is very likely an overestimate on incremental costs because an undetermined number of future consultations will have project modifications that address adverse effects to one or more of the five corals, as well as adverse effects to the new critical habitat. Nearly 86 percent of total high-end incremental costs result from project modifications, primarily for coastal and in-water construction and water quality management consultations. The relative percentage costs by unit and depth is illustrated in Table 3 and Table 4 for the low-end and high-end scenarios, respectively (depth is included to illustrate areas being proposed beyond existing *Acropora* critical habitat, which extends to 30 m). At the high end, approximately 30 percent of these costs is related to activity in Florida and another 50 percent is related to activity occurring in Puerto Rico. This cost distribution is as expected due to the size of the human populations adjacent to the proposed units, and thus human activity, in these jurisdictions, as compared to the other units. In other words, the highest proportion of the incremental costs occurs in those units with the highest number of future consultations, which is proportional to the human population adjacent to those units.

TABLE 3—LOW-END TOTAL INCREMENTAL COSTS (ADMINISTRATIVE) BY UNIT, 2016–2025 ($2015, 7 PERCENT DISCOUNT RATE)

	Present value impacts				Annualized impacts		
Unit	Shore to 30 m	30 m to 90 m	All depths	% of Total	Shore to 30 m	30 m to 90 m	All depths
Florida	$15,000	$25,000	$40,000	30	$2,000	$3,600	$5,700
Puerto Rico	22,000	49,000	70,000	50	3,100	7,000	10,000
STT/STJ	4,000	10,000	14,000	10	600	1,400	2000
St. Croix	4,000	10,000	14,000	0	600	1,400	2000
Navassa	0	0	0	0	0	0	0

TABLE 3—LOW-END TOTAL INCREMENTAL COSTS (ADMINISTRATIVE) BY UNIT, 2016–2025 ($2015, 7 PERCENT DISCOUNT RATE)—Continued

	Present value impacts				Annualized impacts		
Unit	Shore to 30 m	30 m to 90 m	All depths	% of Total	Shore to 30 m	30 m to 90 m	All depths
FGB	0	0	0	0	0	0	0
Total	45,000	95,000	140,000	100	6,300	13,500	20,000

Note: The estimates may not sum to the totals reported due to rounding.

TABLE 4—HIGH-END TOTAL INCREMENTAL COSTS (ADMINISTRATIVE AND PROJECT MODIFICATION) BY UNIT, 2016–2025 ($2015, 7 PERCENT DISCOUNT RATE)

	Present value impacts				Annualized Impacts		
Unit	Shore to 30 m	30 m to 90 m	All depths	% of Total	Shore to 30 m	30 m to 90 m	All depths
Florida	$385,000	$154,000	$540,000	53	$55,000	$22,300	$77,700
Puerto Rico	22,000	408,000	429,000	42	3,100	57,700	60,700
STT/STJ	4,000	29,000	33,000	3	600	3,600	4,700
St. Croix	4,000	10,000	14,000	1	600	1,400	2,000
Navassa	0	0	0	0	0	0	0
FGB	0	0	0	0	0	0	0
Total	415,000	604,000	1,020,000	100	59,000	83,000	140,000

Note: The estimates may not sum to the totals reported due to rounding.

Tables 5 and 6 present total low and high-end incremental costs by activity type. The activity with the highest costs is coastal and in-water construction, ranging from $70,600 to $500,000 over 10 years (discounted at 7 percent). At the high end this represents approximately 50 percent of the total costs. This result is expected because this is the category of activity with the most frequent projects that occur in the marine environment.

TABLE 5—LOW-END TOTAL INCREMENTAL COSTS (ADMINISTRATIVE) BY ACTIVITY, 2016–2025

[$2015, 7 percent discount rate]

Unit	Coastal and in-water construction (USACE)	Beach nourishment (USACE)	Channel dredging (USACE)	Water quality mgmt. (EPA)	Military activities (Navy)	Total	Coastal and in-water construction (USACE)	Beach nourishment (USACE)	Channel dredging (USACE)	Water quality mgmt. (EPA)	Military activities (Navy)	Total
Florida	$14,500	$5,600	$220	$9,200	$11,000	$32,500	$2,100	$800	$31	$670	$1,500	$4,600
Puerto Rico	45,400	4,100	5,000	10,500	3,000	63,000	6,500	580	710	1,000	600	8,900
STT/STJ	5,800	80	230	7,880	0	6,200	830	10	30	600	0	880
St. Croix	4,900	0	950	8,000	0	6,000	700	0	140	600	0	830
Navassa	0	0	0	0	0	0	0	0	0	0	0	0
FGB	0	0	0	0	0	0	0	0	0	0	0	0
Total	70,600	9,700	6,300	36,000	14,000	140,000	10,000	1,400	910	3,000	2,100	18,000

TABLE 6—HIGH-END TOTAL INCREMENTAL COSTS (ADMINISTRATIVE AND PROJECT MODIFICATION) BY ACTIVITY, 2016–2025

[$2015, 7 percent discount rate]

Unit	Coastal & in-water const. (USACE)	Beach nourishment (USACE)	Channel dredging (USACE)	Water quality mgmt. (EPA)	Military (NAVY)	Total	Coastal & in-water const. (USACE)	Beach nourishment (USACE)	Channel dredging (USACE)	Water quality mgmt. (EPA)	Military (NAVY)	Total
FL	$364,500	$80,600	$75,220	$9,200	$11,000	$532,500	$53,000	$11,800	$11,031	$170	$1,500	$76,600
PR	101,400	4,100	5,000	310,500	3,000	422,000	14,500	580	710	43,000	600	59,390
STT/STJ	24,800	80	230	80	0	25,200	3,530	11	33	11	0	3,585
STX	4,900	0	950	8,000	0	6,000	700	0	140	0	0	840
Nav	0	0	0	0	0	0	0	0	0	0	0	0
FGB	0	0	0	0	0	0	0	0	0	0	0	0
Total	500,600	84,700	81,300	336,000	14,000	1,020,000	71,000	12,000	12,000	43,000	2,100	140,000

National Security Impacts

Our critical habitat impacts analyses recognize that impacts to national security result only if a designation would trigger future ESA section 7 consultations because a proposed military activity ''may affect'' the physical or biological feature(s) essential to the listed species' conservation. Anticipated interference with mission-essential training or testing or unit readiness, through the additional commitment of resources to an adverse modification analysis and expected requirements to modify the action to prevent adverse modification of critical habitat, has been identified as an impact of critical habitat designations. Our impacts analyses also recognize that whether national security impacts result from the designation depends on whether future consultations would be required under the jeopardy standard, due to the coral being present, regardless of the critical habitat designation, and whether the designation would add new burdens beyond those related to the consultation on effects to the corals.

As described previously, we identified DoD military operations as a category of activity that has the potential to affect the essential feature of the proposed critical habitat for the five corals. However, most of the actions we have consulted on in the past would not result in incremental impacts in the future, because the consultations would be required to address impacts to either the five corals or the substrate feature of *Acropora* critical habitat. Based on our review of historical consultations, only those activities that would be conducted in the South Florida Ocean Measuring Facility operated by the Navy would involve incremental impacts due to the proposed designations, and thus only consultations on naval activities in this particular area could result in national security impacts.

In 2015, we requested the DoD provide us with information on military activities that may affect the proposed critical habitat and whether the proposed critical habitat would have a national security impact due to the requirement to consult on those activities. The Navy responded that activities associated with the designated restricted area managed by the South Florida Ocean Measuring Facility (SFOMF–RA), defined in 33 CFR 334.580, and located offshore of Dania, Florida, may affect the proposed critical habitat. This assertion is supported by two previous consultations on cable-laying activities in the SFOMF–RA over the past 10 years.

The SFOMF–RA contains underwater cables and benthic sensor systems that enable real-time data acquisition from Navy sensor systems used in Navy exercises. The previous consultations, in 2011 and 2013, were for the installation of new cables. These consultations did not affect any coral species, because the cables were routed to avoid the corals. These consultations did not consider effects to *Acropora* critical habitat because the area was excluded from the 2008 *Acropora* critical habitat designation based on national security impacts. However, installation of the cables would have affected the substrate feature. Because the installation of new cables in the future may affect the proposed critical habitat substrate feature, and the area was excluded from *Acropora* critical habitat, we expect that there may be an incremental impact to the Navy due to the proposed critical habitat designations. The impact would result from the added administrative effort to consider impacts to the proposed critical habitat and project modifications to avoid adverse effects to the substrate aspect of the essential feature. These impacts would likely be incremental due to the critical habitat designations.

The Navy has conducted extensive benthic surveys in the SFOMF–RA and has mapped the locations of all listed corals. Thus, they would be able to avoid impacts to the listed corals from the installation of new cables. However, if the cables were laid over the proposed critical habitat's substrate feature, the cable would make the substrate unavailable for settlement and recruitment. Thus, we would require consultation to evaluate impact of this adverse effect to the essential feature. The administrative costs and project modification costs would be incremental impacts of the proposed critical habitat. The Navy concluded that critical habitat designations at the SFOMF–RA would likely impact national security by diminishing military readiness through the requirement to consult on their activities within critical habitat beyond the requirement to consult on the threatened corals and through any additional project modifications.

In 2019, the Navy requested the exclusion of the Federal Danger Zones and Restricted Areas off NAS Key West designated in 33 CFR 334.610 and 33 CFR 334.620 in Navy's Key West Operations Area. However, at this time NMFS is unable to make a determination and has been in discussion with the Navy to identify the potential national security impacts in these areas. NMFS will provide exclusion determinations for this request in the final rule.

Other Relevant Impacts

We identified three broad categories of other relevant impacts of this proposed critical habitat: Conservation benefits, both to the species and to society; impacts on governmental or private entities that are implementing existing management plans that provide benefits to the listed species; and educational and awareness benefits. Our Draft Impacts Analysis discusses conservation benefits of designating the 28 specific areas, and the benefits of conserving the five corals to society, in both ecological and economic metrics.

Conservation Benefits

The primary benefit of critical habitat designation is the contribution to the conservation and recovery of the five corals. That is, in protecting the features essential to the conservation of the species, critical habitat directly contributes to the conservation and recovery of the species. This analysis contemplates three broad categories of benefits of critical habitat designation:

(1) Increased probability of conservation and recovery of the five corals. The most direct benefits of the critical habitat designations stem from the enhanced probability of conservation and recovery of the five corals. From an economic perspective, the appropriate measure of the value of this benefit is people's ''willingness-to-pay'' for the incremental change. While the existing economics literature is insufficient to provide a quantitative estimate of the extent to which people value incremental changes in recovery potential, the literature does provide evidence that people have a positive preference for listed species conservation, even beyond any direct (*e.g.,* recreation, such as viewing the species while snorkeling or diving) or indirect (*e.g.,* reef fishing that is supported by the presence of healthy reef ecosystems) use for the species.

(2) Ecosystem service benefits. Overall, coral reef ecosystems, including those comprising populations of the five corals, provide important ecosystem services of value to individuals, communities, and economies. These include recreational opportunities (and associated tourism spending in the regional economy), habitat and nursery functions for recreationally and commercially valuable fish species, shoreline protection in the form of wave attenuation and reduced beach erosion, and climate stabilization via carbon sequestration. The total annual

economic value of coral reefs in U.S. jurisdictions in 2012 has been summarized as: (1) Florida—$324M/year, (2) Puerto Rico—$1,161M/year, and (3) USVI—$210M/year (Brander and Van Beukering, 2013). Efforts to conserve the five corals also benefit the broader reef ecosystems, thereby preserving or improving these ecosystem services and values.

Conservation benefits to each coral in all their specific areas are expected to result from the designations. Critical habitat most directly influences the recovery potential of the species and protects coral reef ecosystem services through its implementation under section 7 of the ESA. That is, these benefits stem from the implementation of project modifications undertaken to avoid destruction and adverse modification of critical habitat. Accordingly, critical habitat designation is most likely to generate the benefits discussed in those areas expected to be subject to additional recommendations for project modifications (above and beyond any conservation measures that may be implemented in the baseline due to the listing status of the species or for other reasons). In addition, critical habitat designation may generate ancillary environmental improvements and associated ecosystem service benefits (*i.e.,* to commercial fishing and recreational activities) in areas subject to incremental project modifications. While neither benefit can be directly monetized, existing information on the value of coral reefs provides an indication of the value placed on those ecosystems.

(3) Education and Awareness Benefits. There is the potential for education and awareness benefits arising from the critical habitat designations. This potential stems from two sources: (1) Entities that engage in section 7 consultation and (2) members of the general public interested in coral conservation. The former potential exists from parties who alter their activities to benefit the species or essential feature because they were made aware of the critical habitat designations through the section 7 consultation process. The latter may engage in similar efforts because they learned of the critical habitat designations through outreach materials. For example, we have been contacted by diver groups in the Florida Keys who are specifically seeking the two Caribbean acroporid corals on dives and reporting those locations to NMFS, thus assisting us in planning and implementing coral conservation and management activities. In our experience, designation raises the public's awareness that there are special considerations to be taken within the area.

Similarly, state and local governments may be prompted to enact laws or rules to complement the critical habitat designations and benefit the listed corals. Those laws would likely result in additional impacts of the designations. However, it is impossible to quantify the beneficial effects of the awareness gained through, or the secondary impacts from state and local regulations resulting from, the critical habitat designations.

Impacts to Governmental and Private Entities With Existing Management Plans Benefitting the Essential Features

Among other relevant impacts of the critical habitat designations we considered under section 4(b)(2) of the ESA are impacts on relationships with, or the efforts of, private and public entities involved in management or conservation efforts benefiting listed species. In some cases, the additional regulatory layer of a designation could negatively impact the conservation benefits provided to the listed species by existing or proposed management or conservation plans.

Impacts on entities responsible for natural resource management, conservation plans, or the functioning of those plans depend on the type and number of section 7 consultations that may result from the designations in the areas covered by those plans, as well as any potential project modifications recommended by these consultations. As described in section 10.1.3.5 of the Draft Information Report, there were six past consultations on Federal protected area management plans (three formal, three informal) in the units being proposed as critical habitat. The three formal consultations were related to the NPS management plans at the following Federal protected areas:

- Buck Island Reef National Monument in St. Croix, U.S. VI;
- Everglades National Park in Monroe County, FL; and
- Biscayne National Park in Miami-Dade County, FL.

Negative impacts to the NPS could result if the critical habitat designations interfere with these agencies' ability to provide for the conservation of the species, or otherwise hampers management of these areas. Existing management plans in these three protected areas and their associated regulations protect existing coral reef resources, but they do not specifically protect the substrate and water quality feature for purposes of increasing listed coral abundance and eventual recovery. Thus, the five corals' critical habitat designations would provide unique benefits for the corals, beyond the benefits provided by these existing management plans. However, the identified areas not only contain the essential feature, but they also contain one or more of the five corals, and they overlap with previously designated *Acropora* critical habitat. Hence, any section 7 impacts will likely be limited to administrative costs. Because we identified resource management as a category of activities that may affect both the five corals and the critical habitat, these impacts would not be incremental. In addition, we found no evidence that relationships with the Federal protected area managers would be negatively affected, or that negative impacts to other agencies' ability to provide for the conservation of the listed coral species would result from designation. Therefore, we do not expect the critical habitat designations to impact natural resource agencies implementing management plans.

Discretionary Exclusions Under Section 4(b)(2)

We are not exercising our discretion to consider exclusions based on economic impacts. Our conservative identification of the highest potential incremental economic impacts indicates that any such impacts will be relatively small—$20,000 to $140,000 annually. The incremental costs are split between the incremental administrative effort and incremental project modification costs for the relatively few (about 54) consultations over the next 10 years. Further, the analysis indicates that there is no particular area within the units that meet the definition of critical habitat where economic impacts would be particularly high or concentrated as compared to the human population and level of activities in each unit.

We are proposing to exclude one particular area on the basis of national security impacts. National security impacts would occur in the designated restricted area managed by the SFOMF–RA offshore Dania Beach, Florida, which coincides with all five threatened corals' proposed critical habitats. The area does support the essential feature and contains the five threatened Caribbean corals. The Navy concluded that critical habitat designations at the SFOMF–RA would likely impact national security by diminishing military readiness through the requirement to consult on their activities within critical habitat beyond the requirement to consult on the threatened corals and potentially result in additional project modifications. This

is likely because the Navy, which has comprehensive maps of all threatened coral locations within the SFOMF–RA, would need to avoid impacts to the substrate aspect of the essential feature in addition to avoiding impacts to the listed corals themselves, should any new cables or sensors be installed. The Navy stated that impediments to SFOMF operations would adversely impact the Navy's ability to maintain an underwater stealth advantage of future classes of ships and submarines and impede our nation's ability to address emergent foreign threats. The Navy stated that the critical habitat designations would hinder its ability to continue carrying out the unique submarine training provided by this facility, as no other U.S. facility has the capability to make the cable-to-shore measurements enabled at the SFOMF that satisfy its requirement to assure the newest submarines are not vulnerable to electromagnetic detection. The Navy advised the loss of this capability would directly impact new construction of submarines and submarines already in the fleet that are being readied for deployment. Therefore, SFOMF's activities are necessary to maintain proficiency in mission-essential tactics for winning wars, deterring aggression, and maintaining freedom of the seas. The excluded area comprises a very small portion of the areas that meet the definition of critical habitat. Navy regulations prohibit anchoring, trawling, dredging, or attaching any object within the area; thus, the corals and their habitat will be protected from these threats. Further, the corals and their habitat will still be protected through ESA section 7 consultations that prohibit jeopardizing the species' continued existence and require modifications to minimize the impacts of incidental take. Further, we do not foresee other Federal activities that might adversely impact critical habitat that would be exempted from future consultation requirements due to this exclusion, since this area is under exclusive military control. Therefore, in our judgment, the benefit of including the particular area of the SFOMF–RA is outweighed by the benefit of avoiding the impacts to national security the Navy would experience if it were required to consult based on critical habitat. Given the small area (5.5 mi^2 (14.2 km^2)) that meets the definition of critical habitat encompassed by this area, we conclude that exclusion of this area will not result in extinction of any of the five threatened Caribbean corals.

We are not able to make a determination on the exclusion of the Key West Operations Area at this time due to a lack of information to conduct the proper analysis and our deadline for the proposed designations. NMFS, in close coordination with the Navy, will reconsider this matter consistent with the weighing factors, and will provide exclusion determinations for this request in the final rule.

We are not proposing to exclude any particular area based on other relevant impacts. Other relevant impacts include conservation benefits of the designations, both to the species and to society. Because the feature that forms the basis of the critical habitat designations is essential to the conservation of the five threatened Caribbean corals, the protection of critical habitat from destruction or adverse modification may at minimum prevent loss of the benefits currently provided by the species and their habitat and may contribute to an increase in the benefits of these species to society in the future. While we cannot quantify or monetize the benefits, we believe they are not negligible and would be an incremental benefit of these designations.

Proposed Critical Habitat Designations

Our critical habitat regulations state that we will show critical habitat on a map instead of using lengthy textual descriptions to describe critical habitat boundaries, with additional information discussed in the preamble of the rulemaking and in agency records (50 CFR 424.12(c)). When several habitats, each satisfying the requirements for designation as critical habitat, are located in proximity to one another, an inclusive area may be designated as critical habitat (50 CFR 424.12(d)).

The habitat containing the essential feature and that may require special management considerations or protection is marine habitat of particular depths for each species in the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea. The boundaries of each specific area for each coral species are determined by the species' commonly occupied minimum and maximum depth ranges (*i.e.,* depth contour) within their specific geographic distributions, as described in the literature and observed in monitoring data. All depths are relative to mean low water (MLW). Because the quality of the available GIS data varies based on collection method, resolution, and processing, the proposed critical habitat boundaries are defined by the maps in combination with the textual information included in the proposed regulation. This textual information clarifies and refines the location and boundaries of each area. In particular, the textual information clarifies the proposed boundaries of the critical habitat for each coral species based on a specific water-depth range. The textual information also lists certain particular areas that are not included in the proposed critical habitat.

Occupied Critical Habitat Unit Descriptions

Table 7 describes each unit of critical habitat for each species. It contains the geographic extent and water depths, which generally form the boundaries of each unit.

TABLE 7—DESCRIPTION AND EXTENT OF EACH CRITICAL HABITAT UNIT BY SPECIES

Species	Critical habitat unit name	Location	Geographic extent	Water depth range	Area (approx. rounded)
Orbicella annularis	OANN–1	Florida	Lake Worth Inlet, Palm Beach County to Government Cut, Miami-Dade County.	2–20 m (6.5–65.6 ft).	3,800 km^2 (1,300 mi^2).
		Florida	Government Cut, Miami-Dade County to Dry Tortugas.	0.5–20 m (1.6–65.6 ft).	
	OANN–2	Puerto Rico	All islands	0.5–20 m (1.6–65.6 ft).	2,100 km^2 (830 mi^2).
	OANN–3	USVI	All islands of St. Thomas and St. John.	0.5–20 m (1.6–65.6 ft).	100 km^2 (40 mi^2).
	OANN–4	USVI	All islands of St. Croix	0.5–20 m (1.6–65.6 ft).	230 km^2 (89 mi^2).
	OANN–5	Navassa	Navassa Island	0.5–20 m (1.6–65.6 ft).	0.13 km^2 (0.05 mi^2).

TABLE 7—DESCRIPTION AND EXTENT OF EACH CRITICAL HABITAT UNIT BY SPECIES—Continued

Species	Critical habitat unit name	Location	Geographic extent	Water depth range	Area (approx. rounded)
	OANN–6	FGB	East Flower Garden Bank and West Flower Garden Bank.	17–90 m (55–295 ft).	41 km² (16 mi²).
Orbicella faveolata	OFAV–1	Florida	St. Lucie Inlet, Martin County to Government Cut, Miami-Dade County.	2–90 m (6.5–295 ft).	7,900 km² (3,100 mi²).
		Florida	Government Cut, Miami-Dade County to Dry Tortugas.	0.5–90 m (1.6–295 ft).	
	OFAV–2	Puerto Rico	All islands of Puerto Rico	0.5–90 m (1.6–295 ft).	5,500 km² (2,100 mi²).
	OANN–3	USVI	All islands of St. Thomas and St. John.	0.5–90 m (1.6–295 ft).	1,400 km² (520 mi²).
	OFAV–4	USVI	All islands of St. Croix	0.5–90 m (1.6–295 ft).	360 km² (140 mi²).
	OFAV–5	Navassa	Navassa Island	0.5–90 m (1.6–295 ft).	11 km² (4 mi²).
	OFAV–6	FGB	East Flower Garden Bank and West Flower Garden Bank.	17–90 m (55–295 ft).	41 km² (16 mi²).
Orbicella franksi	OFRA–1	Florida	St. Lucie Inlet, Martin County to Government Cut, Miami-Dade County.	2–90 m (6.5–295 ft).	7,900 km² (3,100 mi²).
		Florida	Government Cut, Miami-Dade County to Dry Tortugas.	0.5–90 m (1.6–295 ft)..	
	OFRA–2	Puerto Rico	All islands of Puerto Rico	0.5–90 m (1.6–295 ft).	5,500 km² (2,100 mi²).
	OFRA–3	USVI	All islands of St. Thomas and St. John.	0.5–90 m (1.6–295 ft).	1,400 km² (520 mi²).
	OFRA–4	USVI	All islands of St. Croix	0.5–90 m (1.6–295 ft).	360 km² (140 mi²).
	OFRA–5	Navassa	Navassa Island	0.5–90 m (1.6–295 ft).	11 km² (4 mi²).
	OFRA–6	FGB	East Flower Garden Bank and West Flower Garden Bank.	17–90 m (55–295 ft).	41 km² (16 mi²).
Dendrogyra cylindrus.	DCYL–1	Florida	Lake Worth Inlet, Palm Beach County to Government Cut, Miami-Dade County.	2–25 m (6.5–82 ft)	4,300 km² (1,700 mi²).
		Florida	Government Cut, Miami-Dade County to Dry Tortugas.	1–25 m (3.3–82 ft).	
	DCYL–2	Puerto Rico	All islands	1–25 m (3.3–82 ft)	2,800 km² (1,100 mi²).
	DCYL–3	USVI	All islands of St. Thomas and St. John.	1–25 m (3.3–82 ft)).	170 km² (65 mi²).
	DCYL–4	USVI	All islands of St. Croix	1–25 m (3.3–82 ft)	300 km² (120 mi²).
	DCYL–5	Navassa	Navassa Island	1–25 m (3.3–82 ft)).	0.5 km² (0.2 mi²).
Mycetophyllia ferox	MFER–1	Florida	Broward County to Dry Tortugas	5–90 m (16.4–295 ft).	6,400 km² (2,500 mi²).
	MFER–2	Puerto Rico	All islands of Puerto Rico	5–90 m (16.4–295 ft).	5,000 km² (1,900 mi²).
	MFER–3	USVI	All islands of St. Thomas and St. John.	5–90 m (16.4–295 ft).	1,300 km² (510 mi²).
	MFER–4	USVI	All islands of St. Croix	5–90 m (16.4–295 ft).	310 km² (120 mi²).
	MFER–5	Navassa	Navassa Island	5–90 m (16.4–295 ft).	11 km² (4 mi²).

Effects of Critical Habitat Designations

Section 7(a)(2) of the ESA requires Federal agencies, including NMFS, to insure that any action authorized, funded, or carried out by the agency is not likely to jeopardize the continued existence of any threatened or endangered species or destroy or adversely modify designated critical habitat. Federal agencies are also required to confer with NMFS regarding any actions likely to jeopardize a species proposed for listing under the ESA, or likely to destroy or adversely modify proposed critical habitat, pursuant to section 7(a)(2).

A conference involves informal discussions in which NMFS may recommend conservation measures to minimize or avoid adverse effects. The discussions and conservation recommendations are documented in a conference report provided to the Federal agency. If requested by the Federal agency, a formal conference report may be issued, including a biological opinion prepared according to 50 CFR 402.14. A formal conference report may be adopted as the biological opinion when the species is listed or critical habitat designated, if no significant new information or changes to the action alter the content of the opinion.

When a species is listed or critical habitat is designated, Federal agencies must consult with NMFS on any agency actions that may affect a listed species or its critical habitat. During the consultation, we evaluate the agency action to determine whether the action may adversely affect listed species or

critical habitat and issue our findings in a letter of concurrence or in a biological opinion. If we conclude in the biological opinion that the agency action would likely result in the destruction or adverse modification of critical habitat, we would also identify any reasonable and prudent alternatives to the action. Reasonable and prudent alternatives are defined in 50 CFR 402.02 as alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that would avoid the destruction or adverse modification of critical habitat.

Regulations at 50 CFR 402.16 require Federal agencies that have retained discretionary involvement or control over an action, or where such discretionary involvement or control is authorized by law, to reinitiate consultation on previously reviewed actions in instances where: (1) Critical habitat is subsequently designated; or (2) new information or changes to the action may result in effects to critical habitat not previously considered in the biological opinion. Consequently, some Federal agencies may request reinitiation of consultation or conference with NMFS on actions for which formal consultation has been completed, if those actions may affect designated critical habitat or adversely modify or destroy proposed critical habitat.

Activities subject to the ESA section 7 consultation process include activities on Federal lands and activities on private or state lands requiring a permit from a Federal agency or some other Federal action, including funding. ESA section 7 consultation would not be required for Federal actions that do not affect listed species or critical habitat and for actions that are not federally funded, authorized, or carried out.

Activities That May Be Affected

Section 4(b)(8) of the ESA requires that we describe briefly, and evaluate in any proposed or final regulation to designate critical habitat, those activities that may adversely modify such habitat or that may be affected by such designation. As described in our Draft Information Report, a wide variety of Federal activities may require ESA section 7 consultation because they may affect the essential feature of critical habitat. Specific future activities will need to be evaluated with respect to their potential to destroy or adversely modify critical habitat, in addition to their potential to affect and jeopardize the continued existence of listed species. For example, activities may adversely modify the substrate portion of the essential feature by removing or altering the substrate or adversely modify the water column portion of the essential feature by reducing water clarity through turbidity. These activities would require ESA section 7 consultation when they are authorized, funded, or carried out by a Federal agency. A private entity may also be affected by these proposed critical habitat designations if it is a proponent of a project that requires a Federal permit or receives Federal funding.

Categories of activities that may be affected by the designations include coastal and in-water construction, channel dredging, beach nourishment and shoreline protection, water quality management, and military activities. Questions regarding whether specific activities may constitute destruction or adverse modification of critical habitat should be directed to us (see **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT**). Identifying concentrations at which the conservation value of habitat for listed corals may be affected is inherently complex and influenced by taxa, exposure duration, and acclimatization to localized seawater regimes. Consequently, the actual responses of the critical habitat (and listed corals) to changes in the essential feature resulting from future Federal actions will be case and site-specific, and predicting such responses will require case and site-specific data and analyses.

Public Comments Solicited

We request that interested persons submit comments, information, and suggestions concerning this proposed rule during the comment period (see **DATES**). We are soliciting comments or suggestions from the public, other concerned governments and agencies, the scientific community, industry, or any other interested party concerning the areas proposed for designation. We also request comment on areas we are proposing for exclusion, including but not limited to the types of areas that qualify as managed area (*e.g.,* areas adjacent to dredged channels, nearshore placement areas). Additionally, we request comment on all aspects of this proposal, including whether specific language regarding such areas should be included in the text of the regulations and whether any discussion of or references to this topic in this preamble or the regulatory text should otherwise be further clarified or defined. We also solicit comments regarding specific, foreseeable benefits and impacts stemming from this designation. We also seek comments on the identified geographic area and depths occupied by the species. You may submit your comments and materials concerning this proposal by any one of several methods (see **ADDRESSES**). We will consider all comments pertaining to these designations received during the comment period in preparing the final rule. Accordingly, the final designations may differ from this proposal.

Information Quality Act and Peer Review

The data and analyses supporting this proposed action have undergone a pre-dissemination review and have been determined to be in compliance with applicable information quality guidelines implementing the Information Quality Act (Section 515 of Pub. L. 106–554). On December 16, 2004, OMB issued its Final Information Quality Bulletin for Peer Review (Bulletin). The Bulletin was published in the **Federal Register** on January 14, 2005 (70 FR 2664), and went into effect on June 16, 2005. The primary purpose of the Bulletin is to improve the quality and credibility of scientific information disseminated by the Federal government by requiring peer review of ''influential scientific information'' and ''highly influential scientific information'' prior to public dissemination. ''Influential scientific information'' is defined as information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. The Bulletin provides agencies broad discretion in determining the appropriate process and level of peer review. Stricter standards were established for the peer review of highly influential scientific assessments, defined as information whose dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest.

The information in the Draft Information Report supporting this proposed critical habitat rule is considered influential scientific information and subject to peer review. To satisfy our requirements under the OMB Bulletin, we obtained independent peer review of the information used to draft this document, and incorporated the peer review comments into this draft prior to dissemination of this proposed rulemaking. Comments received from peer reviewers are available on our website at *http://www.cio.noaa.gov/services_programs/prplans/ID346.html.*

Classification

Takings (Executive Order 12630)

Under E.O. 12630, Federal agencies must consider the effects of their actions on constitutionally protected private property rights and avoid unnecessary takings of private property. A taking of property includes actions that result in physical invasion or occupancy of private property, and regulations imposed on private property that substantially affect its value or use. In accordance with E.O. 12630, this proposed rule would not have significant takings implications. A takings implication assessment is not required. These designations would affect only Federal agency actions (*i.e.,* those actions authorized, funded, or carried out by Federal agencies). Therefore, the critical habitat designations does not affect landowner actions that do not require Federal funding or permits.

Regulatory Planning and Review (Executive Order 12866), Reducing Regulation and Controlling Regulatory Costs (Executive Order 13771)

This proposed rule has been determined to be significant for purposes of E.O. 12866 review. This proposed rulemaking is expected to be regulatory under E.O. 13771. A draft report evaluating the economic impacts of the proposed rule has been prepared and is included the Draft Information Report, incorporating the principles of E.O. 12866.

Based on the economic impacts evaluation in the Draft Information Report, Total incremental costs resulting from the five corals critical habitat are estimated to range from $140,000 to $1.02 million over 10 years, an annualized cost of $20,000 to $140,000 (discounted at 7 percent). The low-end costs are a result of the increased administrative effort to analyze impacts to the proposed critical habitat in future consultations on activities that are not projected to affect Acropora critical habitat (*i.e.,* in areas outside the boundaries, projects with impacts to water temperature, or pesticide registrations). The high-end costs are a result of the increased administrative effort (*i.e.,* low-end costs) plus the incremental project modification costs that stem solely from the proposed critical habitat. Incremental project modification costs are a result of future consultations that are not projected to have effects on Acropora critical habitat. The high-end costs also assume that the project modifications will be solely a result of the proposed critical habitat, and not the presence of the species. However, the high-end estimate is very likely an overestimate on incremental costs because an undetermined number of future consultations will have project modifications that address adverse effects to one or more of the five corals, as well as adverse effects to the new critical habitat.

Federalism (Executive Order 13132)

Pursuant to the Executive Order on Federalism, E.O. 13132, we determined that this proposed rule does not have significant federalism effects and that a federalism assessment is not required. However, in keeping with Department of Commerce policies and consistent with ESA regulations at 50 CFR 424.16(c)(1)(ii), we will request information for this proposed rule from state and territorial resource agencies in Florida, Puerto Rico, and USVI. The proposed designations may have some benefit to state and local resource agencies in that the proposed rule more clearly defines the essential feature and the areas in which that feature is found. It may also assist local governments in allowing them to engage in long-range planning (rather than waiting for case by-case ESA section 7 consultations to occur).

Energy Supply, Distribution, and Use (Executive Order 13211)

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking an action expected to lead to the promulgation of a final rule or regulation that is a significant regulatory action under E.O. 12866 and is likely to have a significant adverse effect on the supply, distribution, or use of energy. OMB Guidance on Implementing E.O. 13211 (July 13, 2001) states that significant adverse effects could include any of the following outcomes compared to a world without the regulatory action under consideration: (1) Reductions in crude oil supply in excess of 10,000 barrels per day; (2) reductions in fuel production in excess of 4,000 barrels per day; (3) reductions in coal production in excess of 5 million tons per year; (4) reductions in natural gas production in excess of 25 million cubic feet per year; (5) reductions in electricity production in excess of 1 billion kilowatt-hours per year or in excess of 500 megawatts of installed capacity; (6) increases in energy use required by the regulatory action that exceed any of the thresholds above; (7) increases in the cost of energy production in excess of one percent; (8) increases in the cost of energy distribution in excess of one percent; or (9) other similarly adverse outcomes. A regulatory action could also have significant adverse effects if it: (1) Adversely affects in a material way the productivity, competition, or prices in the energy sector; (2) adversely affects in a material way productivity, competition or prices within a region; (3) creates a serious inconsistency or otherwise interferes with an action taken or planned by another agency regarding energy; or (4) raises novel legal or policy issues adversely affecting the supply, distribution or use of energy arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866 and 13211.

This rule, if finalized, will not have a significant adverse effect on the supply, distribution, or use of energy. Therefore, we have not prepared a Statement of Energy Effects.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

We prepared an initial regulatory flexibility analysis (IRFA) pursuant to section 603 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601, *et seq.*). The IRFA analyzes the impacts to small entities that may be affected by the proposed designations and is included as Appendix B of the Draft Information Report and is available upon request (see **ADDRESSES** section). The IRFA is summarized below, as required by section 603 of the RFA.

Our IRFA uses the best available information to identify the potential impacts of critical habitat on small entities. However, a number of uncertainties complicate quantification of these impacts. This includes (1) the fact that the manner in which these potential impacts will be allocated between large and small entities is unknown; and (2) as discussed in the main body of the report, uncertainty regarding the potential effects of critical habitat designations, which requires some categories of potential impacts be described qualitatively. This IRFA analysis therefore focuses on providing the best available information regarding the potential magnitude of impacts to small entities in affected industries. As the proposed critical habitat is marine habitat, this analysis references the number of small businesses in each affected industry that is associated with counties and territories sharing coastline with the designations.

The total maximum annualized impacts to small entities are estimated to be $130,000, which represents approximately 90 percent of the total quantified incremental impacts forecasted to result from the proposed rule. This impact assumes that all of the incremental project modification costs

will be incurred by small entities. These impacts are anticipated to be borne by the small entities that obtain funds or permits from Federal agencies that consult with NMFS regarding the five coral species critical habitat in the next 10 years. Given the uncertainty regarding which small entities in a given industry will obtain funds or permits from Federal agencies that will need to consult with NMFS, this analysis estimates impacts to small entities under two different scenarios. These scenarios are intended to reflect the range of uncertainty regarding the number of small entities that may be affected by the designations and the potential impacts of critical habitat designations on their annual revenues within that range.

Under Scenario 1, this analysis assumes that all third parties participating in future consultations are small, and that incremental impacts are distributed evenly across all of these entities. Scenario 1 accordingly reflects a high estimate of the number of potentially affected small entities and a low estimate of the potential effect in terms of percent of revenue. This scenario therefore most likely overstates the number of small entities likely to be affected by the rule and potentially understates the revenue effect. This analysis anticipates that 43 small entities will collectively incur approximately $130,000 in annualized costs under Scenario 1. These costs are distributed between two industries: (1) Approximately $85,000 expected to be borne by 38 entities engaged in coastal and in-water construction and dredging activities (NAICS Codes 237310, 237990, 237990), and (2) approximately $43,000 expected to be borne by 5 entities engaged in water quality activities (NAICS Codes 221112, 324110, 221320). However, because these costs are shared among 38 and 5 entities, respectively, annualized impacts of the rule are estimated to make up less than 0.05 percent of annual revenues for each affected small entity.

Under Scenario 2, this analysis assumes costs associated with each consultation action are borne by a single small entity within an industry. This method understates the number of small entities affected but overstates the likely impacts on an entity. Therefore, this method arrives at a low estimate of potentially affected entities and a high estimate of potential effects on revenue, assuming that quantified costs represent a complete accounting of the costs likely to be borne by private entities. For the coastal and in-water construction and dredging industry, this scenario forecasts $85,000 in annualized impacts would be borne by a single small entity. Though this estimate is almost certainly an overstatement of the costs borne by a single small entity, the impact is nonetheless expected to result in impacts that are less than 3 percent of the average annual revenues for a small entity in this industry. Estimated annualized impacts under this scenario for the industries related to water quality are expected to be $48,000 and comprise less than 2 percent of annual revenues.

While these scenarios present a broad range of potentially affected entities and the associated revenue effects, we expect the actual number of small entities affected and revenue effects will be somewhere in the middle. In other words, some subset greater than 2 and less than 43 of the small entities will participate in section 7 consultations on the five corals' critical habitat and bear associated impacts annually. Regardless, our analysis demonstrates that, even if we assume a low-end estimate of affected small entities, the greatest potential revenue effect is still less than 3 percent.

Even though we cannot definitively determine the numbers of small and large entities that may be affected by this proposed rule, there is no indication that affected project applicants would be only small entities or mostly small entities. It is unclear whether small entities would be placed at a competitive disadvantage compared to large entities. However, as described in the Draft Information Report, consultations and project modifications will be required based on the type of permitted action and its associated impacts on the essential critical habitat feature. Because the costs of many potential project modifications that may be required to avoid adverse modification of critical habitat are unit costs (*e.g.,* per mile of shoreline, per cubic yard of sand moved), such that total project modification costs would be proportional to the size of the project, it is not unreasonable to assume that larger entities would be involved in implementing the larger projects with proportionally larger project modification costs.

There are no record-keeping requirements associated with the rule. Similarly, there are no reporting requirements other than those that might be associated with reporting on the progress and success of implementing project modifications, which do not require specific skills to satisfy.

No Federal laws or regulations duplicate or conflict with this proposed rule. However, other aspects of the ESA may overlap with the critical habitat designations. For instance, listing of the threatened corals under the ESA requires Federal agencies to consult with NMFS to avoid jeopardy to the species, and large portions of the proposed designations overlap with existing *Acropora* critical habitat. However, this analysis examines only the incremental impacts to small entities from these proposed critical habitat designations.

The alternatives to the designations considered consisted of a no-action alternative and an alternative based on identical geographic designations for each of the five corals. The no-action, or no designation, alternative would result in no additional ESA section 7 consultations relative to the status quo of the species' listing. Critical habitat must be designated if prudent and determinable. NMFS determined that the proposed critical habitat is prudent and determinable, and the ESA requires critical habitat designation in that circumstance. Further, we have determined that the physical feature forming the basis for our critical habitat designations is essential to the corals' conservation, and conservation of these species will not succeed without this feature being available. Thus, the lack of protection of the critical habitat feature from adverse modification could result in continued declines in abundance of the five corals. We rejected this no action alternative because it does not provide the level of conservation necessary for the five Caribbean corals. In addition, declines in abundance of the five corals would result in loss of associated economic and other values these corals provide to society, such as recreational and commercial fishing and diving services and shoreline protection services. Thus, small entities engaged in some coral reef-dependent industries would be adversely affected by the continued declines in the five corals. As a result, the no action alternative is not necessarily a ''no cost'' alternative for small entities.

The identical geographic designation alternative would designate exactly the same geography for each of the five corals (*i.e.,* 0.5 to 90 m throughout the maximum geographic extent of all the corals' ranges collectively). This alternative would likely result in the same number and complexity of consultations as the proposed rule, because collectively all of the units in the proposed rule cover the same geography as the identical geographic designation alternative. However, this alternative does not provide the appropriate conservation benefits for

each species, as it would designate areas in which one particular species may not exist (*e.g., Dendrogyra cylindrus* only occupies 1 to 25 m). Therefore, we rejected the identical geographic designation alternative because it does not provide the level of conservation necessary for the five Caribbean corals. The agency seeks specific comments from small entities on its Initial Regulatory Flexibility Act analysis.

Coastal Zone Management Act

We have determined that this action will have no reasonably foreseeable effects on the enforceable policies of approved Florida, Puerto Rico, and USVI coastal zone management plans. Upon publication of this proposed rule, these determinations will be submitted to responsible state agencies for review under section 307 of the Coastal Zone Management Act.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This proposed rule does not contain any new or revised collection of information requirements. This rule, if adopted, would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

This proposed rule will not produce a Federal mandate. The designation of critical habitat does not impose a legally-binding duty on non-Federal government entities or private parties. The only regulatory effect is that Federal agencies must ensure that their actions are not likely to destroy or adversely modify critical habitat under section 7 of the ESA. Non-Federal entities that receive Federal funding, assistance, permits or otherwise require approval or authorization from a Federal agency for an action may be indirectly impacted by the designation of critical habitat, but the Federal agency has the legally binding duty to avoid destruction or adverse modification of critical habitat.

We do not anticipate that this rule, if finalized, will significantly or uniquely affect small governments. Therefore, a Small Government Action Plan is not required.

Consultation and Coordination With Indian Tribal Governments (Executive Order 13175)

The longstanding and distinctive relationship between the Federal and tribal governments is defined by treaties, statutes, executive orders, judicial decisions, and agreements, which differentiate tribal governments from the other entities that deal with, or are affected by, the Federal Government.

This relationship has given rise to a special Federal trust responsibility involving the legal responsibilities and obligations of the United States toward Indian Tribes and with respect to Indian lands, tribal trust resources, and the exercise of tribal rights. Pursuant to these authorities, lands have been retained by Indian Tribes or have been set aside for tribal use. These lands are managed by Indian Tribes in accordance with tribal goals and objectives within the framework of applicable treaties and laws. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, outlines the responsibilities of the Federal Government in matters affecting tribal interests.

In developing this proposed rule, we reviewed maps and did not identify any areas under consideration for critical habitat that overlap with Indian lands. Based on this, we preliminarily found the proposed critical habitat designations for threatened Caribbean corals do not have tribal implications.

References Cited

A complete list of all references cited in this rulemaking can be found on our website at [*https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-caribbean-corals*] and is available upon request from the NMFS SERO in St. Petersburg, Florida (see **ADDRESSES**).

List of Subjects

50 CFR Part 223

Endangered and threatened species, Exports, Imports, Transportation.

50 CFR Part 226

Endangered and threatened species.

Dated: September 22, 2020.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, we propose to amend 50 CFR parts 223 and 226 as follows:

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

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

Authority: 16 U.S.C. 1531–1543; subpart B, § 223.201–202 issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

■ 2. Amend § 223.102(e), under the heading ''Corals'' by revising the entries ''Coral, boulder star''; ''Coral, lobed star''; ''Coral, mountainous star''; ''Coral, pillar''; and ''Coral, rough cactus''.

§ 223.102 Enumeration of threatened marine and anadromous species.

(e) * * *

Species [1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
Corals					
* *	*	*	* *	*	
Coral, boulder star	*Orbicella franksi*	Entire species	79 FR 53852, Sept. 10, 2014	*226.227*	NA.
Coral, lobed star	*Orbicella annularis*	Entire species	79 FR 53852, Sept. 10, 2014	*226.227*	NA.
Coral, mountainous star	*Orbicella faveolata*	Entire species	79 FR 53852, Sept. 10, 2014	*226.227*	NA.
Coral, pillar	*Dendrogyra cylindrus*	Entire species	79 FR 53852, Sept. 10, 2014	*226.227*	NA.
Coral, rough cactus	*Mycetophyllia ferox*	Entire species	79 FR 53852, Sept. 10, 2014	*226.227*	NA.
* *	*	*	* *	*	

[1] Species includes taxonomic species, subspecies, distinct population segments (DPSs) (for a policy statement, see 61 FR 4722; February 7, 1996), and evolutionarily significant units (ESUs) (for a policy statement, see 56 FR 58612; November 20, 1991).

PART 226—DESIGNATED CRITICAL HABITAT

■ 3. The authority citation for part 226 continues to read as follows:

Authority: 16 U.S.C. 1533.

■ 4. Add § 226.227 to read as follows:

§ 226.227 Critical habitat for the Caribbean Boulder Star Coral (*Orbicella franksi*), Lobed Star Coral (*O. annularis*), Mountainous Star Coral (*O. faveolata*), Pillar Coral (*Dendrogyra cylindrus*), and Rough Cactus Coral (*Mycetophyllia ferox*).

Critical habitat is designated in the following states and counties for the following species as depicted in the maps below and described in paragraphs (a) through (h) of this section. The maps can be viewed or obtained with greater resolution (*https://www.fisheries.noaa.gov/action/proposed-rule-designate-critical-habitat-threatened-caribbean-corals*) to enable a more precise inspection of proposed critical habitat for *Orbicella franksi, O. annularis, O. faveolata, Dendrogyra cylindrus,* and *Mycetophyllia ferox.*

(a) *Critical habitat locations.* Critical habitat is designated for the following five Caribbean corals in the following states and counties, and offshore locations:

TABLE 1 TO PARAGRAPH (a)

Species	State—counties
Orbicella annularis	FL—Palm Beach, Broward, Miami-Dade, and Monroe. PR—All. USVI—All. Flower Garden Banks. Navassa Island.
O. faveolata	FL—Martin, Palm Beach, Broward, Miami-Dade, and Monroe. PR—All. USVI—All. Flower Garden Banks. Navassa Island.
O. franksi	FL—Palm Beach, Broward, Miami-Dade, and Monroe. PR—All. USVI—All. Flower Garden Banks. Navassa Island.
Dendrogyra cylindrus	FL—Palm Beach, Broward, Miami-Dade, and Monroe. PR—All. USVI—All. Navassa Island.
Mycetophyllia ferox	FL—Broward, Miami-Dade, and Monroe. PR—All. USVI—All. Navassa Island.

(b) *Critical habitat boundaries.* Except as noted in paragraphs (d) and (e) of this section, critical habitat for the five Caribbean corals is defined as all marine waters in the particular depth ranges relative to mean low water as depicted in the maps below and described in the Table of the locations of the critical habitat units for *Orbicella franksi, O. annularis, O. faveolata, Dendrogyra cylindrus,* and *Mycetophyllia ferox.* Depth contours or other identified boundaries on the maps form the boundaries of the critical habitat units. Specifically, the COLREGS Demarcation Lines (33 CFR 80), the boundary between the South Atlantic Fishery Management Council (SAFMC) and the Gulf of Mexico Fishery Management Council (GMFMC; 50 CFR 600.105), the Florida Keys National Marine Sanctuary (15 CFR part 922 subpart P, appendix I), and the Caribbean Island Management Area (50 CFR part 622, appendix E), create portions of the boundaries in several units.

TABLE 2 TO PARAGRAPH (c)—TABLE OF THE LOCATIONS OF THE CRITICAL HABITAT UNITS FOR ORBICELLA FRANKSI, O. ANNULARIS, O. FAVEOLATA, DENDROGYRA CYLINDRUS, AND MYCETOPHYLLIA FEROX

Species	Critical habitat unit name	Location	Geographic extent	Water depth range
Orbicella annularis	OANN–1	Florida	Lake Worth Inlet, Palm Beach County to Government Cut, Miami-Dade County.	2–20 m, (6.5–65.6 ft).
		Florida	Government Cut, Miami-Dade County to Dry Tortugas	0.5–20m, (1.6–65.6 ft).
	OANN–2	Puerto Rico	All islands	0.5–20m, (1.6–65.6 ft).
	OANN–3	USVI	All islands of St. Thomas and St. John	0.5–20m, (1.6–65.6 ft).
	OANN–4	USVI	All islands of St. Croix	0.5–20m, (1.6–65.6 ft).
	OANN–5	Navassa	Navassa Island	0.5–20m, (1.6–65.6 ft).
	OANN–6	FGB	East Flower Garden Bank and West Flower Garden Bank.	17–90 m, (55–295 ft).
Orbicella faveolata	OFAV–1	Florida	St. Lucie Inlet, Martin County to Government Cut, Miami-Dade County.	2–90 m, (6.5–295 ft).
		Florida	Government Cut, Miami-Dade County to Dry Tortugas	0.5–90 m, (1.6–295 ft).
	OFAV–2	Puerto Rico	All islands of Puerto Rico	0.5–90 m, (1.6–295 ft).

TABLE 2 TO PARAGRAPH (c)—TABLE OF THE LOCATIONS OF THE CRITICAL HABITAT UNITS FOR ORBICELLA FRANKSI, O. ANNULARIS, O. FAVEOLATA, DENDROGYRA CYLINDRUS, AND MYCETOPHYLLIA FEROX—Continued

Species	Critical habitat unit name	Location	Geographic extent	Water depth range
	OANN–3	USVI	All islands of St. Thomas and St. John	0.5–90 m, (1.6–295 ft).
	OFAV–4	USVI	All islands of St. Croix	0.5–90 m, (1.6–295 ft).
	OFAV–5	Navassa	Navassa Island	0.5–90 m, (1.6–295 ft).
	OFAV–6	FGB	East Flower Garden Bank and West Flower Garden Bank.	17–90 m, (55–295 ft).
Orbicella franksi	OFRA–1	Florida	St. Lucie Inlet, Martin County to Government Cut, Miami-Dade County.	2–90 m, (6.5–295 ft).
		Florida	Government Cut, Miami-Dade County to Dry Tortugas	0.5–90 m, (1.6–295 ft).
	OFRA–2	Puerto Rico	All islands of Puerto Rico	0.5–90 m, (1.6–295 ft).
	OFRA–3	USVI	All islands of St. Thomas and St. John	0.5–90 m, (1.6–295 ft).
	OFRA–4	USVI	All islands of St. Croix	0.5–90 m, (1.6–295 ft).
	OFRA–5	Navassa	Navassa Island	0.5–90 m, (1.6–295 ft).
	OFRA–6	FGB	East Flower Garden Bank and West Flower Garden Bank.	17–90 m, (55–295 ft).
Dendrogyra cylindrus	DCYL–1	Florida	Lake Worth Inlet, Palm Beach County to Government Cut, Miami-Dade County.	2–25 m, (6.5–82 ft).
		Florida	Government Cut, Miami-Dade County to Dry Tortugas	1–25 m, (3.3–82 ft).
	DCYL–2	Puerto Rico	All islands	1–25 m, (3.3–82 ft).
	DCYL–3	USVI	All islands of St. Thomas and St. John	1–25 m, (3.3–82 ft).)
	DCYL–4	USVI	All islands of St. Croix	1–25 m, (3.3–82 ft).
	DCYL–5	Navassa	Navassa Island	1–25 m, (3.3–82 ft)).
Mycetophyllia ferox	MFER–1	Florida	Broward County to Dry Tortugas	5–90 m, (16.4–295 ft).
	MFER–2	Puerto Rico	All islands of Puerto Rico	5–90 m, (16.4–295 ft).
	MFER–3	USVI	All islands of St. Thomas and St. John	5–90 m, (16.4–295 ft).
	MFER–4	USVI	All islands of St. Croix	5–90 m, (16.4–295 ft).
	MFER–5	Navassa	Navassa Island	5–90 m, (16.4–295 ft).

(c) *Essential feature.* The feature essential to the conservation of *Orbicella franksi, O. annularis, O. faveolata, Dendrogyra cylindrus,* and *Mycetophyllia ferox* is: Reproductive, recruitment, growth, and maturation habitat. Sites that support the normal function of all life stages of threatened corals are natural, consolidated hard substrate or dead coral skeleton, which is free of algae and sediment at the appropriate scale at the point of larval settlement or fragment reattachment, and the associated water column. Several attributes of these sites determine the quality of the area and influence the value of the associated feature to the conservation of the species:

(1) Substrate with the presence of crevices and holes that provide cryptic habitat, the presence of microbial biofilms, or presence of crustose coralline algae;

(2) Reefscape with no more than a thin veneer of sediment and low occupancy by fleshy and turf macroalgae;

(3) Marine water with levels of temperature, aragonite saturation, nutrients, and water clarity that have been observed to support any demographic function; and

(4) Marine water with levels of anthropogenically-introduced (from humans) chemical contaminants that do not preclude or inhibit any demographic function.

(d) *Areas not included in critical habitat.* Critical habitat does not include the following particular areas where they overlap with the areas described in paragraphs (a) through (c) of this section:

(1) Pursuant to ESA section 4(a)(3)(B), all areas subject to the 2014 Naval Air Station Key West Integrated Natural Resources Management Plan.

(2) Pursuant to ESA section 3(5)(A)(i)(I), areas where the essential feature does not occur;

(3) Pursuant to ESA section 3(5)(A)(i)(I), all managed areas that may contain natural hard substrate but do not provide the quality of substrate essential for the conservation of threatened corals. Managed areas that do not provide the quality of substrate essential for the conservation of the five Caribbean corals are defined as particular areas whose consistently disturbed nature renders them poor habitat for coral growth and survival over time. These managed areas include specific areas where the substrate has been disturbed by planned management authorized by local, state, or Federal governmental entities at the time of critical habitat designation, and will continue to be periodically disturbed by such management. Examples include, but are not necessarily limited to, dredged navigation channels, shipping basins, vessel berths, and active anchorages. Specific federally-authorized channels and harbors considered as managed areas not included in the designations are:

(i) St. Lucie Inlet.
(ii) Palm Beach Harbor.
(iii) Hillsboro Inlet.
(iv) Port Everglades.
(v) Baker's Haulover Inlet.
(vi) Miami Harbor.
(vii) Key West Harbor.
(viii) Arecibo Harbor.
(ix) San Juan Harbor.
(x) Fajardo Harbor.
(xi) Ponce Harbor.
(xii) Mayaguez Harbor.
(xiii) St. Thomas Harbor.
(xiv) Christiansted Harbor.

(4) Pursuant to ESA section 3(5)(A)(i), artificial substrates including but not limited to: Fixed and floating structures, such as aids-to-navigation (AToNs), seawalls, wharves, boat ramps, fishpond walls, pipes, submarine cables, wrecks, mooring balls, docks, and aquaculture cages.

(e) *Areas excluded from critical habitat.* Pursuant to ESA Section 4(b)(2), the following area is excluded from critical habitat where it overlaps with the areas described in paragraphs (a) through (c) of this section: The designated restricted area managed by the South Florida Ocean Measuring Facility, defined in 33 CFR 334.580.

(f) *Maps.* Critical habitat maps for the Caribbean Boulder Star Coral, Lobed Star Coral, Mountainous Star Coral, Pillar Coral, and Rough Cactus Coral:

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Figure 1 to paragraph (f)

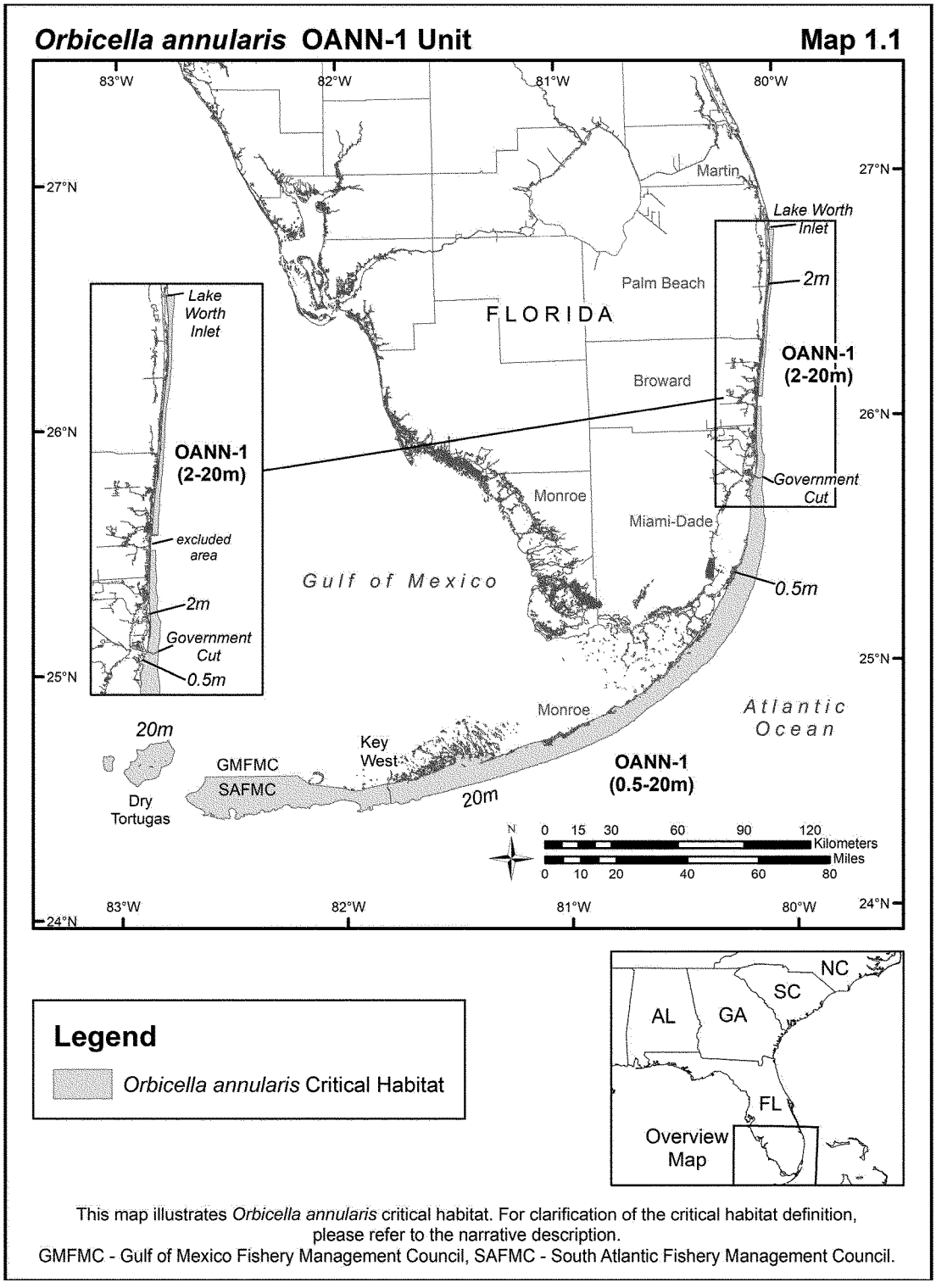


Figure 2 to paragraph (f)

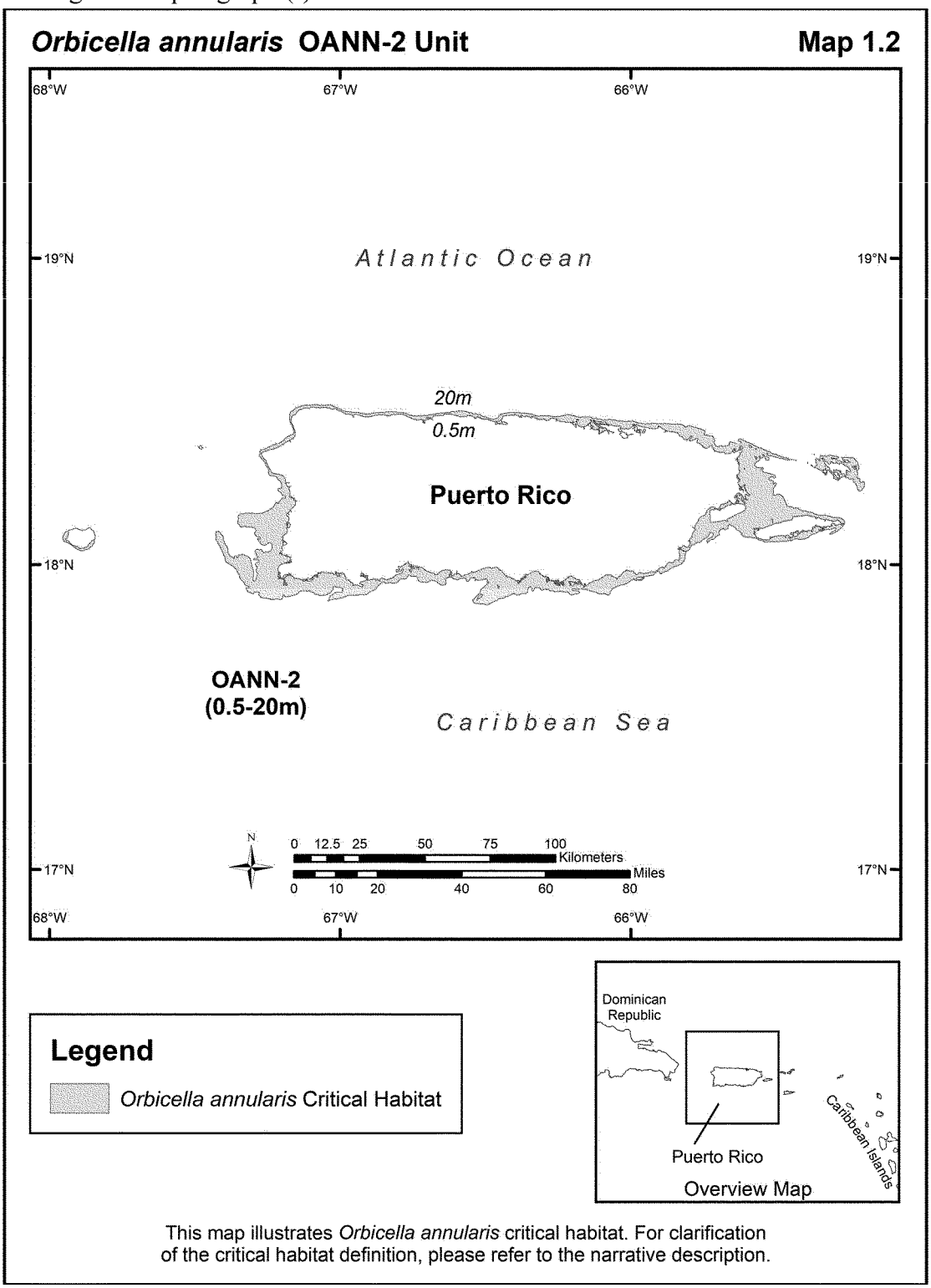
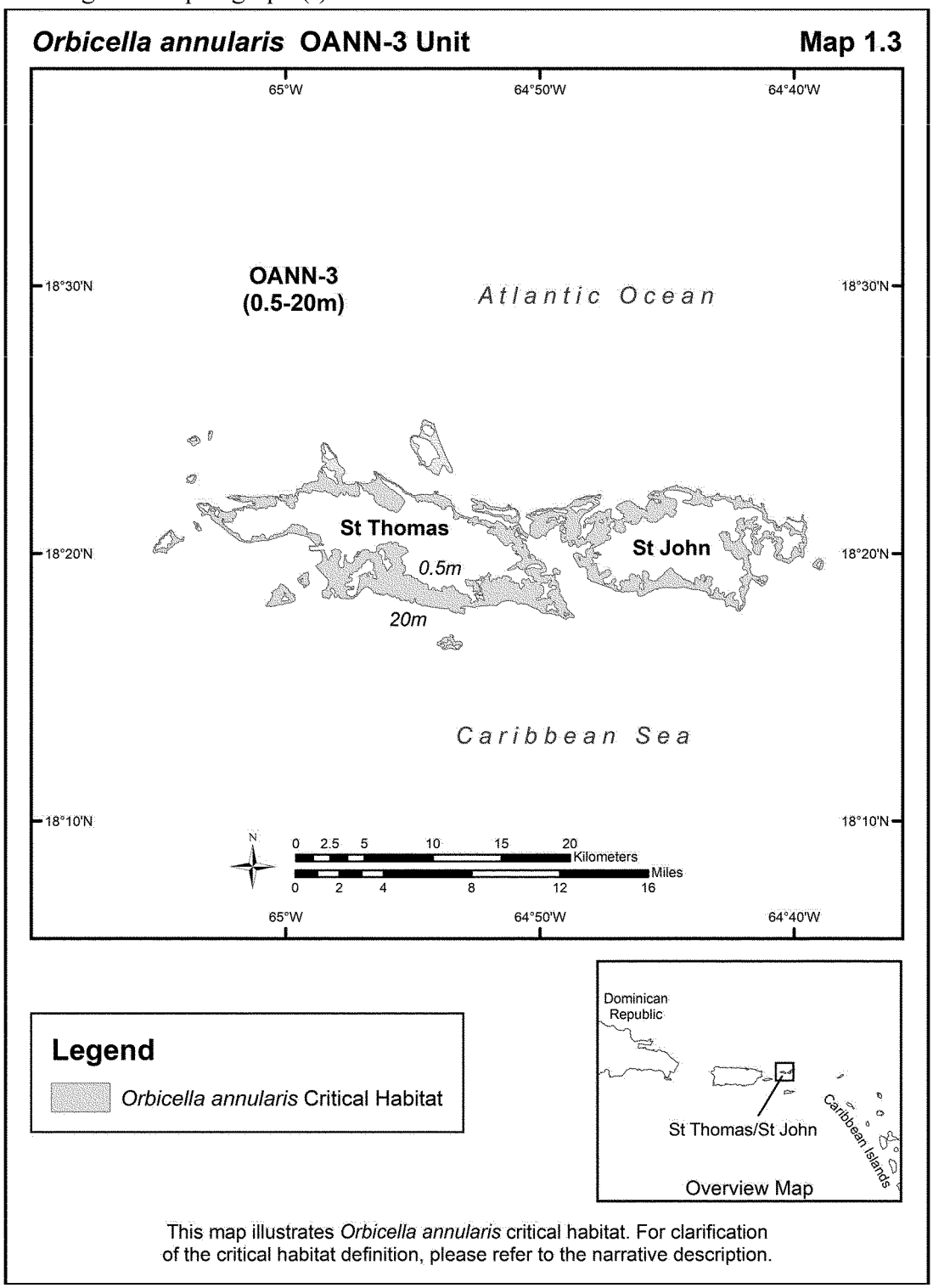


Figure 3 to paragraph (f)



This map illustrates *Orbicella annularis* critical habitat. For clarification of the critical habitat definition, please refer to the narrative description.

Figure 4 to paragraph (f)

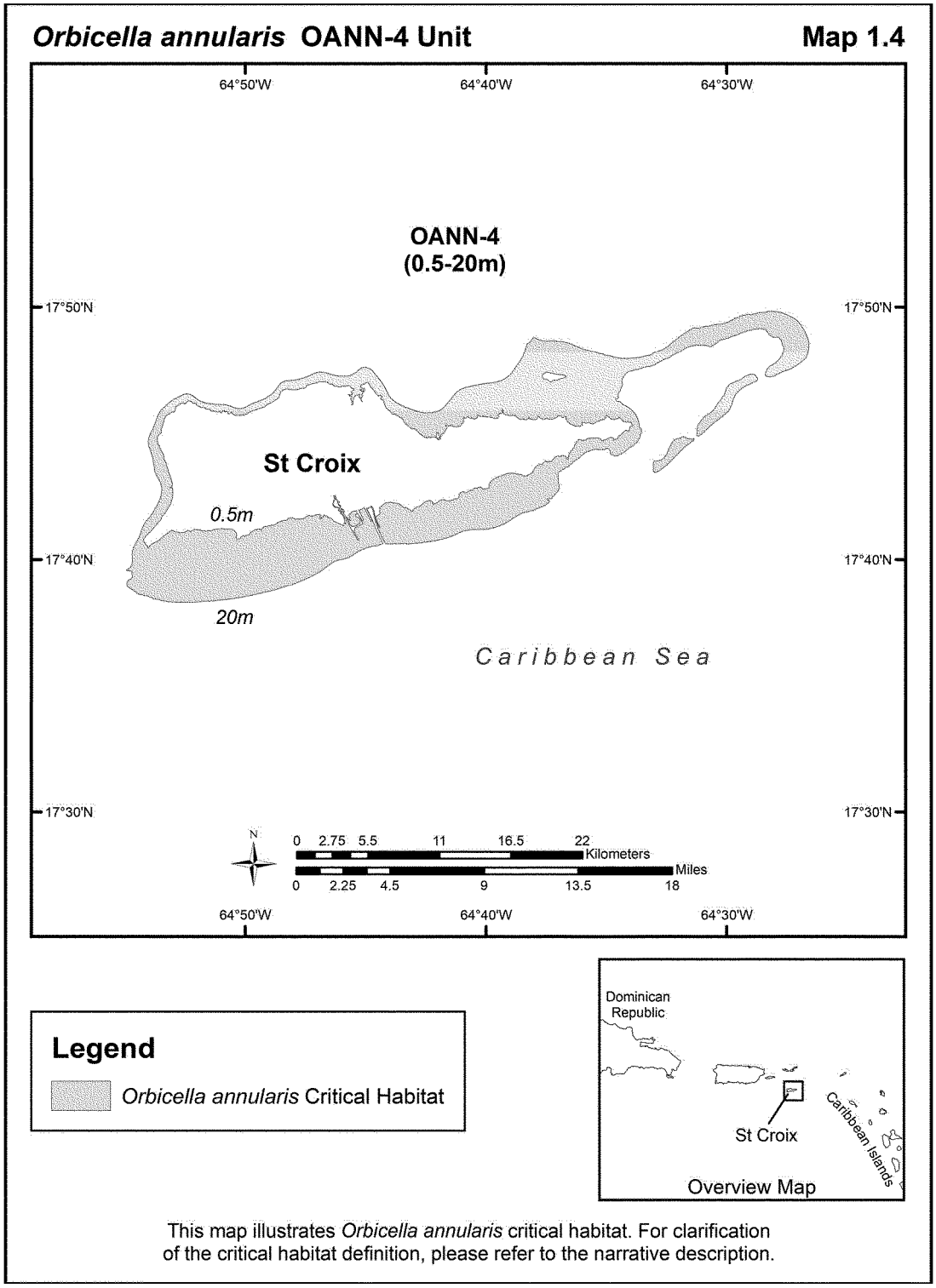


Figure 5 to paragraph (f)

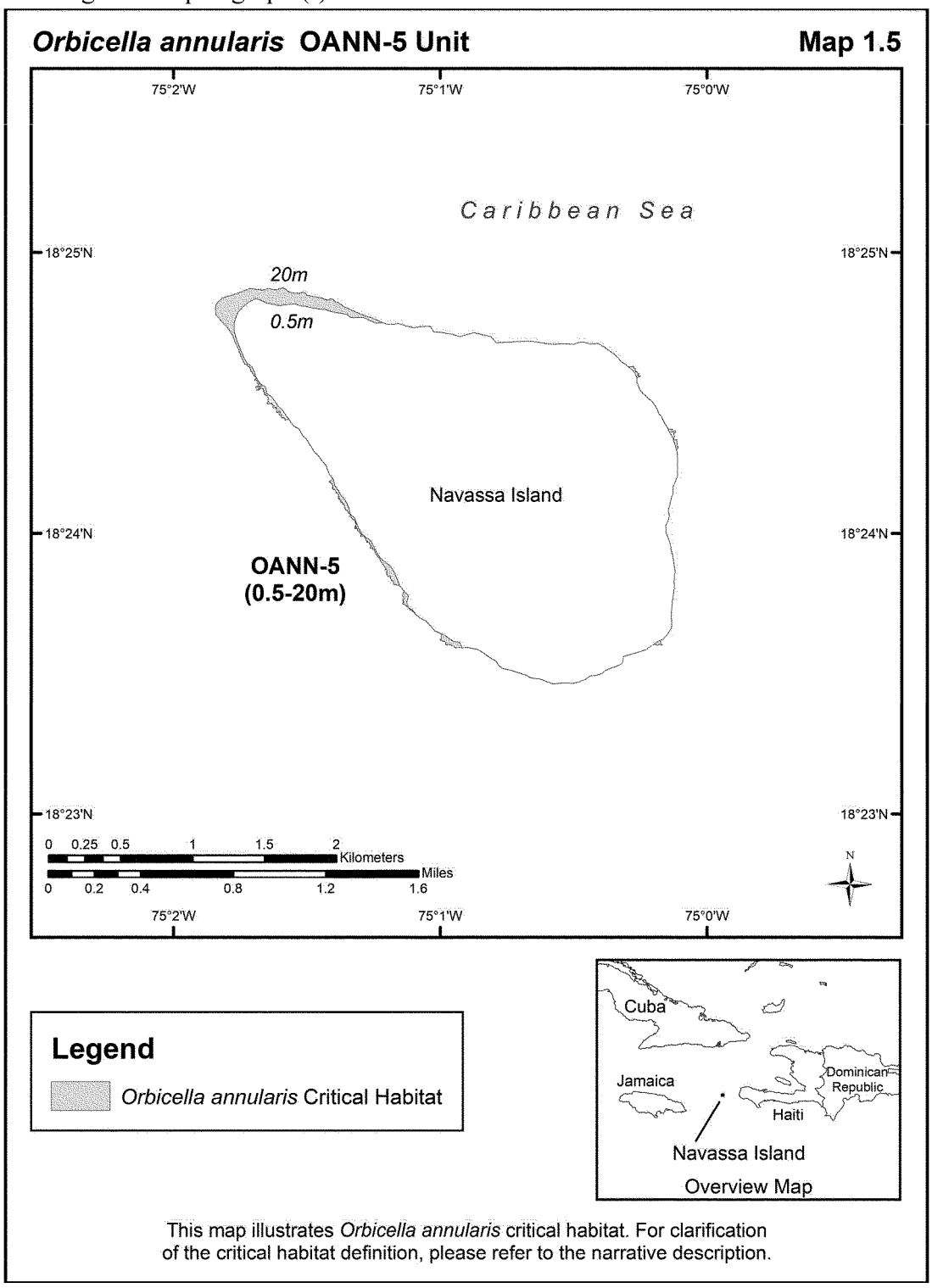
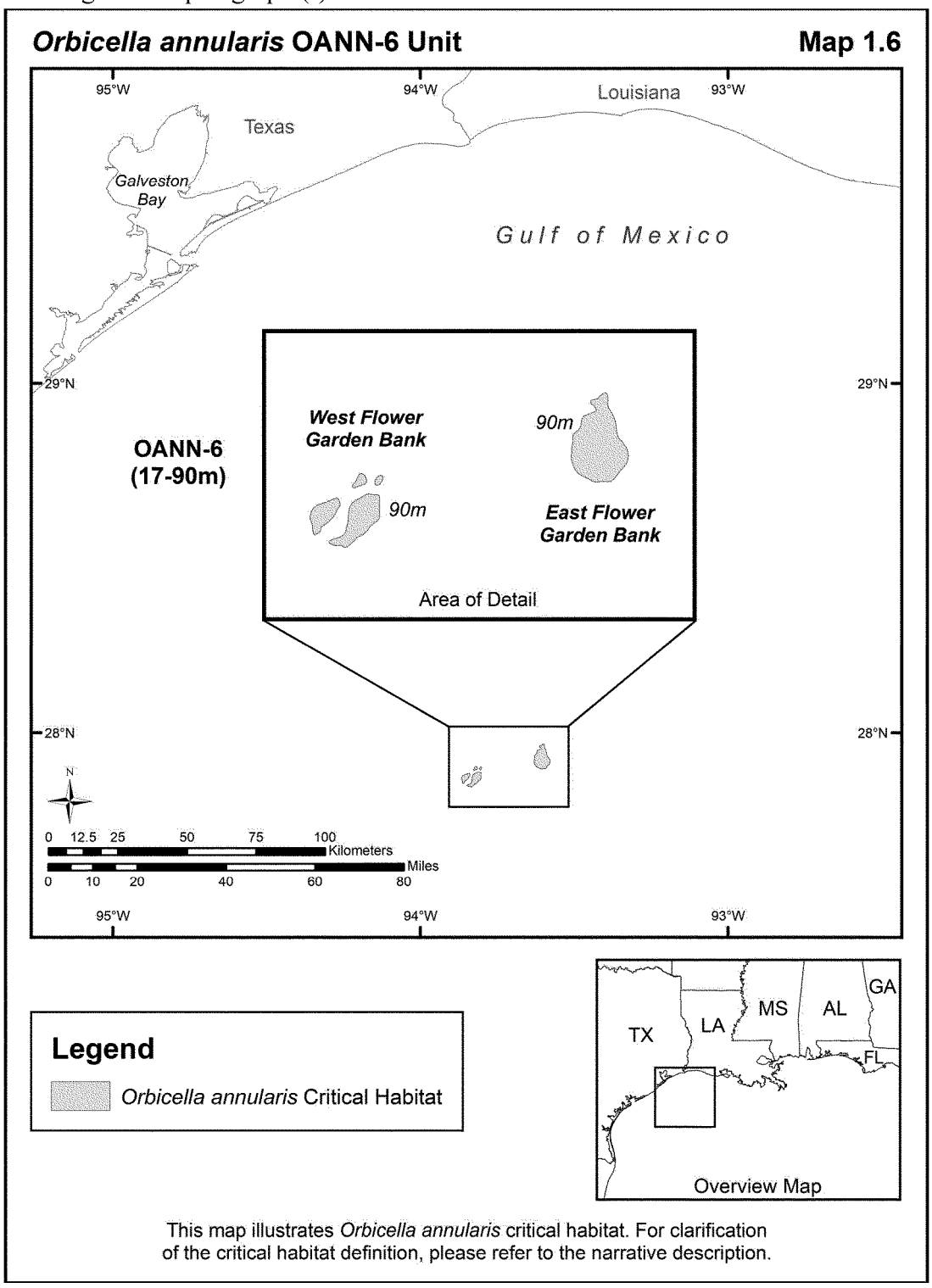
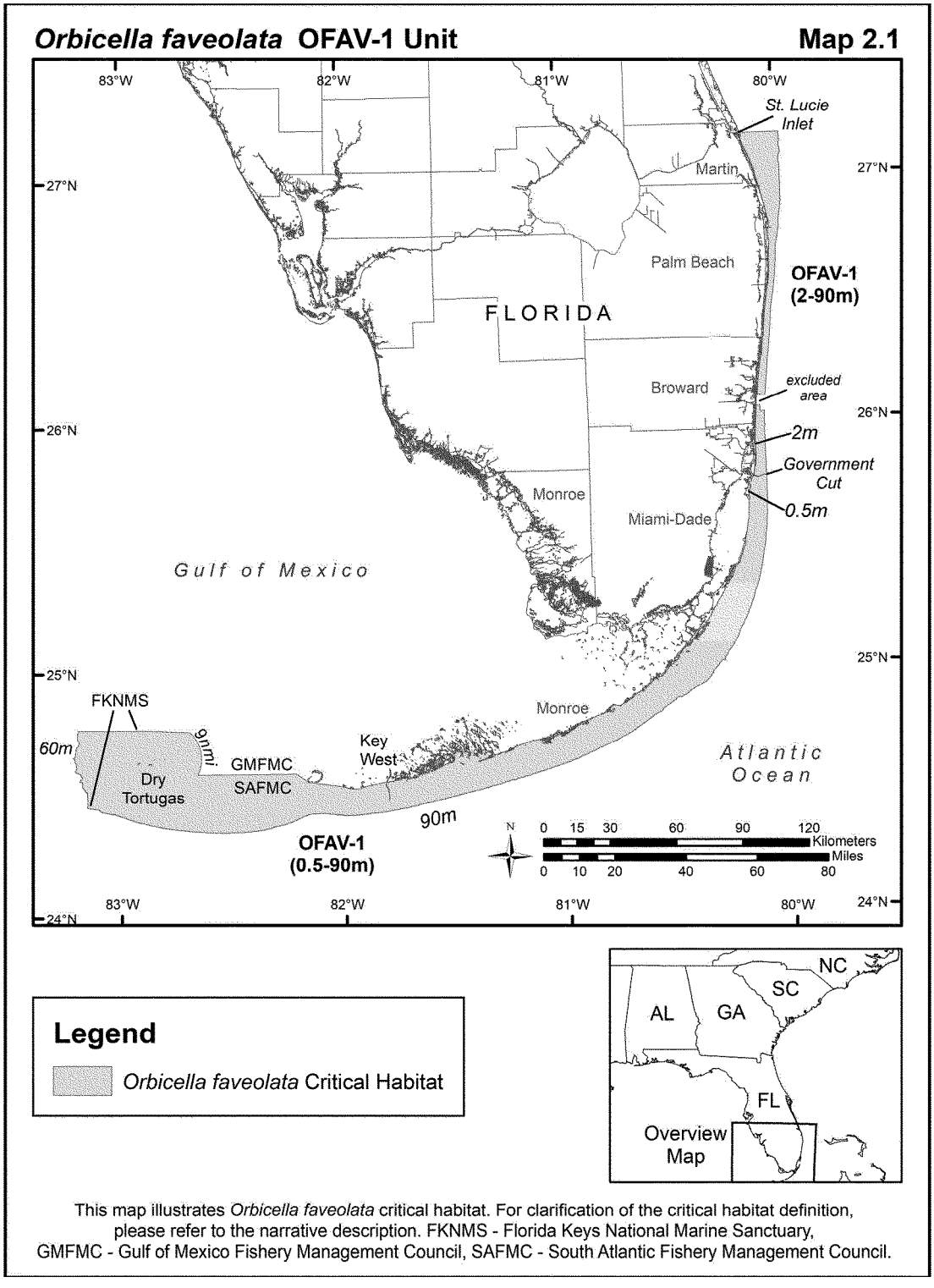


Figure 6 to paragraph (f)



This map illustrates *Orbicella annularis* critical habitat. For clarification of the critical habitat definition, please refer to the narrative description.

Figure 7 to paragraph (f)



This map illustrates *Orbicella faveolata* critical habitat. For clarification of the critical habitat definition, please refer to the narrative description. FKNMS - Florida Keys National Marine Sanctuary, GMFMC - Gulf of Mexico Fishery Management Council, SAFMC - South Atlantic Fishery Management Council.

Figure 8 to paragraph (f)

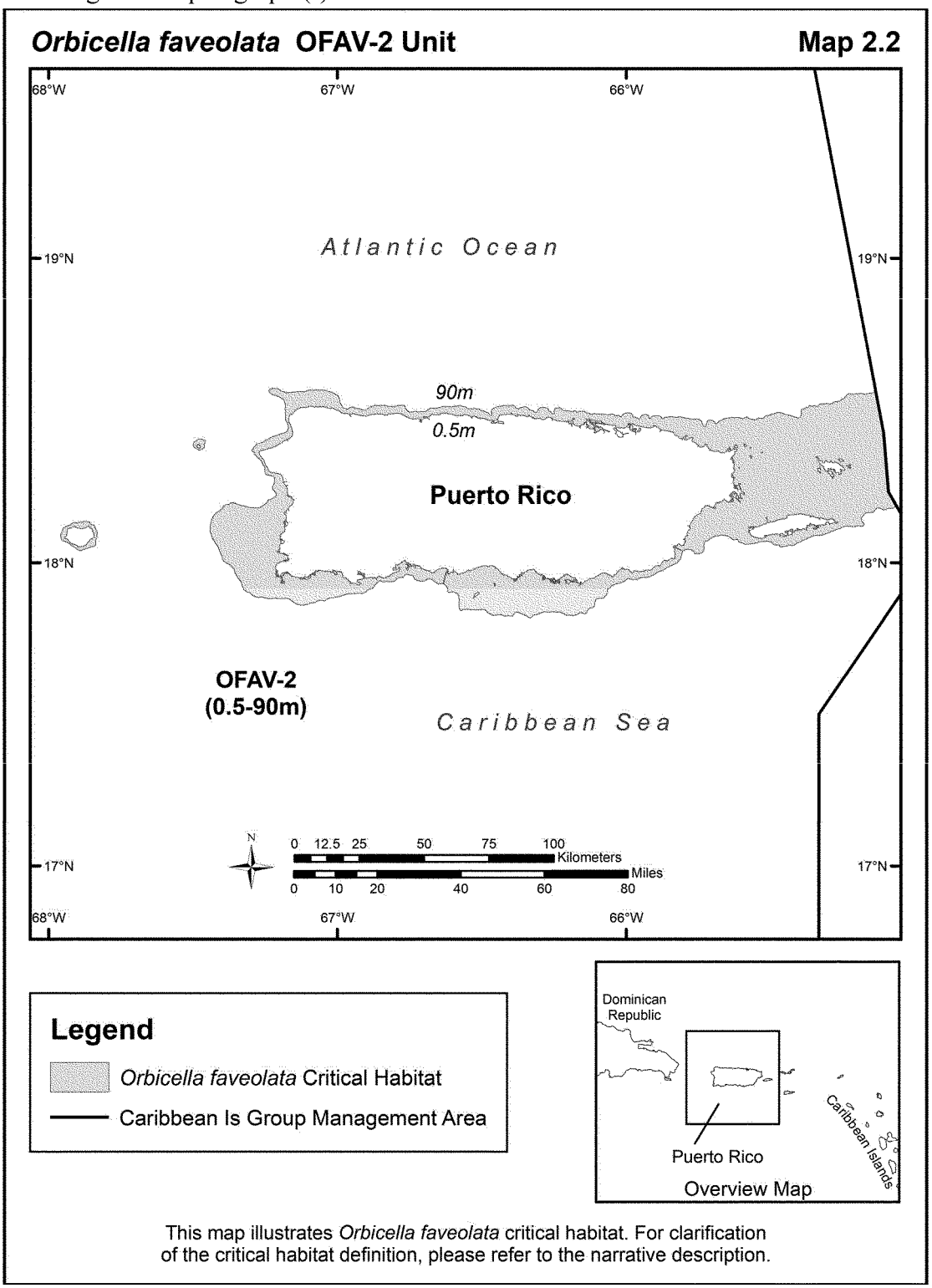


Figure 9 to paragraph (f)

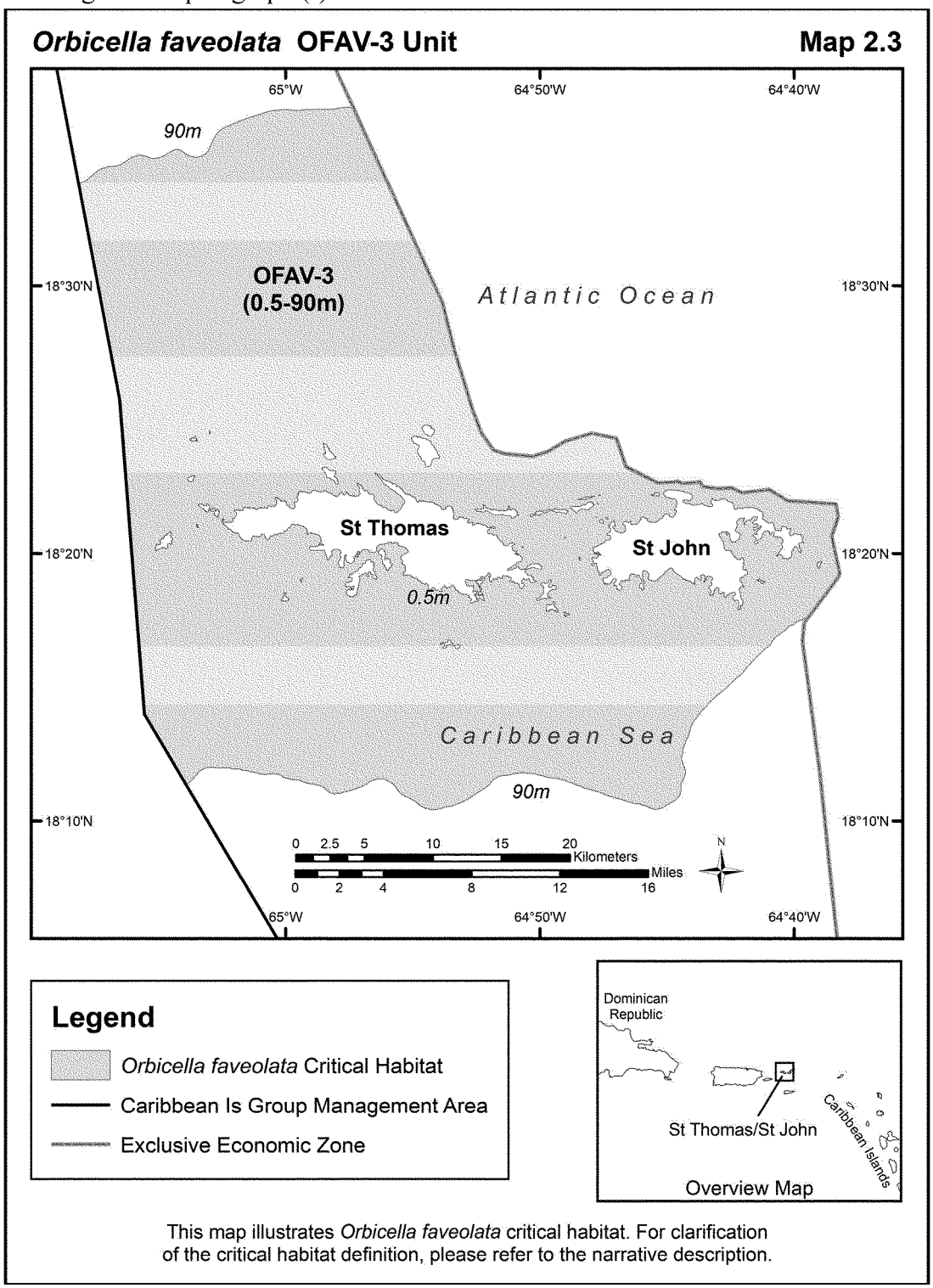


Figure 10 to paragraph (f)

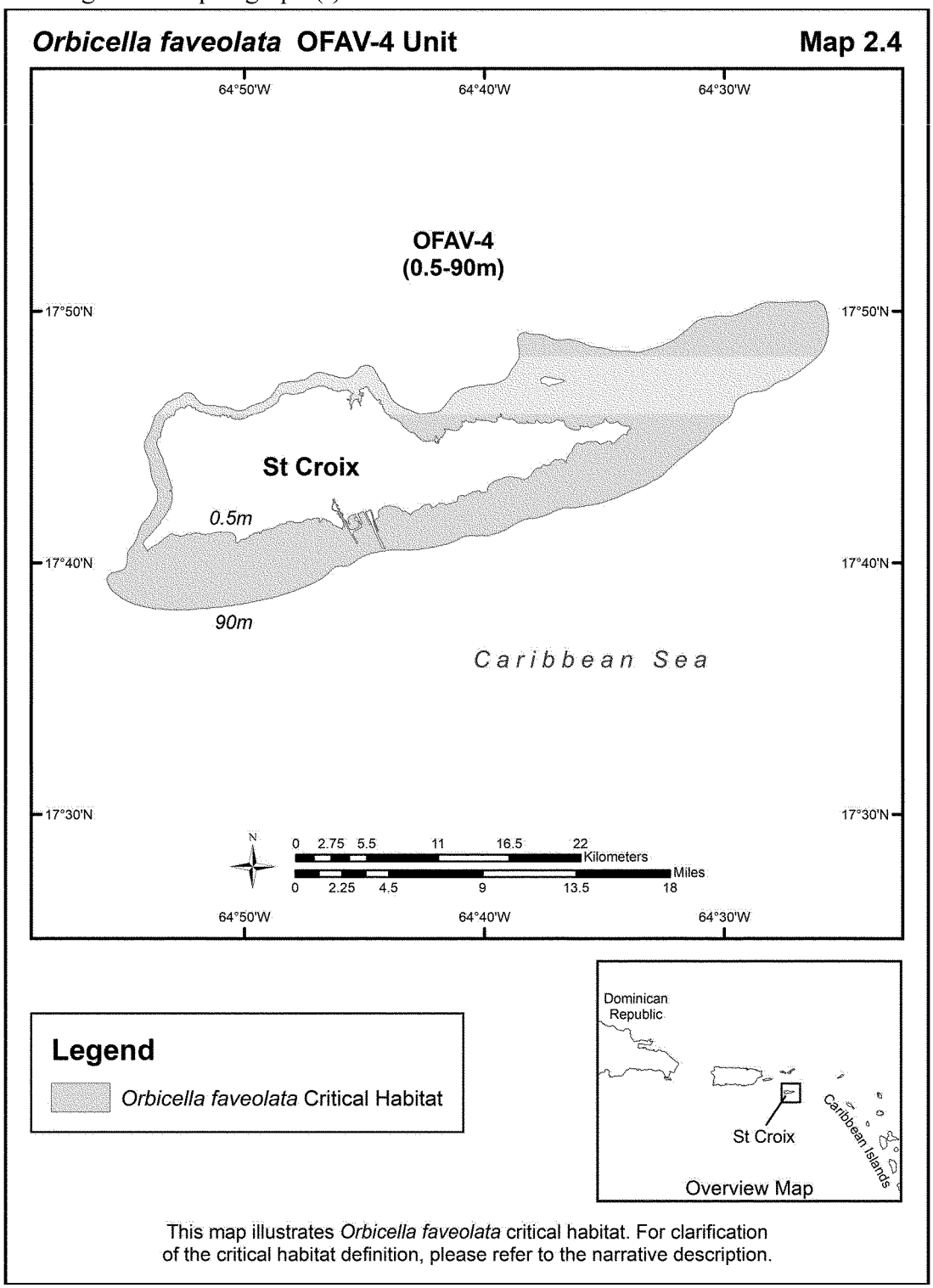
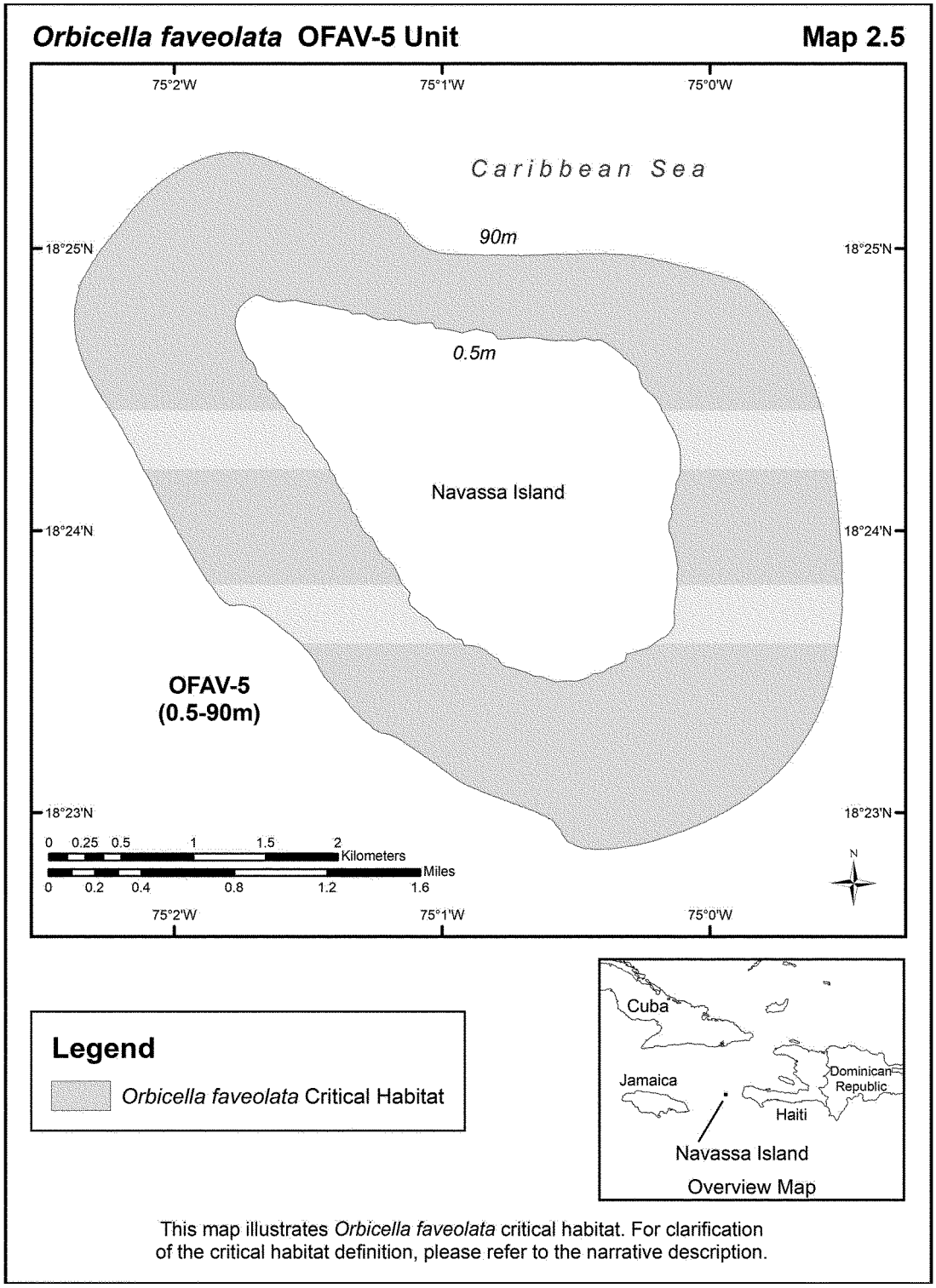
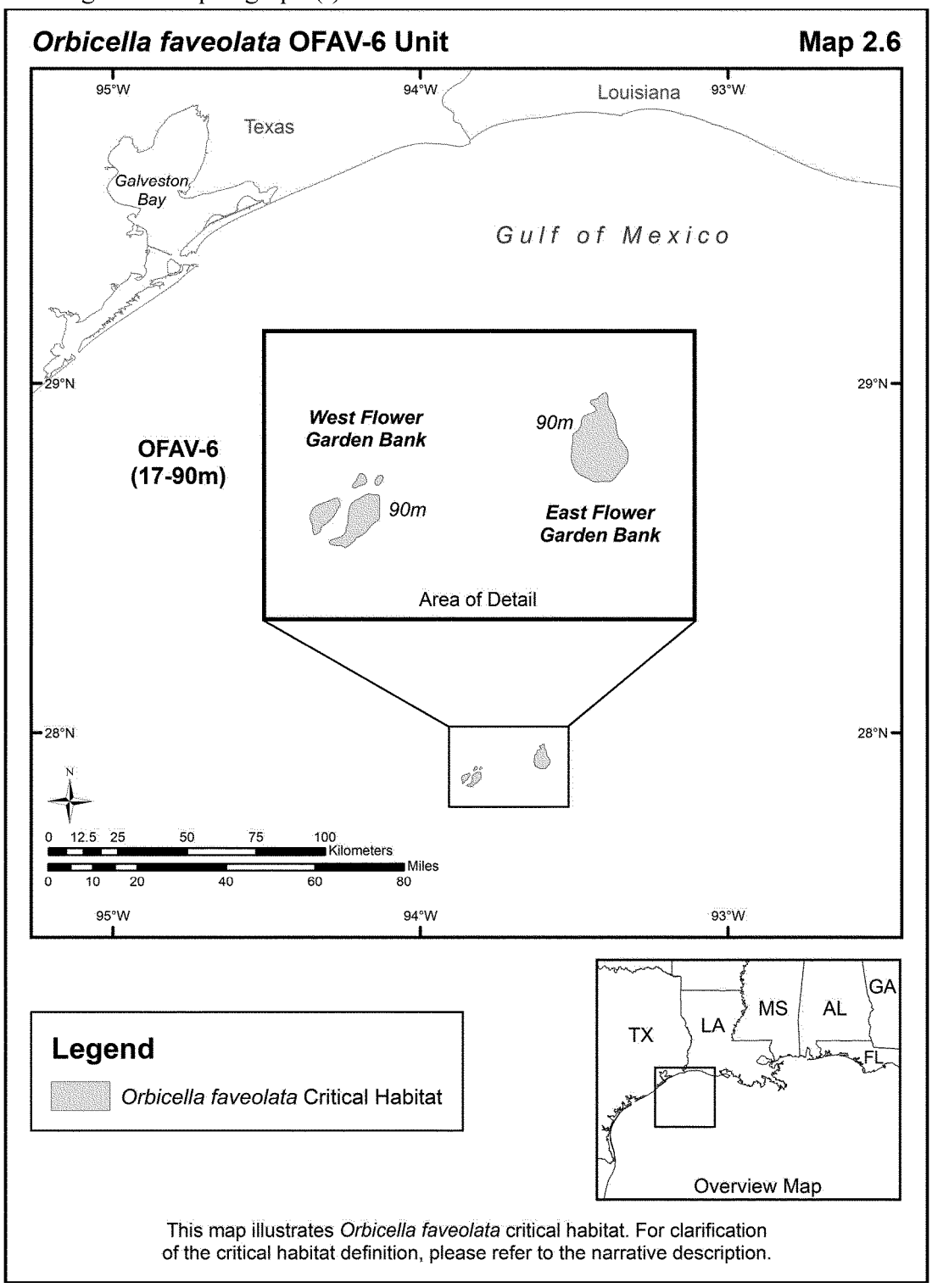


Figure 11 to paragraph (f)



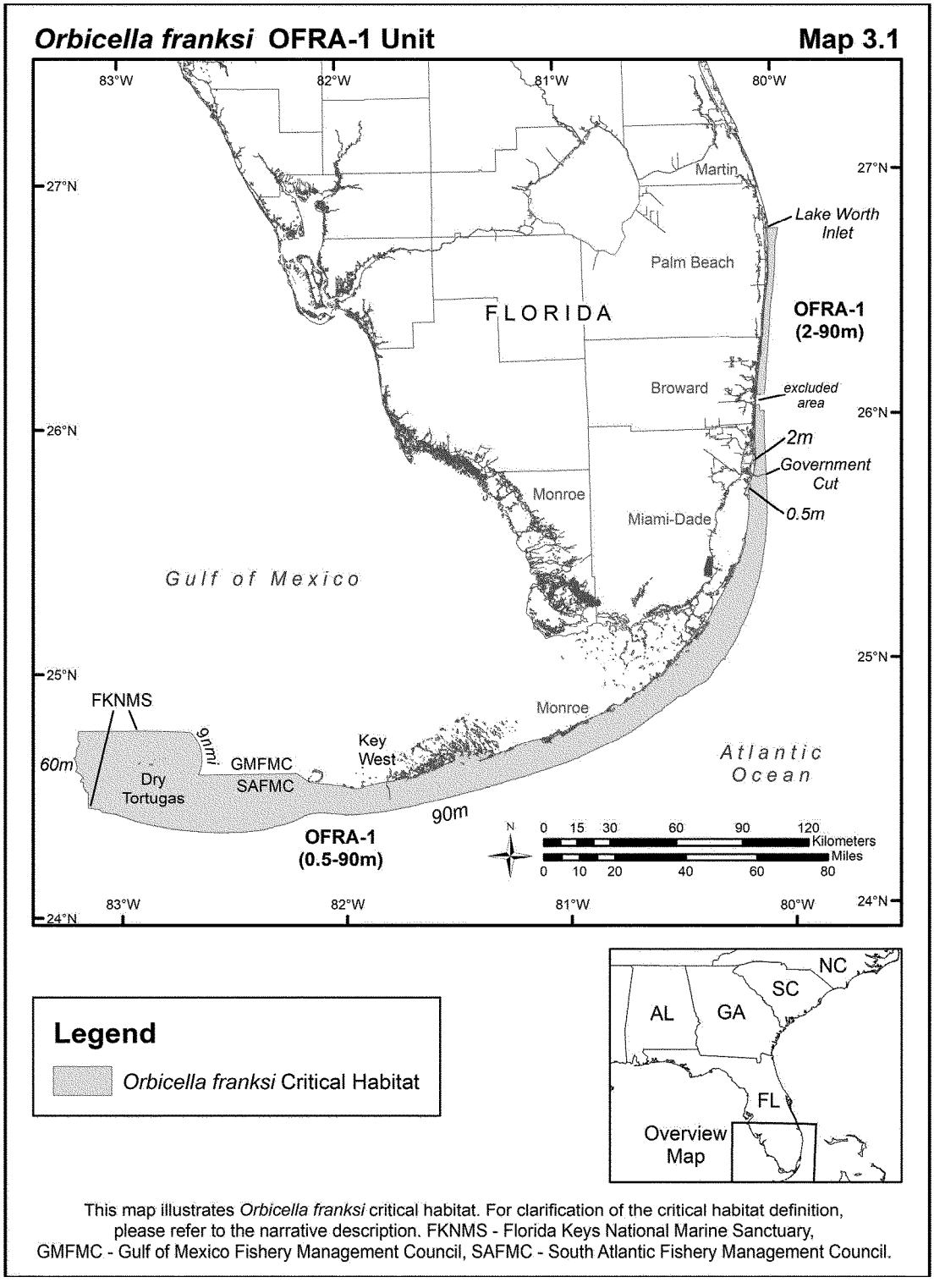
This map illustrates *Orbicella faveolata* critical habitat. For clarification of the critical habitat definition, please refer to the narrative description.

Figure 12 to paragraph (f)



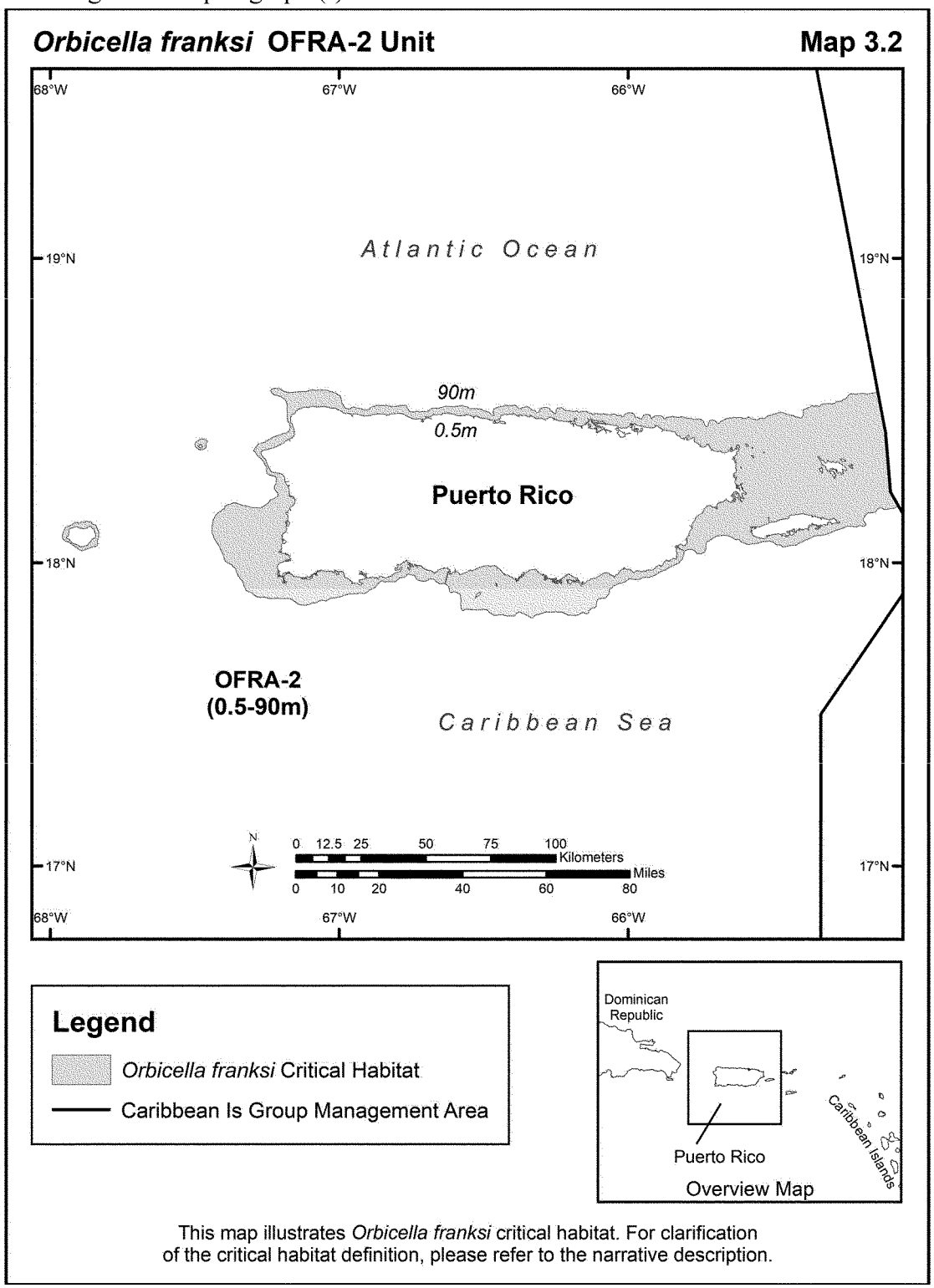
This map illustrates *Orbicella faveolata* critical habitat. For clarification of the critical habitat definition, please refer to the narrative description.

Figure 13 to paragraph (f)



This map illustrates *Orbicella franksi* critical habitat. For clarification of the critical habitat definition, please refer to the narrative description. FKNMS - Florida Keys National Marine Sanctuary, GMFMC - Gulf of Mexico Fishery Management Council, SAFMC - South Atlantic Fishery Management Council.

Figure 14 to paragraph (f)



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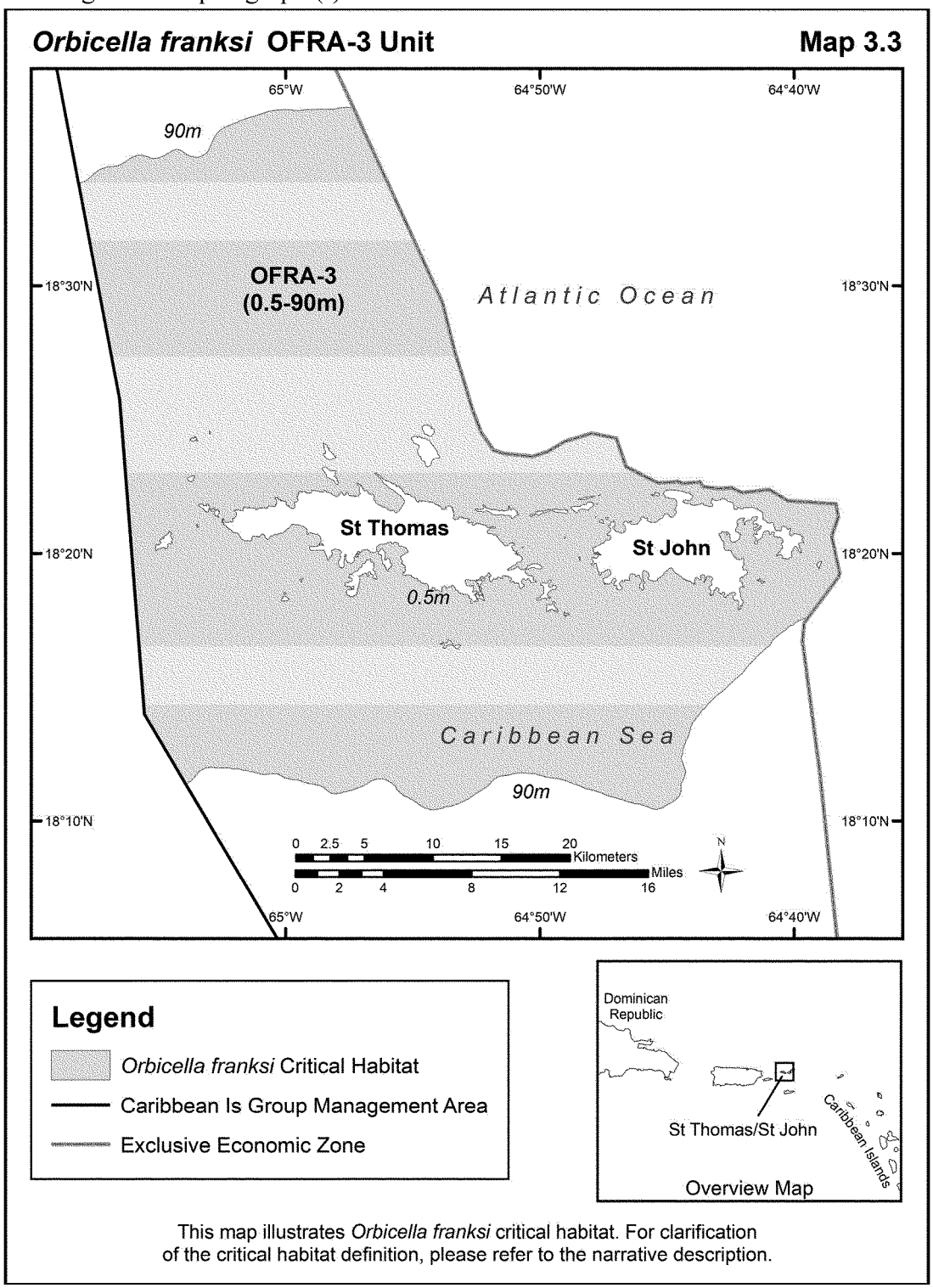

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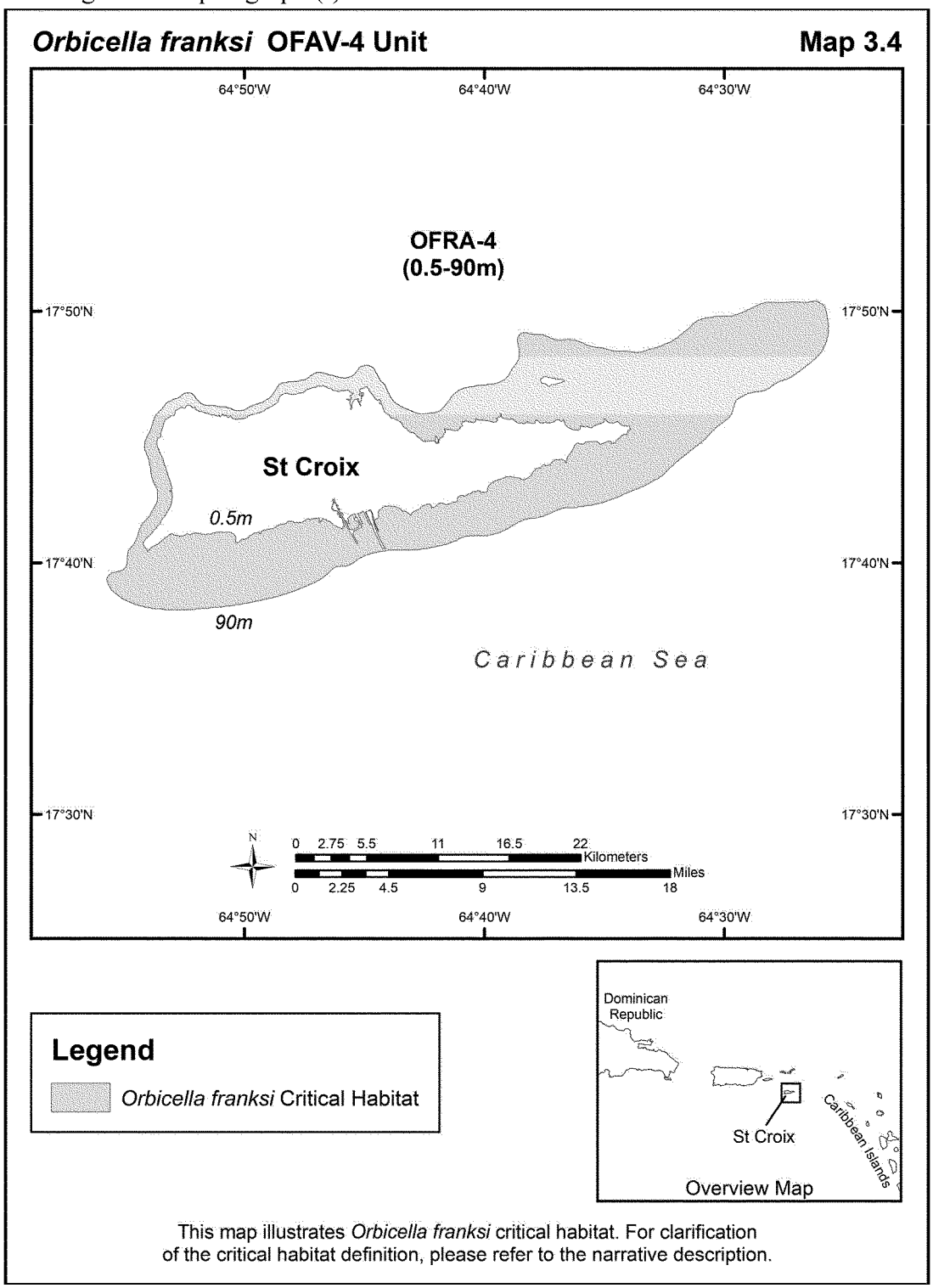

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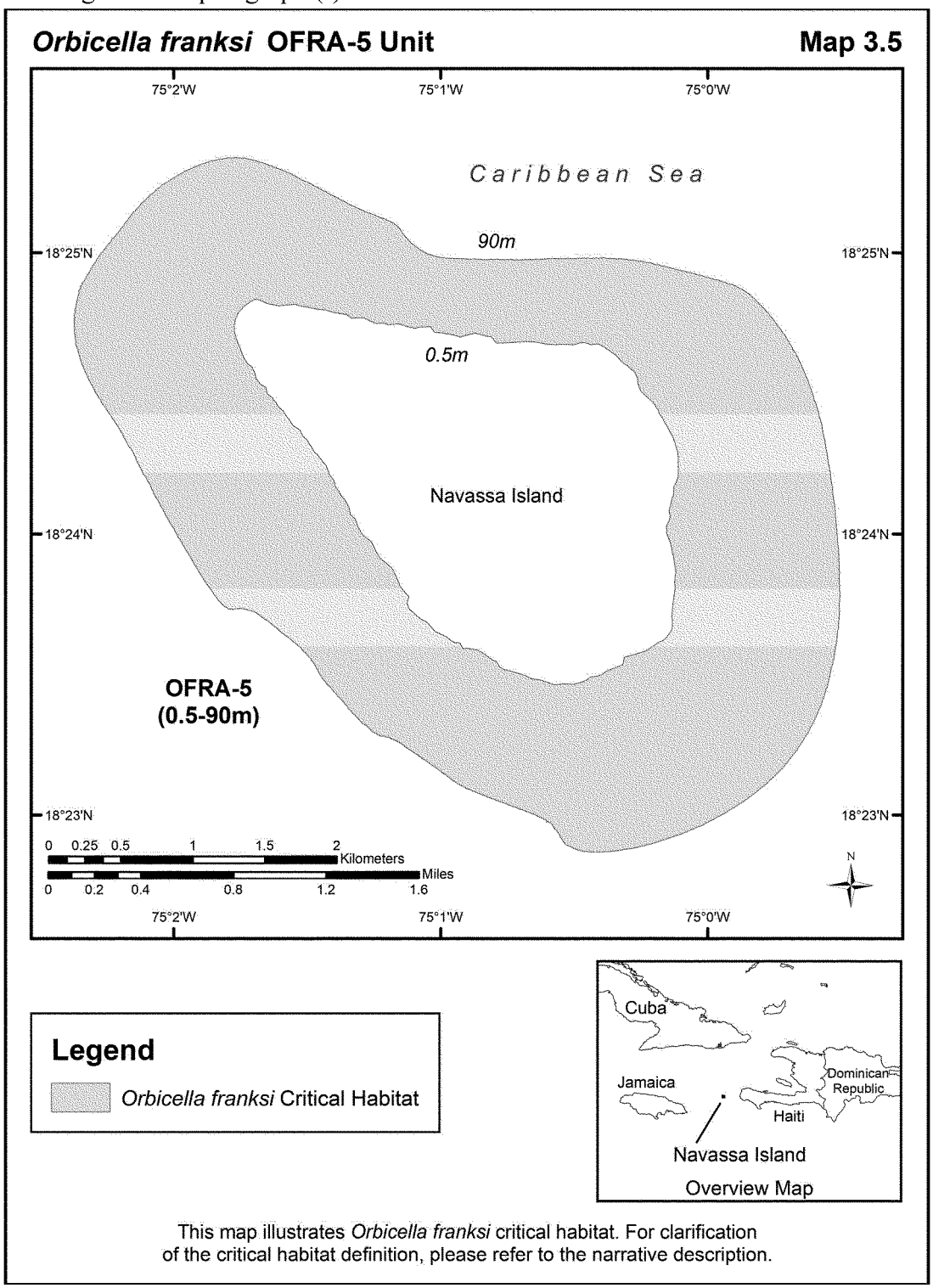

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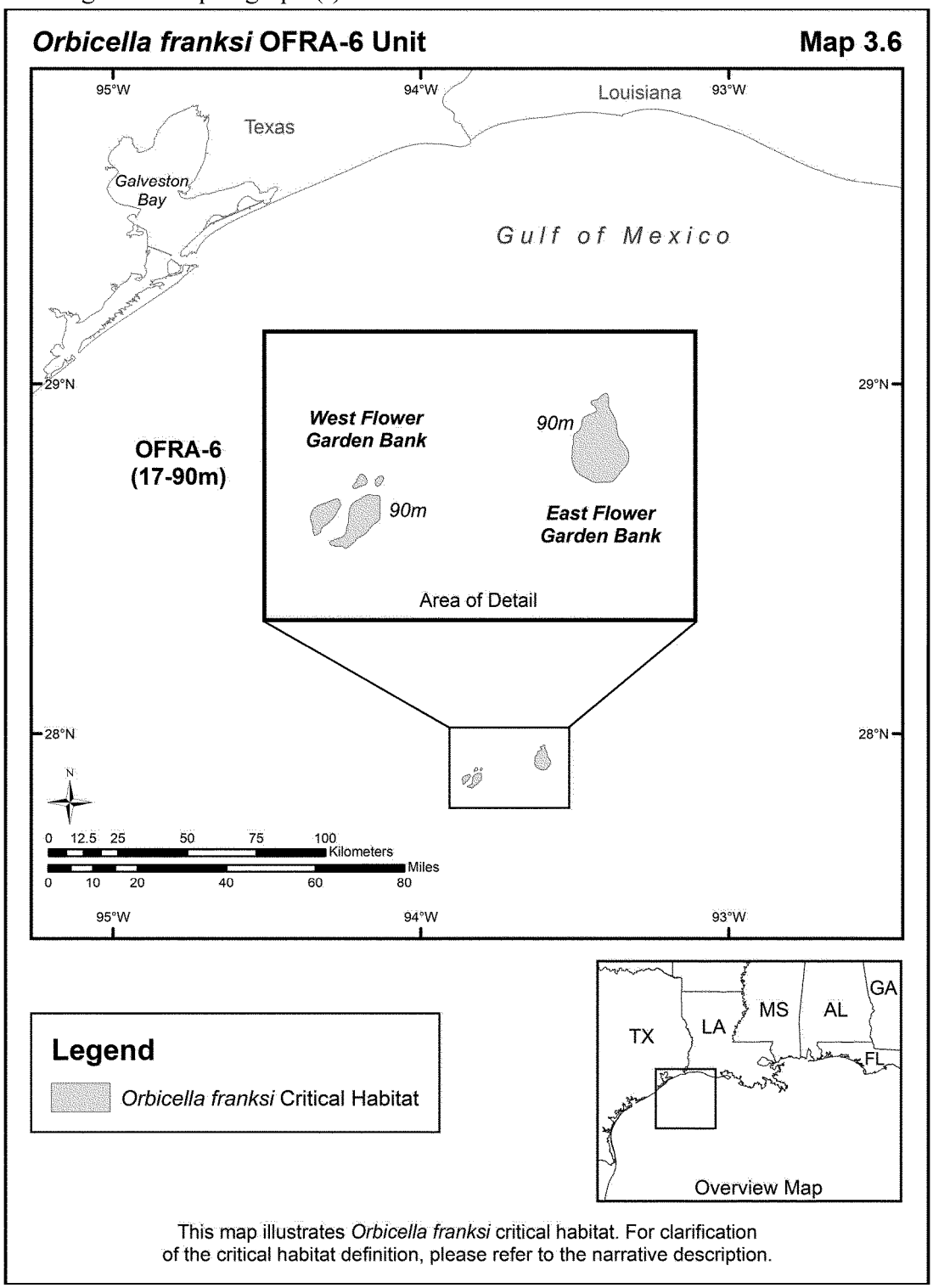
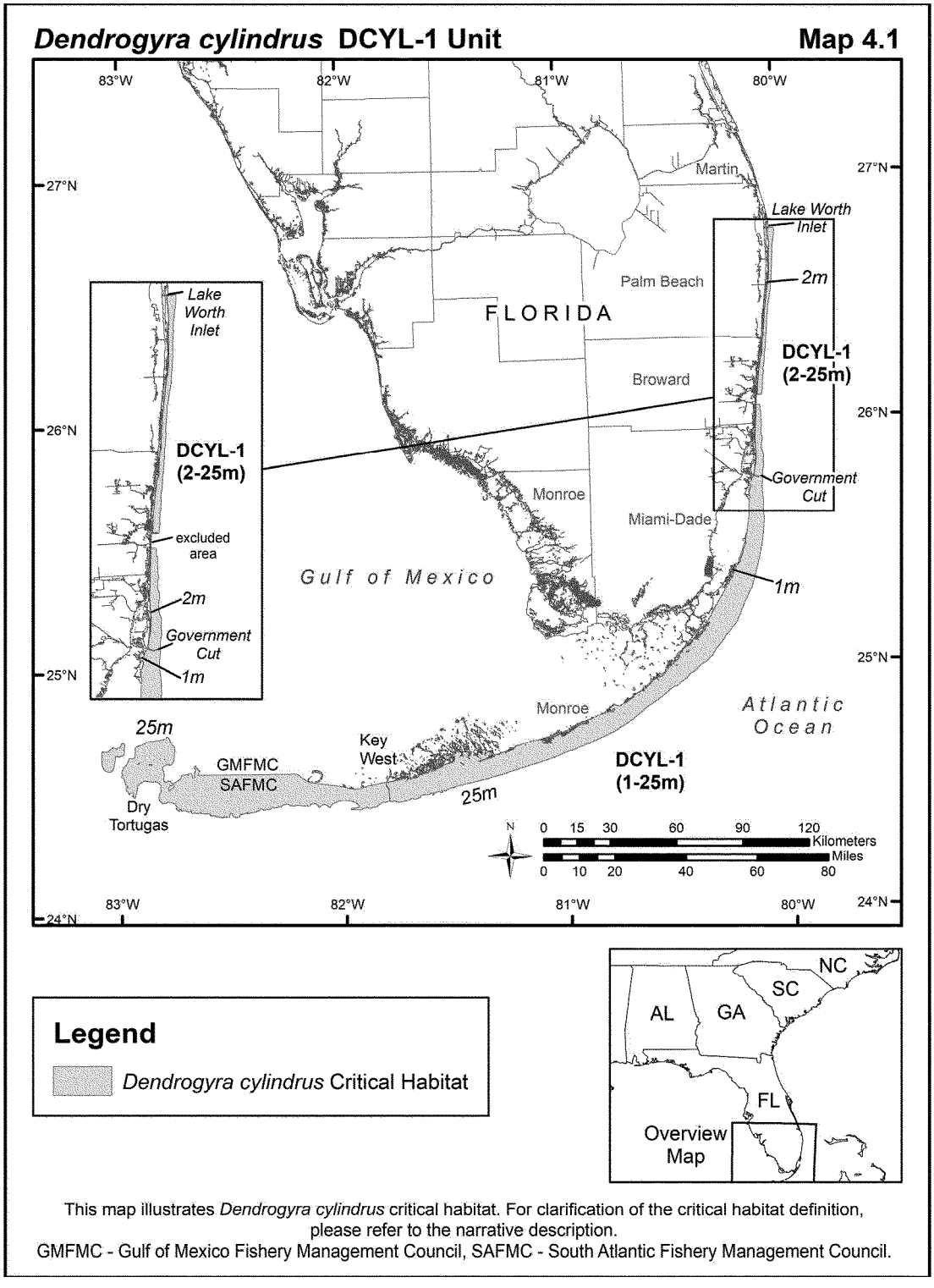


This map illustrates *Orbicella franksi* critical habitat. For clarification of the critical habitat definition, please refer to the narrative description.

Figure 19 to paragraph (f)



This map illustrates *Dendrogyra cylindrus* critical habitat. For clarification of the critical habitat definition, please refer to the narrative description.
GMFMC - Gulf of Mexico Fishery Management Council, SAFMC - South Atlantic Fishery Management Council.

Figure 20 to paragraph (f)

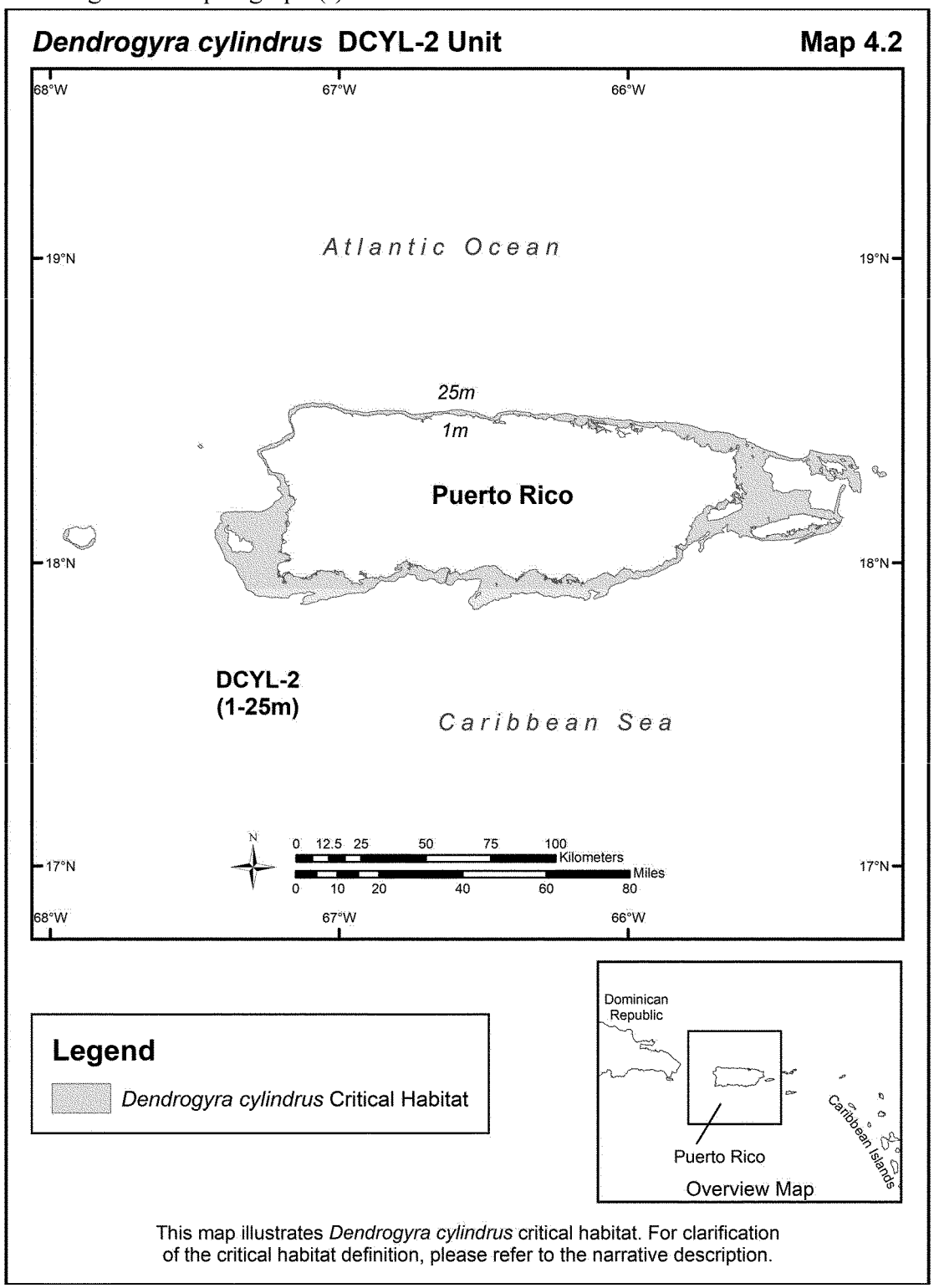
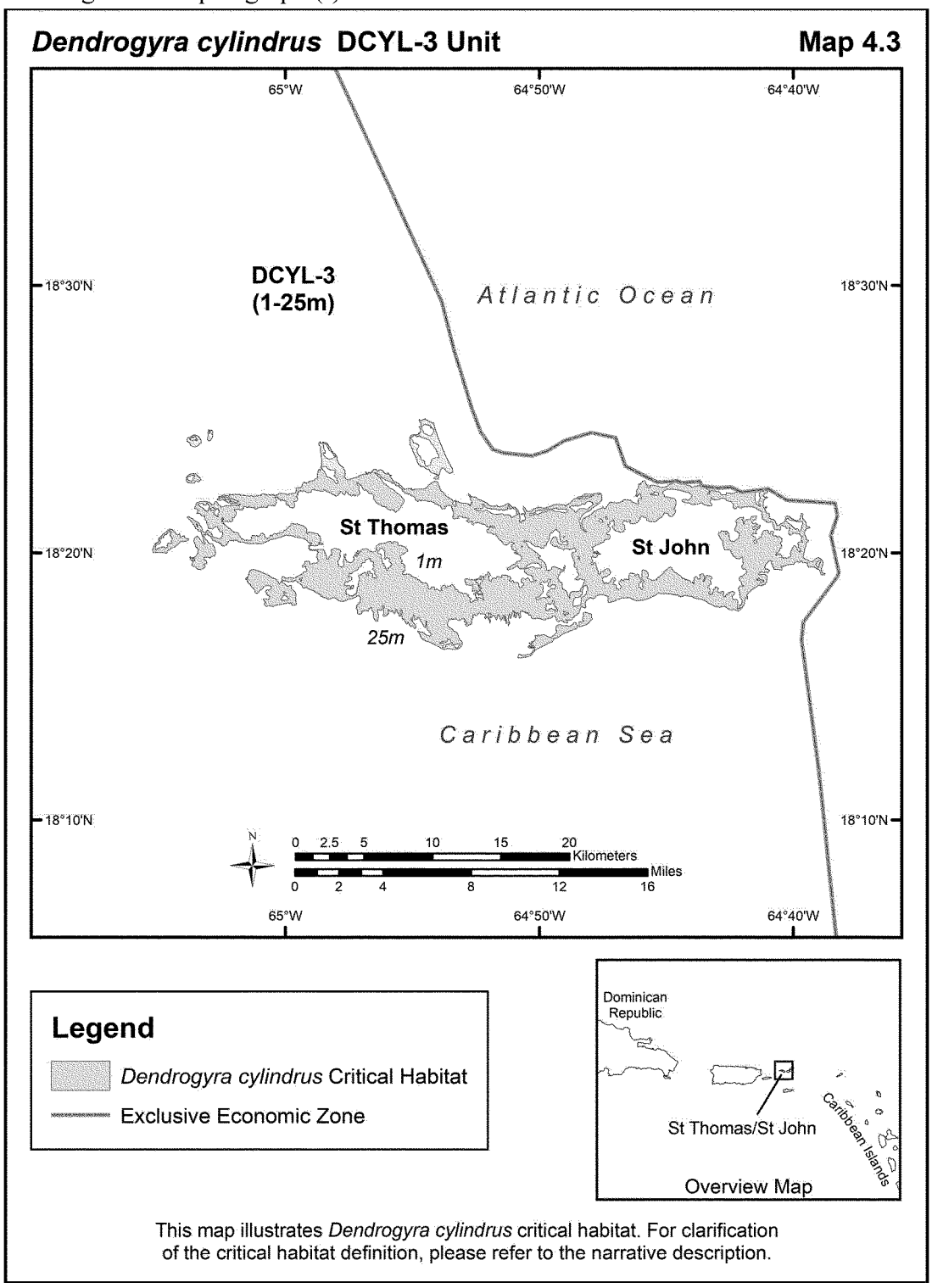


Figure 21 to paragraph (f)



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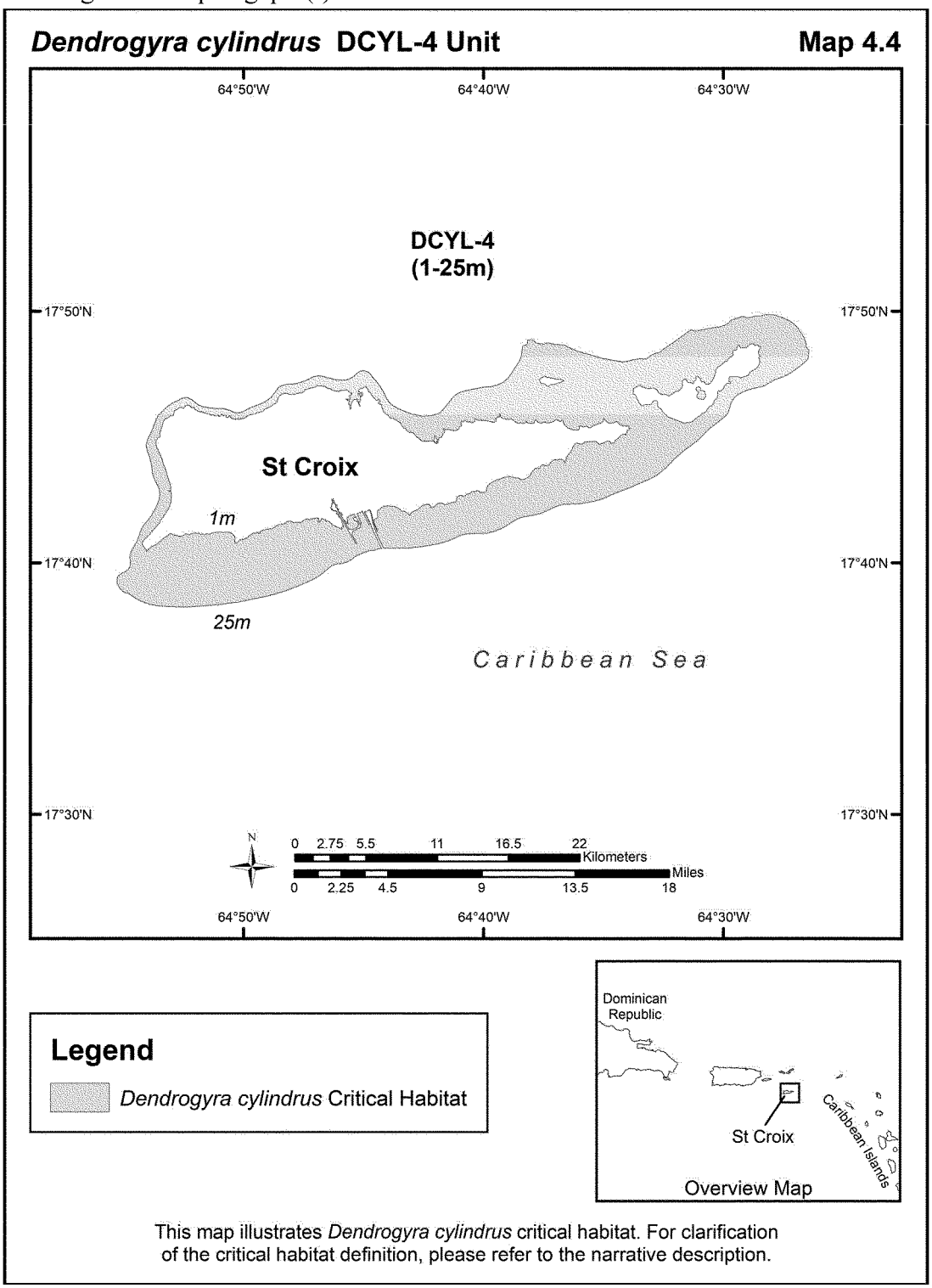


Figure 23 to paragraph (f)

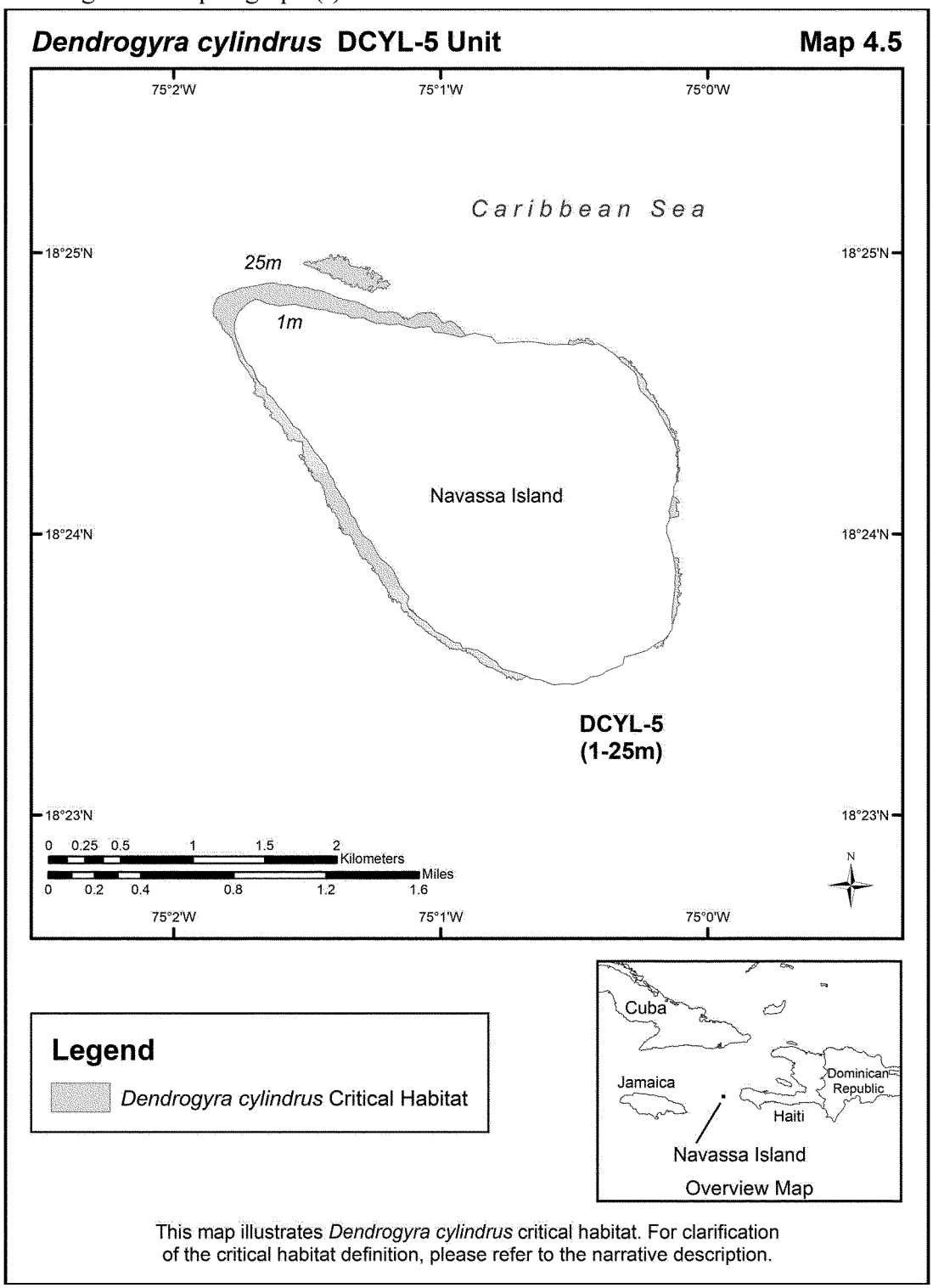
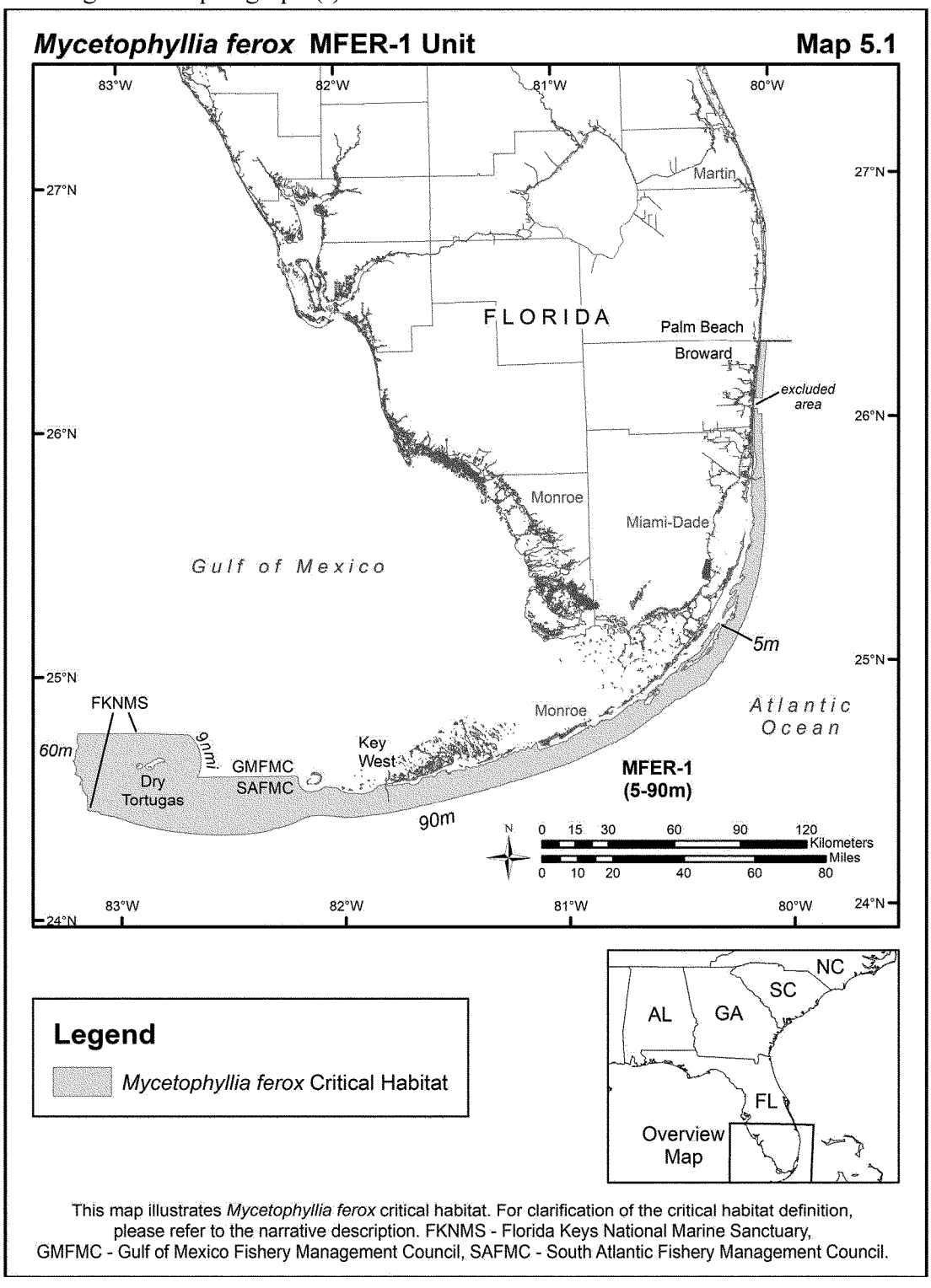


Figure 24 to paragraph (f)



This map illustrates *Mycetophyllia ferox* critical habitat. For clarification of the critical habitat definition, please refer to the narrative description. FKNMS - Florida Keys National Marine Sanctuary, GMFMC - Gulf of Mexico Fishery Management Council, SAFMC - South Atlantic Fishery Management Council.

Figure 25 to paragraph (f)

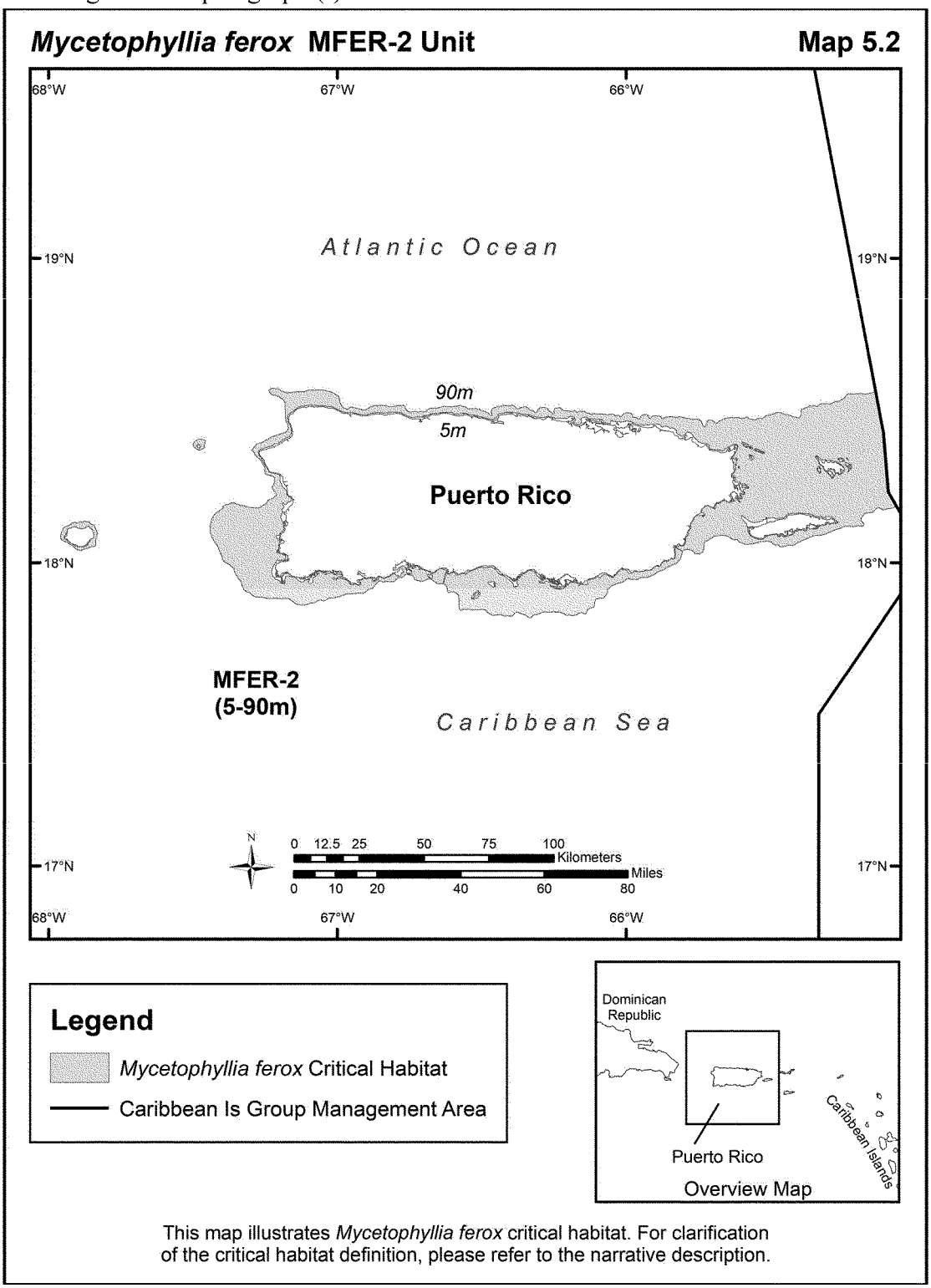


Figure 26 to paragraph (f)

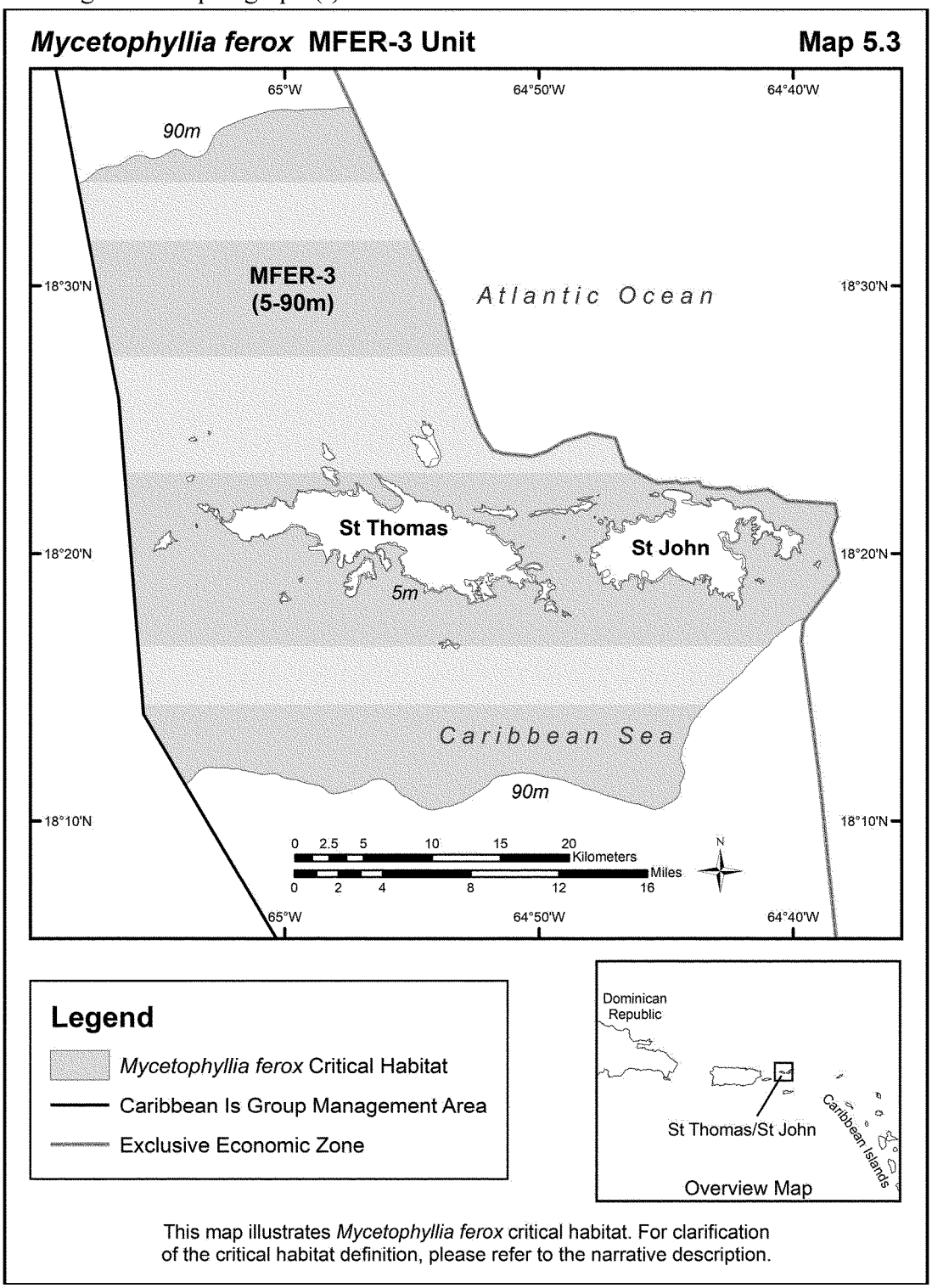
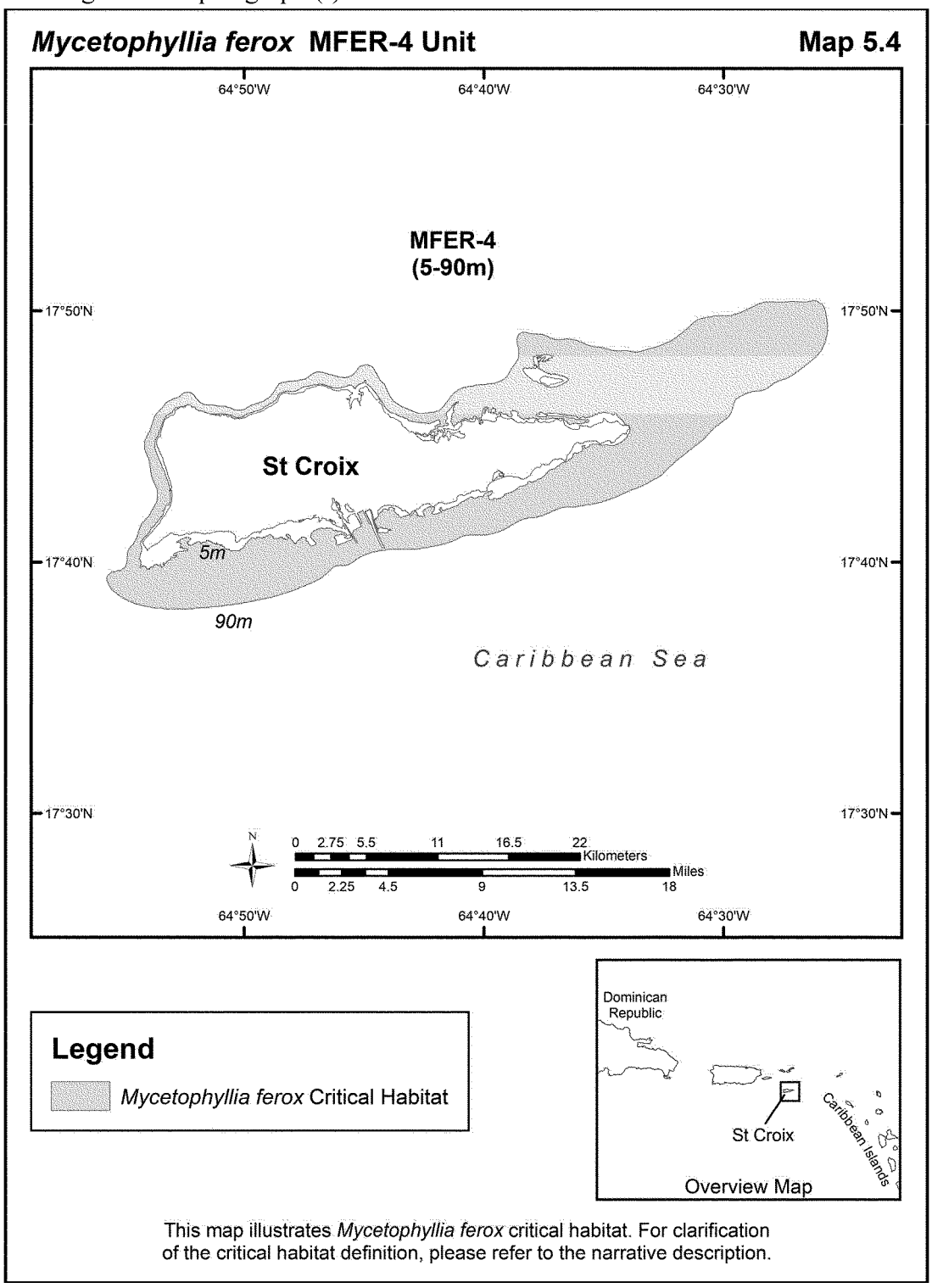


Figure 27 to paragraph (f)



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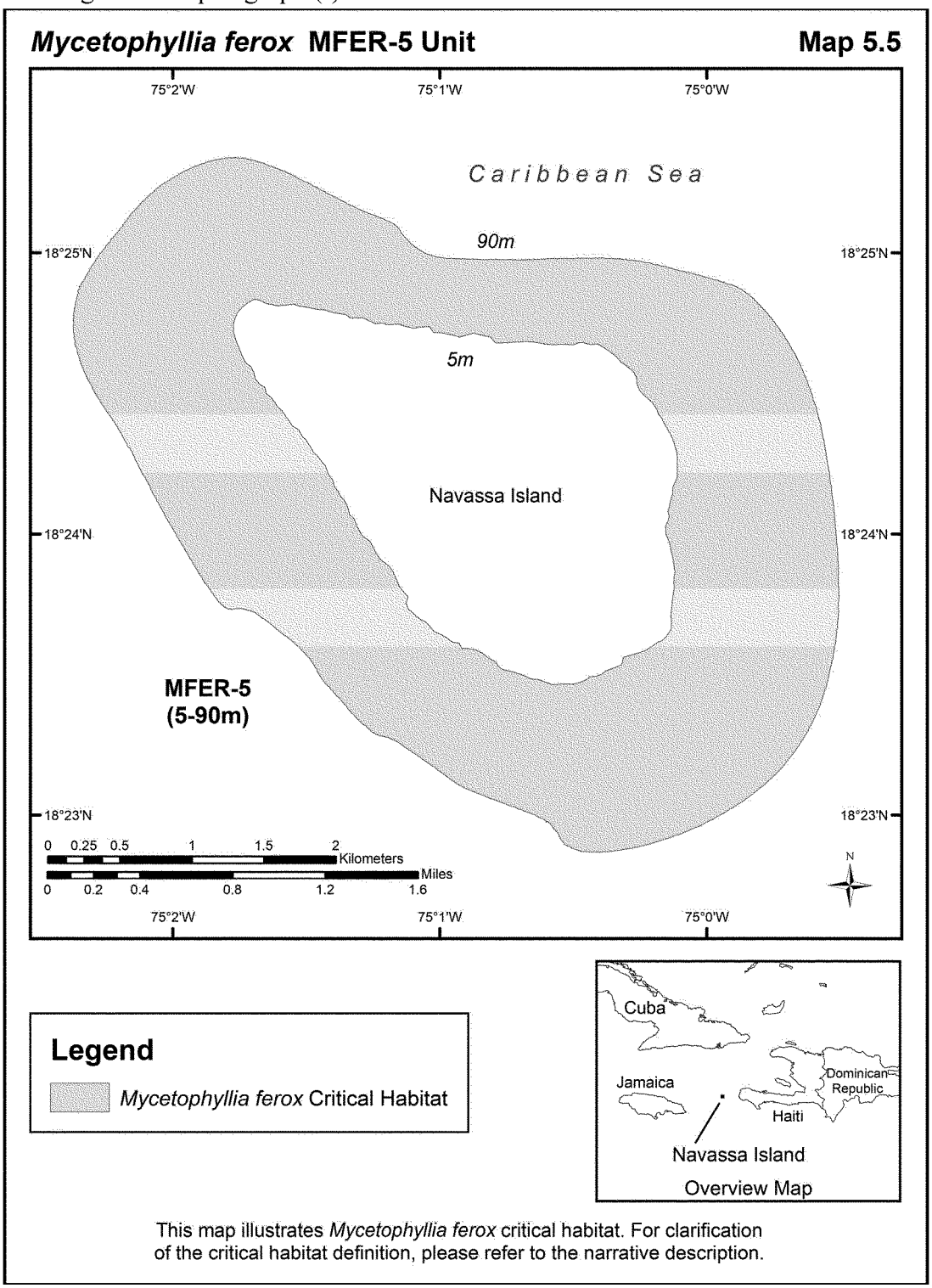

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FEDERAL REGISTER

Vol. 85 Friday,
No. 229 November 27, 2020

Part V

Federal Communications Commission

47 CFR Parts 0, 1, and 63
Process Reform for Executive Branch Review of Certain FCC Applications and Petitions Involving Foreign Ownership; Final Rule

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 1, and 63

[IB Docket No. 16–155; FCC 20–133; FRS 17183]

Process Reform for Executive Branch Review of Certain FCC Applications and Petitions Involving Foreign Ownership

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) adopts rules and procedures that improve the timeliness and transparency of the process by which it seeks the review of executive branch agencies for certain applications with foreign ownership.

DATES: The amendments to §§ 0.261 (instruction 2) and 1.47 (instruction 4) and the addition of part 1, subpart CC (instruction 7), are effective December 28, 2020. The other rule amendments (instructions 5, 6, 8, 9, and 11 through 14) are delayed indefinitely. The Commission will publish a document in the **Federal Register** announcing the effective date for those amendments.

FOR FURTHER INFORMATION CONTACT: Leah Kim, International Bureau, Telecommunications and Analysis Division, at (202) 418–0722. For information regarding the PRA information collection requirements contained in the PRA, contact Cathy Williams, Office of Managing Director, at (202) 418–2918 or *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, FCC 20–133, adopted on September 30, 2020, and released on October 1, 2020. The full text of this document is available on the Commission's website at *https://docs.fcc.gov/public/attachments/FCC-20-133A1.pdf.* To request materials in accessible formats for people with disabilities, send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Final Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) of the possible significant impact on small entities of the policies and rules adopted in this Report and Order.

Congressional Review Act

The Commission will send a copy of this Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A).

Synopsis

I. Introduction

1. In this Report and Order, we adopt rules and procedures that streamline and improve the timeliness and transparency of the process by which the Federal Communications Commission coordinates with the executive branch agencies for assessment of any national security, law enforcement, foreign policy, or trade policy issues regarding certain applications filed with the Commission. The rules we adopt today formalize the review process and establish firm time frames for the executive branch agencies to complete their review consistent with the President's April 4, 2020 Executive Order 13913 that established the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (the Committee).[1] The rules will provide greater regulatory certainty for applicants and facilitate foreign investment in, and the provision of new services and infrastructure by, U.S. authorization holders and licensees in a more timely manner, while continuing to ensure that the Commission receives the benefit of the agencies' views as part of its public interest review of an application.

2. These new rules and procedures will also improve the ability of the executive branch agencies to expeditiously and efficiently review the applications and make the review process more transparent. Among other requirements, for most applications referred by the Commission, the Committee has 120 days for initial review, plus an additional 90 days for secondary assessment if the Committee determines that the risk to national security or law enforcement interests cannot be mitigated with standard mitigation measures.

II. Background

3. For the past two decades, the Commission has referred certain applications that have reportable foreign ownership to the Department of Defense, Department of Homeland Security, Department of Justice, Department of State, U.S. Trade Representative (USTR), and Department of Commerce's National Telecommunications & Information Administration (NTIA) (collectively, executive branch agencies or agencies) for their review. In adopting rules for foreign carrier entry into the U.S. telecommunications market over two decades ago in its *Foreign Participation Order,* the Commission affirmed that it would consider national security, law enforcement, foreign policy, and trade policy concerns in its public interest review of applications for international section 214 authorizations and submarine cable landing licenses and petitions for declaratory ruling under section 310(b) of the Act.[2] Accordingly, the Commission has coordinated such applications with the relevant executive branch agencies for their expertise in identifying and evaluating issues of concern that may arise from the applicants' foreign ownership.

4. Under this practice, when an applicant has a 10% or greater direct or indirect foreign investor, the Commission has referred the following types of applications to the executive branch agencies for their input on any national security, law enforcement, foreign policy, and trade policy concerns: (1) International section 214 authority; (2) assignment or transfer of control of domestic or international section 214 authority; (3) submarine cable landing licenses; and (4) assignment or transfer of control of a submarine cable landing license. The Commission also has referred petitions seeking authority to exceed the section 310(b) foreign ownership benchmarks for broadcast and common carrier wireless and common carrier satellite earth station applicants and licensees.[3]

[1] Executive Order 13913 of April 4, 2020, Establishing the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector, 85 FR 19643 (April 8, 2020) (Executive order) (stating that, ''[t]he security, integrity, and availability of United States telecommunications networks are vital to United States national security and law enforcement interests'').

[2] *Rules and Policies on Foreign Participation in the U.S. Telecommunications Market; Market Entry and Regulation of Foreign-Affiliated Entities,* IB Docket Nos. 97–142 and 95–22, Report and Order and Order on Reconsideration, 62 FR 64741, Dec. 9, 1997, 12 FCC Rcd 23891, 23919, para. 63 (1997) (*Foreign Participation Order*), recon. denied, 65 FR 60113, Oct. 10, 2000, 15 FCC Rcd 18158 (2000). In this Report and Order, applications and petitions are collectively referred to as ''applications,'' and applicants and petitioners are collectively referred to as ''applicants.''

[3] Section 310(b) of the Act requires the Commission to review foreign investment in broadcast, common carrier, aeronautical en route, and aeronautical fixed radio station licensees. 47 U.S.C. 310(b). Section 310(b)(4) establishes a 25% benchmark for investment by foreign individuals, governments, and corporations in the controlling U.S. parent of these licensees; section 310(b)(3) limits foreign investment in the licensee to 20%. 47 U.S.C. 310(b)(3), (4). Although section 310(b) addresses foreign ownership of aeronautical en

The Commission, however, retains discretion to determine which applications it will refer to the agencies for review.

5. The national security and law enforcement agencies (the Department of Defense, Department of Homeland Security and Department of Justice, informally known as Team Telecom), generally initiate review of a referred application by sending the applicant a set of questions seeking further information.[4] The applicant provides answers to these questions and any follow-up questions directly to Team Telecom, without involvement of Commission staff. Team Telecom uses the information gathered through the questions to conduct its review and determine whether it needs to negotiate a mitigation agreement, which can take the form of a letter of assurances or national security agreement (collectively, mitigation agreements), with the applicant to address potential national security or law enforcement issues. A letter of assurances is a letter from the applicant to the agencies in which it agrees to undertake certain actions and that is signed only by the applicant. A national security agreement is a formal agreement between the applicant and the agencies and is signed by all parties.

6. Upon completion of its review, Team Telecom advises the Commission of its recommendation in typically one of two forms: (1) No comment, in which case the agencies file a letter to this effect, and the Commission acts on the application; or (2) no objection to the grant of an application so long as the Commission conditions grant on the applicant's compliance with the terms of the relevant mitigation agreement.[5] In the latter case, a grant of the application will typically be subject to the express condition that the applicant abide by the commitments and undertakings contained in the mitigation agreement.[6] Alternatively, the executive branch may recommend that the Commission deny an application based on national security or law enforcement grounds. In such cases, the executive branch has filed the recommendation on behalf of the full set of agencies to which the Commission referred the application.

7. Pursuant to its authority and obligations under the Communications Act, the Commission accords the appropriate level of deference to the executive branch agencies in their areas of expertise but ultimately makes its own independent decision on whether to grant a particular application. The Commission has recently affirmed this long-standing policy; it has also broadened the scope of referrals to include broadcast petitions for section 310(b) foreign ownership rulings.

8. On April 4, 2020, the President signed Executive Order 13913, which established the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector, composed of the Secretary of Defense, the Secretary of Homeland Security, the head of any other executive department or agency, or any Assistant to the President, as the President determines appropriate, and the Attorney General, who serves as the Chair (together, the Committee Members). The Executive order also provides for Committee Advisors, including the Secretary of State, the Secretary of the Treasury, the Secretary of Commerce, the Director of the Office of Management and Budget, the U.S. Trade Representative, the Director of National Intelligence, the Administrator of General Services, the Assistant to the President for National Security Affairs, the Assistant to the President for Economic Policy, the Director of the Office of Science and Technology Policy, the Chair of the Council of Economic Advisers, and any other Assistant to the President, as the President determines appropriate. The Committee Members and Committee Advisors may designate a senior executive to perform their functions. The Executive order also directed the Committee Members to enter into a Memorandum of Understanding among themselves and with the Director of National Intelligence by July 3, 2020, describing how they will implement and execute the provisions of the Executive order.

9. The Executive order sets out the duties of the Committee Chair, the Committee Members, and the Committee Advisors, as well as the process by which the Committee is to conduct initial reviews and secondary assessments of any application with foreign ownership referred by the Commission. The primary objective of the Committee is to assist the Commission in its public interest review of national security and law enforcement concerns that may be raised by foreign participation in the U.S. telecommunications services sector. The Committee does not expressly review applications for foreign policy and trade policy concerns, although the Committee Advisors represent the agencies with foreign policy and trade policy expertise. The Executive order directs the Chair to designate one or more Committee Members to serve as the lead (Lead Member) for executing any function of the Committee.

10. The Executive order sets out the following time frames for the Committee's review of an application for a ''license'' [7] or transfer of a license referred by the Commission: 120 days for an initial review and a 90-day secondary assessment of an application if the Committee determines that the risk to national security or law enforcement interests cannot be mitigated by standard mitigation

route and aeronautical fixed radio stations, to date the Commission has not received a section 310(b) petition for declaratory ruling for such licensees.

[4] The set of questions seeks information on the 5% or greater owners of the applicant, the names and identifying information of officers and directors of companies, the business plans of the applicant, and details about the network to be used to provide services. *See* Letter from the Honorable Lawrence E. Strickling, Assistant Secretary for Communications and Information, U.S. Department of Commerce, to Marlene H. Dortch, Secretary, FCC at 3 (May 10, 2016) (NTIA Letter) (''Because the Commission currently only requires very limited information in these areas, upon receipt of a request to review from the Commission, the reviewing agencies' current practice is to send an applicant a set of initial questions.''). The Commission's rules, by contrast, require the disclosure of, among other things, the name and citizenship of any person or entity that directly or indirectly owns at least 10% of the equity in the applicant and the percentage of equity owned by each of those entities to the nearest 1%. 47 CFR 1.767(a)(8), 63.04(a)(4), 63.18(h), 63.24(e)(2).

[5] For example, on June 8, 2020, the executive branch filed a petition to adopt conditions, and the Commission conditioned its grant of the authorization on the applicant's compliance with the terms of the applicant's letter of assurances. Petition of the Department of Justice, National Security Division to Adopt Conditions to Authorizations and Licenses, File No. ITC–214–20190131–00073 (filed June 8, 2020), *https://go.usa.gov/xfpSm; International Authorizations Granted Section 214 Applications (47 CFR 63.18, 63.24); Section 310(b) Petitions (47 CFR 1.5000),* Report No. TEL–02025, Public Notice, 35 FCC Rcd 6478 (IB 2020), *https://go.usa.gov/xfpSV.*

[6] More specifically, a typical grant of authorization states that a failure to comply and/or remain in compliance with any of the commitments and undertakings in the mitigation agreement shall constitute a failure to meet a condition of such authorization, and thus grounds for declaring that the authorization has been terminated under the terms of the condition without further action on the part of the Commission. *See* International Authorizations Granted Section 214 Applications (47 CFR 63.18, 63.24); Section 310(b) Petitions (47 CFR 1.5000), Report No. TEL–02031 (IB 2020), *https://go.usa.gov/xfpSp* Failure to meet a condition of the authorization may also result in monetary sanctions or other enforcement action by the Commission. 47 U.S.C. 312, 503.

[7] The Executive order defines a ''license'' as any license, certificate of public interest, or other authorization issued or granted by the Federal Communications Commission after referral of an application by the Commission to the Committee or its predecessor group of agencies. Executive order, Sec. 2(a). It defines an ''application'' as any application, petition, or other request for a license or authorization, or the transfer of a license or authorization, referred by the Commission to the Committee or its predecessor group of agencies. *Id.* Sec.2(b).

measures. The initial time frame begins ''on the date the Chair determines that the applicant's responses to any questions and information requests from the Committee are complete.''

11. At the conclusion of its review, the Committee may: (1) Advise the Commission that the Committee has no recommendation for the Commission on the application and no objection to the Commission granting the license or transfer of the license; (2) recommend that the Commission deny the application due to the risk to the national security or law enforcement interests of the United States; or (3) recommend that the Commission condition grant on the applicant's compliance with standard or non-standard mitigation measures. In cases where the Committee Members and Committee Advisors cannot reach consensus on recommendations to deny or condition on non-standard mitigation, they shall submit a recommendation to the President. The Executive order also provides for Committee review of certain existing authorizations and licenses.

III. Discussion

12. Based on the record developed in this proceeding and in light of the Executive order, we adopt rules and procedures to facilitate a more streamlined and transparent review process. Commenters state that the pre-Executive order review process lacked transparency and certainty and support the initiative by the Commission and the executive branch agencies to clarify and expedite the review process. They emphasize that predictable timelines for the executive branch review process are critical to securing foreign capital in U.S. communications services and infrastructure and maintaining U.S. competition and innovation, especially in light of economic challenges resulting from the global COVID–19 pandemic.

13. First, we continue to refer to the executive branch agencies those applications for international section 214 authorizations and submarine cable licenses or to assign, transfer control or modify such authorizations and licenses where the applicant has reportable foreign ownership,[8] and all petitions for section 310(b) foreign ownership rulings.[9]

14. Second, for those applications that are referred, we require the applicants to provide responses to a set of standardized national security and law enforcement questions directly to the executive branch at the time the applicant files its application with the Commission. This will enable the executive branch agencies to begin their review earlier in the process than is now the case and may eliminate the need to send a specifically tailored questionnaire (Tailored Questions) to each applicant.

15. Third, we require all applicants for international section 214 authorizations and submarine cable landing licenses, applications to assign, transfer control or modify such authorizations and licenses (including those that do not have reportable foreign ownership), and petitioners for section 310(b) foreign ownership rulings to provide certain certifications. These certifications should facilitate faster reviews, make mitigation unnecessary for a number of applications reviewed by the Committee, strengthen compliance, and assist the Commission in its ongoing regulatory obligations.

16. Fourth, we adopt the time frames set forth in the Executive order, a 120-day initial review period followed by a discretionary 90-day secondary assessment.

17. Finally, we adopt other revisions to the application process as proposed in the *Executive Branch Notice of Proposed Rulemaking (NPRM)* (81 FR 46870, July 19, 2016). We establish a new subpart CC in part 1 of the rules to provide a unified and transparent set of rules governing referral of applications to the executive branch agencies.

18. The changes we adopt here will provide greater predictability for industry, the Committee, and the Commission. Knowing which applications will be referred for executive branch review, what information is needed by the executive branch for its initial review, and when a decision will likely be made enables industry to better plan its use of resources. Our rules will likewise strengthen the executive branch agencies' ability to protect national security, assist in law enforcement, and advance foreign policy and trade policy objectives. We find persuasive the executive branch's argument that these requirements are necessary for national security and law enforcement, and when combined with the added benefit of assisting the Commission in its ongoing work, evidence the significant benefits of this order.

19. We note that some of the benefits of our rule changes are difficult to quantify in monetary terms, especially those related to the need to ensure the protection of national security and law enforcement. Yet, the benefits from increased speed of review, predictability of handling of applications, and greater assurance of protection of national security, law enforcement, foreign policy and trade interests, should significantly outweigh the small costs imposed on industry and the executive branch by these changes. Many of the changes outlined here are merely a codification of the Commission's existing informal consultation process with the executive branch. They also represent front-loading certain requirements on applicants when they file an application. For the most part, this is information that most applicants with foreign ownership would have to provide later to the Committee, so any additional costs created by requiring applicants to provide necessary information with their applications is negligible. Accordingly, we find that the benefits of these changes significantly exceed any additional costs.

A. Types of Applications To Be Referred for Executive Branch Review

20. Under the rules we adopt in this document, we will continue to refer applications for international section 214 authorizations and submarine cable landing licenses, as well as applications to assign, transfer control of or modify those authorizations and licenses, where the applicant has reportable foreign ownership.[10] The rules also provide for the continued referral of petitions for section 310(b) foreign ownership rulings for broadcast, common carrier wireless, and common carrier satellite earth station applicants and licensees.[11] In addition, we will refer, at the Commission's discretion, all associated applications. The Commission retains the discretion to refer additional types of applications if we find that the specific circumstances of an application require the input of the executive branch as part of our public interest determination of whether an application presents national security, law enforcement, foreign policy, or trade

[8] These applications are filed pursuant to §§ 1.767, 63.18, and 63.24.

[9] These petitions are filed pursuant to §§ 1.5000 through 1.5004.

[10] These applications are filed pursuant to §§ 1.767, 63.18, and 63.24 of our rules. Applicants must report every individual or entity that directly or indirectly owns at least 10% of the equity in the applicant. 47 CFR 1.767(a)(8), 63.18(h), 63.24(e)(2).

[11] These petitions are filed pursuant to §§ 1.5000 through 1.5004. Broadcast, common carrier wireless and common carrier satellite earth station applicants and licensees must seek Commission prior approval for aggregate foreign ownership that exceeds the statutory benchmarks in sections 310(b)(3) and (4), as applicable. 47 U.S.C. 310(b)(3), (4); *see 2012 Foreign Ownership Forbearance Order,* 77 FR 50628, Aug. 22, 2012, 27 FCC Rcd at 9832, para. 13 (forbearing from applying section 310(b)(3)'s 20% limit to common carrier wireless licensees where the public-interest standard under section 310(b)(4) is satisfied).

policy concerns.[12] The Commission likewise retains the discretion to exclude certain types of applications that it may have referred in the past.

21. In that regard, we adopt the Commission's proposal to no longer routinely refer standalone applications to transfer control of domestic section 214 authority. The Commission has referred a few such applications for transfer of control of domestic section 214 authority with reportable foreign ownership that did not have a corresponding international section 214 transfer of control application. To date, however, the executive branch has not pursued mitigation for such applications. As the Commission noted in the *Executive Branch NPRM,* the NTIA Letter did not request referral of these types of applications. The United States Telecom Association and Satellite Industry Association (SIA) express support for not referring applications for domestic-only section 214 transactions. Based on the record before us, we do not find any reason to continue to refer transactions involving only domestic section 214 authority. However, we will continue referring joint domestic and international section 214 transfer of control applications with reportable foreign ownership filed under § 63.04(b) of the Commission's rules.[13] The Commission also retains the discretion to refer a domestic-only section 214 transaction should we find that a particular application may raise national security, law enforcement, foreign policy, and trade policy concerns for which we would benefit from the advice of the executive branch.

22. We also adopt the Commission's proposal to refrain from referring satellite earth station applications unless they are associated with a request for a section 310(b) foreign ownership ruling. EchoStar Satellite Services L.L.C., Hughes Network System, LLC, and SIA support this proposal. The executive branch included satellite earth stations in the list of applications requested for referral in the NTIA Letter. However, NTIA did not address this issue in its comments or reply comments. As the Commission noted in the *Executive Branch NPRM,* we have not previously referred applications for satellite earth station licenses to the executive branch because most of the stations are authorized on a non-common carrier basis, and thus the foreign ownership provisions of section 310(b) do not apply. We thus have not found a need to collect detailed ownership information in the applications. We do not find any basis in the record to change this practice. In addition, because NTIA did not request that we refer all broadcast and common carrier wireless license applications, and no commenter suggested that we should refer all such applications, we adopt the Commission's proposal to refer broadcast or common carrier wireless applications only if the applicant is required to seek a section 310(b) foreign ownership ruling.[14]

23. Level 3 Communications, LLC (Level 3) questions the use of foreign ownership as the ''trigger'' for referral and recommends identifying ''more reliable indicia of risk.'' But Level 3 does not identify any such alternative indicia, and the executive branch has consistently indicated that substantial foreign ownership is an indicia of risk. Pursuant to the World Trade Organization (WTO) Basic Telecom Agreement, the United States generally has committed to treat foreign service suppliers or investors no less favorably than domestic service suppliers or foreign service suppliers or investors from another WTO member. The Commission addressed this question in the *Foreign Participation Order* and determined that the procedures adopted in that order to review international section 214 applications, submarine cable applications, and section 310(b) foreign ownership petitions are consistent with U.S. national treatment obligations and ''[t]o the extent we discriminate among domestic and foreign carriers with regard to cable landing licenses and foreign investment, such differentiation is based on statutory distinctions founded on national security and law enforcement concerns.'' The Commission also determined that the procedures it adopted then did not ''discriminate impermissibly among foreigners in a manner inconsistent with our [most favored nation] obligations.'' While we reach the same conclusion here as to the referral process, we will continue to monitor trends on other potential indicia of risk.

24. Level 3 also argues that if the Commission continues to rely on foreign ownership as the trigger, the threshold level of foreign ownership to warrant a referral should be increased to 25% in order to reduce the burden on applicants and narrow the scope of executive branch reviews. We reject Level 3's request to use a 25% threshold, instead of a 10% foreign ownership interest, to trigger referral of applications for international section 214 authorizations and submarine cable landing licenses. The 25% threshold that applies under section 310(b)(4) is an aggregate amount of foreign ownership set by statute, whereas the 10% foreign ownership interest threshold we have historically applied derives from the Commission's longstanding practice of requiring applicants to identify all 10%-or-greater owners. Consequently, subject to certain exceptions detailed below, we will continue to refer international section 214 and submarine cable applications with a 10% or greater direct or indirect owner that is not a U.S. citizen or U.S. business entity.

B. Categories of Applications Generally Excluded from Referral

25. The Commission sought comment on whether, within the types of applications that the Commission currently refers, there are categories of applications that should be excluded from referral. The *Executive Branch NPRM* specifically sought comment on excluding applications when the applicant has an existing mitigation agreement and there has been no material change in the foreign ownership since the executive branch and applicant negotiated the relevant mitigation agreement. It also sought comment on excluding applications involving resellers with no facilities. Commenters generally support these exclusions and suggest others. The executive branch does not oppose excluding categories of applications, but requests that the Commission notify the Committee of applications that come within the exclusions.

26. We find that it is appropriate to exclude from referral certain applications that present a low or minimal risk to national security, law enforcement, foreign policy, and trade policy concerns. Based on the record, we exclude the following applications from referral to the executive branch: (1) *Pro forma* notifications and applications; (2) international section 214 applications, submarine cable applications, and section 310(b)

[12] In circumstances where the Commission, in its discretion, refers to the Committee an application not identified in this order, pursuant to the new rules, in those instances, the Commission staff will instruct the applicant to follow specific requirements, such as submitting responses to the standardized national security and law enforcement questions (Standard Questions) to the Committee and making the appropriate certifications. *See* appendix B, § 1.40001.

[13] 47 CFR 63.04(b). When an applicant files joint international and domestic section 214 transfer applications, it will submit its responses to the Standard Questions and make the five certifications as part of its international assignment or transfer application.

[14] *Executive Branch NPRM,* 31 FCC Rcd at 7462, para. 15. When a satellite earth station applicant needs to request a foreign ownership ruling, it will submit responses to the standard questions and make the five certifications as part of its section 310(b) petition.

petitions where the only reportable foreign ownership is through wholly owned intermediate holding companies and the ultimate ownership and control is held by U.S. citizens or entities; (3) international section 214 applications where the applicant has an existing mitigation agreement, there are no new reportable foreign owners of the applicant since the effective date of the mitigation agreement, and the applicant agrees to continue to comply with the terms of that mitigation agreement; and (4) international section 214 applications where the applicant was cleared by the executive branch within the past 18 months without mitigation and there are no new reportable foreign owners of the applicant since that review. We retain discretion, however, to refer these applications to the executive branch if the particular circumstance warrants, such as a change in the relations between the United States and the applicants' home country. In addition, we will notify the Committee of any applications that fall within the exclusions.[15]

27. First, we continue our practice of excluding *pro forma* notifications and applications for international section 214 authorizations and submarine cable landing licenses from referral. As the Commission noted in the *Executive Branch NPRM,* we do not currently refer *pro forma* notifications because by definition there is no change in the ultimate control of the licensee. Commenters universally support maintaining this exclusion, and the executive branch did not address this issue in its comments.

28. Second, we exclude from referral international section 214 applications, submarine cable applications, and section 310(b) petitions where the only reportable foreign ownership interests are held by wholly owned intermediate holding companies and the ultimate ownership and control is held by U.S. citizens or entities. We agree with Morgan, Lewis & Bockius LLP on behalf of certain telecommunications, media, and technology financial sponsor entities (TMT Financial Sponsors) that those applications where the only foreign ownership is through passive, offshore intermediary holding companies and 100% of the ultimate control is held by U.S. citizens or entities present a minimal risk and generally should not be referred to the executive branch. The executive branch, while not supporting any exclusions, does note that review may not be necessary where ownership and control of a company rests with U.S. citizens but there is foreign ownership associated with the application only because of an intermediary entity incorporated outside the United States. Consequently, we will generally not refer these categories of applications.

29. Third, we generally exclude from referral those international section 214 applications where the applicant has an existing mitigation agreement with the executive branch, agrees to continue to comply with that agreement, and has had no new reportable foreign ownership since the agreement went into effect. As Hibernia Atlantic U.S. LLC and Quintillion Subsea Operations LLC state, ''[w]here an applicant is subject to an existing [mitigation agreement], it already has undergone Team Telecom's review process for national security and law enforcement concerns'' and referral of those applications ''introduces unnecessary delays and may result in the waste of time and resources by both the applicant and the government.'' Although the executive branch opposed this exclusion in its 2016 Comments, in its 2020 Supplemental Comments the executive branch did not oppose the exclusion but noted that the Executive order allows the Committee to review at any time any existing license that the Commission had referred to the executive branch. We also note that most, if not all, mitigation agreements have provisions that allow the parties to renegotiate the terms of the agreement.[16] In situations where the applicant and the Committee agree to changes in the mitigation agreement, the applicant can request that the Commission update the condition of the authorization to replace the previous mitigation agreement with the revised agreement. In situations where the Committee seeks to unilaterally revise the mitigation agreement, it can make a recommendation to the Commission and the applicant will have an opportunity to respond to the Committee's recommendation before the Commission takes action.

30. We limit this exclusion to international section 214 applications because those authorizations are for the provision of service and not tied to a specific facility, so obtaining an additional section 214 authorization does not change the service being provided, and the mitigation agreements usually cover future acquisitions. It is also not necessary to provide this exclusion to section 310(b) foreign ownership rulings since under the Commission's rules those rulings already cover the addition of new licenses as well as new subsidiaries, and affiliates. A new ruling is required only if a licensee proposes a change in foreign ownership that would exceed the parameters of its existing ruling and thus would not fit within this exclusion. We do not, however, extend the exclusion to submarine cable licenses subject to an existing mitigation agreement because these licenses are for specific facilities and each submarine cable may present unique national security, law enforcement, foreign policy or trade policy concerns.

31. Fourth, we exclude from referral international section 214 applications where the applicant was cleared by the executive branch within the past 18 months from the filing of the application without mitigation and there are no new reportable foreign owners in the applicant since that review. Many commenters state that we should not refer applications where the applicant has recently undergone executive branch review and there has not been any change in foreign ownership since that review. For example, EQT AB (EQT) states that we should expedite review for applicants that have undergone review in the past 12–18 months, while TMT recommends that we not refer an application if the applicant has been subject to review in the past five years. We find it is reasonable and appropriate to exclude from routine referral international section 214 applicants that recently have been reviewed by the executive branch. These applications are less likely to raise significant risks because the applicant will have recently received review. This will save time and resources for both the applicant and the executive branch. We recognize that the longer the period since the last review the greater the likelihood for potential national security and law enforcement issues to arise. We believe that 18 months provides a reasonable time frame. We conclude that five years is too long as the threat environment and the policies and concerns of the executive branch are more likely to have evolved. As we discussed above, we will provide the Committee notice when such an application is placed on public notice. To the extent that the Committee may want to review an application that we do not refer under this exclusion, as the executive branch noted, the Executive

[15] While the Commission will not formally refer applications that come within the exclusions, as a courtesy we will notify the Committee when such applications are placed on accepted for filing public notice.

[16] Where a mitigation agreement has been renegotiated and a new agreement is reached, the Committee could recommend to the Commission that it modify the applicable condition in the grant of authorization to require compliance with the terms of the newly renegotiated agreement.

order allows the Committee to review at any time an existing ''license'' that the Commission had referred to the executive branch in the past, not just those in which the review resulted in a mitigation agreement.[17]

32. The applicant will need to make a specific showing in its application that it qualifies for one of these exclusions.[18] If upon review of the application, Commission staff determines that the application should be referred to the executive branch, either because the applicant has not sufficiently demonstrated that the application comes within one of these exclusions or that the application otherwise presents issues that warrant executive branch review, the International Bureau will notify the applicant of the referral to the Committee. Commission staff will then refer the application to the executive branch by Public Notice.

33. At this time, we decline to adopt other exclusions to the referral process. In the *Executive Branch NPRM,* the Commission requested comments on whether to refer applications for transactions that involve resellers with no facilities and asked how the Commission could know that no facilities are being assigned/transferred in the proposed transaction. Although some commenters support such an exclusion, the executive branch asserts that applications from non-facilities-based resellers ''require review by the executive branch, because the companies possess records that may be requested in the course of national security or criminal investigations.'' We accept that the executive branch may have legitimate concerns that resellers could raise national security or law enforcement issues. For example, their records might assist the executive branch in discovering instances of activities with national security and law enforcement implications. Therefore, we will continue to refer international section 214 applications from non-facilities-based resellers to the executive branch.

34. We also decline to exclude from referral an application that has undergone review by the Committee on Foreign Investment in the United States (CFIUS), as suggested by Hogan Lovells US LLP. Executive branch review of an application referred by the Commission includes issues that are not addressed by CFIUS. We refer an application for feedback on any national security, law enforcement, foreign policy, and trade policy issues, while CFIUS review focuses on national security risks. Consequently, we will continue to refer an application irrespective of whether the applicant certifies that the underlying transaction has undergone CFIUS review.[19] We expect that in most instances CFIUS review and executive branch review of a transaction will occur simultaneously. To the extent that CFIUS has completed its review prior to the application being filed with the Commission, we expect that the executive branch could complete its review expeditiously, possibly without the need to request deferral of Commission action on the application, if the application raises no issues other than those considered by CFIUS.

35. Finally, we decline to exclude from referral applications from applicants with permanent residence status, as suggested by Thomas Lynch & Associates and T-Mobile USA, Inc. (T-Mobile). Neither commenter provides any basis for excluding these applications. We also note that permanent residents are not U.S. citizens, but remain citizens of other countries.

C. Categories of Information and Standard Questions

36. We adopt the Commission's proposal in the *Executive Branch NPRM,* with certain modifications, to require (1) international section 214 authorization and submarine cable landing license applicants with reportable foreign ownership, and (2) petitioners for a foreign ownership ruling under section 310(b) whose applications are not excluded from routine referral, to provide specific information regarding ownership, network operations, and other matters when filing their applications.[20] In this proceeding, we adopt the categories of information that will be required from applicants, but do not adopt the specific questions. We direct the International Bureau to draft, update as appropriate, and make available on a publicly available website, a standardized set of national security and law enforcement questions (Standard Questions) that elicit the information needed by the Committee within those categories of information that we establish today. Once the Standard Questions are available, we will require applicants to file their responses to the Standard Questions with the Committee prior to or at the same time they file their applications with the Commission.[21] The executive branch supports this proposal and agrees that it will expedite the review process. Applicants also will be required to certify in their FCC application that they have submitted to the Committee responses to the Standard Questions. Finally, in circumstances where the Commission determines to refer, in its discretion, other applications or filings, the rules provide that Commission staff will instruct the applicant which requirements it is required to fulfill, including requiring the applicant to submit to the Committee responses to the Standard Questions and to make the necessary certification to the Commission.

37. We believe, and the executive branch agrees, that having the applicant provide its responses to Standard Questions to the Committee when it files the applications will lead to a swifter and more streamlined review, benefiting both applicants and the Committee. The executive branch agrees that with more fulsome information upfront, the Committee may not need to send an applicant Tailored Questions in many circumstances or, in those instances where Tailored Questions are necessary, the Committee can significantly limit the scope of its additional inquiries (in turn reducing the amount of time needed for the applicant to prepare responses). Under either scenario, the Committee would be able to start the 120-day initial review period sooner.[22]

1. Categories of Information

38. We adopt and codify in our rules the five categories of information for which applicants must provide detailed and comprehensive information to help

[17] We also note that the Committee may always file comments in response to a public notice of an application even if the Commission does not refer the application for executive branch review.

[18] Before the effective date of 47 CFR 1.40001(a)(2), applicants may provide any information in their applications that may help inform the Commission's discretionary decision about whether to refer an application. *See* Letter from Mike Saperstein, Vice President, Strategic Initiatives & Partnerships, USTelecom, to Marlene H. Dortch, FCC (Sept 23, 2020).

[19] CFIUS does not publicly disclose what transactions it is reviewing, and the Commission is not part of CFIUS. Accordingly, we would not know if a transaction has undergone CFIUS review unless the applicant tells us.

[20] *Executive Branch NPRM* at 7463, para. 16. As discussed above, an applicant with reportable foreign ownership filing an application that falls within one of the categories of applications to be excluded from referral to the executive branch will not be required to file this information with its application, although it will need to demonstrate how it falls within the exclusion as well as make the required certifications.

[21] Applicants must also provide the Committee with copies of their FCC applications, with all attachments that were filed with application.

[22] The 120-day initial review period starts on the date the Chair determines that the applicant's responses to any questions and information requests from the Committee, including responses to the Tailored Questions where applicable, are complete. Executive order, Sec. 5(b)(iii).

ensure that the relevant executive branch agencies can promptly commence their review. In the *Executive Branch NPRM,* the Commission sought comment on the executive branch's request that we require applicants with reportable foreign ownership to provide as part of their applications detailed and comprehensive information in the following categories: (1) Corporate structure and shareholder information; (2) relationships with foreign entities; (3) financial condition and circumstances; (4) compliance with applicable laws and regulations; and (5) business and operational information, including services to be provided and network infrastructure. NTIA states that this information is necessary for the executive branch's assessment of whether an application raises national security or law enforcement concerns.[23]

39. Commenters generally support the five categories but suggest that they be narrowly tailored to fall within the scope of executive branch review. For example, BT Americas Inc., Deutsch Telekom, Inc., Orange Business Services U.S., and Telefonica Internacional USA, Inc. (BT Americas) state that ''relationships with foreign entities'' and ''business and operational information'' appear relevant to a national security review and are often included in the questionnaires that the executive branch agencies currently send to applicants. Certain commenters, however, express concerns that certain categories and questions exceed the scope of information needed for executive branch review, are within areas of Commission jurisdiction, or otherwise are duplicative of information required by the Commission's application process.

40. We find that the categories described are important to the executive branch's review of applications with reportable foreign ownership. We find persuasive the executive branch's contention that questions regarding ''financial condition and circumstances'' are relevant to ascertaining potential national security and law enforcement concerns and that an applicant's history of ''compliance with applicable laws and regulations'' is indicative of whether the applicant can be trusted to comply with any negotiated mitigation term. The executive branch states in its 2016 comments that information about an applicant's revenue is collected to assess an applicant's business associations and potential links to entities likely to present national security concerns, *e.g.,* foreign intelligence agencies or terrorist networks. The executive branch reiterates in its 2020 comments the importance of such information in determining national security and law enforcement risks and states that any limitations by the Commission are not warranted. Additionally, although certain categories of information fall within the Commission's jurisdiction, *e.g.,* ownership information, the Commission's and the executive branch agencies' review of the information is relevant for distinct but essential purposes and therefore not duplicative for purposes of this proceeding. Accordingly, we incorporate in the rules the categories of information to be answered by applicants.

2. Standard Questions

41. To expedite the executive branch review process, we will develop a set of Standard Questions that seek detailed and comprehensive information consistent with the categories of information described above and that will be accessible on a publicly available website. Commenters support this approach. Accordingly, we direct the International Bureau, within 90 days, to develop, solicit comment on, and make publicly available on a website the Standard Questions consistent with our determinations in this Report and Order. We also direct the International Bureau to maintain and update the questions as needed. The Bureau will provide notice and comment prior to making future changes to the questions. This approach addresses concerns raised by several 2016 commenters that the Commission allow for public comment on the proposed questions. This additional opportunity for comment will permit the International Bureau to better evaluate commenters' concerns and proposals regarding the contents of the Standard Questions.

42. The *Executive Branch NPRM* included the sample questions provided by NTIA in 2016, and NTIA provided more detailed sample questions in its 2020 comments. National Association of Broadcasters (NAB) proposes limiting the sample questions about corporate and senior officers solely to executive officers, better defining the terms ''remote access'' and ''managed services'' when asking who has access, and narrowing the scope of foreign participation questions to those with 5% or greater interests, or remote access. We agree that applicants would benefit from greater clarity on how to define key terms such as ''corporate officers'' and ''senior-level'' officers as well as ''remote access'' and ''managed services.'' We disagree, however, with NAB's contention that ''because the Committee's review is focused on foreign participation, the Commission should . . . [only] seek information regarding *foreign* investors that have equity interests of five percent or greater in the company, or those that have remote access.'' As we have noted, the executive agencies' review extends beyond just foreign policy considerations; the review process also involves national security and law enforcement issues as well, which could be implicated regardless of whether the equity interest holder is a domestic or foreign entity. We would expect the questions to be otherwise sufficiently tailored to ensure that the Committee receives information germane to its review process. We direct the International Bureau to take into account the comments we have received so far, such as these from NAB, when developing and seeking comment upon the proposed Standard Questions.

43. In its most recent comments, NTIA suggests that the Commission add to its application forms additional questions regarding the applicant's investors with 5% or more equity, and senior-level officials, which are included in the sample triage questions. We decline to add these questions to the Commission's application forms as they are inconsistent with the Commission's ownership disclosure requirements,[24] but we note that they are part of the sample triage questions that the Commission will use as a basis for the Standard Questions.

3. Submission of Responses to Standard Questions

44. We require applicants to file their responses to the Standard Questions directly with the Committee—prior to or at the same time they file their

[23] Concerns regarding national security and law enforcement include preventing abuses of U.S. communications systems, protecting the confidentiality, ensuring the integrity and availability of U.S communications, protecting the national infrastructure, preventing fraudulent or other criminal activity, and preserving the ability to instigate legal process for communications data. *Executive Branch NPRM,* 31 FCC Rcd at 7464, para. 20 (citing NTIA Letter at 4).

[24] The Commission's rules regarding international section 214 authorizations, domestic and international section 214 transfer of control and assignment applications, submarine cable landing licenses, and submarine cable landing license transactions, require the disclosure of, among other things, the name and citizenship of any person or entity that directly or indirectly owns at least 10% of the equity in the applicant and the percentage of equity owned by each of those entities to the nearest one percent. 47 CFR 1.767(a)(8), 63.04(a)(4), 63.18(h), 63.24(e)(2). The ownership disclosure requirements for section 310(b) foreign ownership petitions are set out in §§ 1.5000–1.5004 of the Commission's rules. 47 CFR 1.5000–1.5004.

applications with the Commission—to expedite the review process. Commenters generally support this proposal. NAB, for example, recommends that applicants be allowed to submit responses to standardized questions ''at the same time they file their FCC applications . . . .'' CTIA, on the other hand, suggests an applicant should be allowed to file its responses at some point after the application is filed, while also recognizing that the executive branch review period would start only when the responses have been provided. CTIA states that preparing responses to the questions is typically very time consuming and could delay filing the application and Commission review of the application.

45. We find, and the executive branch agrees, that applicants should provide the answers to the Standard Questions to the Committee prior to or at the same time as they file their application with the Commission as this will allow the executive branch review process to commence sooner than is currently possible and avoid unnecessary delays. If an application fits within one of the categorical exclusions, then the applicant will not be required to submit responses to the Standard Questions when it files its application.[25] However, if upon review of the application, Commission staff determines that the application should be referred to the executive branch, then the applicant will need to submit responses to the Standard Questions and a copy of the application to the Committee. The executive branch supports this approach noting that it will enable the Committee to review the responses to the Standard Questions promptly and more quickly send any Tailored Questions to the applicant. We anticipate that by requiring the applicant to provide responses to the Standard Questions to the Committee with its application the Committee will be able to determine that it has complete information and can begin the 120-day review period sooner.

4. Committee Review of Responses to Standard Questions

46. In the *Executive Branch NPRM,* the Commission contemplated that Commission staff would review the responses to the Standard Questions for completeness as part of the review of an application for acceptability for filing but leave the substantive review to the executive branch. Once the Commission determined that the application was complete, including the responses to the Standard Questions, the Commission would refer the application, which would start the clock on the executive branch review. However, under the Executive order it is the Chair of the Committee that determines when an applicant has provided complete responses to any questions and the 120-day review period starts. Further, industry commenters oppose Commission review of the responses as, among other things, they contain personally identifiable information and business sensitive information. Therefore, we find that there is no benefit to the Commission reviewing the responses prior to the Committee review.

47. NTIA stated in its 2016 comments that the Commission should receive and review applicant answers to the questions in the first instance. Commenters oppose FCC review contending that such review will place a strain on Commission resources or increase the possibility that personally identifiable information or business sensitive information may be inadvertently revealed if it is shared with more agencies. T-Mobile, for example, states that ''the information required for the Committee's review should be submitted directly to the Committee and not as part of the FCC application. Much of the information the Committee seeks is quite sensitive and not relevant to the Commission's review. As such, it should be submitted only to the Committee.'' NAB proposes that ''broadcast petitioners be permitted to exclude [from FCC review information required by the Executive Branch that would otherwise not be required to be made available to the Commission or subject to Commission staff review] from their section 310(b)(4) petitions and provide it directly to the Executive Branch.'' We note that the Executive order addresses confidential treatment of the responses provided to the Committee.

48. Upon consideration of the record, including the new Executive order, we conclude that there is no benefit in having Commission staff review the responses to the Standard Questions either before or at the same time they are submitted to the executive branch. The executive branch will conduct a *de novo* review of the responses regardless of whether Commission staff were to review them first. Initial Commission staff review, therefore, would be redundant to executive branch review, would not be an efficient use of limited agency/government resources, and may delay the overall review process. Additionally, Commission applications are routinely publicly available, and while the Commission regularly handles and protects confidential information, eliminating Commission review of the responses to the Standard Questions addresses commenters' concerns regarding the treatment of personally identifiable information, business sensitive information, and any other confidential information included in the responses. Accordingly, we require applicants to file their responses to the Standard Questions directly with the Committee.

49. Nonetheless, we make it clear that in particular cases where Commission staff needs access to an applicant's responses, the executive branch could share that information on a case-by-case basis subject to applicable rules and the relevant provisions of the Executive order, as necessary to inform the Commission of any subsequent recommendations made by the executive branch to the Commission.

D. Certification Requirements

50. We require all international section 214 and submarine cable applicants (and applicants requesting to assign, transfer control, or modify such authorizations and licenses), with or without foreign ownership, as well as all non-broadcast section 310(b) petitioners, to attest to five certifications, as proposed in the *Executive Branch NPRM* with some minor changes.[26]

51. Specifically, we will require applicants and/or petitioners (other than broadcast section 310(b) petitioners) to certify that they will: (1) Comply with the Communications Assistance for Law Enforcement Act (CALEA) and related Commission rules and orders to the extent applicable; (2) make communications to, from, or within the United States, as well as records thereof, available to U.S. law enforcement officials; (3) designate a U.S. citizen or permanent U.S. resident as a point of contact for the execution of lawful requests and as an agent for legal service of process; (4) affirm that all information submitted to the Commission and the Committee as part of the application process is complete and accurate, and promptly inform the Commission and the executive branch agencies of any (a) substantial and significant changes in such information, while an application is pending, as defined in § 1.65 of the

[25] Even in instances where the applicant is not required to submit responses to the Standard Questions, it will still have to provide the required certifications about compliance with national security and law enforcement and to maintain correct and accurate information regarding the applicant, as discussed below.

[26] These filings are made pursuant to §§ 63.18 and 63.24 (international section 214 authorizations), § 1.767 (submarine cable landing licenses), and §§ 1.5000–50004 (petitions for a foreign ownership ruling).

Commission's rules, and (b) applicant or contact information changes after the application is no longer pending promptly and in any event within thirty (30) days; and (5) affirm their understanding that failure to fulfill any of the conditions of the grant of their applications can result in license revocation or termination and criminal and civil penalties.

52. For reasons discussed below, we require broadcast petitioners seeking a section 310(b) foreign ownership ruling to certify to only three of the certifications. The certifications concerning the provision of telecommunication services related to compliance with CALEA and making communications available within the United States do not apply to broadcast service. We, therefore, will not require broadcast petitioners to make these two certifications. In transactions involving both domestic and international section 214 authority, the certifications will be made only in the international section 214 application. Similarly, the certifications will only be required as part of the petition for a section 310(b) foreign ownership ruling and will not be required in any associated applications such as an application for a broadcast or common carrier wireless license.

53. We find that any burden that these certifications impose on applicants is minimal and outweighed by the public interest benefits of expediting the Committee's review of referred applications for national security and law enforcement concerns, assisting the Commission in its ongoing compliance efforts, and ensuring that the Commission and executive branch agencies have up-to-date and accurate information concerning the Commission's authorization holders and/or licensees.

1. Certifications Applicable to International Section 214 and Submarine Cable Applicants, With or Without Foreign Ownership, and Section 310(b) Petitioners (Other Than Broadcast Petitioners)

54. We require all international section 214 and submarine cable applicants (and applicants requesting to assign, transfer control, or modify such authorizations and licenses), with or without foreign ownership, as well as all non-broadcast section 310(b) petitioners, to make certain certifications as part of their applications to expedite executive branch review of those applications referred by the Commission.[27] As indicated by the executive branch, this requirement ''may obviate the need for any mitigation for a significant number of such applications, and thereby advance the shared goal of making the Executive Branch review process as expeditious and efficient as possible.'' The executive branch agencies recently reiterated support for the certification requirements, stating that ''[r]equiring all applicants to certify . . . at the time of the application is in the public interest, within the Commission's regulatory authority, and will help expedite a Committee review process that is often delayed, because it takes time for applicants to make the necessary arrangements for these routine requirements in mitigation agreements.''

55. Frequently, the filing of an executive branch recommendation to the Commission is extended by time spent by the agencies to negotiate assurances from applicants to comply with the existing law enforcement assistance requirements and draft individualized mitigation agreements. On balance, we find that the certifications will result in a more streamlined executive branch review process, with a two-fold benefit. First, many applicants who certify may potentially not have to enter negotiations that are part of routine mitigation. Second, executive branch resources that would have been allocated to routine mitigation can be re-directed to more complex applications, thereby expediting the overall review process. In general, we agree with the executive branch that the burden on an applicant will be minimal, and we find that any burden is outweighed by the benefits gained from eliminating the need to negotiate the same assurances on an applicant by applicant basis.

56. We disagree that the certifications are no longer necessary based on the Executive order not explicitly making reference to them. The executive branch agencies have explained how certifications would help to expedite the review process. We similarly disagree with commenters who argue that requiring applicants to certify to compliance with CALEA and other legal process requirements would be duplicative or might create legal confusion or uncertainty. The certifications will ensure applicants understand their obligations and the penalties at the time of filing the application, and that the Committee can more quickly evaluate national security and law enforcement issues with that assurance in hand. Further, all five certifications will assist both the Commission and the Committee in its ongoing statutory and regulatory duties and responsibilities under the Executive order.

57. We require international section 214 and submarine cable applicants to attest to the five certifications regardless of foreign ownership. We find that the public interest will be served by requiring these certifications and thus reject proposals to limit the certifications to only those applications with foreign ownership. The executive branch has expressed the need for the certifications to be required of all applicants, including applicants without reportable foreign ownership. The executive branch stated that the certifications should apply to applications even without foreign ownership when, for example, law enforcement agencies may need ''to request emergency assistance (*e.g.,* with respect to kidnappings, terrorist threats, or other exigent circumstances) from companies.'' In this regard, we disagree with CTIA that the executive branch agencies have not explained why such certifications would be beneficial. In addition to addressing the executive branch concerns, the certifications will assist the Commission in its ongoing responsibilities concerning its authorization holders and/or licensees, both those with and without reportable foreign ownership. With this certification requirement, the Commission is assured that applicants seeking a Commission authorization or license to provide service on U.S. critical infrastructure will comply with current law and understand that failure to do so may result in revocation and/or termination. The certification requirement also helps ensure that the applicant will keep its application current and up to date while it is under review by the Commission and the Committee. Overall, the certification requirement is reasonable and will result in a minimal burden on applicants. We find that it is appropriate and reasonable for the Commission to require applicants, with or without foreign ownership, to certify their ability and willingness to comply with the conditions and obligations set forth in the certifications.

a. CALEA Compliance

58. We require all covered applicants, except for broadcast petitioners for a section 310(b) foreign ownership ruling, to certify that they will comply with all applicable provisions of CALEA and

[27] Applications that fall within the categories of applications generally excluded from referral will be required to make the certifications.

related rules and regulations, including Commission orders and opinions governing the application of CALEA and assistance to law enforcement.[28] CALEA and the Commission's implementing rules require telecommunications carriers and manufacturers of telecommunications equipment to design their equipment, facilities, and services to ensure that they have the necessary surveillance capabilities to comply with legal requests for information. The rules are intended to preserve the ability of law enforcement agencies to conduct electronic surveillance while protecting the privacy of information outside the scope of an investigation.

59. We find that this certification will significantly expedite the processing of those applications with reportable foreign ownership referred to the executive branch agencies. The executive branch agencies often seek such assurance of compliance from applicants as routine mitigation measures, despite these applicants already being subject to CALEA and related rules and regulations. NTIA contends that the certification would help ensure that applicants consider and address these law enforcement needs prior to submitting their applications. We agree. Having applicants certify that they will comply with CALEA requirements will alert applicants to the need to address law enforcement needs prior to submitting their applications, thereby significantly reducing the need for the Committee to negotiate standard mitigation measures with each referred applicant on this issue. Moreover, this certification benefits the public interest by ensuring the applicant is fully aware of its CALEA obligations and the Commission's rules prior to submitting its application.

60. Requiring telecommunications applicants to make this certification imposes no significant burden as such applicants are already subject to CALEA obligations regardless of any certification. While some commenters contend that this certification is redundant and unnecessary, as telecommunications companies are already subject to CALEA, we find that requiring certification of compliance with this first condition would serve as an important reminder to applicants of their CALEA obligations at minimal to no expense. We direct the International Bureau to develop or revise any form(s) and/or instruction, as necessary.

b. Availability of Communications and Records

61. We require all covered applicants, except for broadcast petitioners for a section 310(b) foreign ownership ruling, to certify that they will make communications to, from, or within the United States, as well as records thereof, available in a form and location that permits them to be subject to lawful request or valid legal process under U.S. law. We find that this certification requirement will ensure that, to the extent any of an applicant's operations are based principally outside of the United States, such applicant would not be able to use that network configuration to avoid complying with legal requirements that would apply to a U.S.-based provider providing the same services. This certification would require that applicants make communications and records related to services covered by their license or authorization available in response to lawful U.S. request or legal process, regardless of whether communications are carried, or records are maintained, locally in the United States or elsewhere. We direct the International Bureau to develop or revise any form(s) and/or instruction, as necessary.

62. Several commenters express concerns that this certification would create a data localization requirement. We disagree. T-Mobile correctly observes that ''[t]he Executive Branch has made clear that U.S. policy favors the free flow of information, which is antithetical to forced localization.'' As to stored communications and records, the Clarifying Lawful Overseas Use of Data Act (CLOUD Act) requires U.S. service providers to comply with law enforcement orders issued under the Stored Communications Act regardless of whether a communication, record, or other information is located within or outside of the United States. And because the certification does not require a point of presence in the United States but only the ability to make communications and records available so that they may be subject to lawful request or valid legal process under U.S. law, we agree with NTIA that this certification would not force localization or repatriation of data.

63. Others suggest this certification could go beyond existing laws by reducing the ability of certain FCC-regulated companies to use lawful encryption or other security technologies in their networks and services. We again disagree. Under CALEA, ''[a] telecommunications carrier shall not be responsible for decrypting, or ensuring the government's ability to decrypt, any communication encrypted by a subscriber or customer, unless the encryption was provided by the carrier and the carrier possesses the information necessary to decrypt the communication.'' Our intent in adopting this certification is that, as to encryption and other security technologies, the certification requires no more other than what is already required under U.S. law.

c. Point of Contact

64. We require all covered applicants to designate a U.S. citizen or lawful permanent U.S. resident as (1) a point of contact for lawful requests and (2) an agent for legal service of process.[29] We find that, on balance, the public interest benefits of requiring the point of contact to be a U.S. citizen or a lawful permanent U.S. resident outweigh any additional burden that may be imposed on an applicant. Our CALEA rules already require telecommunications carriers to have a point of contact available seven days a week, 24 hours a day. For common carriers and both interconnected and non-interconnected VoIP providers, § 1.47(h) of the Commission's rules requires common carriers to designate a Washington, D.C. agent for service of process. Requiring applicants to designate a U.S. citizen or lawful permanent U.S. resident as the point of contact for service of process is not unreasonable and serves the public interest, given that the reason for contacting the person may concern national security or law enforcement issues. The executive branch maintains that such a requirement will help ''ensure that applicants have considered and addressed these national security and law enforcement needs prior to submitting license applications,'' which will in turn ensure that, for example, applicants are equipped to provide timely assistance in emergency situations. Finally, and similar to the first two certifications, this certification should minimize the need for routine mitigation and thus free up executive branch resources to focus on other pending applications. We adopt this certification and modify § 1.47 of the Commission's rules to ensure consistency of the rules applicable to U.S. international common carriers under §§ 1.47 and 63.18 of the Commission's rules with respect to the

[28] 47 U.S.C. 1001 *et seq.* By requiring applicants to certify that they will comply with all applicable provisions of CALEA and related rules and regulations, the Commission does not intend to expand the scope of telecommunications carriers subject to CALEA compliance as set forth in 47 U.S.C. 1001(8), including any Commission designations pursuant to 47 U.S.C. 1001(8)(B)(ii). *See* Letter from Kent Bressie, Counsel for the North American Submarine Cable Association, to Marlene H. Dortch, FCC (Sept. 24, 2020).

[29] The applicant may designate one person for both roles or a different person for each role.

identification of a D.C. agent who is a U.S. citizen or permanent legal resident.

65. We note that many submarine cable systems are licensed to consortiums of multiple licensees. In those situations, we require the consortium to identify one U.S. citizen or lawful permanent U.S. resident as a point of contact for lawful requests and an agent for legal service of process for each licensee of the consortium cable.[30] Though some commenters contend this certification is duplicative of other Commission rules or that it adds a new burden (*i.e.,* that the point of contact must be a U.S. citizen or permanent U.S. resident),[31] these commenters did not provide information on the scope or size of the burden. The executive branch acknowledges that ''existing authorities may not require . . . that applicants designate points of contact in the United States for execution of legal process,'' but notes that applicants have ''regularly agreed'' to this ''standard'' mitigation measure. We direct the International Bureau and the Media Bureau to develop or revise any form(s) and instructions, as necessary, to ensure that an applicant identifies a U.S. citizen or permanent U.S. resident as an agent for service of process.

d. Accuracy and Completeness

66. We require all covered applicants to certify that they will maintain the accuracy and completeness of all information while the application is pending, as required by § 1.65 of the Commission's rules. Thereafter, the authorization holders and licensees must update the Commission and the Committee as to any changes to the authorization holder(s) or the licensee's contact information. While the application is pending, the certification requires applicants to affirm that all information submitted to the Commission and the executive branch is complete and accurate, including applicant and contact information, and that the applicant agrees to inform the Commission and the Committee of any substantial and significant changes as required under § 1.65 of the Commission rules. After the application is no longer pending for purposes of § 1.65 of the rules, the certification requires authorization holders and licensees to notify the Commission and the Committee of any changes in contact information, promptly and in any event within thirty (30) days. We note that the fourth certification we adopt today varies slightly from what was proposed in the *Executive Branch NPRM* as the certification now specifies that an applicant is required to keep its authorization holder and licensee contact information current with the Commission and the Committee even after the application is no longer pending under § 1.65.

67. This certification will assist the Commission in its ongoing compliance efforts and will ensure that the Commission and executive branch agencies have the same updated accurate contact information concerning the Commission's authorization holders and/or licensees. Since 2015, the International Bureau has terminated 14 international section 214 authorizations because the carriers failed to respond to inquiries from both the executive branch and the Commission, and many times, telephone numbers were not accurate and emails and Commission letters were returned as undeliverable. The executive branch and the International Bureau attempted to contact these carriers but were unable to reach them and the International Bureau terminated their authorizations for failing to comply with the terms of the mitigation agreement entered into with the executive branch agencies, compliance with which was an express condition for holding the section 214 international authorization.

68. In response to the *Executive Branch NPRM,* a commenter questioned the feasibility of the certification with respect to future filings. Contrary to this concern, this certification is for the Commission and the Committee to be able to immediately contact Commission authorization holders and/or licensees given our statutory and regulatory duties and especially in light of the new shared responsibilities in the Executive order. Thus, we require our authorization holders and/or licensees to inform us of any contact information changes after the application is no longer pending for purposes of § 1.65 of the rules, promptly and in any event within thirty (30) days. This certification mostly affirms current obligations and, while we do place an additional burden, we adopt a reasonable time frame to notify the Commission and the executive branch.[32] This includes notifying the Commission, for example, of changes in the authorization holder or licensee's name, a change in the name of a submarine cable system or of a change in the counsel for the authorization holder or licensee. Because the Executive order establishes a coordinated formal process, this additional requirement ensures that both the Commission and the Committee have the same reliable contact information regarding Commission authorization holders and licensees. As with the other certifications, we find that this certification will benefit those applicants subject to executive branch review by reducing the time spent negotiating routine, but individualized mitigation agreements. We direct the International Bureau and Media Bureau to develop or revise any form(s) and/or instructions, as necessary.

e. Consequences

69. Finally, we adopt a certification requirement to provide assurance that the applicant is aware of potential consequences if it knowingly submits materially false, fictitious, or fraudulent information or otherwise fails to fulfill the conditions and obligations set forth in its certifications and the grant of its application, license, or authorization. The importance of this certification is clear as this certification links applicants' non-compliance with the other certifications to the possibility of a license or authorization being revoked or terminated. An applicant that makes willful false, fictitious, or fraudulent statements on Commission applications and/or petitions, fails to comply with the specific conditions of an authorization or license, or otherwise violates Commission rules or U.S. laws is already subject to potential revocation and fines. No commenter specifically addressed this certification.

70. We have revised the wording of this certification proposed in the *Executive Branch NPRM* to clarify that failure to comply with the other certifications as well as conditions on grant of the application may lead to the consequences set out in the certification. Although this certification

[30] Each licensee of a consortium cable may designate one person for both roles or a different person for each role.

[31] BT Americas assert that since carriers are already subject to legal requirements regarding CALEA compliance and the identification of a point of contact for legal process, there is no need to adopt duplicative certification requirements. BT Americas 2016 Comment at 15. BT Americas et al. state that both CALEA and the FCC's Form 499A carrier registration require carriers to identify a point of contact for legal process. BT Americas 2016 Comment at 15. CTIA states that the proposed certification, requiring applicants to designate a point of contact for the execution of lawful requests is already satisfied by existing statutory obligations, but seeks to impose new burdens on companies by requiring the point of contact to be a U.S. citizen or lawful permanent resident. CTIA 2016 Comment at 12; CTIA 2016 Reply at 7.

[32] The certification NTIA proposed in its May 2016 letter is as follows: ''Applicant certifies that all information submitted, whether at the time of submission of the application/petition or subsequently in response to either FCC or Executive Branch agency request, is accurate and complete to the best of Applicant's knowledge.'' The NTIA-proposed language lacks the trailing phrase ''*at the time of submission*'' set out in the proposed rules. NTIA Letter at 6, Attach. A.

may seem repetitive, we believe that it will both strengthen and clarify the need for compliance because it alerts an applicant that a failure to meet the legal requirements that applicant has knowingly affirmed through this certification would provide the Commission with a firm basis upon which to terminate the authorization or license, as needed. We direct the International Bureau and Media Bureau to develop or revise any form(s) and/or instructions, as necessary.

2. Certifications Applicable to Broadcast Section 310 Petitioners

71. The first two certifications set forth above concern the provision of telecommunications service and not broadcast service. Accordingly, broadcast petitioners seeking a section 310(b) foreign ownership ruling will only be required to certify to the certifications related to point of contact, accuracy and completeness, and consequences. As CBS Corporation, 21st Century Fox, Inc., Univision Communications, Inc., and the National Association of Broadcasters note, ''broadcasters do not own or control telecommunications networks, do not provide services to any sectors of critical U.S. infrastructure, do not have telecommunications intercept capabilities, and do not have compliance obligations under the Communications Assistance for Law Enforcement Act.'' The executive branch acknowledges that certain certifications, such as CALEA compliance, are inapplicable to broadcasters. We agree that the first two certifications concern the provision of telecommunications and are inapplicable to broadcast service. Therefore, we require a broadcast petitioner seeking a section 310(b) foreign ownership ruling to attest only to the certifications in sections c, d, and e above. We direct the Media Bureau, in coordination with the International Bureau, to develop or revise any form(s) and/or instruction, as necessary, to ensure that a petitioner for a foreign ownership ruling under section 310(b) for broadcast services is required to make only the certifications that apply to the services it provides.

E. Time Frames for Executive Branch Review

72. Consistent with the Executive order, we adopt a 120-day initial review period for applications with reportable foreign ownership that the Commission refers to the executive branch, with a possible 90-day extension for a secondary assessment in those instances where ''national security or law enforcement interests cannot be mitigated by standard mitigation measures.'' [33] Although the Commission proposed a 90-day time frame with the possibility of one 90-day extension in the *Executive Branch NPRM,* we find it is in the public interest to modify the time frames to ensure consistency with the process established by the Executive order. These modified Commission time frames apply to review of applications by the Committee for national security and law enforcement issues pursuant to the Executive order and review of applications for foreign policy and trade policy considerations, which is not expressly covered by the Executive order. Because the Executive order provides that the Chair of the Committee determines when the 120-day initial review period starts, we adopt rules to encourage the Committee to send the Tailored Questions to an applicant promptly. Doing so will ensure that the Committee receives the information it needs to start the review period as quickly as possible. Through these rules, most executive branch reviews should be completed within 127 days,[34] and the most complex cases within 238 days, according to the provisions of the Executive order.[35] The modified Commission time frames will benefit the Commission and applicants alike, by promoting transparency regarding an application's status and facilitating expectations for resolution of pending cases.[36] The establishment of Commission time frames may also be of use to the executive branch by providing a basis for prioritizing its work.

1. 120-Day and 90-Day Time Frames for Executive Branch Review

73. We adopt rules establishing a 120-day initial review period with a possible 90-day period for a secondary assessment, consistent with the Executive order. Commenters generally agree that the time frames are an improvement over the current informal process and will promote transparency and predictability of executive branch review. NTIA states that the procedures set forth in the Executive order ''will allow the Committee to complete a thorough review in a timely fashion of even the most complex applications.'' Although we expect the executive branch to notify the Commission of all decisions, as a safeguard, if the executive branch does not communicate to the Commission at the end of the 120-day initial review period or at the end of the 90-day secondary assessment, the Commission has discretion to take action on the application after assessing compliance with Commission rules and any issues raised by the application.[37] Finally, in order to maintain consistency of all executive branch reviews, we also require executive branch review of referred applications for foreign policy or trade policy concerns, discussed below, to follow the time frames established by the Executive order.

74. To account for any inconsistency between the time frames proposed in the *Executive Branch NPRM* and those set forth in the Executive order, we adopt new rules that track the process outlined in the Executive order. In this regard, we expect the executive branch agencies to complete their national security and law enforcement review of applications and file their recommendation (if any) within the initial 120-day time frame and secondary 90-day time frame established by the Executive order. We recognize that additional weeks of review could be necessary after the 90-day secondary assessment period ends if Committee Members and Committee Advisors are unable to reach consensus and the review escalates to the President.[38] We expect those cases to be rare. We also recognize that after the Committee renders its final

[33] Both the 120-day initial review period and the 90-day secondary assessment are subject to extension by the Committee. Executive order, Sec. 5.

[34] The Executive order sets out a 120-day initial review period, and it allows up to 7 additional days for NTIA to notify the Commission of the Committee's recommendation. Executive order, Sec. 9(h).

[35] In certain extraordinary situations the review may go past 238 days (120-day initial review + 90-day secondary assessment + 21-day Committee Advisor notification and review + 7-day for NTIA to notify the Commission). *See* Executive order, Sec. 9(e)–(g).

[36] *Executive Branch NPRM,* 31 FCC Rcd at 7470–71, para. 36. The Commission has adopted rules to facilitate expectations regarding the timing of the resolution of an application. For example, § 63.03(c)(2) of the Commission's rules states with regard to domestic section 214 transfer of control applications that ''except in extraordinary circumstances, final action on the application should be expected no later than 180 days from public notice that the application has been accepted for filing.'' 47 CFR 63.03(c)(2).

[37] Pursuant to the Executive order, NTIA has seven days to notify the Commission of the Committee's recommendation, so we may not hear from the executive branch until day 127 or day 238. Still as noted below, we will require that the executive branch provide status notifications every 30 days during secondary assessments.

[38] We also recognize that secondary assessments are warranted when the Committee finds that risks to national security or law enforcement cannot be mitigated by standard mitigation measures, and that should the Committee recommend use of non-standard mitigation or denial, the Committee Advisors have up to 21 days after the 90-day secondary assessment period ends to consider that recommendation. Executive order, Secs. 5(b)(i)(C), 9(f).

recommendation, NTIA has seven additional days by which to notify the Commission of that recommendation. Our time frames for executive branch review will accommodate these provisions of the Executive order.

75. We do not require expedited review for certain applications as suggested by some commenters. EQT, GlobeNet Cabos Submarinos Americas, Inc, Hawaiki Submarine Cabe USA, LLC, and Servicio di Telecomunicacion di Aruba (SETAR) N.V. argue that applicants from countries that are allies of the United States should be considered to have little to no national security risk. EQT proposes a system akin to the Visa Waiver Program where ''[t]he Commission, in consultation with the Executive Branch, should consider a similar approach that expedites review of foreign ownership from certain allied countries that pose no material threat to U.S. national security. . . .'' T-Mobile suggests that foreign ownership from countries on the CFIUS Excepted Foreign State List also presents low national security risks. We decline to deviate from the time frames established by the Executive order. We also note that executive branch review involves more than national security concerns. Although these countries would not necessarily pose a national security risk, it does not follow that the applicants themselves would not pose such a risk. To the extent that these applications do present lower risks, we expect that the executive branch would be able to complete its review during the 120-day initial review period.

76. We agree with the commenters that the Commission should be able to act on an application at the conclusion of the 120-day initial review period if the executive branch has not provided its final recommendation or advised the Commission that a secondary assessment is warranted, as this approach provides certainty and transparency to the application review process.

2. Referral of an Application to the Executive Branch and Start of the Committee's 120-Day Initial Review Period

77. We adopt the Commission's proposal in the *Executive Branch NPRM* to refer an application to the executive branch when the application is placed on an accepted for filing public notice, and to process the application on a non-streamlined basis given the likelihood that executive branch review will exceed the established time frames for streamlined processing.[39] Our determination of whether an application is acceptable for filing will include an assessment of whether the applicant has certified that it has submitted its responses to the Standard Questions to the Committee, the application complies with the Commission's rules, and the applicant has made the other required certifications. We also require the applicant to send a copy of its FCC application(s), including the file number(s), to the Committee within three business days of filing it. This ensures that the executive branch has timely access to the application and can promptly begin the review process, prior to our referral. The Commission's public notice of the application will note that the application has been referred to the executive branch for input on any national security, law enforcement, foreign policy, or trade policy concerns related to the foreign ownership in the applicant, and the public notice will serve as the referral.[40] If the executive branch wants the Commission to defer action on the application pending executive branch review of the application for any of these concerns, it must file a letter in the record of the proceeding by the comment date established in the public notice, and request that the Commission defer action pending the executive branch review. If the Commission does not receive a deferral request by the comment date, we will assume that the executive branch does not seek deferral of that application and the Commission will act on the application in its discretion after assessing compliance with Commission rules and any issues raised by the application. We expect the process of referring applications via public notice and requiring deferral requests to be filed in the relevant FCC record will improve the transparency of the executive branch review.

78. Under the Executive order, the Committee's 120-day review clock starts when the Chair determines that an applicant's responses are complete. To ensure that the 120-day initial review clock begins as quickly as possible, we adopt rules intended to shorten the time between our referral of an application and the date on which the Committee sends any Tailored Questions to the applicant. First, as we have explained, we will require an applicant to submit its responses to the Standard Questions directly to the Committee prior to or at the same time as it files its application with the Commission and to submit a copy of its application to the Committee within three business days of filing it.[41] The executive branch supports this and agrees that it should expedite the Committee review. Second, while it is our expectation that the Committee will send any Tailored Questions to the applicant within 30 days of the referral of the application, the Commission will start the 120-day review period on its own 30 days after the date of referral in the event the Committee does not send the Tailored Questions to the applicant by then. We believe that 30 days from the referral date is a reasonable amount of time for the Committee to prepare and send any Tailored Questions, particularly because it will have the applicant's responses to the Standard Questions even before the referral, so in practicality it will have more than 30 days. If, however, the Committee provides the Tailored Questions to the applicant within 30 days of referral, or within any extension granted by the Commission, we are not limiting by rule the time the Chair has to certify that the applicant responses are deemed complete. We believe that these requirements will expedite the commencement of the Committee's review and are not inconsistent with the Executive order.

79. If the Committee intends to review an application(s) for national security and law enforcement concerns during the comment period for the application(s), the Committee must electronically file in all applicable Commission file numbers and dockets associated with the application(s) a request that the Commission defer action until the Committee completes its review. In that deferral request, the Committee must notify the Commission that it: (1) Has already sent Tailored Questions to the applicant and state when the questionnaire was sent; (2)

[39] *Executive Branch NPRM,* 31 FCC Rcd at 7471–72, para. 37–38. If the application falls within one of the categories of applications excluded from referral, it may be eligible for streamlined processing. In the case of joint international and domestic section 214 transfer of control applications filed pursuant to § 63.04(b) of the Commission's rules, 47 CFR 63.04(b), the Wireline Competition Bureau will also accept the domestic portion of the application for non-streamlined filing. This will eliminate the need to remove an application from streamlined processing in response to a deferral request.

[40] Commission staff may send a courtesy copy of the public notice to the executive branch agencies, *e.g.,* Department of Defense, Department of Homeland Security, Department of Justice, State Department, USTR, NTIA, but the public notice itself is the official referral of the application.

[41] NTIA observed that the availability of the standardized questions on the Commission's website alone ''will in many cases expedite the Committee's review of referred applications.'' We believe that going a step further—requiring that applicants provide responses to the standardized questions directly to the Committee—will ensure expedited reviews.

will provide the Tailored Questions to the applicant by a specified date not to exceed 30 days from the Commission's referral; or (3) has determined that no Tailored Questions are needed. We note that the Committee will have the responses to the Standard Questions before the application is referred. If the Committee indicates that no Tailored Questions are necessary, the 120-day review clock will begin on the date of that notification. If the Committee intends to send Tailored Questions but does not send them within 30 days of referral, it may request additional time to send the questions. The Commission may, in its discretion, choose to allow the Committee additional time for development of the Tailored Questions or instead start its 120-day review clock.

80. Although our rule does not go as far as some commenters request, we believe it strikes a balance between the process that the Committee must follow under the Executive order and our goal of bringing clarity and predictability to coordination with the executive branch. Therefore, the Commission will have the discretion to start its 120-day initial review clock if the Tailored Questions are not provided to an applicant within 30 days of our referral (or within a specified extension period), and the Committee's initial review must be completed within that time frame.

3. Required Committee Notifications to the Commission on the Status of Its Review

81. We require the Committee to provide for each referred Commission application notice of the status of its review at various points in the review via electronic filings in all applicable Commission file numbers and dockets associated with the application(s). Specifically, we require the Committee, or NTIA as appropriate, to file in the record notifications that: (1) The Committee will be reviewing an application and requests that the Commission defer action on the application until the Committee completes its review; (2) the Committee has sent Tailored Questions to the applicant;[42] (3) the Committee recommends dismissal of the application without prejudice because the applicant has failed to respond to requests for information; (4) the Chair has determined that ''the applicant's responses to any questions and information requests from the Committee are complete,'' and the initial 120-day review has begun; (5) the 120-day initial review has been extended and for how long;[43] (6) the Committee has determined that it will conduct a secondary assessment and an explanation as to why that is warranted;[44] (7) the 90-day secondary assessment has been extended and for how long[45] and a status update of the secondary assessment, at 30-day intervals;[46] and (8) the Committee has arrived at a final recommendation.[47] We will provide public notice of the date of the Committee's acceptance of an applicant's responses as complete and the start of the 120-day initial review period, that the review period has been extended, that a secondary assessment will be required, and that a secondary assessment has been extended. These notices will allow the applicant and the Commission to track the progress of the Committee's review and thus will provide more transparency to the process.

82. Although certain of these notification requirements go beyond what is set out in the Executive order,[48] we believe that any extra burden placed on the Committee is minimal and outweighed by the benefits of the added transparency from these notifications. In the *Executive Branch NPRM,* the Commission proposed to require the executive branch to notify the Commission if it required additional time after the initial review period and to explain why the executive branch required the additional time. Commenters agree with this requirement, and we adopt it here. Because we expect secondary assessments to be rare, the requirement that the executive branch provide justification for the secondary assessment should not place a significant burden on the Committee. Similarly, the Commission proposed to require the executive branch to provide status updates during the additional 90-day review period. Commenters supported such a requirement. We also note than once a secondary assessment begins, the only other notification the Executive order requires the Committee to provide to the Commission is when the Committee has arrived at a final recommendation. We find it will be in the public interest to maintain transparency during the secondary assessment period or afterward if the review of the application is escalated to the Committee Advisors or the President.

4. Time Frames for Executive Branch Review of Foreign Policy and Trade Policy Issues

83. We refer applications to the executive branch for review of foreign policy and trade policy concerns as well as national security and law enforcement concerns. The Executive order addresses review of applications for national security and law enforcement issues. It does not expressly cover reviews based on foreign policy or trade policy concerns, although the Committee Advisors include foreign policy and trade policy agencies.[49] We find that there should be

[42] The notification that the Committee has sent Tailored Questions to the applicant could be included as part of its deferral request.

[43] The initial review period may be extended if the applicant has not been responsive to information requests. Executive order, Sec. 5(d). The filing of major amendments during the pendency of a referred application will not restart the 120-day review clock. Rather, we expect that the Committee will factor its review of an amendment, including the possibility of follow-up questions for the applicant(s), into its 120-day review (or 90-day secondary assessment, should an amendment be filed during the secondary assessment). The Committee could extend either the initial review or secondary assessment in the course of obtaining additional information from an applicant in connection with the amendment (*e.g.,* ownership information if the amendment pertains to a newly added applicant owner). Depending on the nature and timing of the amendment, the Commission may also consider Committee requests for prolonged extensions of either the initial review or secondary assessment. The Commission will continue to place major amendments on public notice, and applicants may be required to submit new responses to the Standard Questions to the Committee, and potentially to new Tailored Questions. We understand the Committee's need to have ample time to review major changes to an application, particularly if the amendment is filed near the end of a review period. *See* NTIA 2020 Supplemental Comments at 12–13.

[44] We recognize that the Committee's response may need to be filed on a confidential basis with the Commission.

[45] Executive order, Sec. 5(d). Although the Executive order allows extensions of the secondary assessment, it does not require the Chair to notify the Commission when they occur.

[46] These updates could extend beyond the Committee's 90-day review period if the escalated review provisions of the Executive order are triggered. *See* Executive order, Secs. 9(f)–(g). We do not expect the Committee to disclose internal deliberative decisions or steps as part of these status updates.

[47] The Executive order states that when initial review or secondary assessment results in a final recommendation, NTIA will notify the Commission of the Committee's recommendation within seven days of the Chair's notification to NTIA of that recommendation. Executive order, Sec. 9(h).

[48] The Executive order requires notification to the Commission when (1) the Chair has found that the applicant's responses are complete and that initial review has begun; (2) the 120-day initial review has been extended; (3) the Committee recommends dismissal of the application; (4) the Committee has determined that it will conduct a secondary assessment; and, (5) the Committee has arrived at a final recommendation. Executive order, Secs. 5(c), (d), 9(h).

[49] In the *April 2020 Proposed Record of Proceeding* (85 FR 29914, May 19, 2020), the International Bureau sought comment on the effect of the Executive order on the proposals in the *Executive Branch NPRM. See April 2020 Proposed Record of Proceeding.* No commenters addressed

Continued

consistent requirements for executive branch review of an application regardless of whether the review includes national security and law enforcement concerns or foreign policy or trade policy concerns, or some combination of these concerns. Consequently, we will require all executive branch reviews of referred Commission applications to follow the same time frames (*i.e.,* 120 days for initial review and 90 days for secondary assessment when warranted). In the absence of any national security or law enforcement concerns, we will apply to executive branch reviews of foreign and trade policy issues essentially the same process requirements as national security and law enforcement reviews. However, in cases where there are conflicting national security, law enforcement, foreign policy, and trade policy concerns, our objective remains that the executive branch agencies reach consensus on a recommendation. NTIA advises that the Executive order provides an opportunity to resolve such conflicts by escalating the matter to the President.

84. We will notify the executive branch agencies with foreign and trade policy expertise and the public of our referral of an application with reportable foreign ownership to the executive branch through our public notices.[50] Once an application is placed on public notice, an executive branch agency may file a request asking the Commission to defer action on an application while the particular agency reviews the application for foreign policy and trade policy concerns. The agency should file such a request via electronic filing in all applicable Commission file numbers and dockets associated with the application during the applicable comment period. Because the Executive order does not expressly cover foreign and trade policy reviews, a review based solely on foreign policy or trade policy concerns may not be subject to the Executive order's provision that the 120-day review begins when the Chair determines that the applicant's responses to any questions and information requests from the Committee are complete. Therefore, in such standalone instances, the 120-day review period will commence on the day the executive branch agency or agencies file a deferral request based solely on foreign policy or trade policy concerns. The agencies will need to notify us no later than the end of the 120-day time frame if they have determined that they will conduct a secondary assessment and the reason(s) why that is warranted. The agencies are subject to the same notification requirements we discuss above. If the executive branch does not communicate to the Commission by the end of the 120-day initial review period or by the end of the 90-day secondary assessment, the Commission may act on the application without waiting for further input from the executive branch.

5. Single Point of Contact at the Executive Branch

85. To ensure that applicants can communicate effectively with the executive branch, we adopt the Commission's proposal in the *Executive Branch NPRM* that the executive branch identify a single point of contact or a point agency for referral of applications and any inquiries the Commission and applicants have during the course of the executive branch review process. Commenters support the executive branch identifying a single point of contact for information to provide transparency during application review. Consistent with its responsibility under the NTIA Act, NTIA states that the Executive order designates ''the Attorney General as Chair of the Committee with the exclusive authority to act, and to designate other Committee members to act, on behalf of the Committee, including communicating with the Commission, applicants, and licensees.'' As such, the National Security Division, through its Foreign Investment Review Section (FIRS), will represent the Attorney General on the Committee, and will be the point of contact for the Commission and applicants. We direct the International Bureau to include the contact information for FIRS or any future point of contact on its website along with any other information concerning how applicants can best communicate with that point of contact concerning pending applications. As discussed in the previous section, there may be occasions when an application does not raise any law enforcement or national security concerns but does present foreign or trade policy concerns that other executive branch agencies, such as the Department of State or USTR, may want to review. In order to have a single contact available for these situations, we direct the International Bureau to include contact information for NTIA concerning these matters on our website.

F. Committee Review of Existing Licenses

86. Section 6 of the Executive order provides that the Committee may at any time ''review existing licenses to identify any additional or new risks to national security or law enforcement interests of the United States.'' The Executive order narrowly defines ''license'' as an ''authorization granted by the Federal Communications Commission (FCC) after referral of an application by the FCC. . . .'' Pursuant to the Executive order, Committee review of an authorization or license will result in one of the following actions: (1) A recommendation that the Commission modify an existing authorization or license to include new mitigation conditions; (2) a recommendation that the Commission revoke the authorization or license; or (3) a Committee decision to make no recommendation to the Commission with respect to the authorization. The Executive order does not contain a provision expressly requiring the Committee to notify the Commission when it decides to investigate an existing authorization or license, and if it ultimately decides to make no recommendation to the Commission after reviewing the existing authorization or license. Under the terms of the Executive order, the only notification the Commission would receive concerning an investigation of an existing license is when the Committee communicates its final recommendation regarding new mitigation conditions or revocation of the existing license.

87. The *Executive Branch NPRM* did not raise the question of executive branch review of existing licenses. As part of the *April 2020 Proposed Record of Proceeding,* the International Bureau entered the Executive order into the record of this proceeding and expressly asked for comment on its effect on the specific proposals and issues in this proceeding. Several of the *April 2020 Proposed Record of Proceeding* commenters express concern that the review of existing licenses and possibility of revocation without warning could inhibit foreign investment. Commenters assert that licensees must be afforded an opportunity to respond before a license is revoked or modified with new conditions. T-Mobile also asserts that the standard for imposing a new condition or revoking an existing license ''must be high and rigorous.'' Some commenters argue that the

whether, in the absence of any national security and law enforcement concerns, foreign and trade policy reviews should be treated the same as or differently than national security and law enforcement reviews in light of the Executive order.

[50] Commission staff may send a courtesy copy of the public notice to the executive branch agencies, *e.g.,* State Department, USTR, NTIA, but the public notice itself is the official referral of the application.

Committee should inform the Commission and the authorization holder when the Committee decides to start looking into a license (*i.e.,* after Committee members vote on whether to start a review), rather than at the end of the review. Windstream argues that because the *Executive Branch NPRM* did not address executive branch review of existing licenses, a further notice of proposed rulemaking or separate proceeding is needed to address it.

88. Consistent with current practice, the Commission will provide any affected authorization holder or licensee an opportunity to respond to the Committee's recommendation prior to any action by the Commission. This will address the commenters' concern that the Commission might proceed with modification or revocation of an existing authorization or license without warning or the opportunity to comment. We find that new rules or a separate proceeding are unnecessary to address Committee reviews of existing licenses [51] as the Commission already has procedural safeguards in place to protect licensees' due process rights, and that until such time as the Commission has more experience with such Committee recommendations, it is more appropriate to tailor such procedures to the facts and circumstances of a particular Committee recommendation.[52] If the Committee decides to review an existing license, one possible outcome of that review is that the Committee decides not to make a recommendation to the Commission. In that case, neither the Commission nor the licensee is disadvantaged by any lack of prior notice. If the outcome of the license review is a recommendation to revoke, then the Commission would provide the authorization holder such notice and an opportunity to respond as is required by due process and applicable law, and appropriate in light of the facts and circumstances, including any opportunity for the Committee to reply. The Commission would consider all arguments in acting on the Committee recommendation. If the outcome of a license review is that the Committee recommends that the Commission condition the authorization on new mitigation terms, then the Commission would not learn about the new terms until the Committee files a petition to modify the license. In a large number of cases, we expect that the licensee would have been involved with negotiating the new mitigation terms and conditions and would have been contacted by the Committee well before any petition is filed with the Commission. In the event that the proposed mitigation terms were not previously negotiated with the licensee, and the licensee learns about them for the first time when the Committee files its petition to modify the license, we would provide the licensee an opportunity to respond consistent with due process and other legal requirements. In such a situation, it is incumbent on the licensee to comment promptly and fully on the record so that the Commission can consider all arguments in issuing its decision in the matter. We would act on the petition only after consideration of the record, including any filings by the authorization holder.

G. Sharing of Business Confidential Information

89. As proposed in the *Executive Branch NPRM,* we also provide for the sharing of business confidential information with the relevant agencies in the context of reviews within the scope of the Executive order.[53] No party has opposed sharing of business confidential information. The Executive order provides a basis to share confidential information with the Committee by establishing that the members of the Committee have a legitimate need for such information. The policy of the Executive order is to ensure the ''[t]he security, integrity, and availability of the United States telecommunications networks [that] are vital to United States national security and law enforcement interests.'' With the adoption of these formal procedures, we will continue to work closely with the Committee to ensure the safety, reliability, and security of the nation's communications systems. Rather than modifying § 0.442 of the Commission's rules, however, we establish a new rule at § 1.40001. Because the current practice already involves submission of similar information in application materials for review by these agencies, and in light of their legitimate need for the information and the executive branch's important role in this process, we adopt § 1.40001 of the Commission's rules to make clear that sharing of business confidential information with executive branch agencies under these restrictions is permissible without the pre-notification procedures of that rule.

H. Monitoring Progress

90. Our goal in adopting these new rules and procedures is to increase the timeliness and transparency in the executive branch review of applications the Commission refers for expert executive branch agencies' feedback on any national security, law enforcement, foreign policy, and trade policy considerations that the Commission should consider as part of its overall public interest analysis. To ensure that these changes are having the intended effect, we task the International Bureau to report to the Commission on an annual basis regarding how implementation of the Executive order and the Commission's rules has impacted executive branch reviews of applications. We note that the Executive order requires the Committee to review and report on its implementation to the President on an annual basis, including any recommendations for policy, administrative, or legislative proposals. Based on the effectiveness of these efforts, the Commission may need to revisit the rules to ensure that applications are reviewed by the executive branch in a timely manner consistent with public interest considerations.

[51] We note that ''licenses'' in this context is limited to licenses where the Commission had referred the application to the executive branch agencies, including the Committee, both prior to and after the Executive order. *See* Executive order, Sec. 2(a).

[52] For example, on April 9, 2020, NTIA filed a recommendation on behalf of the executive branch agencies requesting that the Commission revoke and terminate China Telecom Americas' international section 214 authorizations. Executive Branch Recommendation to the Federal Communications Commission to Revoke and Terminate China Telecom Americas' International Section 214 Common Carrier Authorizations, File Nos. ITC–214–20010613–00346, ITC–214–20020716–00371, ITC–T/C–20070725–00285, at 1 (filed Apr. 9, 2020). On April 24, 2020, the International Bureau, Wireline Competition Bureau, and Enforcement Bureau together released Orders to Show Cause to four companies that are ultimately subject to the ownership and control of the Chinese government: China Telecom Americas, China Unicom Americas, Pacific Networks, and ComNet. The Orders directed each of the companies to explain why the Commission should not initiate the process of revoking its international and domestic section 214 authority and international signaling point codes. These matters remain pending. *See* China Telecom (Americas) Corporation, GN Docket 20–109, ITC–214–20010613–00346, ITC–214–20020716–00371, ITC–T/C–20070725–00285, Order to Show Cause, 36 FCC Rcd 3713 (IB/WCB/EB 2020); China Unicom (Americas) Operations Limited, GN Docket 20–110, ITC–214–20020728–00361, ITC–214–20020724–00427, Order to Show Cause, 35 FCC Rcd 3721 (IB/WCB/EB 2020); and Pacific Networks Corp. and ComNet (USA) LLC, GN Docket No. 20–111, ITC–214–20090105–00006, ITC–214–20090424–00199, Order to Show Cause, 35 FCC Rcd 3733 (IB/WCB/EB 2020).

[53] The *Executive Branch NPRM* proposed to amend § 0.442(c) to address business confidential filings under § 1.6001. *Executive Branch NPRM,* 31 FCC Rcd at 7480–85, Appendix B. The rule as adopted refers to part 1, subpart CC, review by executive branch agencies for national security, law enforcement, foreign policy, and trade policy concerns.

I. Other Changes to the Application Process

1. Voting Interests To Be Included in Applications

91. As proposed in the *Executive Branch NPRM,* we amend our rules to require that applicants for domestic section 214 transactions, international section 214 authorizations, and submarine cable licenses must identify the voting interests, in addition to the equity interests, of individuals or entities with 10% or greater direct or indirect ownership in the applicant.[54] Currently, an applicant is required to provide the name, address, citizenship, and principal businesses of any individual or entity that owns directly or indirectly at least 10% of the equity of the applicant. Applicants often have multiple classes of ownership and equity interests that differ from the voting interests. As the Commission noted in the *Executive Branch NPRM,* if an application does not provide information about the voting interests, either by providing separate equity and voting share information or noting that the voting interests track the equity interests, it is the practice of Commission staff to contact applicants and request the information. Having to request this information delays review of the application. We already require disclosure of both voting and equity interests in other contexts and in light of the current practice of Commission staff to contact applicants and request voting interest information, we view this rule as a codification of an existing process. TMT Financial Sponsors argues that calculation of multiple types of ownership through multiple layers in the ownership chain is ''very burdensome,'' and asserts that the rules should require disclosure of 10% or greater equity or voting interests, but not both, although they believe that voting interest is the better indicator of control. Although it may be more burdensome for applicants to provide both equity and voting ownership interests, we find that it is important for the Commission to have information on both equity and voting interests,[55] and that the minimal burden associated with including 10% or greater voting and equity interests in the application is outweighed by the benefit gained in preventing delays in review that are introduced when staff is required to seek supplemental information to understand the ownership structure. The requirement is also consistent with our overall goal to streamline and facilitate the efficiency of the review process of applications.

2. Ownership Diagram

92. We also amend the rules to require applicants to include in their applications a diagram of the applicant's ownership, showing the 10% or greater direct or indirect ownership interests in the applicant. As the Commission stated in the *Executive Branch NPRM,* inclusion of a diagram showing the 10% or greater interests in the applicant can also help speed the processing of an application.[56] Many applicants have complex ownership structures, particularly those with private equity ownership. Commission staff find that a diagram can help distill a lengthy description of an ownership structure and make it more easily understood. The Commission has found this especially helpful in the context of foreign ownership petitions and previously included such a requirement in the rules regarding the contents of a request for declaratory ruling under section 310(b) of the Act. While many applicants already provide ownership diagrams in their applications, Commission staff often request such a diagram from an applicant after the application has been filed. We received no comments objecting to the proposal to require ownership diagrams in applications. NTIA supports this rule change, as the executive branch already frequently seeks ownership diagrams from applicants in the course of its review. Requiring the application to include the diagram will impose a minimal burden on applicants, which will be offset by the Commission staff's ability to process applications more expeditiously and ensure that all potential commenters addressing an application have clear information.

3. Cable Landing Licensing Rules

93. Finally, we amend the cable landing license rules to impose reporting requirements on licensees affiliated with a carrier with market power in a cable's destination market for all countries regardless of whether the country is a WTO Member. In 2014, the Commission eliminated the effective competitive opportunities test that applies to international section 214 applications and cable landing license applications filed by foreign carriers or their affiliates that have market power in countries that are not members of the WTO. The test was ''a set of criteria first adopted in the *1995 Foreign Carrier Entry Order,* 60 FR 67332 (1995), as a condition of entry into the U.S. international telecommunications services market by foreign carriers that possess market power on the foreign end of a U.S.-international route on which they seek to provide service pursuant to section 214. . . .'' [57] The test applied only to foreign carriers that have market power in a non-WTO Member country and required such carriers or certain of their affiliates to demonstrate in their applications that there are no legal or practical restrictions on U.S. carriers' entry into the foreign carrier's market.

94. When the Commission eliminated the competitive opportunities test, it failed to amend the reporting requirement for licensees affiliated with a carrier with market power in a cable's destination market to remove the limitation that such reporting requirement applies only to destination markets in WTO Member countries. The Commission proposed to remove that limitation in the *Executive Branch NPRM* and apply the reporting requirements to licensees affiliated with a carrier with market power in a cable's destination market for all countries, whether or not they are a WTO Member. We received no comments on the proposal to remove this limitation, and adopt the rule change as proposed.

Final Regulatory Flexibility Analysis

95. As required by the Regulatory Flexibility Act (RFA), the Commission has prepared this Final Regulatory Flexibility Analysis (FRFA) of the possible significant economic impact on small entities by the policies and rules adopted in this Report and Order (Order). The Commission will send a copy of the Order, including this FRFA, to the Chief Counsel for Advocacy of the Small Business Administration. In addition, the Order and FRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Report and Order

96. This Report and Order adopts rules and procedures regarding coordination with the executive branch agencies for the review of certain applications and petitions for declaratory rulings filed with the Commission with foreign ownership, for

[54] *Executive Branch NPRM,* 31 FCC Rcd at 7475, para. 48. We also add language to § 63.18(h)(1) to assist applicants in calculating indirect equity and voting interests, consistent with § 1.5002.

[55] For example, Commission staff review of transfer of control applications cannot be completed without having voting interest information, which is necessary to assess who currently has the ''control'' that is being transferred and to whom such control is being transferred.

[56] Consequently, we amend §§ 1.767(a)(8), 63.04(a)(4), and 63.18(h) to require the provision of an ownership diagram.

[57] 79 FR 31874, June 3, 2014.

national security, law enforcement, foreign policy, and trade policy issues. The Commission's objective is to improve the timelines and transparency of the executive branch review process as Industry has expressed concern about the uncertainty and lengthy review times that make it difficult for parties to put a business plan in place and move forward on it.

97. For over 20 years, the Commission has been referring certain applications and petitions with foreign ownership to the executive branch agencies for review through an informal procedure. This process, often referred to as the ''Team Telecom'' process, has led to delays in Commission action on applications as the Commission waits for the executive branch agencies to complete their review. Consequently, new services have been delayed and parties have had to wait, over a year in many instances, to complete transactions.

98. These rules adopted in the Report and Order will not only formalize the review process, but also improve the timeliness and transparency of the executive branch review by establishing time frames consistent with the process and time frames set forth in the President's Executive Order 13913, Establishing the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector.

99. The rules that the Commission adopts, as summarized below, will expedite the executive branch review process and provide for a more transparent review.

• *Types of Applications Referred to the Executive Branch.* The Commission will refer: (1) Applications for an international section 214 authorization or to assign or transfer control of an international section 214 authorization with reportable foreign ownership; (2) applications for a submarine cable landing license or to assign or transfer control of a submarine cable landing license with reportable foreign ownership; and (3) petitions seeking a foreign ownership ruling under section 310(b) of the Communications Act of 1934, as amended (the ''Act'') for broadcast, common carrier wireless, or common carrier earth station applicants and licensees; [58]

• When such applications are part of a larger transaction, the Commission will also refer all associated applications involved in the transaction;

• The Commission will no longer refer standalone domestic section 214 authorizations, and nor will it refer applications for broadcast or common carrier wireless or satellite earth station licenses unless the applicant is required to seek a section 310(b) foreign ownership ruling;

• Within the types of applications referred, the Commission will exclude the following categories of applications from referral to the executive branch: (1) *Pro forma* notifications; (2) applications for international section 214 authorizations and submarine cable landing licenses, and petitions for section 310(b) foreign ownership rulings where the only reportable foreign ownership is held through wholly owned intermediate holding companies and the ultimate ownership and control is held by U.S. citizens or entities; (3) international section 214 applications where the applicant has an existing mitigation agreement with the executive branch, the applicant certifies that it will continue to comply with the mitigation agreement, and there has been no change in foreign ownership since the effective date of the mitigation agreement; and (4) international section 214 applications where the executive branch has cleared the applicant in the past 18 months without requiring a mitigation agreement, and there has been no change in foreign ownership since the executive branch cleared;

• *All Applicants Required to Submit Certifications.* All applicants for international section 214 authority, submarine cable licenses, and section 310(b) foreign ownership declaratory rulings are required to certify that they: (1) Will comply with the Communications Assistance for Law Enforcement Act (CALEA); (2) will make certain communications and records available and subject to lawful request or valid legal process under U.S. law; (3) will designate a point of contact in the United States who is a U.S. citizen or lawful permanent resident; (4) will keep all submitted information accurate and complete during application process and after the application is no longer pending for purposes of § 1.65 of the rules, the authorization holder and/or license must notify the Commission and Committee of any contact information change within thirty (30) days; and (5) understand that failing to fulfill any condition of the grant or providing materially false information could result in revocation or termination of their authorization and other penalties. Broadcast licensee petitions for a section 310(b) declaratory ruling are excluded from the first two certification requirements;

• *Applicants Required to File Responses to Standard Questions.* Applicants with reportable foreign ownership when applying for international section 214 authority, submarine cable licenses, and section 310(b) foreign ownership declaratory rulings, are required to file with the Committee—prior to or at the same time they file their application with the Commission—responses to a standardized set of national security and law enforcement questions (Standard Questions) regarding: (1) Corporate structure and shareholder information; (2) relationships with foreign entities; (3) financial condition and circumstances; (4) compliance with applicable laws and regulations; and (5) business and operational information, including services to be provided and network infrastructure;

• *Committee Required to Send Tailored Questions Within 30 days.* The Committee is required to send any specifically tailored national security and law enforcement questions (Tailored Questions), the complete response to which will commence the Committee's 120-day initial review period, to an applicant within thirty (30) days of Commission referral of an application;

• The Commission has discretion to start the Committee's initial review 120-day time frame if the Committee has not issued Tailored Questions by the end of the 30-day window;

• *Initial Review—120-Day Time Frame.* Commencement of the initial 120-day review time frame begins when the Committee Chair notifies the Commission that it has determined that the responses to the national security and law enforcement questions are complete, or, at Commission discretion, when the Committee fails to provide Tailored Questions to the applicant within thirty (30) days of Commission referral;

• The Commission will have discretion to act on any application if, after 127 days (the initial review period plus seven (7) days for the NTIA to notify the Commission), the Committee has not provided a final recommendation, notification of an extension granted to applicants, or written justification for a secondary assessment;

• *Secondary Assessment—Additional 90-Day Time Frame.* Commencement of the secondary assessment, an additional review period of up to 90 days, begins

[58] Applicants must report any foreign individual or entity that directly or indirectly owns at least 10% of the equity in the applicant. 47 CFR 1.767(a)(8), 63.18(h), 63.24(e)(2). Broadcast, common carrier wireless and common carrier satellite earth station licensees must seek Commission prior approval for aggregate foreign ownership that exceeds the statutory benchmarks in sections 310(b)(3) and (4), as applicable. 47 U.S.C. 310(b)(3), (4).

when the Committee Chair notifies the Commission that it seeks secondary review of the application because it poses a risk to the national security or law enforcement interests of the United States that cannot be mitigated through standard mitigation measures; and

• *Other Rule Changes.* To assist the Commission in its timely review of applications, an applicant is required to include in its application the voting interests, in addition to the equity interests, and a diagram of individuals or entities with 10% or greater direct or indirect ownership or controlling interests at any level of ownership.

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

100. There were no comments filed that specifically addressed the rules and policies in the IRFA. Nonetheless, in adopting the rules and procedures reflected in the Report and Order, the Commission has considered the potential impact of the rules and procedures proposed in the IRFA on small entities in order to reduce the economic impact of the rules and procedures enacted herein on such entities.

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

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

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

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

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

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

105. *Competitive Local Exchange Carriers (CLECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate NAICS Code category is Wired Telecommunications Carriers, as defined in paragraph 104 of this FRFA. Under that size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Based on this data, the Commission concludes that the majority of CLECs, CAPs, shared-tenant service providers, and other local service providers are small entities. According to the Commission's Industry Analysis Division of the Wireline Competition Bureau data, 1,442 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services. Of these 1,442 carriers, an estimate of 1,256 carriers have 1,500 or fewer employees. In addition, 17 carriers have reported that they are shared-tenant service providers, and all 17 are estimated to have 1,500 or fewer employees. The data also show that 72 carriers have reported as other local service providers. Of this total, 70 have 1,500 or fewer employees. Consequently, the Commission estimates that most providers of competitive local exchange services, competitive access providers, shared-tenant service providers, and other local service providers are small entities that will be affected by the rules and procedures adopted pursuant to the *Order.*

106. *Interchange* Carriers *(IXCs).* Neither the Commission nor the SBA has developed a small business size standard specifically for Interexchange Carriers. The closest applicable NAICS Code category is Wired Telecommunications Carriers. The applicable size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. According to Commission's Industry analysis Division of the Wireline Competition Bureau data, 359 companies reported that their primary telecommunications services activity was the provision of interexchange services. Of this total, an estimate of 317 companies have 1,500 or fewer employees, whereas 42 companies have more than 1,500 employees. Consequently, the Commission estimates that the majority of interexchange service providers are small entities that may be affected by the rules and procedures adopted pursuant to the *Order.*

107. *Prepaid Calling Card Providers.* Neither the Commission nor the SBA has developed a small business definition specifically for prepaid calling card providers. The most appropriate NAICS code-based category for defining prepaid calling card providers is Telecommunications Resellers. This industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual networks operators (MVNOs) are included in this industry. Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 show that 1,341 firms provided resale services

during that year. Of that number, 1,341 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these prepaid calling card providers can be considered small entities. According to the Commission's Form 499 Filer Database, 500 companies reported that they were engaged in the provision of prepaid calling cards. The Commission does not have data regarding how many of these 500 companies have 1,500 or fewer employees. The Commission estimates that there are 500 or fewer prepaid calling card providers that may be affected by these rules.

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

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

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

111. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves, such as cellular services, paging services, wireless internet access, and wireless video services. The appropriate size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. For this industry, Census Data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms had fewer than 1,000 employees. Thus, under this category and the associated size standard, the Commission estimates that the majority of wireless telecommunications carriers (except satellite) are small entities. The Commission's own data—available in its Universal Licensing System—indicate that, as of August 31, 2018 there are 265 Cellular licensees that will be affected by our actions. The Commission does not know how many of these licensees are small, as the Commission does not collect that information for these types of entities. Similarly, according to internally developed Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service (PCS), and Specialized Mobile Radio (SMR) Telephony services. Of this total, an estimated 261 have 1,500 or fewer employees, and 152 have more than 1,500 employees. Thus, using available data, we estimate that the majority of wireless firms can be considered small.

112. *All Other Telecommunications.* ''All Other Telecommunications'' is defined as follows: This U.S. industry comprises establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing Internet services or Voice over Internet protocol (VoIP) services via client-supplied telecommunications connections are also included in this industry. The SBA has developed a small business size standard for ''All Other Telecommunications,'' which consists of all such firms with gross annual receipts of $35 million or less. For this category, census data for 2012 shows that there were 1,442 firms that operated for the entire year. Of this total, 1,400 had annual receipts below $25 million per year. Consequently, we estimate that the majority of ''All Other Telecommunications'' firms are small entities.

113. *Satellite Telecommunications.* This category comprises firms ''primarily engaged in providing telecommunications services to other establishments in the

telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.'' Satellite telecommunications service providers include satellite and earth station operators. The category has a small business size standard of $35 million or less in average annual receipts, under SBA rules. For this category, U.S. Census Bureau data for 2012 show that there was a total of 333 firms that operated for the entire year. Of this total, 299 firms had annual receipts of less than $25 million. Consequently, we estimate that the majority of satellite telecommunications providers are small entities.

114. *Radio Stations.* This Economic Census category ''comprises establishments primarily engaged in broadcasting aural programs by radio to the public. Programming may originate in their own studio, from an affiliated network, or from external sources.'' The SBA has established a small business size standard for this category as firms having $41.5 million or less in annual receipts. U.S. Census Bureau data for 2012 show that 2,849 radio station firms operated during that year. Of that number, 2,806 firms operated with annual receipts of less than $25 million per year and 17 with annual receipts between $25 million and $49,999,999 million. Therefore, based on the SBA's size standard the majority of such entities are small entities.

115. According to Commission staff review of the BIA/Kelsey, LLC's Media Access Pro Radio Database as of January 2018, about 11,261 (or about 99.9 percent) of 11,383 commercial radio stations had revenues of $38.5 million or less and thus qualify as small entities under the SBA definition. The Commission has estimated the number of licensed commercial AM radio stations to be 4,580 stations and the number of commercial FM radio stations to be 6,726, for a total number of 11,306. We note the Commission has also estimated the number of licensed noncommercial (NCE) FM radio stations to be 4,172. Nevertheless, the Commission does not compile and otherwise does not have access to information on the revenue of NCE stations that would permit it to determine how many such stations would qualify as small entities.

116. We also note, that in assessing whether a business entity qualifies as small under the above definition, business control affiliations must be included.[59] The Commission's estimate therefore likely overstates the number of small entities that might be affected by its action, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. In addition, to be determined a ''small business,'' an entity may not be dominant in its field of operation. We further note, that it is difficult at times to assess these criteria in the context of media entities, and the estimate of small businesses to which these rules may apply does not exclude any radio station from the definition of a small business on these basis, thus our estimate of small businesses may therefore be over-inclusive. Also, as noted above, an additional element of the definition of ''small business'' is that the entity must be independently owned and operated. The Commission notes that it is difficult at times to assess these criteria in the context of media entities and the estimates of small businesses to which they apply may be over-inclusive to this extent.

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

117. The Report and Order adopts a number of rule changes that would affect reporting, recordkeeping, and other compliance requirements for applicants who file international section 214 authorizations, submarine cable landing licenses or applications to assign or transfer control of such authorizations, and section 310(b) petitions for declaratory ruling (common carrier wireless, common carrier satellite earth stations, or broadcast). Applicants with reportable foreign ownership will be required to submit responses to standard national security and law enforcement questions and will need to certify in their applications that they have made that submission and will send a copy of the FCC application to the Committee. All applicants for international section 214 authority and submarine cable licenses, regardless of whether they have reportable foreign ownership will be required to certify that they: (1) Will comply with the Communications Assistance for Law Enforcement Act (CALEA); (2) will make certain communications and records available and subject to lawful request or valid legal process under U.S. law; (3) will designate a point of contact in the United States who is a U.S. citizen or lawful permanent resident; (4) will keep all submitted information accurate and complete during application process and after the application is no longer pending for purposes of section 1.65 of the rules, the authorization holder and/or licensee must inform the Commission and the Committee of any contact name changes; and (5) understand that failing to fulfill any condition of the grant or providing materially false information could result in revocation or termination of their authorization and other penalties. Petitioners for broadcast licensee petitions for a section 310(b) declaratory ruling for broadcast licenses will make the last three certifications but will not need to make the first two certifications.

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

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

119. In this Report and Order, the adopted changes for executive branch's review of FCC applications involving foreign ownership will help improve the timeliness and transparency of the review process, thus lessening the burden of the licensing process on all applicants, including small entities. The adopted certification requirements may help reduce the need for routine mitigation, which should facilitate a faster response by the executive branch on its review and advance the shared goal of the Commission and industry, including small entities, including to make the executive branch review process as efficient as possible. Time frames for review of FCC applications referred to the executive branch have also been adopted, which will help prevent unnecessary delays and make the process more efficient and transparent, which ultimately benefits all applicants, including small entities.

120. The Commission declined to adopt a proposal from commenters to exclude from referral applications that

[59] ''[Business concerns] are affiliates of each other when one concern controls or has the power to control the other, or a third party or parties controls or has power to control both.'' 13 CFR 121.103(a)(1).

involve resellers with no facilities, which are often small businesses. Although the commenters support such an exclusion, the executive branch asserts that applications from non-facilities-based resellers ''require review by the Executive Branch, because the companies possess records that may be requested in the course of national security or criminal investigations.'' The Commission agreed with the executive branch that resellers without facilities could potentially raise national security or law enforcement issues because their records, for example, might assist the executive branch discover instances of money laundering or other activities with national security and law enforcement implications.

G. Report to Congress

The Commission will send a copy of the *Order,* including this FRFA, in a report to be sent to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996. In addition, the Commission will send a copy of the *Order,* including the FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the *Order* and the FRFA (or summaries thereof) will also be published in the **Federal Register**.

Ordering Clauses

121. *It is ordered* that, pursuant to sections 4(i), 4(j), 214, 303, 309, 310 and 413 of the Communications Act as amended, 47 U.S.C. 154(i), 154(j), 214, 303, 309, 310 and 413, and the Cable Landing License Act of 1921, 47 U.S.C. 34–39, and Executive Order 10530, Section 5(a) reprinted as amended in 3 U.S.C. 301, this Report and Order *is adopted.*

122. *It is further ordered* that parts 0, 1, and 63 of the Commission's rules *are amended* as set forth in the Final Rules.

123. *It is further ordered* that as discussed herein, pursuant to 47 U.S.C. 155(c) and 47 CFR 0.261, the Chief of the International Bureau *is directed* to administer and make available on a public website, a standardized set of national security and law enforcement questions for the Categories of Information set forth in part 1, subpart CC, of the Commission's rules.

124. *It is further ordered* that this Report and Order *shall become effective* 30 days after publication in the **Federal Register**, except those provisions that contain new or modified information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act *will become effective* after the Commission publishes a document in the **Federal Register** announcing such approval and the relevant effective date.

125. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

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

List of Subjects in 47 CFR Parts 0, 1, and 63

Authority delegations, Communications, Communications common carriers, Organization and functions, Telecommunications.

Federal Communications Commission.

Marlene Dortch,

Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends title 47 of the CFR, parts 0, 1, and 63, as follows:

PART 0—COMMISSION ORGANIZATION

■ 1. The authority citation for part 0 continues to read as follows:

Authority: 47 U.S.C. 151, 154(i), 154(j), 155, 225, and 409, unless otherwise noted.

■ 2. Effective December 28, 2020, amend § 0.261 by adding paragraph (a)(16) to read as follows:

§ 0.261 Authority delegated.

(a) * * *

(16) To administer and make available on a public website, a standardized set of national security and law enforcement questions for the categories of information set forth in part 1, subpart CC, of this chapter.

* * * * *

PART 1—PRACTICE AND PROCEDURE

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

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

■ 4. Effective December 28, 2020, amend § 1.47 by revising paragraph (h) to read as follows:

§ 1.47 Service of documents and proof of service.

* * * * *

(h) Every common carrier and interconnected VoIP provider, as defined in § 54.5 of this chapter, and non-interconnected VoIP provider, as defined in § 64.601(a)(15) of this chapter and with interstate end-user revenues that are subject to contribution to the Telecommunications Relay Service Fund, that is subject to the Communications Act of 1934, as amended, shall designate an agent in the District of Columbia, and may designate additional agents if it so chooses, upon whom service of all notices, process, orders, decisions, and requirements of the Commission may be made for and on behalf of such carrier, interconnected VoIP provider, or non-interconnected VoIP provider in any proceeding before the Commission. Every international section 214 authorization holder must also designate an agent in the District of Columbia who is a U.S. citizen or lawful U.S. permanent resident pursuant to § 63.18(q)(1)(iii) of this chapter. Such designation shall include, for the carrier, interconnected VoIP provider, or non-interconnected VoIP provider and its designated agents, a name, business address, telephone or voicemail number, facsimile number, and, if available, internet email address. Such carrier, interconnected VoIP provider, or non-interconnected VoIP provider shall additionally list any other names by which it is known or under which it does business, and, if the carrier, interconnected VoIP provider, or non-interconnected VoIP provider is an affiliated company, the parent, holding, or management company. Within thirty (30) days of the commencement of provision of service, such carrier, interconnected VoIP provider, or non-interconnected VoIP provider shall file such information with the Chief of the Enforcement Bureau's Market Disputes Resolution Division. Such carriers, interconnected VoIP providers, and non-interconnected VoIP providers may file a hard copy of the relevant portion of the Telecommunications Reporting Worksheet, as delineated by the Commission in the **Federal Register,** to satisfy the requirement in the preceding sentence. Each Telecommunications Reporting Worksheet filed annually by a common carrier, interconnected VoIP provider, or non-interconnected VoIP provider must contain a name, business address, telephone or voicemail number, facsimile number, and, if available, internet email address for its designated agents, regardless of whether such information has been revised since

the previous filing. Carriers, interconnected VoIP providers, and non-interconnected VoIP providers must notify the Commission within one week of any changes in their designation information by filing revised portions of the Telecommunications Reporting Worksheet with the Chief of the Enforcement Bureau's Market Disputes Resolution Division. A paper copy of this designation list shall be maintained in the Office of the Secretary of the Commission. Service of any notice, process, orders, decisions or requirements of the Commission may be made upon such carrier, interconnected VoIP provider, or non-interconnected VoIP provider by leaving a copy thereof with such designated agent at his office or usual place of residence. If such carrier, interconnected VoIP provider, or non-interconnected VoIP provider fails to designate such an agent, service of any notice or other process in any proceeding before the Commission, or of any order, decision, or requirement of the Commission, may be made by posting such notice, process, order, requirement, or decision in the Office of the Secretary of the Commission.

■ 5. Delayed indefinitely, amend § 1.767 by revising paragraphs (a)(8)(i), (a)(11)(i), and (j), adding paragraph (k)(5), and revising the introductory text of paragraph (l) to read as follows:

§ 1.767 Cable landing licenses.

(a) * * * *

(8) * * *

(i) The place of organization and the information and certifications required in § 63.18(h), (o), (p), and (q) of this chapter.

* * * * *

(11)(i) If applying for authority to assign or transfer control of an interest in a cable system, the applicant shall complete paragraphs (a)(1) through (3) of this section for both the transferor/assignor and the transferee/assignee. Only the transferee/assignee needs to complete paragraphs (a)(8) and (9) of this section. The applicant shall include both the pre-transaction and post-transaction ownership diagram of the licensee as required under paragraph (a)(8)(i) of this section. The applicant shall also include a narrative describing the means by which the transfer or assignment will take place. The applicant shall also specify, on a segment specific basis, the percentage of voting and ownership interests being transferred or assigned in the cable system, including in a U.S. cable landing station. The Commission reserves the right to request additional information concerning the transaction to aid it in making its public interest determination.

* * * * *

(j) *Submission of application to executive branch agencies.* On the date of filing with the Commission, the applicant shall also send a complete copy of the application, or any major amendments or other material filings regarding the application, to: U.S. Coordinator, EB/CIP, U.S. Department of State, 2201 C Street NW, Washington, DC 20520–5818; Office of Chief Counsel/NTIA, U.S. Department of Commerce, 14th St. and Constitution Ave. NW, Washington, DC 20230; and Defense Information Systems Agency, ATTN: GC/DO1, 6910 Cooper Avenue, Fort Meade, MD 20755–7088, and shall certify such service on a service list attached to the application or other filing.

(k) * * *

(5) Certifying that all ten percent or greater direct or indirect equity and/or voting interests, or a controlling interest, in the applicant are U.S. citizens or entities organized in the United States.

(l) *Reporting requirements applicable to licensees affiliated with a carrier with market power in a cable's destination market.* Any licensee that is, or is affiliated with, a carrier with market power in any of the cable's destination countries must comply with the following requirements:

* * * * *

■ 6. Delayed indefinitely, amend § 1.5001 by adding paragraphs (m) and (n) to read as follows:

§ 1.5001 Contents of petitions for declaratory ruling under section 310(b) of the Communications Act of 1934, as amended.

* * * * *

(m) *Submission of petition and responses to standard questions to the Committee for the assessment of foreign participation in the United States telecommunications services sector.* For each petition subject to a referral to the executive branch pursuant to § 1.40001, the petitioner must submit:

(1) Responses to standard questions, prior to or at the same time the petitioner files its petition with the Commission, pursuant to subpart CC of this part, directly to the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee). The standard questions and instructions for submitting the responses are available on the FCC website. The required information shall be submitted separately from the petition and shall be submitted directly to the Committee.

(2) A complete and unredacted copy of its FCC petition(s), including the file number(s) and docket number(s), to the Committee within three (3) business days of filing it with the Commission. The instructions for submitting a copy of the FCC petition(s) to the Committee are available on the FCC website.

(n) *Certifications.* (1) Broadcast applicants and licensees shall make the following certifications by which they agree:

(i) To designate a point of contact who is located in the United States and is a U.S. citizen or lawful U.S. permanent resident, for the execution of lawful requests and as an agent for legal service of process;

(ii)(A) That the petitioner is responsible for the continuing accuracy and completeness of all information submitted, whether at the time of submission of the petition or subsequently in response to either the Commission or the Committee's request, as required in § 1.65(a), and that the petitioner agrees to inform the Commission and the Committee of any substantial and significant changes while a petition is pending; and

(B) After the petition is no longer pending for purposes of § 1.65, the petitioner must notify the Commission and the Committee of any changes in petitioner information and/or contact information promptly, and in any event within thirty (30) days; and

(iii) That the petitioner understands that if the petitioner or an applicant or licensee covered by the declaratory ruling fails to fulfill any of the conditions and obligations in the certifications set out in paragraph (n)(1) of this section or in the grant of an application, petition, license, or authorization associated with the declaratory ruling and/or that if the information provided to the United States Government is materially false, fictitious, or fraudulent, the petitioner, applicants, and licensees may be subject to all remedies available to the United States Government, including but not limited to revocation and/or termination of the Commission's declaratory ruling, authorization or license, and criminal and civil penalties, including penalties under 18 U.S.C. 1001.

(2) Common carrier applicants, licensees, or spectrum lessees shall make the following certifications by which they agree:

(i) To comply with all applicable Communications Assistance for Law Enforcement Act (CALEA) requirements and related rules and regulations, including any and all FCC orders and

opinions governing the application of CALEA, pursuant to the Communications Assistance for Law Enforcement Act and the Commission's rules and regulations in subpart Z of this part;

(ii) To make communications to, from, or within the United States, as well as records thereof, available in a form and location that permits them to be subject to a valid and lawful request or legal process in accordance with U.S. law, including but not limited to:

(A) The Wiretap Act, 18 U.S.C. 2510 *et seq.;*

(B) The Stored Communications Act, 18 U.S.C. 2701 *et seq.;*

(C) The Pen Register and Trap and Trace Statute, 18 U.S.C. 3121 *et seq.;* and

(D) Other court orders, subpoenas, or other legal process;

(iii) To designate a point of contact who is located in the United States and is a U.S. citizen or lawful U.S. permanent resident, for the execution of lawful requests and as an agent for legal service of process;

(iv)(A) That the petitioner is responsible for the continuing accuracy and completeness of all information submitted, whether at the time of submission of the petition or subsequently in response to either the Commission or the Committee's request, as required in § 1.65(a), and that the petitioner agrees to inform the Commission and the Committee of any substantial and significant changes while a petition is pending; and

(B) After the petition is no longer pending for purposes of § 1.65 of the rules, the petitioner must notify the Commission and the Committee of any changes in petitioner information and/or contact information promptly, and in any event within thirty (30) days; and

(v) That the petitioner understands that if the petitioner or an applicant or licensee covered by the declaratory ruling fails to fulfill any of the conditions and obligations set forth in the certifications set out in paragraph (n)(2) of this section or in the grant of an application, petition, license, or authorization associated with this declaratory ruling and/or that if the information provided to the United States Government is materially false, fictitious, or fraudulent, the petitioner, applicants, and licensees may be subject to all remedies available to the United States Government, including but not limited to revocation and/or termination of the Commission's declaratory ruling, authorization or license, and criminal and civil penalties, including penalties under 18 U.S.C. 1001.

■ 7. Effective December 28, 2020, add subpart CC to part 1 to read as follows:

Subpart CC—Review of Applications, Petitions, Other Filings, and Existing Authorizations or Licenses with Reportable Foreign Ownership By Executive Branch Agencies for National Security, Law Enforcement, Foreign Policy, and Trade Policy Concerns

Sec.

§ 1.40001 Executive branch review of applications, petitions, other filings, and existing authorizations or licenses with reportable foreign ownership.

(a) The Commission, in its discretion, may refer applications, petitions, and other filings to the executive branch for review for national security, law enforcement, foreign policy, and/or trade policy concerns.

(1) The Commission will generally refer to the executive branch applications filed for an international section 214 authorization and submarine cable landing license as well as an application to assign, transfer control of, or modify those authorizations and licenses where the applicant has reportable foreign ownership and petitions for section 310(b) foreign ownership rulings for broadcast, common carrier wireless, and common carrier satellite earth station licenses pursuant to §§ 1.767, 63.18 and 63.24 of this chapter, and 1.5000 through 1.5004.

(2)–(3) [Reserved]

(b) The Commission will consider any recommendations from the executive branch on pending application(s) for an international section 214 authorization or cable landing license(s) or petition(s) for foreign ownership ruling(s) pursuant to §§ 1.5000 through 1.5004 or on existing authorizations or licenses that may affect national security, law enforcement, foreign policy, and/or trade policy as part of its public interest analysis. The Commission will evaluate concerns raised by the executive branch and will make an independent decision concerning the pending matter.

(c) In any such referral pursuant to paragraph (a) of this section or when considering any recommendations pursuant to paragraph (b) of this section, the Commission may disclose to relevant executive branch agencies, subject to the provisions of 44 U.S.C. 3510, any information submitted by an applicant, petitioner, licensee, or authorization holder in confidence pursuant to § 0.457 or § 0.459 of this chapter. Notwithstanding the provisions of § 0.442 of this chapter, notice will be provided at the time of disclosure.

(d) As used in this subpart, ''reportable foreign ownership'' for applications filed pursuant to §§ 1.767 and 63.18 and 63.24 of this chapter means any foreign owner of the applicant that must be disclosed in the application pursuant to § 63.18(h); and for petitions filed pursuant to §§ 1.5000 through 1.5004 ''reportable foreign ownership'' means foreign disclosable interest holders pursuant to § 1.5001(e) and (f).

§ 1.40002 Referral of applications, petitions, and other filings with reportable foreign ownership to the executive branch agencies for review.

(a) The Commission will refer any applications, petitions, or other filings for which it determines to seek executive branch review by placing the application, petition, or other filing on an accepted for filing public notice that will provide a comment period for the executive branch to seek deferral for review for national security, law enforcement, foreign policy, and/or trade policy concerns.

(b)(1) The executive branch agency(ies) must electronically file in all applicable Commission file numbers and dockets associated with the application(s), petition(s), or other filing(s) a request that the Commission defer action until the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee) completes its review. In the request for deferral the executive branch agency must notify the Commission on or before the comment date and must state whether the executive branch:

(i) Sent tailored questions to the applicant(s), petitioner(s), and/or other filer(s);

(ii) Will send tailored questions to the applicant(s), petitioner(s), and/or other filer(s) by a specific date not to be later than thirty (30) days after the date on which the Commission referred the application to the executive branch in accordance with paragraph (a) of this section; or

(iii) Will not transmit tailored questions to the applicant(s), petitioner(s), and/or other filer(s).

(2) The executive branch agency(ies) must electronically file in all applicable Commission file numbers and dockets associated with the application(s), petition(s), or other filing(s) a request by the comment date if it needs additional time beyond the comment period set out in the accepted for filing public notice to determine whether it will seek deferral.

(c) If an executive branch agency(ies) does not notify the Commission that it seeks deferral of referred application(s), petition(s), and/or other filing(s) within the comment period established by an accepted for filing public notice, the Commission will deem that the executive branch does not have any national security, law enforcement, foreign policy, and/or trade policy concerns with the application(s), petition(s), and/or other filing(s) and may act on the application(s), petition(s), and/or other filing(s) as appropriate based on its determination of the public interest.

§ 1.40003 [Reserved]

§ 1.40004 Time frames for executive branch review of applications, petitions, and/or other filings with reportable foreign ownership.

(a) *Tailored questions.* For application(s), petition(s), and/or other filing(s) referred to the executive branch, in accordance with § 1.40002(b)(1), the executive branch agency(ies) shall notify the Commission:

(1) That the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee) has sent tailored questions to the applicant(s), petitioner(s), and/or other filer(s); and

(2) When the Chair of the Committee determines that the applicant's, petitioner's, and/or other filer's responses to any questions and information requests from the Committee are complete.

(b) *Initial review—120-day time frame.* The executive branch shall notify the Commission by filing in the public record, in all applicable Commission file numbers and dockets for the application(s), petition(s), or other filing(s), no later than 120 days, plus any additional days as needed for escalated review and for NTIA to notify the Commission of the Committee's final recommendation in accordance with Executive Order 13913 (or as it may be amended), from the date that the Chair of the Committee determines that the applicant's, petitioner's, or other filer's responses to the tailored questions are complete, provided that the Committee sent tailored questions within thirty (30) days of the date of the Commission's referral in accordance with § 1.40002(a), and subject to paragraphs (e) and (f) of this section, whether it:

(1) Has no recommendation and no objection to the FCC granting the application;

(2) Recommends that the FCC only grant the application contingent on the applicant's compliance with mitigation measures; or

(3) Needs additional time to review the application(s), petition(s), or other filing(s).

(c) *Secondary assessment—additional 90-day time frame.* When the executive branch notifies the Commission that it needs an additional 90-day period beyond the initial 120-day period for review of the application, petition, or other filing under paragraph (a) of this section, in accordance with the secondary assessment provisions of Executive Order 13913 (or as it may be amended), the executive branch must:

(1) Explain in a filing on the record why it was unable to complete its review within the initial 120-day review period and state when the secondary assessment began; and

(2) Notify the Commission by filing in the public record, in all applicable Commission file numbers and dockets for the application(s), petition(s), or other filing(s) no later than 210 days, plus any additional days as needed for escalated review and for NTIA to notify the Commission of the Committee's final recommendation in accordance with Executive Order 13913 (or as it may be amended), from the date that the Chair of the Committee determines that the applicant's, petitioner's, or other filer's responses to the tailored questions are complete, provided that the Committee sent tailored questions within thirty (30) days of the date of the Commission's referral in accordance with § 1.40002(a), and subject to paragraphs (e) and (f) of this section, whether it:

(i) Has no recommendation and no objection to the FCC granting the application;

(ii) Recommends that the FCC only grant the application contingent on the applicant's compliance with mitigation measures; or

(iii) Recommends that the FCC deny the application due to the risk to the national security or law enforcement interests of the United States.

(d) *Executive branch notifications to the Commission.* (1) The executive branch shall file its notifications as to the status of its review in the public record established in all applicable Commission file numbers and dockets for the application, petition, or other filing. Status notifications include notifications of the date on which the Committee sends the tailored questions to an applicant, petitioner, or other filer and the date on which the Chair accepts an applicant's, petitioner's, or other filer's responses to the tailored questions as complete. Status notifications also include extensions of the 120-day review period and 90-day extension period (to include the start and end day of the extension) and updates every thirty (30) days during the 90-day extension period. If the executive branch recommends dismissal of the application, petition, or other filing without prejudice because the applicant, petitioner, or other filer has failed to respond to requests for information, the executive branch shall file that recommendation in the public record established in all applicable Commission file numbers and dockets.

(2) In circumstances where the notification of the executive branch contains non-public information, the executive branch shall file a public version of the notification in the public record established in all applicable Commission file numbers and dockets for the application, petition, or other filing and shall file the non-public information with the Commission pursuant to § 0.457 of this chapter.

(e) *Alternative start dates for the executive branch's initial 120-day review.* (1) In the event that the executive branch has not transmitted the tailored questions to an applicant within thirty (30) days of the Commission's referral of an application, petition, or other filing, the executive branch may request additional time by filing a request in the public record established in all applicable Commission file numbers and dockets associated with the application, petition, or other filing. The Commission, in its discretion, may allow an extension or start the executive branch's 120-day review clock immediately. If the Commission allows an extension and the executive branch does transmit the tailored questions to the applicant, petitioner, or other filer within the authorized extension period, the initial 120-day review period will begin on the date that executive branch determines the applicant's, petitioner's, or other filer's responses to be complete. If the executive branch does not transmit the tailored questions to the applicant, petitioner, or other filer within the authorized extension period, the Commission, in its discretion, may start the initial 120-day review period.

(2) In the event that the executive branch's notification under § 1.40002(b) indicates that no tailored questions are

necessary, the 120-day initial review period will begin on the date of that notification.

(f) *Extension of executive branch review periods.* In accordance with Executive Order 13913 (or as it may be amended), the executive branch may in its discretion extend the initial 120-day review period and 90-day secondary assessment period. The executive branch shall file notifications of all extensions in the public record.

■ 8. Delayed indefinitely, amend § 1.40001 by adding paragraphs (a)(2) and (3) to read as follows:

§ 1.40001 Executive branch review of applications, petitions, other filings, and existing authorizations or licenses with reportable foreign ownership.

(a) * * *

(2) The Commission will generally exclude from referral to the executive branch certain applications set out in paragraph (a)(1) of this section when the applicant makes a specific showing in its application that it meets one or more of the following categories:

(i) Pro forma notifications and applications;

(ii) Applications filed pursuant to §§ 1.767 and 63.18 and 63.24 of this chapter if the applicant has reportable foreign ownership and petitions filed pursuant to §§ 1.5000 through 1.5004 where the only reportable foreign ownership is through wholly owned intermediate holding companies and the ultimate ownership and control is held by U.S. citizens or entities;

(iii) Applications filed pursuant to §§ 63.18 and 63.24 of this chapter where the applicant has an existing international section 214 authorization that is conditioned on compliance with an agreement with an executive branch agency concerning national security and/or law enforcement, there are no new reportable foreign owners of the applicant since the effective date of the agreement, and the applicant agrees to continue to comply with the terms of that agreement; and

(iv) Applications filed pursuant to §§ 63.18 and 63.24 of this chapter where the applicant was reviewed by the executive branch within 18 months of the filing of the application and the executive branch had not previously requested that the Commission condition the applicant's international section 214 authorization on compliance with an agreement with an executive branch agency concerning national security and/or law enforcement and there are no new reportable foreign owners of the applicant since that review.

(3) In circumstances where the Commission, in its discretion, refers to the executive branch an application, petition, or other filing not identified in this paragraph (a)(3) or determines to refer an application or petition identified in paragraph (a)(2) of this section, the Commission staff will instruct the applicant, petitioner, or filer to follow the requirements for a referred application or petition set out in this subpart, including submitting responses to the standard questions to the Committee and making the appropriate certifications.

* * * * *

■ 9. Delayed indefinitely, add § 1.40003 to read as follows:

§ 1.40003 Categories of information to be provided to the executive branch agencies.

(a) Each applicant, petitioner, and/or other filer subject to a referral to the executive branch pursuant to § 1.40001:

(1) Must submit detailed and comprehensive information in the following categories:

(i) Corporate structure and shareholder information;

(ii) Relationships with foreign entities;

(iii) Financial condition and circumstances;

(iv) Compliance with applicable laws and regulations; and

(v) Business and operational information, including services to be provided and network infrastructure, in responses to standard questions, prior to or at the same time the applicant files its application(s), petition(s), and/or other filing(s) with the Commission directly to the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee).

(2) Must submit a complete and unredacted copy of its FCC application(s), petition(s), and/or other filing(s) to the Committee, including the file number(s) and docket number(s), within three (3) business days of filing it with the Commission.

(b) The standard questions and instructions for submitting the responses and the FCC application(s), petition(s), and/or other filing(s) are available on the FCC website.

(c) The responses to the standard questions shall be submitted directly to the Committee.

PART 63—EXTENSION OF LINES, NEW LINES, AND DISCONTINUANCE, REDUCTION, OUTAGE AND IMPAIRMENT OF SERVICE BY COMMON CARRIERS; AND GRANTS OF RECOGNIZED PRIVATE OPERATING AGENCY STATUS

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

Authority: 47 U.S.C. 151, 154(i), 154(j), 160, 201–205, 214, 218, 403, 571, unless otherwise noted.

■ 11. Delayed indefinitely, amend § 63.04 by revising paragraph (a)(4) to read as follows:

§ 63.04 Filing procedures for domestic transfer of control applications.

(a) * * *

(4)(i) The name, address, citizenship, and principal business of any person or entity that directly or indirectly owns ten percent or more of the equity interests and/or voting interests, or a controlling interest, of the applicant, and the percentage of equity and/or voting interest owned by each of those entities (to the nearest one percent). Where no individual or entity directly or indirectly owns ten percent or more of the equity interests and/or voting interests, or a controlling interest, of the applicant, a statement to that effect; and

(ii) An ownership diagram that illustrates the applicant's vertical ownership structure, including the direct and indirect ownership (equity and voting) interests held by the individuals and entities named in response to paragraph (a)(4)(i) of this section. Every individual or entity with ownership shall be depicted and all controlling interests must be identified. The ownership diagram shall include both the pre-transaction and post-transaction ownership of the authorization holder; and

* * * * *

■ 12. Delayed indefinitely, amend § 63.12 by redesignating paragraph (c)(3) as paragraph (c)(4) and adding a new paragraph (c)(3) to read as follows:

§ 63.12 Processing of international Section 214 applications.

* * * * *

(c) * * *

(3) An individual or entity that is not a U.S. citizen holds a ten percent or greater direct or indirect equity or voting interest, or a controlling interest, in any applicant; or

* * * * *

■ 13. Delayed indefinitely, amend § 63.18 by revising paragraph (h), redesignating paragraphs (p), (q), and (r) as paragraphs (r), (s), and (t), and adding

new paragraphs (p) and (q) to read as follows:

§ 63.18 Contents of applications for international common carriers.

* * * * *

(h)(1) The name, address, citizenship, and principal businesses of any individual or entity that directly or indirectly owns ten percent or more of the equity interests and/or voting interests, or a controlling interest, of the applicant, and the percentage of equity and/or voting interest owned by each of those entities (to the nearest one percent). Where no individual or entity directly or indirectly owns ten percent or more of the equity interests and/or voting interests, or a controlling interest, of the applicant, a statement to that effect.

(i) *Calculation of equity interests held indirectly in the carrier.* Equity interests that are held by an individual or entity indirectly through one or more intervening entities shall be calculated by successive multiplication of the equity percentages for each link in the vertical ownership chain, regardless of whether any particular link in the chain represents a controlling interest in the company positioned in the next lower tier. Example: Assume that an entity holds a non-controlling 30 percent equity and voting interest in Corporation A which, in turn, holds a non-controlling 40 percent equity and voting interest in the carrier. The entity's equity interest in the carrier would be calculated by multiplying the individual's equity interest in Corporation A by that entity's equity interest in the carrier. The entity's equity interest in the carrier would be calculated as 12 percent (30% × 40% = 12%). The result would be the same even if Corporation A held a de facto controlling interest in the carrier.

(ii) *Calculation of voting interests held indirectly in the carrier.* Voting interests that are held through one or more intervening entities shall be calculated by successive multiplication of the voting percentages for each link in the vertical ownership chain, except that wherever the voting interest for any link in the chain is equal to or exceeds 50 percent or represents actual control, it shall be treated as if it were a 100 percent interest. A general partner shall be deemed to hold the same voting interest as the partnership holds in the company situated in the next lower tier of the vertical ownership chain. A partner of a limited partnership (other than a general partner) shall be deemed to hold a voting interest in the partnership that is equal to the partner's equity interest. Example: Assume that an entity holds a non-controlling 30 percent equity and voting interest in Corporation A which, in turn, holds a controlling 70 percent equity and voting interest in the carrier. Because Corporation A's 70 percent voting interest in the carrier constitutes a controlling interest, it is treated as a 100 percent interest. The entity's 30 percent voting interest in Corporation A would flow through in its entirety to the carrier and thus be calculated as 30 percent (30% × 100% = 30%).

(2) An ownership diagram that illustrates the applicant's vertical ownership structure, including the direct and indirect ownership (equity and voting) interests held by the individuals and entities named in response to paragraph (h)(1) of this section. Every individual or entity with ownership shall be depicted and all controlling interests must be identified. The ownership diagram shall include both the pre-transaction and post-transaction ownership of the authorization holder.

(3) The applicant shall also identify any interlocking directorates with a foreign carrier.

* * * * *

(p) Each applicant for which an individual or entity that is not a U.S. citizen holds a ten percent or greater direct or indirect equity or voting interest, or a controlling interest, in the applicant, must submit:

(1) Responses to standard questions, prior to or at the same time the applicant files its application with the Commission, pursuant to part 1, subpart CC, of this chapter directly to the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee). The standard questions and instructions for submitting the responses are available on the FCC website. The required information shall be submitted separately from the application and shall be submitted directly to the Committee.

(2) A complete and unredacted copy of its FCC application(s), including the file number(s) and docket number(s), to the Committee within three (3) business days of filing it with the Commission. The instructions for submitting a copy of the FCC application(s) to the Committee are available on the FCC website.

(q)(1) Each applicant shall make the following certifications by which they agree:

(i) To comply with all applicable Communications Assistance for Law Enforcement Act (CALEA) requirements and related rules and regulations, including any and all FCC orders and opinions governing the application of CALEA, pursuant to the Communications Assistance for Law Enforcement Act and the Commission's rules and regulations in part 1, subpart Z, of this chapter;

(ii) To make communications to, from, or within the United States, as well as records thereof, available in a form and location that permits them to be subject to a valid and lawful request or legal process in accordance with U.S. law, including but not limited to:

(A) The Wiretap Act, 18 U.S.C. 2510 *et seq.;*

(B) The Stored Communications Act, 18 U.S.C. 2701 *et seq.;*

(C) The Pen Register and Trap and Trace Statute, 18 U.S.C. 3121 *et seq.;* and

(D) Other court orders, subpoenas or other legal process;

(iii) To designate a point of contact who is located in the United States and is a U.S. citizen or lawful U.S. permanent resident, for the execution of lawful requests and as an agent for legal service of process;

(iv)(A) That the applicant is responsible for the continuing accuracy and completeness of all information submitted, whether at the time of submission of the application or subsequently in response to either the Commission or the Committee's request, as required in § 1.65(a) of this chapter, and that the applicant agrees to inform the Commission and the Committee of any substantial and significant changes while an application is pending; and

(B) After the application is no longer pending for purposes of § 1.65 of the rules, the applicant must notify the Commission and the Committee of any changes in the authorization holder or licensee information and/or contact information promptly, and in any event within thirty (30) days; and

(v) That the applicant understands that if the applicant or authorization holder fails to fulfill any of the conditions and obligations set forth in the certifications set out in paragraph (q) of this section or in the grant of an application or authorization and/or that if the information provided to the United States Government is materially false, fictitious, or fraudulent, applicant and authorization holder may be subject to all remedies available to the United States Government, including but not limited to revocation and/or termination of the Commission's authorization or license, and criminal and civil penalties, including penalties under 18 U.S.C. 1001.

* * * * *

■ 14. Delayed indefinitely, amend § 63.24 by revising paragraphs (e)(2) and (f)(2)(i) to read as follows:

§ 63.24 Assignments and transfers of control.

* * * * *

(e) * * *

(2) The application shall include the information requested in paragraphs (a) through (d) of § 63.18 for both the transferor/assignor and the transferee/assignee. The information requested in paragraphs (h) through (q) of § 63.18 is required only for the transferee/assignee. The ownership diagram required under § 63.18(h)(2) shall include both the pre-transaction and post-transaction ownership of the authorization holder. The applicant shall include a narrative describing the means by which the proposed transfer or assignment will take place.

* * * * *

(f) * * *

(2) * * *

(i) The information requested in paragraphs (a) through (d) and (h) of § 63.18 for the transferee/assignee. The ownership diagram required under § 63.18(h)(2) shall include both the pre-transaction and post-transaction ownership of the authorization holder; and

* * * * *

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Part VI

Small Business Administration

13 CFR Part 121
Small Business Size Standards: Education Services; Health Care and Social Assistance; Arts, Entertainment and Recreation; Accommodation and Food Services; Other Services; Proposed Rule

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

RIN 3245–AG88

Small Business Size Standards: Education Services; Health Care and Social Assistance; Arts, Entertainment and Recreation; Accommodation and Food Services; Other Services

AGENCY: U.S. Small Business Administration.

ACTION: Proposed rule.

SUMMARY: The U.S. Small Business Administration (SBA) proposes to increase its receipts-based small business size definitions (commonly referred to as ''size standards'') for North American Industry Classification System (NAICS) Sectors related to Education Services; Health Care and Social Assistance; Arts, Entertainment and Recreation; Accommodation and Food Services; and Other Services. SBA proposes to increase size standards for 70 industries in those sectors, including 14 industries in NAICS Sector 61 (Education Services), 18 industries in Sector 62 (Health Care and Social Assistance), 11 industries in Sector 71 (Arts, Entertainment and Recreation), 4 industries in Sector 72 (Accommodation and Food Services), and 23 industries in Sector 81 (Other Services). SBA's proposed revisions rely on its recently revised ''Size Standards Methodology'' (Methodology). SBA seeks comments on its proposed changes to size standards in the above sectors, and the data sources it evaluated to develop the proposed size standards.

DATES: SBA must receive comments to this proposed rule on or before January 26, 2021.

ADDRESSES: Identify your comments by RIN 3245–AG88 and submit them by one of the following methods: (1) Federal eRulemaking Portal: *www.regulations.gov;* follow the instructions for submitting comments; or (2) Mail/Hand Delivery/Courier: Khem R. Sharma, Ph.D., Chief, Office of Size Standards, 409 Third Street SW, Mail Code 6530, Washington, DC 20416.

SBA will post all comments to this proposed rule on *www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *www.regulations.gov,* you must submit such information to U.S. Small Business Administration, Khem R. Sharma, Ph.D., Chief, Office of Size Standards, 409 Third Street SW, Mail Code 6530, Washington, DC 20416, or send an email to *sizestandards@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review your information and determine whether it will make the information public.

FOR FURTHER INFORMATION CONTACT: Jorge Laboy-Bruno, Ph.D., Economist, Office of Size Standards, (202) 205–6618 or *sizestandards@sba.gov.*

SUPPLEMENTARY INFORMATION:

Discussion of Size Standards

To determine eligibility for Federal small business assistance, SBA establishes small business size definitions (usually referred to as ''size standards'') for private sector industries in the United States. SBA uses 2 primary measures of business size for size standards purposes: Average annual receipts and average number of employees. SBA uses financial assets for certain financial industries and refining capacity, in addition to employees, for the petroleum refining industry to measure business size. In addition, SBA's Small Business Investment Company (SBIC), Certified Development Company (504), and 7(a) Loan Programs use either the industry-based size standards or tangible net worth and net income-based alternative size standards to determine eligibility for those programs.

In September 2010, Congress passed the Jobs Act (Pub. L. 111–240, 124 Stat. 2504, September 27, 2010) requiring SBA to review all size standards every 5 years and make necessary adjustments to reflect current industry and market conditions. In accordance with the Jobs Act, in early 2016 SBA completed the first 5-year review of all size standards—except those for agricultural enterprises for which size standards were previously set by Congress—and made appropriate adjustments to size standards for a number of industries to reflect current industry and Federal market conditions.

During the previous 5-year comprehensive review SBA reviewed the receipts-based size standards for 17 industries and 1 exception within NAICS Sector 61; 39 industries within Sector 62; 25 industries within Sector 71; 15 industries within Sector 72; and 48 industries within Sector 81. These reviews of receipts-based size standards occurred from October 2010 to December 2013. SBA's analyses of the relevant industry and Federal contracting data available at that time supported lowering size standards for 41 industries and 1 exception in these sectors. However, taking into consideration economic conditions at the time, SBA decided to either retain all size standards for which the industry analysis suggested a lower size standard at existing levels or bring them up to the relevant common size standard. In the final rules, SBA increased receipts-based size standards for 77 of those industries, including 9 industries in Sector 61 (77 FR 58739, September 24, 2012), 28 industries in Sector 62 (77 FR 58755, September 24, 2012), 17 industries in Sector 71 (78 FR 37417, June 20, 2013), 5 industries in Sector 72 (75 FR 61604, October 6, 2010), and 18 industries in Sector 81 (75 FR 61591, October 6, 2010). SBA retained the existing size standards for the remaining 68 industries and 1 exception in these sectors. Table 1, Size Standards Revisions During the First 5-Year Review, provides a summary of these revisions by NAICS sector.

TABLE 1—SIZE STANDARDS REVISIONS DURING THE FIRST 5-YEAR REVIEW

NAICS sector	Sector name	Number of size standards reviewed	Number of size standards increased	Number size standards lowered	Number of size standards maintained
61	Education Services	18	9	0	9
62	Health Care and Social Assistance	39	28	0	11
71	Arts, Entertainment and Recreation	25	17	0	8
72	Accommodation and Food Services	15	5	0	10
81	Other Services	48	18	0	30
All Sectors		145	77	0	68

Currently, there are 27 different size standards levels covering 1,023 NAICS industries and 14 subindustry activities (commonly known as ''exceptions'' in SBA's table of size standards). 16 of these size levels are based on average annual receipts, 9 are based on average number of employees, and 2 are based on other measures.

SBA also adjusts its monetary-based size standards for inflation at least once every 5 years. An interim final rule on SBA's latest inflation adjustment to size standards, effective August 19, 2019, was published in the **Federal Register** on July 18, 2019 (84 FR 34261). SBA also updates its size standards, every 5 years to adopt the Office of Management and Budget's (OMB) quinquennial NAICS revisions to its table of small business size standards. Effective October 1, 2017, SBA adopted the OMB's 2017 NAICS revisions to its size standards (82 FR 44886, September 27, 2017).

This proposed rule is one of a series of proposed rules that will review size standards of industries grouped by various NAICS sectors. Rather than review all size standards at one time, SBA is reviewing size standards by grouping industries within various NAICS sectors that use the same size measure (*i.e.,* employees or receipts). In the current review, SBA will review size standards in 6 groups of NAICS sectors. (In the prior review, SBA reviewed size standards mostly on a sector-by-sector basis.) Once SBA completes its review of size standards for a group of sectors, it issues for public comments a proposed rule to revise size standards for those industries based on the latest available data and other factors deemed relevant by the SBA's Administrator.

Below is a discussion of SBA's revised ''Size Standards Methodology'' (Methodology), available at *www.sba.gov/size,* for establishing, reviewing, or modifying receipts-based size standards that SBA has applied to this proposed rule. SBA examines the structural characteristics of an industry as a basis to assess industry differences and the overall degree of competitiveness of an industry and of firms within the industry. Industry structure is typically examined by analyzing 4 primary factors—average firm size, degree of competition within an industry, start-up costs and entry barriers, and distribution of firms by size. To assess the ability of small businesses to compete for Federal contracting opportunities under the current size standards, as the fifth primary factor, SBA also examines, for each industry averaging $20 million or more in average annual Federal contract dollars, the small business share in Federal contract dollars relative to the small business share in total industry's receipts. When necessary, SBA also considers other secondary factors that are relevant to the industries and the interests of small businesses, including impacts of size standards changes on small businesses.

Size Standards Methodology

SBA has recently revised its Methodology for establishing, reviewing, or modifying size standards when necessary. See the notification in the April 11, 2019, edition of the **Federal Register** (84 FR 14587). The revised methodology is available on SBA's size standards web page at *www.sba.gov/size.* Prior to finalizing the revised Methodology, SBA issued a notification in the April 27, 2018 edition of the **Federal Register** (83 FR 18468) to solicit comments from the public and notify stakeholders of the proposed changes to the Methodology. SBA considered all public comments in finalizing the revised Methodology. For a summary of comments and SBA's responses, refer to the SBA's April 11, 2019, **Federal Register** notification.

The revised Methodology represents a major change from the previous methodology, which was issued on October 21, 2009 (74 FR 53940). Specifically, in its revised Methodology SBA is replacing the ''anchor'' approach applied in the previous methodology with a ''percentile'' approach for evaluating differences in characteristics among various industries. Under the ''anchor'' approach, SBA generally evaluated the characteristics of individual industries relative to the average characteristics of industries with the anchor size standard to determine whether they should have a higher or a lower size standard than the anchor. In the ''percentile'' approach, SBA ranks each industry among all industries with the same measure of size standards (such as receipts or employees) in terms of 4 primary industry factors, discussed in the Industry Analysis subsection below. The ''percentile'' approach is explained more fully elsewhere in this proposed rule. For a more detailed explanation please see the revised methodology at *www.sba.gov/size.* Additionally, as the fifth factor, SBA evaluates the difference between the small business share in Federal contract dollars and the small business share in total industry's receipts to compute the size standard for the Federal contracting factor. The overall size standard for an industry is then obtained by averaging all size standards supported by each primary factor. The evaluation of the Federal contracting factor is explained more fully elsewhere in this proposed rule.

SBA does not apply all aspects of its Methodology to all proposed rules because not all features are relevant for every industry covered by each proposed rule. For example, since all industries covered by this proposed rule have receipts-based size standards, the Methodology described in this proposed rule applies only to establishing, reviewing, or modifying receipts-based size standards. SBA's Methodology is available on its website at *www.sba.gov/size.*

Industry Analysis

Congress granted SBA's Administrator discretion to establish detailed small business size standards (see 15 U.S.C. 632(a)(2)). Specifically, section 3(a)(3) of the Small Business Act (15 U.S.C. 632(a)(3)) requires that ''. . .the [SBA] Administrator shall ensure that the size standard varies from industry to industry to the extent necessary to reflect the differing characteristics of the various industries and consider other factors deemed to be relevant by the Administrator.'' Accordingly, the economic structure of an industry is the basis for establishing, reviewing, or modifying small business size standards. In addition, SBA considers current economic conditions, its mission and program objectives, the Administration's current policies, impacts on small businesses under current size and proposed or revised size standards, suggestions from industry groups and Federal agencies, and public comments on the proposed rule. SBA also examines whether a size standard based on industry and other relevant data successfully excludes businesses that are dominant in the industry.

The goal of SBA's size standards review is to determine whether its existing small business size standards reflect the current industry structure and Federal market conditions and revise them when the latest available data suggest that revisions are warranted. In the past, SBA compared the characteristics of each industry with the average characteristics of a group of industries associated with the ''anchor'' size standard. For example, in the first 5-year comprehensive review of size standards under the Jobs Act, $7 million (now $8.0 million due to the inflation adjustment in 2019; see 84 FR 34261 (July 18, 2019)) was considered the ''anchor'' for receipts-based size standards and 500 employees was the ''anchor'' for employee-based size standards. If the characteristics of a

specific industry under review were similar to the average characteristics of industries in the anchor group, SBA generally adopted the anchor size standard for that industry. If the specific industry's characteristics were significantly different from those in the anchor group, SBA assigned a size standard that was higher or lower than the anchor. To determine a size standard above or below the anchor size standard, SBA evaluated the characteristics of a second comparison group of industries with higher size standards. For industries with receipts-based standards, the second comparison group consisted of industries with size standards between $23 million and $35.5 million, with the weighted average size standard for the group equaling $29 million. For manufacturing industries and other industries with employee-based size standards (except for Wholesale Trade and Retail Trade), the second comparison group included industries with a size standard of 1,000 employees or 1,500 employees, with the weighted average size standard of 1,323 employees. Using the anchor size standard and average size standard for the second comparison group, SBA computed a size standard for an industry's characteristic (factor) based on the industry's position for that factor relative to the average values of the same factor for industries in the anchor and second comparison groups.

Under the ''percentile'' approach, for each industry factor, an industry is ranked and compared with the 20th percentile and 80th percentile values of that factor among the industries sharing the same measure of size standards (*i.e.,* receipts or employees). Combining that result with the 20th percentile and 80th percentile values of size standards among the industries with the same measure of size standards, SBA computes a size standard supported by each industry factor for each industry. In the previous Methodology, comparison industry groups were predetermined independent of the data, while in the revised Methodology they are established using the actual data. A more detailed description of the percentile method is provided in SBA's Methodology, available at *www.sba.gov/size.*

The primary factors that SBA evaluates to examine industry structure include average firm size, startup costs and entry barriers, industry competition, and distribution of firms by size. SBA also evaluates, as an additional primary factor, small business success in receiving Federal contracting assistance under the current size standards. Specifically, for the Federal contracting factor, SBA examines the small business share of Federal contract dollars relative to small business share of total receipts within an industry. These are, generally, the 5 most important factors SBA examines when establishing, reviewing, or revising a size standard for an industry. However, SBA will also consider and evaluate other secondary factors that it believes are relevant to a particular industry (such as technological changes, growth trends, SBA financial assistance, and other program factors). SBA also considers possible impacts of size standard revisions on eligibility for Federal small business assistance, current economic conditions, the Administration's policies, and suggestions from industry groups and Federal agencies. Public comments on proposed rules also provide important additional information. SBA thoroughly reviews all public comments before making a final decision on its proposed revisions to size standards. Below are brief descriptions of each of the 5 primary factors that SBA has evaluated for each industry being reviewed in this proposed rule. A more detailed description of this analysis is provided in the SBA's Methodology, available at *www.sba.gov/size.*

1. Average Firm Size

SBA computes 2 measures of average firm size: Simple average and weighted average. For industries with receipts-based size standards, the simple average is the total receipts of the industry divided by the total number of firms in the industry. The weighted average firm size is the summation of all the receipts of the firms in an industry multiplied by their share of receipts in the industry. The simple average weighs all firms within an industry equally regardless of their size. The weighted average overcomes that limitation by giving more weight to larger firms. The size standard supported by average firm size is obtained by averaging size standards supported by simple average firm size and weighted average firm size.

If the average firm size of an industry is higher than the average firm size for most other industries, this would generally support a size standard higher than the size standards for other industries. Conversely, if the industry's average firm size is lower than that of most other industries, it would provide a basis to assign a lower size standard as compared to size standards for most other industries.

2. Startup Costs and Entry Barriers

Startup costs reflect a firm's initial size in an industry. New entrants to an industry must have sufficient capital and other assets to start and maintain a viable business. If firms entering an industry under review have greater capital requirements than firms in most other industries, all other factors remaining the same, this would be a basis for a higher size standard. Conversely, if the industry has smaller capital needs compared to most other industries, a lower size standard would be considered appropriate.

Given the lack of actual data on startup costs and entry barriers by industry, SBA uses average assets as a proxy for startup costs and entry barriers. To calculate average assets, SBA begins with the sales to total assets ratio for an industry from the Risk Management Association's Annual Statement Studies, available at *https://rmau.org.* SBA then applies these ratios to the average receipts of firms in that industry obtained from the Economic Census tabulation. An industry with average assets that are significantly higher than most other industries is likely to have higher startup costs; this in turn will support a higher size standard. Conversely, an industry with average assets that are similar to or lower than most other industries is likely to have lower startup costs; this will support either lowering or maintaining the size standard.

3. Industry Competition

Industry competition is generally measured by the share of total industry receipts generated by the largest firms in an industry. SBA generally evaluates the share of industry receipts generated by the 4 largest firms in each industry. This is referred to as the ''4-firm concentration ratio,'' a commonly used economic measure of market competition. Using the 4-firm concentration ratio, SBA compares the degree of concentration within an industry to the degree of concentration of the other industries with the same measure of size standards. If a significantly higher share of economic activity within an industry is concentrated among the 4 largest firms compared to most other industries, all else being equal, SBA would set a size standard that is relatively higher than for most other industries. Conversely, if the market share of the 4 largest firms in an industry is appreciably lower than the similar share for most other industries, the industry will be assigned a size standard that is lower than those for most other industries.

4. Distribution of Firms by Size

SBA examines the shares of industry total receipts accounted for by firms of

different receipts and employment sizes in an industry. This is an additional factor SBA considers in assessing competition within an industry besides the 4-firm concentration ratio. If the preponderance of an industry's economic activity is attributable to smaller firms, this generally indicates that small businesses are competitive in that industry, which would support adopting a smaller size standard. A higher size standard would be supported for an industry in which the distribution of firms indicates that most of the economic activity is concentrated among the larger firms.

Concentration is a measure of inequality of distribution. To determine the degree of inequality of distribution in an industry, SBA computes the Gini coefficient, using the Lorenz curve. The Lorenz curve presents the cumulative percentages of units (firms) along the horizontal axis and the cumulative percentages of receipts (or other measures of size) along the vertical axis. (For further detail, see SBA's Methodology on its website at *www.sba.gov/size.*) Gini coefficient values vary from zero to one. If receipts are distributed equally among all the firms in an industry, the value of the Gini coefficient will equal zero. If an industry's total receipts are attributed to a single firm, the Gini coefficient will equal one.

SBA compares the degree of inequality of distribution for an industry under review with other industries with the same type of size standards. If an industry shows a higher degree of inequality of distribution (hence a higher Gini coefficient value) compared to most other industries in the group this would, all else being equal, warrant a size standard that is higher than the size standards assigned to most other industries. Conversely, an industry with lower degree of inequality (*i.e.,* a lower Gini coefficient value) than most others will be assigned a lower size standard relative to others.

5. Federal Contracting

As the fifth factor, SBA examines the success small businesses are having in winning Federal contracts under the current size standard as well as the possible impact a size standard change may have on Federal small business contracting opportunities. The Small Business Act requires the Federal Government to ensure that small businesses receive a ''fair proportion'' of Federal contracts. The legislative history also discusses the importance of size standards in Federal contracting. To incorporate the Federal contracting factor in the size standards analysis, SBA evaluates small business participation in Federal contracting in terms of the share of total Federal contract dollars awarded to small businesses relative to the small business share of industry's total receipts. In general, if the share of Federal contract dollars awarded to small businesses in an industry is significantly smaller than the small business share of total industry's receipts, all else remaining the same, a justification would exist for considering a size standard higher than the current size standard. In cases where small business share of the Federal market is already appreciably high relative to the small business share of the overall market, SBA generally assumes that the existing size standard is adequate with respect to the Federal contracting factor.

The disparity between the small business Federal market share and industry-wide small business share may be due to various factors, such as extensive administrative and compliance requirements associated with Federal contracts, the different skill set required to perform Federal contracts as compared to typical commercial contracting work, and the size of Federal contracts. These, as well as other factors, are likely to influence the type of firms within an industry that compete for Federal contracts. By comparing the small business Federal contracting share with the industry-wide small business share, SBA includes in its size standards analysis the latest Federal market conditions.

Besides the impact on Federal contracting, SBA also examines impacts on SBA's loan programs both under the current and revised size standards.

Sources of Industry and Program Data

SBA's primary source of industry data used in this proposed rule for evaluating industry characteristics and developing size standards is a special tabulation of the Economic Census from the U.S. Census Bureau (*https://www.census.gov/programs-surveys/economic-census.html*). The tabulation based on the 2012 Economic Census is the latest available. The special tabulation provides industry data on the number of firms, number of establishments, number of employees, annual payroll, and annual receipts of companies by Industry (6-digit level), Industry Group (4-digit level), Subsector (3-digit level), and Sector (2-digit level). These data are arrayed by various classes of firms' size based on the overall number of employees and receipts of the entire enterprise (all establishments and affiliated firms) from all industries. The special tabulation also contains information for different levels of NAICS categories on average and median firm size in terms of both receipts and employment, total receipts generated by the 4 and 8 largest firms, the Herfindahl-Hirschman Index (HHI), the Gini coefficient, and size distributions of firms by various receipts and employment size groupings.

In some cases, where data were not available due to disclosure prohibitions in the Census Bureau's tabulation, SBA either estimated missing values using available relevant data or examined data at a higher level of industry aggregation, such as at the NAICS 2-digit (Sector), 3-digit (Subsector), or 4-digit (Industry Group) level. In some instances, SBA's analysis was based only on those factors for which data were available or estimates of missing values were possible.

To evaluate some industries that are not covered by the Economic Census, SBA used a similar special tabulation of the latest County Business Patterns (CBP) published by the U.S. Census Bureau (*www.census.gov/programs-surveys/cbp.html*). Similarly, to evaluate industries in NAICS Sector 11 that are also not covered by the Economic Census and CBP, SBA evaluated a similar special tabulation based on the 2012 Census of Agriculture (*www.nass.usda.gov*) from the National Agricultural Statistics Service (NASS). Besides the Economic Census, Agricultural Census and CBP tabulations, SBA also evaluates relevant industry data from other sources when necessary, especially for industries that are not covered by the Economic Census or CBP. These include the Quarterly Census of Employment and Wages (QCEW, also known as ES–202 data) (*www.bls.gov/cew/*) and Business Employment Dynamics (BED) data (*www.bls.gov/bdm/*) from the U.S. Bureau of Labor Statistics. Similarly, to evaluate certain financial industries that have assets-based size standards, SBA examines the data from the Statistics on Depository Institutions (SDI) database (*www5.fdic.gov/sdi/main.asp*) of the Federal Depository Insurance Corporation (FDIC). Finally, to evaluate the capacity component of the Petroleum Refiners (NAICS 324110) size standard, SBA evaluates the petroleum production data from the Energy Information Administration (*www.eia.gov*).

To calculate average assets, SBA used sales to total assets ratios from the Risk Management Association's Annual eStatement Studies, 2016–2018 (*https://rmau.org*). To evaluate Federal contracting trends, SBA examined the data on Federal prime contract awards

from the Federal Procurement Data System—Next Generation (FPDS–NG) (*www.fpds.gov)* for fiscal years 2016–2018. To assess the impact on financial assistance to small businesses, SBA examined its internal data on 7(a) and 504 loan programs for fiscal years 2016–2018. For some portion of impact analysis, SBA also evaluated the data from the System of Award Management (*www.sam.gov*). Data sources and estimation procedures SBA uses in its size standards analysis are documented in detail in SBA's Methodology, which is available at *www.sba.gov/size.*

Dominance in Field of Operation

Section 3(a) of the Small Business Act (15 U.S.C. 632(a)) defines a small business concern as one that is: (1) Independently owned and operated; (2) not dominant in its field of operation; and (3) within a specific small business definition or size standard established by SBA Administrator. SBA considers as part of its evaluation whether a business concern at a proposed size standard would be dominant in its field of operation. For this, SBA generally examines the industry's market share of firms at the proposed or revised size standard as well as the distribution of firms by size. Market share and size distribution may indicate whether a firm can exercise a major controlling influence on a national basis in an industry where a significant number of business concerns are engaged. If a contemplated size standard includes a dominant firm, SBA will consider a lower size standard to exclude the dominant firm from being defined as small.

Selection of Size Standards

In the 2009 Methodology SBA applied to the first 5-year comprehensive review of size standards, SBA adopted a fixed number of size standards levels as part of its effort to simplify size standards. In response to public comments to the 2009 Methodology white paper, and the 2013 amendment to the Small Business Act (section 3(a)(8)) under section 1661 of the National Defense Authorization Act for Fiscal Year 2013 (''NDAA 2013'') (Pub. L. 112–239, January 2, 2013), in the revised Methodology, SBA relaxed the limitation on the number of small business size standards. Specifically, section 1661 of NDAA 2013 states ''SBA cannot limit the number of size standards, and shall assign the appropriate size standard to each industry identified by NAICS.''

In the revised Methodology, SBA calculates a separate size standard for each NAICS industry. However, to account for errors and limitations associated with various data SBA evaluates in the size standards analysis, SBA rounds the calculated size standard value for a receipts-based size standard to the nearest $500,000, except for agricultural industries in Subsectors 111 and 112 for which the calculated size standards will be rounded to the nearest $250,000. This rounding procedure is applied both in calculating a size standard for each of the 5 primary factors and in calculating the overall size standard for the industry.

As a policy decision, SBA continues to maintain the minimum and maximum levels for both receipts and employee-based size standards. Accordingly, SBA will not generally propose or adopt a size standard that is either below the minimum level or above the maximum, even though the calculations yield values below the minimum or above the maximum. The minimum size standard reflects the size an established small business should be to have adequate capabilities and resources to be able to compete for and perform Federal contracts (but does not account for small businesses that are newly formed or just starting operations). On the other hand, the maximum size standard represents the level above which businesses, if qualified as small, would outcompete much smaller businesses when accessing Federal assistance.

With respect to receipts-based size standards, SBA has established $6 million and $41.5 million, respectively, as the minimum and maximum size standard levels (except for most agricultural industries in NAICS Subsectors 111 and 112). These levels reflect the current minimum of $6.0 million and the current maximum of $41.5 million. The industry data suggests that $6 million minimum and $41.5 million maximum size standards would be too high for agricultural industries. Accordingly, SBA has established $1 million as the minimum size standard and $5 million as the maximum size standard for industries in Subsector 111 (Crop Production) and Subsector 112 (Animal Production and Aquaculture).

Evaluation of Industry Factors

As mentioned earlier, to assess the appropriateness of the current size standards SBA evaluates the structure of each industry in terms of 4 economic characteristics or factors, namely average firm size, average assets size as a proxy for startup costs and entry barriers, the 4-firm concentration ratio as a measure of industry competition, and size distribution of firms using the Gini coefficient. For each size standard type (*i.e.,* receipts-based or employee-based) SBA ranks industries both in terms of each of the 4 industry factors and in terms of the existing size standard and computes the 20th percentile and 80th percentile values for both. SBA then evaluates each industry by comparing its value for each industry factor to the 20th percentile and 80th percentile values for the corresponding factor for industries under a particular type of size standard.

If the characteristics of an industry under review within a particular size standard type are similar to the average characteristics of industries within the same size standard type in the 20th percentile, SBA will consider adopting as an appropriate size standard for that industry the 20th percentile value of size standards for those industries. For each size standard type, if the industry's characteristics are similar to the average characteristics of industries in the 80th percentile, SBA will assign a size standard that corresponds to the 80th percentile in the size standard rankings of industries. A separate size standard is established for each factor based on the amount of differences between the factor value for an industry under a particular size standard type and 20th percentile and 80th percentile values for the corresponding factor for all industries in the same type. Specifically, the actual level of the new size standard for each industry factor is derived by a linear interpolation using the 20th percentile and 80th percentile values of that factor and corresponding percentiles of size standards. Each calculated size standard is bounded between the minimum and maximum size standards levels, as discussed before. As noted earlier, the calculated value for a receipts-based size standard for each industry factor is rounded to the nearest $500,000, except for industries in Subsectors 111 and 112 for which a calculated size standard is rounded to the nearest $250,000.

Table 2, 20th and 80th Percentiles of Industry Factors for Receipts-based Size Standards, shows the 20th percentile and 80th percentile values for average firm size (simple and weighted), average assets size, 4-firm concentration ratio, and Gini coefficient for industries with receipts-based size standards.

TABLE 2—20TH AND 80TH PERCENTILES OF INDUSTRY FACTORS FOR RECEIPTS-BASED SIZE STANDARDS

Industries/percentiles	Simple average receipts size ($ million)	Weighted average receipts size ($ million)	Average assets size ($ million)	4-firm concentration ratio (%)	Gini coefficient
Industries, excluding Subsectors 111 and 112					
20th percentile	0.83	19.42	0.34	7.9	0.686
80th percentile	7.52	830.65	5.19	42.4	0.834
Industries in Subsectors 111 and 112					
20th percentile	0.06	1.48	0.07	1.7	0.608
80th percentile	0.83	13.32	0.88	12.3	0.908

Estimation of Size Standards Based on Industry Factors

An estimated size standard supported by each industry factor is derived by comparing its value for a specific industry to the 20th percentile and 80th percentile values for that factor. If an industry's value for a particular factor is near the 20th percentile value in the distribution, the supported size standard will be one that is close to the 20th percentile value of size standards for industries in the size standards group, which is $8.0 million. If a factor for an industry is close to the 80th percentile value of that factor, it would support a size standard that is close to the 80th percentile value in the distribution of size standards, which is $35.0 million. For a factor that is within, above, or below the 20–80th percentile range, the size standard is calculated using linear interpolation based on the 20th percentile and 80th percentile values for that factor and the 20th percentile and 80th percentile values of size standards.

For example, if an industry's simple average receipts are $1.9 million, that would support a size standard of $11.5 million. According to Table 2, the 20th percentile and 80th percentile values of average receipts are $0.83 million and $7.52 million, respectively. The $1.9 million is 15.9% between the 20th percentile value ($0.83 million) and the 80th percentile value ($7.52 million) of simple average receipts (($1.9 million − $0.83 million) ÷ ($7.52 million − $0.83 million) = 0.159 or 15.9%). Applying this percentage to the difference between the 20th percentile value ($8 million) and 80th percentile ($35.0 million) value of size standards and then adding the result to the 20th percentile size standard value ($8.0 million) yields a calculated size standard value of $12.32 million ([{$35.0 million − $8.0 million} * 0.159] + $8.0 million = $11.49 million). The final step is to round the calculated $11.49 million size standard to the nearest $500,000, which in this example yields $11.5 million. This procedure is applied to calculate size standards supported by other industry factors.

Detailed formulas involved in these calculations are presented in SBA's Methodology,'' which is available on its website at *www.sba.gov/size.*

Derivation of Size Standards Based on Federal Contracting Factor

Besides industry structure, SBA also evaluates Federal contracting data to assess the success of small businesses in getting Federal contracts under the existing size standards. For each industry with $20 million or more in annual Federal contract dollars, SBA evaluates the small business share of total Federal contract dollars relative to the small business share of total industry receipts. All other factors being equal, if the share of Federal contracting dollars awarded to small businesses in an industry is significantly less than the small business share of that industry's total receipts, a justification would exist for considering a size standard higher than the current size standard. Conversely, if the small business share of Federal contracting activity is near or above the small business share in total industry receipts, this will support the current size standard.

SBA increases the existing size standards by certain percentages when the small business share of total industry receipts exceeds the small business share of total Federal contract dollars by 10 or more percentage points. Proposed percentage increases generally reflect receipts levels needed to bring the small business share of Federal contracts on par with the small business share of industry receipts. These proposed percentage increases for receipts-based size standards are given in Table 3, Proposed Adjustments to Size Standards Based on Federal Contracting Factor.

TABLE 3—PROPOSED ADJUSTMENTS TO SIZE STANDARDS BASED ON FEDERAL CONTRACTING FACTOR

Size standards	Percentage difference between the small business shares of total Federal contract dollars in an industry and of total industry receipts		
	> −10%	−10% to −30%	< −30%
Receipts-based standards:			
<$15 million	No change	Increase 30%	Increase 60%.
$15 million to <$25 million	No change	Increase 20%	Increase 40%.
$25 million to <$41.5 million	No change	Increase 15%	Increase 25%.

For example, if an industry with the current size standard of $8.0 million had an average of $50 million in Federal contracting dollars, of which 15% went to small businesses, and if that small businesses accounted for 40% of total receipts of that industry, the small business share of total Federal contract dollars would be 25 percentage points less than the small business share of total industry receipts (40% − 15%). According to the above rule, the new

size standard for the Federal contracting factor for that industry would be set by multiplying the current $8.0 million standard by 1.3 (*i.e.,* 30% increase) and then by rounding the result to the nearest $500,000, yielding a size standard of $10.5 million.

SBA evaluated the small business share of total Federal contract dollars for the 54 industries covered by this proposed rule—13 in Sector 61, 26 in Sector 62, 2 in Sector 71, 2 in Sector 72, and 11 in Sector 81—that had $20 million or more in average annual Federal contract dollars during fiscal years 2016–2018. The Federal contracting factor was significant (*i.e.,* the difference between the small business share of total industry receipts and small business share of Federal contracting dollars was 10 percentage points or more) in 29 of these industries, prompting an upward adjustment of their existing size standards based on that factor. For the remaining 25 industries that averaged $20 million or more in average annual contract dollars, the Federal contracting factor was not significant, and the existing size standard was applied for that factor. For industries with less than $20 million in average annual contract dollars no size standard was calculated for the Federal contracting factor.

Derivation of Overall Industry Size Standard

The SBA's Methodology presented above results in 5 separate size standards based on evaluation of the 5 primary factors (*i.e.,* 4 industry factors and one Federal contracting factor). SBA typically derives an industry's overall size standard by assigning equal weights to size standards supported by each of these 5 factors. However, if necessary, SBA's Methodology would allow assigning different weights to some of these factors in response to its policy decisions and other considerations. For detailed calculations, see SBA's Methodology, available on its website at *www.sba.gov/size.*

Calculated Size Standards Based on Industry and Federal Contracting Factors

Table 4, Size Standards Supported by Each Factor for Each Industry (Receipts), below, shows the results of analyses of industry and Federal contracting factors for each industry and subindustry (exception) covered by this proposed rule. NAICS industries in columns 2, 3, 4, 5, 6, 7, and 8 show 2 numbers. The upper number is the value for the industry or Federal contracting factor shown on the top of the column and the lower number is the size standard supported by that factor. Column 9 shows a calculated new size standard for each industry. This is the average of the size standards supported by each factor (the size standard for average firm size is an average of size standards supported by simple average firm size and weighted average firm size), rounded to the nearest $500,000 for non-agriculture industries and rounded to the nearest $250,000 for agriculture industries. Analytical details involved in the averaging procedure are described in SBA's Methodology, which is available on its website at *www.sba.gov/size.* For comparison with the calculated new size standards, the current size standards are in column 10 of Table 4.

TABLE 4—SIZE STANDARDS SUPPORTED BY EACH FACTOR FOR EACH INDUSTRY (Receipts)

[Upper value = calculated factor, lower value = size standard supported]

NAICS code NAICS industry title	Type	Simple average firm size ($ million)	Weighted average firm size ($ million)	Average assets size ($ million)	Four-firm ratio %	Gini coefficient	Federal contract factor (%)	Calculated size standard ($ million)	Current size standard ($ million)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
611110 Elementary and Secondary Schools	Factor	$4.0	$31.8	$6.6	2.0	0.683	−48.4		
	Size Std.	20.5	8.5	41.5	$6.0	$7.5	$19.0	$17.5	$12.0
611210 Junior Colleges	Factor	18.2	291.6	30.3	27.7	0.779	39.0		
	Size Std.	41.5	17.0	41.5	$23.5	$25.0	$22.0	28.5	22.0
611310 Colleges, Universities, and Professional Schools.	Factor	97.7	1,801.8	244.1	9.8	0.802	−1.2		
	Size Std.	41.5	41.5	41.5	$9.5	$29.0	$30.0	30.5	30.0
611410 Business and Secretarial Schools	Factor	2.0	14.1	0.8	38.7	0.747			
	Size Std.	13.0	8.0	10.5	$32.0	$19.0		18.0	8.0
611420 Computer Training	Factor	1.3	27.3	0.5	18.8	0.774	3.8		
	Size Std.	9.5	8.5	8.5	$16.5	$24.0	$12.0	14.0	12.0
611430 Professional and Management Development Training.	Factor	1.2	25.6	0.6	7.8	0.762	−17.1		
	Size Std.	9.5	8.0	9.5	$8.0	$22.0	$15.5	13.0	12.0
611511 Cosmetology and Barber Schools	Factor	1.4	28.9	1.1	19.9	0.678			
	Size Std.	10.0	8.5	12.5	$17.5	$6.5		11.5	8.0
611512 Flight Training	Factor	3.2	311.3	2.0	53.2	0.831	−3.7		
	Size Std.	17.5	17.5	17.5	$41.5	$34.5	$30.0	28.0	30.0
611513 Apprenticeship Training	Factor	1.2	8.9	0.7	11.4	0.683	−57.1		
	Size Std.	9.5	7.5	10.0	$10.5	$7.5	$13.0	10.0	8.0
611519 Other Technical and Trade Schools	Factor	2.3	105.2	1.6	18.0	0.815	−9.9		
	Size Std.	14.0	11.0	15.0	$16.0	$31.5	$16.5	18.5	16.5
Exception, Job Corps Centers	Factor	166.5	1,031.7	116.2	83.5	0.686	20.3		
	Size Std.	41.5	41.5	41.5	$41.5	$19.0	$41.5	37.0	41.5
611610 Fine Arts Schools	Factor	0.3	2.1	0.4	2.2	0.593			
	Size Std.	6.0	7.5	8.0	$6.0	$6.0		7.0	8.0
611620 Sports and Recreation Instruction	Factor	0.4	12.9	0.1	7.7	0.616			
	Size Std.	6.0	8.0	7.0	$8.0	$6.0		7.0	8.0
611630 Language Schools	Factor	1.1	64.3	0.5	35.4	0.804	19.9		
	Size Std.	9.0	9.5	9.0	$29.5	$29.5	$12.0	18.0	12.0
611691 Exam Preparation and Tutoring	Factor	0.6	33.5	0.3	13.6	0.724	−36.1		
	Size Std.	7.0	8.5	7.5	$12.5	$15.0	$13.0	11.0	8.0
611692 Automobile Driving Schools	Factor	0.3	4.2	0.2	13.5	0.639	−50.3		
	Size Std.	6.0	7.5	7.0	$12.5	$6.0	$13.0	9.0	8.0
611699 All Other Miscellaneous Schools and Instruction.	Factor	0.7	64.0	0.6	23.6	0.760	−5.5		
	Size Std.	7.5	9.5	9.5	$20.5	$21.5	$12.0	14.5	12.0
611710 Educational Support Services	Factor	1.9	308.3	1.6	28.7	0.829	−1.7		
	Size Std.	12.0	17.5	15.0	$24.5	$34.0	$16.5	21.0	16.5
621111 Offices of Physicians (except Mental Health Specialists).	Factor	2.3	523.8	0.4	5.5	0.739	−37.6		
	Size Std.	14.0	25.0	8.0	$6.0	$17.5	$19.0	14.0	12.0
621112 Offices of Physicians, Mental Health Specialists.	Factor	0.5	4.2	0.1	3.7	0.583	−12.3		
	Size Std.	6.5	7.5	6.5	$6.0	$6.0	$15.5	8.0	12.0
621210 Offices of Dentists	Factor	0.8	19.1	0.3	2.0	0.482	−22.5	7.5	8.0
	Size Std.	8.0	8.0	7.5	$6.0	$6.0	$10.5		
621310 Offices of Chiropractors	Factor	0.3	1.0	0.1	0.8	0.469		6.5	8.0
	Size Std.	6.0	7.5	6.5	$6.0	$6.0			

TABLE 4—SIZE STANDARDS SUPPORTED BY EACH FACTOR FOR EACH INDUSTRY (Receipts)—Continued
[Upper value = calculated factor, lower value = size standard supported]

NAICS code NAICS industry title (1)	Type (2)	Simple average firm size ($ million) (3)	Weighted average firm size ($ million) (4)	Average assets size ($ million) (5)	Four-firm ratio % (6)	Gini coefficient (7)	Federal contract factor (%) (8)	Calculated size standard ($ million) (9)	Current size standard ($ million) (10)
621320 Offices of Optometrists	Factor	0.6	2.7	0.1	1.4	0.502		6.5	8.0
	Size Std.	7.0	7.5	7.0	$6.0	$6.0			
621330 Offices of Mental Health Practitioners (except Physicians).	Factor	0.4	5.5	0.1	3.2	0.681	14.5	7.0	8.0
	Size Std.	6.0	7.5	6.5	$6.0	$7.0	$8.0		
621340 Offices of Physical, Occupational and Speech Therapists, and Audiologists.	Factor	1.0	152.5	0.2	13.4	0.726	−25.2	11.0	8.0
	Size Std.	8.5	12.5	7.0	$12.5	$15.5	$10.5		
621391 Offices of Podiatrists	Factor	0.5	1.5	0.1	1.2	0.492		6.5	8.0
	Size Std.	7.0	7.5	6.5	$6.0	$6.0			
621399 Offices of All Other Miscellaneous Health Practitioners.	Factor	0.4	111.1	0.1	16.1	0.681	−8.5	9.0	8.0
	Size Std.	6.5	11.0	6.5	$14.5	$7.0	$8.0		
621410 Family Planning Centers	Factor	1.6	32.9	1.1	18.0	0.793		16.5	12.0
	Size Std.	11.0	8.5	12.5	$16.0	$27.5			
621420 Outpatient Mental Health and Substance Abuse Centers.	Factor	3.0	19.7	1.7	3.4	0.728	−13.9	14.0	16.5
	Size Std.	16.5	8.0	16.0	$6.0	$15.5	$20.0		
621491 HMO Medical Centers	Factor	410.2	3,312.1	157.8	93.6	0.817		39.0	35.0
	Size Std.	41.5	41.5	41.5	$41.5	$32.0			
621492 Kidney Dialysis Centers	Factor	37.2	5,760.6	18.6	86.2	0.870	−6.1	41.5	41.5
	Size Std.	41.5	41.5	41.5	$41.5	$41.5	$41.5		
621493 Freestanding Ambulatory Surgical and Emergency Centers.	Factor	5.3	198.9	2.1	16.3	0.693		15.5	16.5
	Size Std.	26.0	14.0	18.0	$14.5	$9.5			
621498 All Other Outpatient Care Centers	Factor	6.6	208.7	3.5	9.5	0.801	−13.4	22.5	22.0
	Size Std.	31.5	14.5	25.5	$9.5	$29.0	$26.5		
621511 Medical Laboratories	Factor	9.7	2,287.8	4.1	42.4	0.842	−14.2	36.5	35.0
	Size Std.	41.5	41.5	28.5	$35.0	$36.5	$40.5		
621512 Diagnostic Imaging Centers	Factor	3.4	56.0	1.5	7.4	0.759	32.3	15.0	16.5
	Size Std.	18.5	9.0	14.5	$7.5	$21.5	$16.5		
621610 Home Health Care Services	Factor	3.0	249.7	0.9	9.4	0.796	17.9	16.5	16.5
	Size Std.	17.0	15.5	11.5	$9.0	$28.0	$16.5		
621910 Ambulance Services	Factor	3.9	337.1	1.8	29.1	0.777	−6.5	20.0	16.5
	Size Std.	20.5	18.5	16.0	$24.5	$24.5	$16.5		
621991 Blood and Organ Banks	Factor	30.7	607.1	27.9	34.6	0.796	−14.6	34.5	35.0
	Size Std.	41.5	27.5	41.5	$29.0	$28.0	$40.5		
621999 All Other Miscellaneous Ambulatory Health Care Services.	Factor	2.7	119.6	1.4	18.3	0.814	29.4	18.0	16.5
	Size Std.	15.5	11.5	13.5	$16.0	$31.0	$16.5		
622110 General Medical and Surgical Hospitals	Factor	288.5	3,522.1	262.2	8.8	0.733	62.0	30.0	41.5
	Size Std.	41.5	41.5	41.5	$8.5	$16.5	$41.5		
622210 Psychiatric and Substance Abuse Hospitals	Factor	49.7	414.3	33.2	17.2	0.546		23.5	41.5
	Size Std.	41.5	21.0	41.5	$15.5	$6.0			
622310 Specialty (except Psychiatric and Substance Abuse) Hospitals.	Factor	113.3	1,124.0	81.0	27.2	0.713		30.0	41.5
	Size Std.	41.5	41.5	41.5	$23.0	$13.0			
623110 Nursing Care Facilities (Skilled Nursing Facilities).	Factor	12.7	512.2	8.5	11.2	0.694	−2.8	25.0	30.0
	Size Std.	41.5	24.5	41.5	$10.5	$9.5	$30.0		
623210 Residential Intellectual and Developmental Disability Facilities.	Factor	3.5	85.6	2.3	9.9	0.749		15.5	16.5
	Size Std.	19.0	10.0	19.0	$9.5	$19.5			
623220 Residential Mental Health and Substance Abuse Facilities.	Factor	3.2	52.7	2.3	8.9	0.701	−40.4	15.0	16.5
	Size Std.	17.5	9.0	19.0	$9.0	$11.0	$23.0		
623311 Continuing Care Retirement Communities	Factor	7.9	99.3	19.9	8.5	0.733		22.5	30.0
	Size Std.	36.5	10.5	41.5	$8.5	$16.5			
623312 Assisted Living Facilities for the Elderly	Factor	1.8	389.5	2.6	22.7	0.779		20.5	12.0
	Size Std.	12.0	20.5	20.5	$19.5	$25.0			
623990 Other Residential Care Facilities	Factor	2.6	24.0	2.0	6.4	0.730	−31.9	14.0	12.0
	Size Std.	15.0	8.0	17.5	$7.0	$16.0	$19.0		
624110 Child and Youth Services	Factor	1.5	23.1	1.1	4.5	0.759	−42.9	13.5	12.0
	Size Std.	11.0	8.0	12.0	$6.0	$21.5	$19.0		
624120 Services for the Elderly and Persons with Disabilities.	Factor	1.7	45.3	1.1	3.5	0.761	−27.5	13.0	12.0
	Size Std.	11.5	9.0	12.0	$6.0	$21.5	$15.5		
624190 Other Individual and Family Services	Factor	1.4	83.1	1.1	6.9	0.777	−20.5	14.0	12.0
	Size Std.	10.5	10.0	12.0	$7.0	$24.5	$15.5		
624210 Community Food Services	Factor	2.6	38.6	2.2	6.0	0.816		17.0	12.0
	Size Std.	15.0	8.5	18.0	$6.5	$31.5			
624221 Temporary Shelters	Factor	1.4	11.0	2.0	5.9	0.623	−55.9	11.5	12.0
	Size Std.	10.0	7.5	17.0	$6.5	$6.0	$19.0		
624229 Other Community Housing Services	Factor	1.8	48.0	3.6	14.1	0.692	−54.1	16.5	6.5
	Size Std.	12.0	9.0	26.0	$13.0	$9.0	$23.0		
624230 Emergency and Other Relief Services	Factor	13.9	478.8	13.9	37.9	0.878	23.8	36.5	35.0
	Size Std.	41.5	23.5	41.5	$31.5	$41.5	$35.0		
624310 Vocational Rehabilitation Services	Factor	2.9	48.1	1.8	8.3	0.728	24.9	13.0	12.0
	Size Std.	16.5	9.0	16.5	$8.5	$15.5	$12.0		
624410 Child Day Care Services	Factor	0.5	93.8	0.2	8.4	0.687		8.5	8.0
	Size Std.	7.0	10.5	7.0	$8.5	$8.5			
711110 Theater Companies and Dinner Theaters	Factor	2.2	106.8	3.2	19.7	0.791		20.0	22.0
	Size Std.	13.5	11.0	23.5	$17.5	$27.0			
711120 Dance Companies	Factor	1.4	15.6	0.7	24.7	0.771		16.0	12.0
	Size Std.	10.0	8.0	10.0	$21.0	$23.5			
711130 Musical Groups and Artists	Factor	1.1	20.6	1.0	7.4	0.772		13.0	12.0
	Size Std.	9.0	8.0	12.0	$7.5	$23.5			
711190 Other Performing Arts Companies	Factor	3.9	454.6	2.1	71.4	0.850		29.5	30.0
	Size Std.	20.5	22.5	17.5	$41.5	$38.0			
711211 Sports Teams and Clubs	Factor	25.9	218.1	21.6	8.2	0.858		29.5	41.5
	Size Std.	41.5	14.5	41.5	$8.0	$39.5			
711212 Racetracks	Factor	12.8	256.3	10.7	26.0	0.865		33.5	41.5
	Size Std.	41.5	16.0	41.5	$22.0	$40.5			
711219 Other Spectator Sports	Factor	1.3	43.9	0.9	18.8	0.761		14.5	12.0
	Size Std.	9.5	9.0	11.0	$16.5	$21.5			
711310 Promoters of Performing Arts, Sports, and Similar Events with Facilities.	Factor	3.9	173.1	3.6	21.5	0.815		23.5	35.0
	Size Std.	20.5	13.0	26.0	$18.5	$31.5			
711320 Promoters of Performing Arts, Sports, and Similar Events without Facilities.	Factor	2.1	274.6	0.9	29.3	0.791		19.5	16.5
	Size Std.	13.0	16.5	11.0	$25.0	$27.0			

TABLE 4—SIZE STANDARDS SUPPORTED BY EACH FACTOR FOR EACH INDUSTRY (Receipts)—Continued
[Upper value = calculated factor, lower value = size standard supported]

NAICS code NAICS industry title	Type	Simple average firm size ($ million)	Weighted average firm size ($ million)	Average assets size ($ million)	Four-firm ratio %	Gini coefficient	Federal contract factor (%)	Calculated size standard ($ million)	Current size standard ($ million)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
711410 Agents and Managers for Artists, Athletes, Entertainers, and Other Public Figures.	Factor	1.6	94.9	0.7	22.3	0.761	.....	15.5	12.0
	Size Std.	11.0	10.5	10.0	$19.5	$21.5			
711510 Independent Artists, Writers, and Performers	Factor	0.7	9.5	0.2	2.0	0.704	10.3	8.0	8.0
	Size Std.	7.5	7.5	7.5	$6.0	$11.5	$8.0		
712110 Museums	Factor	1.9	58.9	6.3	10.9	0.811	−16.8	25.5	30.0
	Size Std.	12.5	9.5	41.5	$10.5	$31.0	$34.5		
712120 Historical Sites	Factor	0.7	7.5	0.9	15.1	0.716	.....	11.5	8.0
	Size Std.	7.5	7.5	11.0	$13.5	$13.5			
712130 Zoos and Botanical Gardens	Factor	5.3	52.7	10.7	17.5	0.778	.....	25.0	30.0
	Size Std.	26.0	9.0	41.5	$15.5	$24.5			
712190 Nature Parks and Other Similar Institutions	Factor	1.5	19.2	1.8	26.1	0.748	.....	17.0	8.0
	Size Std.	10.5	8.0	16.0	$22.5	$19.5			
713110 Amusement and Theme Parks	Factor	34.9	2,658.3	29.1	72.1	0.877	.....	41.5	41.5
	Size Std.	41.5	41.5	41.5	$41.5	$41.5			
713120 Amusement Arcades	Factor	0.7	7.4	0.5	9.5	0.658	.....	8.0	8.0
	Size Std.	7.5	7.5	9.0	$9.5	$6.0			
713210 Casinos (except Casino Hotels)	Factor	69.1	319.9	57.6	19.4	0.700	.....	25.0	30.0
	Size Std.	41.5	18.0	41.5	$17.0	$10.5			
713290 Other Gambling Industries	Factor	5.0	191.4	4.5	21.3	0.815	.....	25.0	35.0
	Size Std.	24.5	13.5	31.5	$18.5	$31.5			
713910 Golf Courses and Country Clubs	Factor	1.9	35.5	2.8	6.3	0.664	.....	11.0	16.5
	Size Std.	12.5	8.5	21.5	$6.5	$6.0			
713920 Skiing Facilities	Factor	6.5	160.1	7.2	39.6	0.792	.....	31.0	30.0
	Size Std.	31.0	12.5	41.5	$33.0	$27.5			
713930 Marinas	Factor	1.1	7.3	1.8	5.7	0.612	.....	9.5	8.0
	Size Std.	9.0	7.5	16.0	$6.5	$6.0			
713940 Fitness and Recreational Sports Centers	Factor	1.0	220.5	0.9	17.4	0.772	.....	15.5	8.0
	Size Std.	8.5	14.5	11.0	$15.5	$23.5			
713950 Bowling Centers	Factor	0.9	65.9	0.7	22.7	0.630	.....	11.0	8.0
	Size Std.	8.0	9.5	10.0	$19.5	$6.0			
713990 All Other Amusement and Recreation Industries.	Factor	0.5	6.5	0.4	3.4	0.658	.....	7.0	8.0
	Size Std.	7.0	7.5	8.5	$6.0	$6.0			
721110 Hotels (except Casino Hotels) and Motels	Factor	3.5	1,805.2	7.0	19.7	0.792	7.4	30.5	35.0
	Size Std.	18.5	41.5	41.5	$17.5	$27.5	$35.0		
721120 Casino Hotels	Factor	241.7	2,353.8	241.7	34.3	0.708	.....	31.0	35.0
	Size Std.	41.5	41.5	41.5	$28.5	$12.0			
721191 Bed-and-Breakfast Inns	Factor	0.4	1.4	0.2	3.9	0.558	.....	6.5	8.0
	Size Std.	6.0	7.5	7.5	$6.0	$6.0			
721199 All Other Traveler Accommodation	Factor	0.5	4.2	0.3	11.2	0.624	.....	8.0	8.0
	Size Std.	6.5	7.5	7.5	$10.5	$6.0			
721211 RV (Recreational Vehicle) Parks and Campgrounds.	Factor	0.6	10.3	0.9	10.4	0.613	.....	9.0	38.0
	Size Std.	7.0	7.5	11.5	$10.0	$6.0			
721214 Recreational and Vacation Camps (except Campgrounds).	Factor	0.9	5.1	1.0	5.5	0.624	.....	8.0	8.0
	Size Std.	8.5	7.5	12.0	$6.0	$6.0			
721310 Rooming and Boarding Houses, Dormitories, and Workers' Camps.	Factor	0.7	22.8	2.3	21.0	0.639	.....	12.5	8.0
	Size Std.	7.5	8.0	18.5	$18.0	$6.0			
722310 Food Service Contractors	Factor	12.2	4,854.8	3.4	66.6	0.882	11.5	38.0	41.5
	Size Std.	41.5	41.5	25.0	$41.5	$41.5	$41.5		
722320 Caterers	Factor	0.8	5.2	0.2	1.8	0.676	.....	6.5	8.0
	Size Std.	7.5	7.5	7.0	$6.0	$6.0			
722330 Mobile Food Services	Factor	0.2	1.9	0.1	6.8	0.668	.....	6.5	.8.0
	Size Std.	6.0	7.5	6.5	$7.0	$6.0			
722410 Drinking Places (Alcoholic Beverages)	Factor	0.5	6.6	0.2	2.5	0.598	.....	6.5	8.0
	Size Std.	6.5	7.5	7.0	$6.0	$6.0			
722511 Full-Service Restaurants	Factor	1.1	562.0	0.3	7.9	0.668	.....	10.0	8.0
	Size Std.	9.0	26.0	7.5	$8.0	$6.0			
722513 Limited-Service Restaurants	Factor	1.3	293.4	0.4	6.2	0.731	.....	11.0	12.0
	Size Std.	10.0	17.0	8.5	$6.5	$16.0			
722514 Cafeterias, Grill Buffets, and Buffets	Factor	1.4	208.6	0.4	29.5	0.731	.....	15.5	30.0
	Size Std.	10.0	14.5	8.5	$25.0	$16.5			
722515 Snack and Nonalcoholic Beverage Bars	Factor	0.8	2,361.1	0.3	35.9	0.732	.....	20.0	8.0
	Size Std.	8.0	41.5	8.0	$30.0	$16.5			
811111 General Automotive Repair	Factor	0.5	8.3	0.1	2.0	0.540	−79.9	8.0	8.0
	Size Std.	7.0	7.5	7.0	$6.0	$6.0	$13.0		
811112 Automotive Exhaust System Repair	Factor	0.4	4.2	0.1	8.9	0.512	.....	7.0	8.0
	Size Std.	6.0	7.5	6.5	$8.5	$6.0			
811113 Automotive Transmission Repair	Factor	0.5	3.6	0.1	5.0	0.488	.....	6.5	8.0
	Size Std.	6.5	7.5	6.5	$6.0	$6.0			
811118 Other Automotive Mechanical and Electrical Repair and Maintenance.	Factor	0.5	8.5	0.2	10.6	0.589	.....	7.5	8.0
	Size Std.	6.5	7.5	7.0	$10.0	$6.0			
811121 Automotive Body, Paint, and Interior Repair and Maintenance.	Factor	0.9	21.6	0.2	4.5	0.617	.....	7.0	8.0
	Size Std.	8.0	8.0	7.0	$6.0	$6.0			
811122 Automotive Glass Replacement Shops	Factor	0.7	333.2	0.3	35.5	0.701	.....	15.5	12.0
	Size Std.	7.5	18.5	7.5	$29.5	$11.0			
811191 Automotive Oil Change and Lubrication Shops	Factor	1.0	49.6	0.4	16.1	0.663	.....	9.5	8.0
	Size Std.	8.5	9.0	8.5	$14.5	$6.0			
811192 Car Washes	Factor	0.5	17.8	0.7	8.2	0.646	.....	8.0	8.0
	Size Std.	7.0	8.0	10.0	$8.0	$6.0			
811198 All Other Automotive Repair and Maintenance	Factor	0.5	17.0	0.2	17.5	0.666	.....	9.0	8.0
	Size Std.	6.5	8.0	7.0	$15.5	$6.0			
811211 Consumer Electronics Repair and Maintenance	Factor	1.0	191.4	0.4	50.4	0.802	.....	22.5	8.0
	Size Std.	8.5	13.5	8.0	$41.5	$29.0			
811212 Computer and Office Machine Repair and Maintenance.	Factor	1.0	50.5	0.4	14.1	0.790	15.8	17.5	30.0
	Size Std.	8.5	9.0	8.0	$13.0	$27.0	$30.0		
811213 Communication Equipment Repair and Maintenance.	Factor	1.9	158.3	0.7	38.4	0.791	−27.9	19.5	12.0
	Size Std.	12.5	12.5	9.5	$32.0	$27.0	$15.5		
811219 Other Electronic and Precision Equipment Repair and Maintenance.	Factor	2.3	265.7	0.8	35.1	0.795	−19.2	22.0	22.0
	Size Std.	14.0	16.0	10.5	$29.5	$28.0	$26.5		

TABLE 4—SIZE STANDARDS SUPPORTED BY EACH FACTOR FOR EACH INDUSTRY (Receipts)—Continued
[Upper value = calculated factor, lower value = size standard supported]

NAICS code NAICS industry title	Type	Simple average firm size ($ million)	Weighted average firm size ($ million)	Average assets size ($ million)	Four-firm ratio %	Gini coefficient	Federal contract factor (%)	Calculated size standard ($ million)	Current size standard ($ million)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
811310 Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance.	Factor	1.6	63.8	0.6	4.9	0.750	−10.7	11.0	8.0
	Size Std.	11.0	9.5	9.5	$6.0	$19.5	$10.5		
811411 Home and Garden Equipment Repair and Maintenance.	Factor	0.3	2.4	0.1	9.2	0.557		7.0	8.0
	Size Std.	6.0	7.5	6.5	$9.0	$6.0			
811412 Appliance Repair and Maintenance	Factor	0.5	137.5	0.2	31.6	0.670		12.5	16.5
	Size Std.	6.5	12.0	7.0	$26.5	$6.0			
811420 Reupholstery and Furniture Repair	Factor	0.3	1.1	0.1	3.6	0.555		6.5	8.0
	Size Std.	6.0	7.5	6.5	$6.0	$6.0			
811430 Footwear and Leather Goods Repair	Factor	0.2	1.0	0.1	10.4	0.521		7.5	8.0
	Size Std.	6.0	7.5	6.5	$10.0	$6.0			
811490 Other Personal and Household Goods Repair and Maintenance.	Factor	0.3	2.4	0.1	2.9	0.607		6.5	8.0
	Size Std.	6.0	7.5	6.5	$6.0	$6.0			
812111 Barber Shops	Factor	0.2	7.3	0.0	15.6	0.612		8.5	8.0
	Size Std.	6.0	7.5	6.5	$14.0	$6.0			
812112 Beauty Salons	Factor	0.3	162.0	0.1	12.3	0.653		8.5	8.0
	Size Std.	6.0	12.5	6.5	$11.5	$6.0			
812113 Nail Salons	Factor	0.2	0.4	0.0	0.7	0.480		6.5	8.0
	Size Std.	6.0	7.5	6.5	$6.0	$6.0			
812191 Diet and Weight Reducing Centers	Factor	1.5	355.8	0.4	61.1	0.814		24.0	22.0
	Size Std.	11.0	19.0	8.5	$41.5	$31.5			
812199 Other Personal Care Services	Factor	0.3	6.5	0.1	5.5	0.660		6.5	8.0
	Size Std.	6.0	7.5	6.5	$6.0	$6.0			
812210 Funeral Homes and Funeral Services	Factor	1.1	205.9	0.9	15.7	0.550		11.0	8.0
	Size Std.	9.5	14.0	11.0	$14.0	$6.0			
812220 Cemeteries and Crematories	Factor	0.8	121.2	1.2	30.1	0.786		18.5	22.0
	Size Std.	8.0	11.5	12.5	$25.5	$26.0			
812310 Coin-Operated Laundries and Drycleaners	Factor	0.4	87.4	0.2	28.5	0.626		11.5	8.0
	Size Std.	6.0	10.5	7.5	$24.0	$6.0			
812320 Dry cleaning and Laundry Services (except Coin-Operated).	Factor	0.4	2.7	0.2	1.5	0.564	−20.0	7.0	6.0
	Size Std.	6.0	7.5	7.0	$6.0	$6.0	$8.0		
812331 Linen Supply	Factor	8.7	374.0	4.3	46.4	0.808		32.0	35.0
	Size Std.	39.5	20.0	30.0	$38.0	$30.0			
812332 Industrial Launderers	Factor	16.8	1,478.3	9.3	72.2	0.839	32.8	40.5	41.5
	Size Std.	41.5	41.5	41.5	$41.5	$36.0	$41.5		
812910 Pet Care (except Veterinary) Services	Factor	0.2	2.3	0.1	3.8	0.575		6.5	8.0
	Size Std.	6.0	7.5	6.5	$6.0	$6.0			
812921 Photofinishing Laboratories (except One-Hour)	Factor	2.6	299.5	0.8	64.4	0.833		26.0	22.0
	Size Std.	15.0	17.5	10.5	$41.5	$34.5			
812922 One-Hour Photofinishing	Factor	0.3	10.2	0.1	50.1	0.690		16.0	16.5
	Size Std.	6.0	7.5	6.5	$41.0	$9.0			
812930 Parking Lots and Garages	Factor	2.6	211.8	1.6	29.2	0.811	9.7	25.5	41.5
	Size Std.	15.0	14.5	15.0	$24.5	$30.5	$41.5		
812990 All Other Personal Services	Factor	0.6	85.4	0.2	21.5	0.745	−56.8	13.0	8.0
	Size Std.	7.0	10.0	7.0	$18.5	$19.0	$13.0		
813110 Religious Organizations	Factor	0.7	59.2	2.3	3.2	0.706		11.5	8.0
	Size Std.	7.5	9.5	19.0	$6.0	$11.5			
813211 Grantmaking Foundations	Factor	5.6	815.3	18.8		0.821		35.0	35.0
	Size Std.	27.5	34.5	41.5		$32.5			
813212 Voluntary Health Organizations	Factor	5.9	386.9	3.9	23.5	0.841		27.0	30.0
	Size Std.	28.5	20.0	28.0	$20.0	$36.0			
813219 Other Grantmaking and Giving Services	Factor	3.5	97.1	5.0	12.2	0.807		22.5	41.5
	Size Std.	19.0	10.5	34.0	$11.5	$30.0			
813311 Human Rights Organizations	Factor	2.7	352.9	3.4	35.1	0.822	−33.1	28.5	30.0
	Size Std.	15.5	19.0	25.0	$29.5	$33.0	$37.5		
813312 Environment, Conservation and Wildlife Organizations.	Factor	1.6	131.6	2.2	16.4	0.774		17.0	16.5
	Size Std.	11.0	11.5	18.5	$14.5	$24.0			
813319 Other Social Advocacy Organizations	Factor	1.4	92.8	1.4	17.5	0.776		16.0	8.0
	Size Std.	10.0	10.5	13.5	$15.5	$24.5			
813410 Civic and Social Organizations	Factor	0.6	12.5	1.1	3.0	0.684		8.5	8.0
	Size Std.	7.0	8.0	12.0	$6.0	$8.0			
813910 Business Associations	Factor	1.5	46.1	1.5	5.1	0.772		13.5	8.0
	Size Std.	10.5	9.0	14.5	$6.0	$23.5			
813920 Professional Organizations	Factor	2.8	92.6	4.0	9.5	0.792	−39.7	20.5	16.5
	Size Std.	16.0	10.5	28.5	$9.0	$27.5	$23.0		
813930 Labor Unions and Similar Labor Organizations	Factor	1.2	41.2	1.5	5.1	0.797		14.5	8.0
	Size Std.	9.5	8.5	14.5	$6.0	$28.0			
813940 Political Organizations	Factor	0.8	19.6	0.7	14.0	0.753		12.5	8.0
	Size Std.	8.0	8.0	10.0	$12.5	$20.0			
813990 Other Similar Organizations (except Business, Professional, Labor, and Political Organizations).	Factor	1.1	103.8	1.1	10.6	0.729		12.0	8.0
	Size Std.	9.0	11.0	12.0	$10.0	$16.0			

Evaluation of Size Standards for Subindustry Categories or ''Exceptions''

In accordance with SBA's approach to evaluating size standards for subindustry categories (or ''exceptions''), SBA has evaluated 1 exception covered by this rule using the procedures described in the revised SBA's Methodology. The results of that analysis are discussed in the following subsection.

Exception to NAICS 611519: Job Corps Centers

The current size standard for Federal contracts for Job Corps Centers (exception to NAICS 611519, Other Technical and Trade Schools) is $41.5 million in average annual receipts. For Federal procurement programs, this size standard applies to Federal contracts that meet specific criteria. The criteria required of a Jobs Corps Center contract or SBA-recognized operator are detailed in Footnote 16 to SBA's table of size standards (13 CFR 121.201): ''For

classifying a Federal procurement, the purpose of the solicitation must be for the management and operation of a U.S. Department of Labor Job Corps Center. The activities involved include admissions activities, life skills training, educational activities, comprehensive career preparation activities, career development activities, career transition activities, as well as the management and support functions and services needed to operate and maintain the facility. For SBA assistance as a small business concern, other than for Federal Government procurements, a concern must be primarily engaged in providing the services to operate and maintain Federal Job Corps Centers.''

As noted previously, the data from the Economic Census special tabulation are limited to the 6-digit NAICS industry level and hence do not provide data to assess economic characteristics at the sub-industry level. For example, the Economic Census data for NAICS 611519 are aggregates of both Other Technical and Trade Schools and the more specialized establishments under the Job Corps exception. The lack of relevant data at the sub-industry level is a challenge to determining whether the size standard for the exception should be revised or left unchanged. Thus, the results based on the Economic Census data alone may not accurately reflect the characteristics of businesses providing specialized services included under the exception.

To determine whether the Agency should propose revising the exception under NAICS 611519, SBA analyzed data from the U.S. Department of Labor (DOL) website which includes a listing of Job Corps centers and their operators (available at *https://www.dol.gov/agencies/eta/jobcorps/contact*). SBA found that there were 23 non-governmental operators listed on the DOL website. SBA also evaluated the data from FPDS–NG and SAM. From FPDS–NG, SBA first identified firms that have a principal NAICS code of 611519. SBA then identified Product and Service Codes (PSCs) that correspond to the Job Corps Center exception by filtering the data for contracts awarded to private firms providing job corps services. SBA identified 7 PSCs from this search, namely: M1CZ—*Operation Of Other Educational Buildings,* U006—*Education/Training- Vocational/ Technical,* M139—*Operation of Govt Other Educational Buildings,* U099—*Education/Training- Other,* U009—*Education/Training- General,* 7610—*Books And Pamphlets* and U008—*Education/Training- Training/ Curriculum Development.* Using this method, SBA identified 35 firms (including the firms listed on the DOL website) that had a principal NAICS code of 611519 and were active in Federal contracting involving the identified PSCs. For fiscal years 2016–2018, the total average contract dollars obligated under these PSCs was $436.3 million. However, since the additional 11 operators from FPDS–NG were not included in the list of operators from the DOL website, SBA did not include them in its analysis of industry and Federal procurement factors for this NAICS exception. The average total contract dollars obligated under the identified PSCs to the list of operators from only the DOL website was $401.4 million, which represents 92% of the total dollars obligated to Jobs Corps Centers. SBA's analysis did not include firms that were considered outliers based on net de-obligations for each year of the analysis period and those with extremely large operating revenues.

The results from SBA's analysis are presented in Table 4 of this proposed rule. The analysis supports decreasing the current size standard to $37.0 million. However, for reasons discussed below in the special considerations section, SBA proposes to retain the $41.5 million size standard.

Summary of Calculated Size Standards

Of the 144 industries and one subindustry (*i.e.* exception) reviewed in this proposed rule, the results from analyses of the latest available data on the 5 primary factors from Table 4, Size Standards Supported by Each Factor for Each Industry (millions of dollars), above, would support increasing size standards for 70 industries, decreasing size standards for 63 industries, and maintaining size standards for 12 industries. Table 5, Summary of Calculated Size Standards, summarizes these results by NAICS sector.

TABLE 5—SUMMARY OF CALCULATED SIZE STANDARDS

NAICS sector	Sector name	Number of size standards reviewed	Number of size standards increased	Number of size standards decreased	Number of size standards unchanged
61	Education Services	18	14	4	0
62	Health Care and Social Assistance	39	18	18	3
71	Arts, Entertainment and Recreation	25	11	11	3
72	Accommodation and Food Services	15	4	9	2
81	Other Services	48	23	21	4
All Sectors		145	70	63	12

Evaluation of SBA Loan Data

Before proposing or deciding on an industry's size standard revision, SBA also considers the impact of size standards revisions on SBA's loan programs. Accordingly, SBA examined its internal 7(a) and 504 loan data for fiscal years 2016–2018 to assess whether the calculated size standards in Table 4 (above) need further adjustments to ensure credit opportunities for small businesses through those programs. For the industries reviewed in this rule, the data shows that it is mostly businesses much smaller than the current or proposed size standards that receive SBA's 7(a) and 504 loans. For example, for industries covered by this rule, more than 99.3% of 7(a) and 504 loans in fiscal years 2016–2018 went to businesses below the current or proposed size standards.

Proposed Changes to Size Standards

Based on the analytical results in Table 4 and considerations of impacts of calculated size standards in terms of access by currently small businesses to SBA's loans, as discussed above, of a total of 145 industries or subindustries (exceptions) with receipts-based size standards in Sectors 61, 62, 71, 72 and 81 that are covered by this rule, and considering the current situation due to the COVID–19 related national emergency and its impacts on small businesses and the overall economy, SBA proposes to increase size standards for 70 industries, and retain the current size standards for the remaining 75 industries.

Special Considerations

On March 13, 2020, the ongoing Coronavirus Disease 2019 (COVID–19) was declared a pandemic of enough severity and magnitude to warrant an emergency declaration for all states, territories, and the District of Columbia. With the COVID–19 emergency, many small businesses nationwide are experiencing economic hardship as a direct result of the Federal, State, and local public health measures that are being taken to minimize the public's exposure to the virus. These measures, some of which are Government-mandated, are being implemented nationwide and include the closures of restaurants, bars, and gyms. In addition, based on the advice of public health officials, other measures, such as keeping a safe distance from others or even stay-at-home orders, are being implemented, resulting in a dramatic decrease in economic activity as the public avoids malls, retail stores, and other businesses.

The Coronavirus Aid, Relief, and Economic Security Act (the CARES Act or the Act) (Pub. L. 116–136) was signed on March 27, 2020, to provide emergency assistance and health care response for individuals, families, and businesses affected by the coronavirus pandemic. Section 1102 of the Act temporarily permits SBA to guarantee 100% of 7(a) loans under a new program titled the Paycheck Protection Program (PPP). Section 1106 of the Act provides for forgiveness of up to the full principal amount of qualifying loans guaranteed under the PPP. The PPP and loan forgiveness are intended to provide economic relief to small businesses nationwide adversely impacted under the COVID–19. On April 24, 2020, additional funding for the CARES Act, including for the PPP, was provided.

The Agency is following closely the development of the pandemic and the economic situation and recovery. The consequence of the initial response of the public to the COVID–19 pandemic as well as the different measures taken by the Government to contain it (*e.g.* stay at home orders, social distancing, etc.) have resulted in the present economic decline. A variety of economic indicators such as the Gross Domestic Product (GDP) and the unemployment rate shows that this recession is significantly worse than any other recession since World War II. The GDP decreased nearly 5%, and the personal consumption in goods and services decreased 6.9% in the first quarter of 2020. The Bureau of Economic Analysis (BEA) third estimate for the second quarter of 2020 shows that the GDP decreased 31.4%, and the personal consumption in goods and services decreased 33.2%; In August 2020, personal income decreased 2.7%, after having decreased by a lower percentage in June (1.2%) and slightly increased in July 2020 (0.5%). In September 2020, the unemployment rate declined to 7.9% from August 2020, when the unemployment rate was 8.4%. After reaching 14.7% in April 2020, the unemployment rate has been decreasing from May to September 2020, but still it is greater than in February 2020 when it was 3.5%. For the month of September 2020, non-farm payroll increased 661,000 from August 2020, but the decrease in employment since February 2020 is about 10.5 million. Specifically, for the sectors evaluated in this proposed rule, in September 2020 the unemployment rate for Education and Health Services industries was 5.1%, the Leisure and Hospitality industries showed an unemployment rate of 19.0% and the Other Services sector, In September 2019, the unemployment rates for these sectors were 2.2%, 4.8% and 3.2%, respectively. The latest Federal Reserve Board's Monetary Policy Report shows that in general the most impacted firms in these sectors are the small businesses.[1]

Accordingly, in view of above impacts on small businesses from the COVID–19 pandemic and Federal Government efforts to provide relief to small businesses and support to the overall economy, SBA proposes to adopt increases to size standards for 70 industries and retain the current size standards for 63 industries for which analytical results suggested their size standards could be lowered.

The proposed size standards are presented in Table 6, Proposed Size Standards Revisions. Also presented in Table 6 are current and calculated size standards for comparison.

TABLE 6—PROPOSED SIZE STANDARDS REVISIONS

NAICS code	NAICS industry title	Calculated size standard ($ million)	Proposed size standard ($ million)	Current size standard ($ million)
611110	Elementary and Secondary Schools	$17.5	$17.5	$12.0
611210	Junior Colleges	28.5	28.5	22.0
611310	Colleges, Universities, and Professional Schools	30.5	30.5	30.0
611410	Business and Secretarial Schools	18.0	18.0	8.0
611420	Computer Training	14.0	14.0	12.0
611430	Professional and Management Development Training	13.0	13.0	12.0
611511	Cosmetology and Barber Schools	11.5	11.5	8.0
611512	Flight Training	28.0	30.0	30.0
611513	Apprenticeship Training	10.0	10.0	8.0
611519	Other Technical and Trade Schools	18.5	18.5	16.5
Exception 611519	Job Corps Centers	37.0	41.5	41.5
611610	Fine Arts Schools	7.0	8.0	8.0
611620	Sports and Recreation Instruction	7.0	8.0	8.0
611630	Language Schools	18.0	18.0	12.0
611691	Exam Preparation and Tutoring	11.0	11.0	8.0
611692	Automobile Driving Schools	9.0	9.0	8.0
611699	All Other Miscellaneous Schools and Instruction	14.5	14.5	12.0
611710	Educational Support Services	21.0	21.0	16.5
621111	Offices of Physicians (except Mental Health Specialists)	14.0	14.0	12.0
621112	Offices of Physicians, Mental Health Specialists	8.0	12.0	12.0

[1] Board of Governors of the Federal Reserve System (June 2020), Monetary Policy Report, p. 24 (see *https://www.federalreserve.gov/monetarypolicy/files/20200612_mprfullreport.pdf*) and U.S. Census Bureau, see *https://portal.census.gov/pulse/data*. The latest is a recent survey created by the Census Bureau to provide high-frequency, detailed information on participation in small business-specific initiatives such as the PPP.

TABLE 6—PROPOSED SIZE STANDARDS REVISIONS—Continued

NAICS code	NAICS industry title	Calculated size standard ($ million)	Proposed size standard ($ million)	Current size standard ($ million)
621210	Offices of Dentists	7.5	8.0	8.0
621310	Offices of Chiropractors	6.5	8.0	8.0
621320	Offices of Optometrists	6.5	8.0	8.0
621330	Offices of Mental Health Practitioners (except Physicians)	7.0	8.0	8.0
621340	Offices of Physical, Occupational and Speech Therapists, and Audiologists.	11.0	11.0	8.0
621391	Offices of Podiatrists	6.5	8.0	8.0
621399	Offices of All Other Miscellaneous Health Practitioners	9.0	9.0	8.0
621410	Family Planning Centers	16.5	16.5	12.0
621420	Outpatient Mental Health and Substance Abuse Centers	14.0	16.5	16.5
621491	HMO Medical Centers	39.0	39.0	35.0
621492	Kidney Dialysis Centers	41.5	41.5	41.5
621493	Freestanding Ambulatory Surgical and Emergency Centers	15.5	16.5	16.5
621498	All Other Outpatient Care Centers	22.5	22.5	22.0
621511	Medical Laboratories	36.5	36.5	35.0
621512	Diagnostic Imaging Centers	15.0	16.5	16.5
621610	Home Health Care Services	16.5	16.5	16.5
621910	Ambulance Services	20.0	20.0	16.5
621991	Blood and Organ Banks	34.5	35.0	35.0
621999	All Other Miscellaneous Ambulatory Health Care Services	18.0	18.0	16.5
622110	General Medical and Surgical Hospitals	30.0	41.5	41.5
622210	Psychiatric and Substance Abuse Hospitals	23.5	41.5	41.5
622310	Specialty (except Psychiatric and Substance Abuse) Hospitals	30.0	41.5	41.5
623110	Nursing Care Facilities (Skilled Nursing Facilities)	25.0	30.0	30.0
623210	Residential Intellectual and Developmental Disability Facilities	15.5	16.5	16.5
623220	Residential Mental Health and Substance Abuse Facilities	15.0	16.5	16.5
623311	Continuing Care Retirement Communities	22.5	30.0	30.0
623312	Assisted Living Facilities for the Elderly	20.5	20.5	12.0
623990	Other Residential Care Facilities	14.0	14.0	12.0
624110	Child and Youth Services	13.5	13.5	12.0
624120	Services for the Elderly and Persons with Disabilities	13.0	13.0	12.0
624190	Other Individual and Family Services	14.0	14.0	12.0
624210	Community Food Services	17.0	17.0	12.0
624221	Temporary Shelters	11.5	12.0	12.0
624229	Other Community Housing Services	16.5	16.5	16.5
624230	Emergency and Other Relief Services	36.5	36.5	35.0
624310	Vocational Rehabilitation Services	13.0	13.0	12.0
624410	Child Day Care Services	8.5	8.5	8.0
711110	Theater Companies and Dinner Theaters	20.0	22.0	22.0
711120	Dance Companies	16.0	16.0	12.0
711130	Musical Groups and Artists	13.0	13.0	12.0
711190	Other Performing Arts Companies	29.5	30.0	30.0
711211	Sports Teams and Clubs	29.5	41.5	41.5
711212	Racetracks	33.5	41.5	41.5
711219	Other Spectator Sports	14.5	14.5	12.0
711310	Promoters of Performing Arts, Sports, and Similar Events with Facilities.	23.5	35.0	35.0
711320	Promoters of Performing Arts, Sports, and Similar Events without Facilities.	19.5	19.5	16.5
711410	Agents and Managers for Artists, Athletes, Entertainers, and Other Public Figures.	15.5	15.5	12.0
711510	Independent Artists, Writers, and Performers	8.0	8.0	8.0
712110	Museums	25.5	30.0	30.0
712120	Historical Sites	11.5	11.5	8.0
712130	Zoos and Botanical Gardens	25.0	30.0	30.0
712190	Nature Parks and Other Similar Institutions	17.0	17.0	8.0
713110	Amusement and Theme Parks	41.5	41.5	41.5
713120	Amusement Arcades	8.0	8.0	8.0
713210	Casinos (except Casino Hotels)	25.0	30.0	30.0
713290	Other Gambling Industries	25.0	35.0	35.0
713910	Golf Courses and Country Clubs	11.0	16.5	16.5
713920	Skiing Facilities	31.0	31.0	30.0
713930	Marinas	9.5	9.5	8.0
713940	Fitness and Recreational Sports Centers	15.5	15.5	8.0
713950	Bowling Centers	11.0	11.0	8.0
713990	All Other Amusement and Recreation Industries	7.0	8.0	8.0
721110	Hotels (except Casino Hotels) and Motels	30.5	35.0	35.0
721120	Casino Hotels	31.0	35.0	35.0
721191	Bed-and-Breakfast Inns	6.5	8.0	8.0
721199	All Other Traveler Accommodation	8.0	8.0	8.0

TABLE 6—PROPOSED SIZE STANDARDS REVISIONS—Continued

NAICS code	NAICS industry title	Calculated size standard ($ million)	Proposed size standard ($ million)	Current size standard ($ million)
721211	RV (Recreational Vehicle) Parks and Campgrounds	9.0	9.0	8.0
721214	Recreational and Vacation Camps (except Campgrounds)	8.0	8.0	8.0
721310	Rooming and Boarding Houses, Dormitories, and Workers' Camps	12.5	12.5	8.0
722310	Food Service Contractors	38.0	41.5	41.5
722320	Caterers	6.5	8.0	8.0
722330	Mobile Food Services	6.5	8.0	8.0
722410	Drinking Places (Alcoholic Beverages)	6.5	8.0	8.0
722511	Full-Service Restaurants	10.0	10.0	8.0
722513	Limited-Service Restaurants	11.0	12.0	12.0
722514	Cafeterias, Grill Buffets, and Buffets	15.5	30.0	30.0
722515	Snack and Nonalcoholic Beverage Bars	20.0	20.0	8.0
811111	General Automotive Repair	8.0	8.0	8.0
811112	Automotive Exhaust System Repair	7.0	8.0	8.0
811113	Automotive Transmission Repair	6.5	8.0	8.0
811118	Other Automotive Mechanical and Electrical Repair and Maintenance.	7.5	8.0	8.0
811121	Automotive Body, Paint, and Interior Repair and Maintenance	7.0	8.0	8.0
811122	Automotive Glass Replacement Shops	15.5	15.5	12.0
811191	Automotive Oil Change and Lubrication Shops	9.5	9.5	8.0
811192	Car Washes	8.0	8.0	8.0
811198	All Other Automotive Repair and Maintenance	9.0	9.0	8.0
811211	Consumer Electronics Repair and Maintenance	22.5	22.5	8.0
811212	Computer and Office Machine Repair and Maintenance	17.5	30.0	30.0
811213	Communication Equipment Repair and Maintenance	19.5	19.5	12.0
811219	Other Electronic and Precision Equipment Repair and Maintenance	22.0	22.0	22.0
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance.	11.0	11.0	8.0
811411	Home and Garden Equipment Repair and Maintenance	7.0	8.0	8.0
811412	Appliance Repair and Maintenance	12.5	16.5	16.5
811420	Reupholstery and Furniture Repair	6.5	8.0	8.0
811430	Footwear and Leather Goods Repair	7.5	8.0	8.0
811490	Other Personal and Household Goods Repair and Maintenance	6.5	8.0	8.0
812111	Barber Shops	8.5	8.5	8.0
812112	Beauty Salons	8.5	8.5	8.0
812113	Nail Salons	6.5	8.0	8.0
812191	Diet and Weight Reducing Centers	24.0	24.0	22.0
812199	Other Personal Care Services	6.5	8.0	8.0
812210	Funeral Homes and Funeral Services	11.0	11.0	8.0
812220	Cemeteries and Crematories	18.5	22.0	22.0
812310	Coin-Operated Laundries and Drycleaners	11.5	11.5	8.0
812320	Drycleaning and Laundry Services (except Coin-Operated)	7.0	7.0	6.0
812331	Linen Supply	32.0	35.0	35.0
812332	Industrial Launderers	40.5	41.5	41.5
812910	Pet Care (except Veterinary) Services	6.5	8.0	8.0
812921	Photofinishing Laboratories (except One-Hour)	26.0	26.0	22.0
812922	One-Hour Photofinishing	16.0	16.5	16.5
812930	Parking Lots and Garages	25.5	41.5	41.5
812990	All Other Personal Services	13.0	13.0	8.0
813110	Religious Organizations	11.5	11.5	8.0
813211	Grantmaking Foundations	35.0	35.0	35.0
813212	Voluntary Health Organizations	27.0	30.0	30.0
813219	Other Grantmaking and Giving Services	22.5	41.5	41.5
813311	Human Rights Organizations	28.5	30.0	30.0
813312	Environment, Conservation and Wildlife Organizations	17.0	17.0	16.5
813319	Other Social Advocacy Organizations	16.0	16.0	8.0
813410	Civic and Social Organizations	8.5	8.5	8.0
813910	Business Associations	13.5	13.5	8.0
813920	Professional Organizations	20.5	20.5	16.5
813930	Labor Unions and Similar Labor Organizations	14.5	14.5	8.0
813940	Political Organizations	12.5	12.5	8.0
813990	Other Similar Organizations (except Business, Professional, Labor, and Political Organizations).	12.0	12.0	8.0

Table 7, Summary of Proposed Size Standards Revisions by Sector, below, summarizes the proposed changes to size standards by NAICS sector.

TABLE 7—SUMMARY OF PROPOSED SIZE STANDARDS REVISIONS BY SECTOR

NAICS sector	Sector name	Size standards increased	Size standards lowered	Size standards maintained
61	Education Services	14	0	4
62	Health Care and Social Assistance	18	0	21
71	Arts, Entertainment and Recreation	11	0	14
72	Accommodation and Food Services	4	0	11
81	Other Services	23	0	25
All Sectors		70	0	75

Evaluation of Dominance in Field of Operation

SBA has determined that for the industries which it has evaluated in this proposed rule, no individual firm at or below the proposed size standard would be large enough to dominate its field of operation. At the proposed size standards levels, if adopted, the small business share of total industry receipts among those industries would be, on average, 0.63%, varying from 0.003% to 22.3%. These market shares effectively preclude a firm at or below the proposed size standards from exerting control on any of the industries.

Alternatives Considered

By law, SBA is required to develop numerical size standards for establishing eligibility for Federal small business assistance programs and to review every 5 years all size standards and make necessary adjustments to reflect the current industry structure and Federal market conditions. Other than varying the levels of size standards by industry and changing the measures of size standards (*e.g.,* using annual receipts vs. the number of employees), no practical alternatives exist to the systems of numerical size standards.

The proposal is to increase size standards where the data suggested increases are warranted, and to retain, in response to COVID–19 emergency and resultant economic impacts on small businesses, all current size standards where the data suggested lowering is appropriate.

Nonetheless, SBA considered 2 other alternatives. Alternative option one was to propose changes exactly as suggested by the analytical results. Alternative option two was to retain all current size standards.

Alternative option one would cause a substantial number of currently small businesses to lose their small business status and hence to lose their access to Federal small business assistance, especially small business set-aside contracts and SBA's financial assistance in some cases.

During the first 5-year review of size standards, some commenters had expressed concerns about the SBA's policy of not lowering size standards based on the analytical results. In response to these comments, SBA considered as part of option one (*i.e.* to adopt changes exactly as suggested by the analytical results) to mitigate the impact of the decreases to size standards. The mitigation would provide additional adjustments to the calculated sizes after evaluation of the impact of the potential reductions on small business access to Federal contracting and loans. However, due to the global COVID–19 pandemic resulting in high levels of risk and dramatic reductions in economic activity of unprecedented nature, SBA is not considering any mitigation to decreases in size standards as part of option one. SBA will adopt this approach temporarily and may reevaluate this approach as the economic situation evolves. Under option two, given the current COVID–19 pandemic, SBA considered retaining the current level of all size standards even though the current analysis may suggest changing them. SBA considers that the option of retaining all size standards at this moment provides the opportunity to reassess the economic situation once the economic recovery starts. Under this option, as the current situation develops, SBA will be able to assess new data available on economic indicators, federal procurement, and SBA loans as well, before adopting changes to size standards. However, SBA is not adopting option two because the Regulatory Impact Analysis shows that retaining all size standards at their current levels is more onerous for the small businesses than the option of adopting 70 increases and retaining 75 size standards. SBA may reevaluate this approach as the current economic situation evolves.

Request for Comments

SBA invites public comments on this proposed rule, especially on the following issues:

1. SBA seeks feedback on whether SBA's proposal to increase 70 size standards and retain 75 size standards is appropriate given the results from the latest available industry and Federal contracting data of each industry and subindustry (exception) reviewed in this proposed rule, along with ongoing uncertainty and dramatic contraction in economic activity due to the global COVID–19 pandemic. SBA also seeks suggestions, along with supporting facts and analysis, for alternative size standards, if they would be more appropriate than the proposed size standards.

2. SBA also seeks comments on whether SBA should not lower any size standards in view of the COVID–19 pandemic and its adverse impacts on small businesses as well as on the overall economic situation when analytical results suggest some size standards could be lowered. SBA believes that lowering size standards under the current economic environment would run counter to what Congress and Federal Government are doing to aid and provide relief to the nation's small businesses impacted by the COVID–19 pandemic.

3. Given the uncertainty produced by the global COVID–19 pandemic and the economic consequences, SBA would like to receive comments from the public on the possibility of lowering size standards while mitigating the consequences of the lower standards, instead of not lowering any size standards.

4. In calculating the overall industry size standard, SBA has assigned equal weight to each of the 5 primary factors in all industries and subindustries covered by this proposed rule. SBA seeks feedback on whether it should assign equal weight to each factor or on whether it should give more weight to one or more factors for certain industries or subindustries. Recommendations to weigh some factors differently than others should include suggested weights for each factor along with supporting facts and analysis.

5. Finally, SBA seeks comments on data sources it used to examine industry and Federal market conditions, as well as suggestions on relevant alternative data sources that the Agency should evaluate in reviewing or modifying size standards for industries covered by this proposed rule.

Public comments on the above issues are very valuable to SBA for validating its proposed size standards revisions in this proposed rule. Commenters addressing size standards for a specific industry or a group of industries should include relevant data and/or other information supporting their comments. If comments relate to the application of size standards for Federal procurement programs, SBA suggests that commenters provide information on the size of contracts in their industries, the size of businesses that can undertake the contracts, start-up costs, equipment and other asset requirements, the amount of subcontracting, other direct and indirect costs associated with the contracts, the use of mandatory sources of supply for products and services, and the degree to which contractors can mark up those costs.

Compliance With Executive Orders 12866 and 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), Executive Orders 13563, 12988, and 13132, and the Paperwork Reduction Act (44 U.S.C. Ch. 35)

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this proposed rule is a significant regulatory action for purposes of Executive Order 12866. Accordingly, in the next section SBA provides a Regulatory Impact Analysis of this proposed rule, including: (1) A statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—both quantitative and qualitative—of the proposed action and the alternatives considered. However, this rule is not a ''major rule'' under the Congressional Review Act, 5 U.S.C. 800.

Regulatory Impact Analysis

1. What is a need for this regulatory action?

Under the Small Business Act (Act) (15 U.S.C. 632(a)), SBA's Administrator is responsible for establishing small business size definitions (or ''size standards'') and ensuring that such definitions vary from industry to industry to reflect differences among various industries. The Jobs Act requires SBA to review every 5 years all size standards and make necessary adjustments to reflect current industry and Federal market conditions. This proposed rule is part of the second 5-year review of size standards in accordance with the Jobs Act. The first 5-year review of size standards was completed in early 2016. Such periodic reviews of size standards provide SBA with an opportunity to incorporate ongoing changes to industry structure and Federal market environment into size standards and to evaluate the impacts of prior revisions to size standards on small businesses. This also provides SBA with an opportunity to seek and incorporate public input to the size standards review and analysis. SBA believes that proposed size standards revisions for industries being reviewed in this rule will make size standards more reflective of the current economic characteristics of businesses in those industries and the latest trends in Federal marketplace.

SBA's mission is to aid and assist small businesses through a variety of financial, procurement, business development and counseling, and disaster assistance programs. To determine the actual intended beneficiaries of these programs, SBA establishes numerical size standards by industry to identify businesses that are deemed small.

The proposed revisions to the existing size standards for 70 industries in NAICS Sectors 61, 62, 71, 72 and 81 are consistent with SBA's statutory mandates to help small businesses grow and create jobs and to review and adjust size standards every 5 years. This regulatory action promotes the Administration's goals and objectives as well as meets the SBA's statutory responsibility. One of SBA's goals in support of promoting the Administration's objectives is to help small businesses succeed through fair and equitable access to capital and credit, Federal Government contracts and purchases, and management and technical assistance. Reviewing and modifying size standards, when appropriate, ensures that intended beneficiaries are able to access Federal small business programs that are designed to assist them to become competitive and create jobs.

2. What are the potential benefits and costs of this regulatory action?

OMB directs agencies to establish an appropriate baseline to evaluate any benefits, costs, or transfer impacts of regulatory actions and alternative approaches considered. The baseline should represent the agency's best assessment of what the world would look like absent the regulatory action. For a new regulatory action promulgating modifications to an existing regulation (such as modifying the existing size standards), a baseline assuming no change to the regulation (*i.e.,* making no changes to current size standards) generally provides an appropriate benchmark for evaluating benefits, costs, or transfer impacts of proposed regulatory changes and their alternatives.

Proposed Changes to Size Standards

Based on the results from analyses of latest industry and Federal contracting data, as well as consideration of impact of size standards changes on small businesses and significant adverse impacts of the COVID–19 pandemic on small businesses and the overall economic activity, of the total of 145 industries in Sectors 61, 62, 71, 72 and 81 that have receipts-based size standards, SBA proposes to increase size standards for 70 industries, and maintain current size standards for the remaining 75 industries.

The Baseline

For purposes of this regulatory action, the baseline represents maintaining the ''status quo,'' *i.e.,* making no changes to the current size standards. Using the number of small businesses and levels of benefits (such as set-aside contracts, SBA's loans, disaster assistance, etc.) they receive under the current size standards as a baseline, one can examine the potential benefits, costs and transfer impacts of proposed changes to size standards on small businesses and on the overall economy.

Based on the 2012 Economic Census (the latest available), of a total of about 2.0 million businesses in industries in Sectors 61, 62, 71, 72, and 81, 98% are considered small under the current size standards. That percentage varies from 95.9% in Sector 61 to 98.8% in Sectors 72 and 81. Based on the data from FPDS–NG for fiscal years 2016–2018, about 26,174 unique firms in those industries received at least one Federal contract during that period, of which 78.2% were small under the current size standards. A total of $15.2 billion in average annual contract dollars were awarded to businesses in those industries during the period of evaluation, and 30.7% of the dollars awarded went to small businesses. For these sectors, providing contract dollars to small business through set-asides is quite important. From the total small business contract dollars awarded during the period considered, 65.0% were awarded through various small business set-aside programs and 35.0% were awarded through non-set aside

contracts. Based on the SBA's internal data on its loan programs for fiscal years 2016–2018, small businesses in those industries received, on an annual basis, a total of 25,070 7(a) and 504 loans in that period, totaling about $12.9 billion, of which 83.2% was issued through the 7(a) program and 16.8% was issued through the 504/CDC program. During fiscal years 2016–2018, small businesses in those industries also received 1,612 loans through the SBA's Economic Injury Disaster Loan (EIDL) program, totaling about $186 million on an annual basis. Table 8, Baseline for All Industries, below, provides these baseline results by sector.

TABLE 8—BASELINE FOR ALL INDUSTRIES

	Sector 61	Sector 62	Sector 71	Sector 72	Sector 81	Total
Baseline All Industries (current size standards)	18	39	25	15	48	145
Total firms (Economic Census)	84,084	653,143	114,926	496,856	667,318	2,016,327
Total small firms under current size standards (Economic Census)	80,620	632,077	112,612	490,773	659,559	1,975,640
Small firms as % of total firms	95.9	96.8	98.0	98.8	98.8	98.0
Total contract dollars ($ million) (FPDS–NG FY2016–2018)	$3,548.9	$8,474.5	$157.4	$785.2	$2,848.9	$15,814.9
Total small business contract dollars under current standards ($ million) (FPDS–NG FY2016–2018)	$1,257.0	$2,335.5	$114.7	$356.9	$784.6	$4,848.7
Small business dollars as % of total dollars (FPDS–NG FY2016–2018)	35.4	27.6	72.9	45.5	27.5	30.7
Total No. of unique firms getting contracts (FPDS–NG FY2016–2018)	4,425	6,853	1,128	3,733	10,786	26,174
Total No. of unique small firms getting small business contracts (FPDS–NG FY2016–2018)	3,514	5,758	1,023	3,088	7,476	20,475
Small business firms as % of total firms	79.4	84.0	90.7	82.7	69.3	78.2
No. of 7(a) and 504/CDC loans (FY2016–2018)	993	6,251	2,280	9,313	6,233	25,070
Amount of 7(a) and 504 loans ($ million) (FY2016–2018)	$371.8	$3,324.0	$1,104.6	$5,826.6	$2,301.6	$12,928.7
No. of EIDL loans (FY2016–2018)	68	376	140	382	646	1,612
Amount of EIDL loans ($ million) (FY2016–2018)	$6.1	$41.7	$17.8	$48.7	$72.0	$186.4

Increases to Size Standards

As stated above, of 145 receipts-based size standards in Sectors 61, 62, 71, 72 and 81 that are reviewed in this rule, based on the results from analyses of latest industry and Federal market data as well as impacts of size standards changes on small businesses, in this rule, SBA proposes to increase 70 size standards. Below are descriptions of the benefits, costs and transfer impacts of these proposed increases to size standards.

Benefits of Increases to Size Standards

The most significant benefit to businesses from proposed increases to size standards is gaining eligibility for Federal small business assistance programs or retaining that eligibility for a longer period. These include SBA's business loan programs, EIDL program, and Federal procurement programs intended for small businesses. Federal procurement programs provide targeted, set-aside opportunities for small businesses under the SBA's various business development and contracting programs. These include the 8(a)/BD (business development) Program, the Small Disadvantaged Businesses (SDB) Program, the Historically Underutilized Business Zones (HUBZone) Program, the Women-Owned Small Businesses (WOSB) Program, the Economically Disadvantaged Women-Owned Small Businesses (EDWOSB) Program, and the Service-Disabled Veteran-Owned Small Businesses (SDVOSB) Program.

Besides set-aside contracting and financial assistance discussed above, small businesses also benefit through reduced fees, less paperwork, and fewer compliance requirements that are available to small businesses through the Federal Government. However, SBA has no data to estimate the number of small businesses receiving such benefits.

Based on the 2012 Economic Census (latest available), SBA estimates that in 70 industries in NAICS Sectors 61, 62, 71, 72 and 81 for which it has proposed to increase size standards, more than 4,708 firms (see Table 9, below), not small under the current size standards, will become small under the proposed size standards increases and therefore become eligible for these programs. That represents about 0.4% of all firms classified as small under the current size standards in industries for which SBA has proposed increasing size standards. If adopted, proposed size standards would result in an increase to the small business share of total receipts in those industries from 37.4% to 38.5%.

With more businesses qualifying as small under the proposed increases to size standards, Federal agencies will have a larger pool of small businesses from which to draw for their small business procurement programs. Growing small businesses that are close to exceeding the current size standards will be able to retain their small business status for a longer period under the higher size standards, thereby enabling them to continue to benefit from the small business programs.

Based on the FPDS–NG data for fiscal years 2016–2018, SBA estimates that about 233 firms that are active in Federal contracting in those industries would gain small business status under the proposed size standards. Based on the same data, SBA estimates that those newly-qualified small businesses under the proposed increases to size standards, if adopted, could receive Federal small business contracts totaling about $47.0 million annually. That represents a 1.9% increase to small business dollars from the sector baseline.

The added competition from more businesses qualifying as small can result in lower prices to the Government for procurements set aside or reserved for small businesses, but SBA cannot quantify this impact. Costs could be higher when full and open contracts are awarded to HUBZone businesses that receive price evaluation preferences. However, with agencies likely setting aside more contracts for small businesses in response to the availability of a larger pool of small

businesses under the proposed increases to size standards, HUBZone firms might actually end up getting more set-aside contracts and fewer full and open contracts, thereby resulting in some cost savings to agencies. While SBA cannot estimate such costs savings as it is impossible to determine the number and value of unrestricted contracts to be otherwise awarded to HUBZone firms will be awarded as set-asides, such cost savings are likely to be relatively small as only a small fraction of full and open contracts are awarded to HUBZone businesses.

Under SBA's 7(a) and 504 loan programs, based on the data for fiscal years 2016–2018, SBA estimates up to about 54 of SBA's 7(a) and 504 loans totaling about $23.0 million could be made to these newly-qualified small businesses in those industries under the proposed size standards. That represents a 0.4% increase to the loan amount compared to the baseline for all industries covered by this proposed rule.

Newly-qualified small businesses will also benefit from the SBA's EIDL program. Since the benefit provided through this program is contingent on the occurrence and severity of a disaster in the future, SBA cannot make a meaningful estimate of this impact. However, based on the historical trends of the EIDL data, SBA estimates that, on an annual basis, the newly defined small businesses under the proposed increases to size standards, if adopted, could receive six (6) EIDL loans, totaling about $0.7 million. Additionally, the newly-defined small businesses would also benefit through reduced fees, less paperwork, and fewer compliance requirements that are available to small businesses through the Federal Government, but SBA has no data to quantify this impact. Table 9, Impacts of Proposed Increases to Size Standards, provides these results by NAICS sector.

TABLE 9—IMPACTS OF PROPOSED INCREASES TO SIZE STANDARDS

	Sector 61	Sector 62	Sector 71	Sector 72	Sector 81	Total
No. of industries with proposed increases to size standards	14	18	11	4	23	70
Total current small businesses in industries with Proposed increases to size standards (Economic Census 2012)	53,788	350,287	47,893	243,299	428,410	1,123,676
Additional firms qualifying as small under proposed standards (2012 Economic Census)	707.9	1464.4	264.9	599.3	1671.3	4,708
Percentage of additional firms qualifying as small relative to current small businesses in industries with proposed increases to size standards	1.32	0.42	0.55	0.25	0.39	0.42
No. of current unique small firms getting small business contracts in industries with proposed increases to size standards (FPDS–NG FY2016–2018) [1]	3,365	3,482	395	722	3,300	11,080
Additional small business firms getting small business status (FPDS–NG FY2016–2018)	33	30	8	1	168	233
% increase to small businesses relative to current unique small firms getting small business contracts in industries with proposed increases to size standards (FPDS–NG FY2016–2018) [1]	0.98	0.86	2.03	0.14	5.09	2.10
Total small business contract dollars under current standards in industries with proposed increases to size standards ($ million) (FPDS–NG FY2016–2018)	$1,091.7	$1,094.3	$26.6	$12.4	$233.0	$2,458.0
Estimated small business dollars available to newly-qualified small firms (Using avg dollars obligated to SBs) ($ million) FPDS–NG FY 2016–2018) [1]	$19.4	$14.8	$0.9	$0.0	$11.8	$47.0
% increase to small business dollars relative to total small business contract dollars under current standards in industries with proposed increases to size standards	1.78	1.35	3.28	0.31	5.08	1.91
Total no. of 7(a) and 504 loans to small business in industries with proposed increases to size standards (FY2016–2018)	565	3,209	1,502	4,437	2,856	12,569
Total amount of 7(a) and 504 loans to small businesses in industries with proposed increases to size standards ($ million) (FY2016–2018)	$208.0	$1,827.2	$652.6	$1,688.3	$943.1	$5,319.3
Estimated no. of 7(a) and 504 loans to newly-qualified small firms	8	14	9	11	12	54
Estimated 7(a) and 504 loan amount to newly-qualified small firms ($ million)	$2.9	$8.0	$3.9	$4.2	$4.0	$23.0
% increase to 7(a) and 504 loan amount relative to the total amount of 7(a) and 504 loans in industries with proposed increases to size standards	1.4%	0.4%	0.6%	0.2%	0.4%	0.4%
Total no. of EIDL loans to small businesses in industries with proposed increases to size standards (FY2016–2018)	49	213	51	197	423	933
Total amount of EIDL loans to small businesses in industries with proposed increases to size standards ($ million) (FY2016–2018)	$5.0	$20.8	$6.2	$23.8	$56.9	$112.7
Estimated no. of EIDL loans to newly-qualified small firms	1	1	1	1	2	6
Estimated EIDL loan amount to newly-qualified small firms ($ million)	$0.10	$0.10	$0.12	$0.12	$0.27	$0.71

TABLE 9—IMPACTS OF PROPOSED INCREASES TO SIZE STANDARDS—Continued

	Sector 61	Sector 62	Sector 71	Sector 72	Sector 81	Total
% increase to EIDL loan amount relative to the total amount of EIDL loans in industries with proposed increases to size standards	2.0%	0.5%	2.0%	0.5%	0.5%	0.6%

[1] Additional dollars are calculated multiplying average small business dollars obligated per DUNS times change in number of firms. Numbers of firms are calculated using the SBA current size standard, not the contracting officer's size designation.
[2] Total impact represents total unique number of firms impacted to avoid double counting as some firms are participating in more than one industry.

Costs of Increases to Size Standards

Besides having to register in SAM to be able to participate in Federal contracting and update the SAM profile annually,[2] small businesses incur no direct costs to gain or retain their small business status as a result of increases to size standards. All businesses willing to do business with Federal Government must register in SAM and update their SAM profiles annually, regardless of their size status. SBA believes that a vast majority of businesses that are willing to participate in Federal contracting are already registered in SAM and update their SAM profiles annually. More importantly, this proposed rule does not establish the new size standards for the very first time; rather it intends to modify the existing size standards in accordance with a statutory requirement and the latest data and other relevant factors.

To the extent that the newly-qualified small businesses could become active in Federal procurement, the proposed increases to size standards, if adopted, may entail some additional administrative costs to the Government as a result of more businesses qualifying as small for Federal small business programs. For example, there will be more firms seeking SBA's loans, more firms eligible for enrollment in the Dynamic Small Business Search (DSBS) database or in *certify.sba.gov,* more firms seeking certification as 8(a)/BD or HUBZone firms or qualifying for small business, SDB, WOSB, EDWOSB, and SDVOSB status, and more firms applying for SBA's 8(a)/BD and all small business mentor-protégé programs. With an expanded pool of small businesses, it is likely that Federal agencies would set aside more contracts for small businesses under the proposed increases to size standards. One may surmise that this might result in a higher number of small business size protests and additional processing costs to agencies. However, the SBA's historical data on size protests shows that the number of size protests decreased following the increases to receipts-based size standards as part of the first 5-year review of size standards. Specifically, on an annual basis, the number of size protests fell from about 600 during fiscal years 2011–2013 (review of most receipts-based size standards was completed by the end of FY 2013), as compared to about 500 during fiscal years 2014–2016 when size standards increases were in effect. That represents a 17% decline. Among those newly-defined small businesses seeking SBA's loans, there could be some additional costs associated with verification of their small business status. However, small business lenders have an option of using the tangible net worth and net income based alternative size standard instead of using the industry-based size standards to establish eligibility for SBA's loans. For these reasons, SBA believes that these added administrative costs will be minor because necessary mechanisms are already in place to handle these added requirements.

Additionally, some Federal contracts may possibly have higher costs. With a greater number of businesses defined as small due to the proposed increases to size standards, Federal agencies may choose to set aside more contracts for competition among small businesses only instead of using a full and open competition. The movement of contracts from unrestricted competition to small business set-aside contracts might result in competition among fewer total bidders, although there will be more small businesses eligible to submit offers under the proposed size standards. However, the additional costs associated with fewer bidders are expected to be minor since, by law, procurements may be set aside for small businesses under the 8(a)/BD, SDB, HUBZone, WOSB, EDWOSB, or SDVOSB programs only if awards are expected to be made at fair and reasonable prices.

Costs may also be higher when full and open contracts are awarded to HUBZone businesses that receive price evaluation preferences. However, with agencies likely setting aside more contracts for small businesses in response to the availability of a larger pool of small businesses under the proposed increases to size standards, HUBZone firms might actually end up getting fewer full and open contracts, thereby resulting in some cost savings to agencies. However, such cost savings are likely to be minimal as only a small fraction of unrestricted contracts are awarded to HUBZone businesses.

Transfer Impacts of Increases to Size Standards

The proposed increases to size standards, if adopted, may result in some redistribution of Federal contracts between the newly qualified small businesses and large businesses and between the newly-qualified small businesses and small businesses under the current standards. However, it would have no impact on the overall economic activity since total Federal contract dollars available for businesses to compete for will not change with changes to size standards. While SBA cannot quantify with certainty the actual outcome of the gains and losses from the redistribution of contracts among different groups of businesses, it can identify several probable impacts in qualitative terms. With the availability of a larger pool of small businesses under the proposed increases to size standards, some unrestricted Federal contracts which would otherwise be awarded to large businesses may be set aside for small businesses. As a result, large businesses may lose some Federal contracting opportunities. Similarly, some small businesses under the current size standards may obtain fewer set-aside contracts due to the increased competition from larger businesses qualifying as small under the proposed increases to size standards. This impact may be offset by a greater number of procurements being set aside for all small businesses. With larger businesses qualifying as small under the higher size standards, smaller small businesses could face some disadvantage in competing for set aside contracts against their larger counterparts. However, SBA cannot quantify these impacts.

[2] For a clarification of what the FAR's annual representation in SAM requirement is, see number 3 under the Initial Regulatory Flexibility Analysis section on page 92.

3. What alternatives have been considered?

Under OMB Circular A–4, SBA is required to consider regulatory alternatives to the proposed changes in the proposed rule. In this section, SBA describes and analyzes 2 such alternatives to the proposed rule. Alternative Option One to the proposed rule, a more stringent alternative to the proposed rule, would propose adopting size standards based solely on the analytical results. In other words, the size standards of 70 industries for which the analytical results suggest raising size standards would be raised. However, the size standards of 63 industries for which the analytical results suggest lowering size standards would be maintained. Alternative Option Two would propose retaining all size standards for all industries, given the uncertainty generated by the ongoing COVID–19 pandemic. Below, SBA discusses and presents the net impacts of each option.

Alternative Option One: Consider Adopting All Calculated Size Standards

As discussed elsewhere in this proposed rule, Alternative Option One would cause a substantial number of currently small businesses to lose their small business status and hence to lose their access to Federal small business assistance, especially small business set-aside contracts and SBA's financial assistance in some cases. SBA could adopt one or more of the following three actions with respect to adopting size standards for which the analytical results suggest a decrease is appropriate: (1) To accept decreases in size standards as suggested by the analytical results, (2) to decrease size standards by a smaller amount than the calculated threshold, and (3) to retain the size standards at their current levels. Actions 2 and 3 would mitigate the impacts of a decrease to size standards.

SBA has adopted action 3 in previous size reviews. For example, in response to the 2008 Financial Crisis and economic conditions that followed, SBA adopted a general policy in the first 5-year comprehensive size standards review to not lower any size standard (except to exclude one or more dominant firms) even when the analytical results suggested the size standard should be lowered. Currently, because of the economic challenges presented by the COVID–19 pandemic and the measures taken to protect public health, SBA has decided to adopt same general policy of not lowering size standards in the ongoing second 5-year comprehensive size standards review as well.

The primary benefit of adopting all changes in size standards as suggested by the analytical results is that SBA's procurement, management, technical and financial assistance resources would be targeted to the most appropriate beneficiaries of such programs according to the analytical results. Adopting the size standards suggested by the analytical results would also promote consistency with analytical results in SBA's exercise of its authority to determine size standards. SBA seeks public comment on the impact of adopting the size standard as suggested by the analytical results.

We have discussed already the benefits and costs of increasing 70 size standards. Below we discuss the benefits and costs of decreasing 63 size standards.

Benefits of Decreases to Size Standards

The most significant benefit to businesses from decreases to size standards when the SBA's analysis suggests such decreases is to ensure that size standards are more reflective of latest industry structure and Federal market trends and that Federal small business assistance is more effectively targeted to its intended beneficiaries. These include SBA's loan programs, EIDL program, and Federal procurement programs intended for small businesses. Federal procurement programs provide targeted, set-aside opportunities for small businesses under SBA's business development programs, such as small business, 8(a)/BD, SDB HUBZone, WOSB, EDWOSB, and SDVOSB programs. The adoption of smaller size standards when the results support them diminishes the risk of awarding contracts to firms which are not small anymore.

Decreasing size standards may reduce the administrative costs of the Government, because the risk of awarding contracts to other than small businesses may diminish when the size standards reflect better the structure of the market. The risks of providing SBA's loans to firms that are not needing them the most, or allowing firms that are not eligible for small business set-asides or to participate on the SBA procurement programs will provide for a better chance for smaller firms to grow and benefit from the opportunities available in the Federal market, and strengthen the small business industrial base for the Federal Government.

Costs of Decreases to Size Standards

With fewer businesses qualifying as small under the decreases to size standards, Federal agencies will have a smaller pool of small businesses from which to draw for their small business procurement programs. For example, in Option One, during fiscal years 2016–2018, agencies awarded, on an annual basis, about $2,004 million in small business contracts in those 63 industries for which this Option considered decreasing size standards. Table 10 below shows that lowering 63 size standards would reduce Federal contract dollars awarded to small businesses by $76.4 million or about 3.8% relative to the baseline level. Nevertheless, since Federal agencies are still required to meet the statutory small business contracting goal of 23%, actual impacts on the overall set aside activity is likely to be smaller as agencies are likely to award more set aside contracts to small businesses that continue to remain small under the reduced size standards.

With fewer businesses qualifying as small, the decreased competition can also result in higher prices to the Government for procurements set aside or reserved for small businesses, but SBA cannot quantify this impact. However, SBA estimates an almost null impact or non-significant reduction in dollars obligated to small businesses, if mitigation measures are adopted. Decreases to size standards would have a very minor impact on small businesses applying for SBA's 7(a) and 504 loans because a vast majority of such loans are issued to businesses that are far below the reduced size standards. For example, based on the loan data for fiscal years 2016–2018, Option One estimates that about 26 SBA's 7(a) and 504 loans with total amounts of $19.8 million could not be made to those small businesses that would lose eligibility under the reduced size standards (before mitigation). That represents about a 0.3% decrease of the loan amounts compared to the baseline. Table 10 Impacts of Decreases to Size Standards Under Alternative Option One, below, shows these results by sector. However, the actual impact could be much less as businesses losing small business eligibility under the decreases to industry-based size standards could still qualify for SBA's loans under the tangible net worth and net income-based alternative size standard.

Businesses losing small business status would also be impacted in terms of access to loans through the SBA's EIDL program. However, SBA expects such impact to be minimal as only a small number of businesses in those industries received such loans during fiscal years 2016–2018. Since this

program is contingent on the occurrence and severity of a disaster in the future, SBA cannot make a meaningful estimate of this impact.

Small businesses becoming other than small if size standards were decreased might lose benefits through reduced fees, less paperwork, and fewer compliance requirements that are available to small businesses through Federal Government, but SBA has no data to quantify this impact. However, if agencies determine that SBA's size standards do not adequately serve such purposes, they can establish a different size standard with an approval from SBA if they are required to use SBA's size standards for their programs.

TABLE 10—IMPACTS OF DECREASES TO SIZE STANDARDS UNDER ALTERNATIVE OPTION ONE

	Sector 61	Sector 62	Sector 71	Sector 72	Sector 81	Total
No. of industries for which SBA considered decreasing size standards (2012 Economic Census)	4	18	11	9	21	63
Total current small businesses in industries for which SBA considered decreasing size standards (EC 2012)	26,832	257,179	39,737	243,637	129,388	696,774
Estimated no. of firms losing small status for which SBA considered decreasing size standards (2012 Economic Census)	21	828	259	399	211	1,718
% of Firms losing small status relative to current small businesses in industries for which SBA considered decreasing size standards	0.08	0.32	0.65	0.16	0.16	0.25
No. of current unique small firms getting small business contracts in industries for which SBA considered decreasing size standards (FPDS–NG FY2016–2018) [1]	167	2,300	290	2,351	2,541	7,611
Estimated number of small business firms that would have lost small business status in the decreases that SBA considered	1	45	3	31	105	183
% decrease to small business firms relative to current unique small firms getting small business contracts in industries for which SBA considered decreasing size standards (FPDS–NG FY2016–2018) [1]	0.60	1.96	1.03	1.32	4.13	2.40
Total small business contract dollars under current size standards in industries for which SBA considered decreasing size standards ($ million) (FPDS–NG FY2016–2018)	$165.2	$1,190.7	$19.4	$343.5	$284.9	$2,003.8
Estimated small business dollars not available to firms losing small business status (Using avg dollars obligated to SBs) ($ million) [1] (FPDS–NG FY 2016–2018)	$0.1	$52.8	$0.2	$2.6	$20.8	$76.4
% decrease to small business dollars relative to total small business contract dollars under current size standards in industries for which SBA considered decreasing size standards	0.04	4.43	1.02	0.75	7.30	3.81
Total no. of 7(a) and 504 loans to small businesses in industries for which SBA considered decreasing size standards (FY2016–2018)	428	2,604	593	4,835	1,899	10,359
Total amount of 7(a) and 504 loans to small businesses in industries for which SBA considered decreasing size standards ($ million) (FY2016–2018)	$163.8	$1,317.2	$375.7	$4,119.1	$566.6	$6,542.3
Estimated no. of 7(a) and 504 loans not available to firms that would have lost small business status	1	9	4	8	4	26
Estimated 7(a) and 504 loan amount not available to firms that would have lost small status ($ million)	$0.4	$4.6	$6.8	$6.8	$1.2	$19.8
% decrease to 7(a) and 504 loan amount relative to the total amount of 7(a) and 504 loans in industries for which SBA considered decreasing size standards	0.2%	0.3%	1.8%	0.2%	0.2%	0.3%
Total no. of EIDL loans to small businesses in industries for which SBA considered decreasing size standards (FY2016–2018)	19	142	64	171	133	529
Total amount of EIDL loans to small businesses in industries for which SBA considered decreasing size standards ($ million) (FY2016–2018)	$1.1	$18.4	$10.3	$22.5	$8.9	$61.2
Estimated no. of EIDL loans not available to firms that would have lost small business status	1	1	1	1	1	5
Estimated EIDL loan amount not available to firms that would have lost small business status ($ million)	$0.06	$0.13	$0.16	$0.13	$0.07	$0.55
% decrease to EIDL loan amount relative to the baseline	5.3%	0.7%	1.6%	0.6%	0.8%	0.9%

[1] Additional dollars are calculated multiplying average small business dollars obligated per DUNS times change in number of firms.

[2] Total impact represents total unique industries impacted to avoid double counting as some industries have large firms gaining small business status and small firms extending small business status.

Transfer Impacts of Decreases to Size Standards

If the size standards were decreased under Alternative Option One, it may result in a redistribution of Federal contracts between small businesses losing the small business status and large businesses and between small businesses losing the small business status and small businesses remaining small under the reduced size standards. However, as under the proposed increases to size standards, it would have no impact on the overall economic activity since total Federal contract dollars available for businesses to compete for will stay the same. While SBA cannot estimate with certainty the actual outcome of the gains and losses among different groups of businesses from contract redistribution resulting from decreases to size standards, it can identify several probable impacts. With a smaller pool of small businesses under the decreases to size standards, some set-aside Federal contracts to be otherwise awarded to small businesses may be competed in unrestricted basis. As a result, large businesses may have more Federal contracting opportunities. However, because agencies are still required by law to award 23 percent of dollars to small businesses, SBA expects the movement of set-aside contracts to unrestricted competition to be limited. For the same reason, small businesses remaining small under the reduced size standards are likely to obtain more set aside contracts due to the reduced competition from fewer businesses qualifying as small under the decreases to size standards. With some larger small businesses losing small business status under the decreases to size standards, smaller small businesses would likely become more competitive in obtaining set aside contracts. However, SBA cannot quantify these impacts.

Net Impact of Alternative Option One

To estimate the net impacts of Alternative Option One, SBA followed the same methodology used to evaluate the impacts of the proposed size standards (see Table 9 above). However, under Alternative Option One, SBA used the calculated size standards instead of the proposed ones to determine the impacts of changes to current thresholds. The impact of the increases of the calculated size standards were already shown in Table 9 above. Table 10 (above) and Table 11, Net Impacts of Size Standards Changes under Alternative Option One, below, present the impact of the decreases of size standards and the net impact of adopting the calculated results under Alternative Option One, respectively.

Based on the 2012 Economic Census, SBA estimates that in 132 industries in NAICS Sectors 61, 62, 71, 72 and 81 for which the analytical results suggested to change size standards, about 2,990 firms (see Table 11, below), would become small under the Option One. That represents about 0.2 percent of all firms classified as small under the current size standards.

Based on the FPDS–NG data for fiscal years 2016–2018, SBA estimates that about 38 active firms in Federal contracting in those industries would gain small business status under Option One. This represents an increase of about 0.2% of the total number of small businesses participating in Federal contracting under the current size standards. Based on the same data, SBA estimates that about $29.5 million of Federal procurement dollars would not be available to firms losing their small status. This represents a decrease of 0.7% from the baseline for all industries covered by this proposed rule.

Based on the SBA's loan data for fiscal years 2016–2018, the total number of 7(a) and 504 loans may experience an overall increase by about 28 loans, and the loan amounts by about $3.2 million. This represents a 0.02% increase in the loan amounts relative to the baseline for all industries covered by this proposed rule.

Firms' participation under the SBA's EIDL program will be affected as well. Since the benefit provided through this program is contingent on the occurrence and severity of a disaster in the future, SBA cannot make a meaningful estimate of this impact. However, based on the historical trends of the EIDL data, SBA estimates that, on an annual basis, the net impact of the Option One is 1 additional loan, and an additional loan amount of about $0.16 million relative to the baseline for all industries covered by this proposed rule. Table 11, below, provides these results by NAICS sector.

TABLE 11—NET IMPACTS OF SIZE STANDARDS CHANGES UNDER ALTERNATIVE OPTION ONE

	Sector 61	Sector 62	Sector 71	Sector 72	Sector 81	Total
No. of industries with proposed changes to size standards	17	36	22	13	44	132
Total no. of small business under the current size standards (2012 Economic Census)	80,620	607,466	87,630	486,936	557,798	1,820,450
Additional firms qualifying as small under proposed size standards (2012 Economic Census)	687	636	6	200	1,460	2,990
% of additional firms qualifying as small relative to total current small businesses	0.85	0.10	0.01	0.04	0.26	0.16
No. of current unique small firms getting small business contracts (FPDS–NG FY2016–2018) [1]	3,514	5,566	672	3,069	5,672	18,184
Additional small firms getting small business status (FPDS–NG FY2016–2018)	32	−14	5	−30	50	38
% increase to small firms relative to current unique small firms getting small business contracts (FPDS–NG FY2016–2018) [1]	0.91	−0.25	0.74	−0.98	0.88	0.21
Total small business small business contract dollars under current size standards ($ million) (FPDS–NG FY2016–2018)	$1,257.0	$2,285.1	$46.1	$355.9	$517.9	$4,461.8
Estimated small business dollars available to newly-qualified small firms ($ million) (FPDS–NG FY 2016–2018) [1]	$19.3	−$38.0	$0.7	−$2.6	−$9.0	−$29.5
% increase to dollars relative to total small business contract dollars under current size standards	1.54	−1.66	1.47	−0.72	−1.73	−0.66
Total no. of 7(a) and 504 loans to small businesses (FY2016–2018)	993	6,251	2,280	9,313	6,233	25,070

TABLE 11—NET IMPACTS OF SIZE STANDARDS CHANGES UNDER ALTERNATIVE OPTION ONE—Continued

	Sector 61	Sector 62	Sector 71	Sector 72	Sector 81	Total
Total amount of 7(a) and 504 loans to small businesses (FY2016–2018)	$371.8	$3,324.0	$1,104.6	$5,826.6	$2,301.6	$12,928.7
Estimated no. of additional 7(a) and 504 loans to newly-qualified small firms	7	5	5	3	8	28
Estimated additional 7(a) and 504 loan amount to newly-qualified small firms ($ million)	$2.6	$3.4	−$2.9	−$2.6	$2.8	$3.2
% increase to 7(a)and 504 loan amount relative to the total amount of 7(a) and 504 loans to small businesses	0.7%	0.1%	−0.3%	0.0%	0.1%	0.02%
Total no. of EIDL loans to small businesses (FY2016–2018)	68	376	140	382	646	1,612
Total amount of EIDL loans to small businesses (FY2016–2018)	$6.1	$41.7	$17.8	$48.7	$72.0	$186.4
Estimated no. of additional EIDL loans to newly-qualified small firms	0	0	0	0	1	1
Estimated additional EIDL loan amount to newly-qualified small firms ($ million)	$0.04	-$0.03	-$0.04	-$0.01	$0.20	$0.16
% increase to EIDL loan amount relative to the total amount of EIDL loans to small businesses	0.7%	-0.1%	-0.2%	0.0%	0.3%	0.1%

[1] Additional dollars are calculated multiplying average small business dollars obligated per DUNS times change in number of firms.
[2] Total impact represents total unique industries impacted to avoid double counting as some industries have large firms gaining small business status and small firms extending small business status.

Alternative Option Two: To Retain All Current Size Standards

Under this option, given the current COVID–19 pandemic, as discussed elsewhere, SBA considered retaining the current levels of all size standards even though the analytical results may suggest changing them. SBA considers that the option of retaining all size standards at this moment provides the opportunity to reassess the economic situation once the economic recovery starts. Under this option, as the current situation develops, SBA will be able to assess new data available on economic indicators, federal procurement, and SBA loans as well. SBA estimates a net impact of zero for this option, when compared to the baseline. However, if we compare the proposal of increasing 70 size standards and retaining 75 with this alternative approach, the benefits for small businesses of adopting the proposal will not be attained, because of which SBA is not proposing the Alternative Option Two.

Executive Order 13771

SBA has determined, subject to the approval of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB), that this proposed rule is not subject to the requirements of Executive Order 13771, because most of the rule's impacts are income transfers between small and other than small businesses. According to the Executive Order 13771 guidance in OMB M–17–21, dated April 5, 2017 (E.O. 13771 Guidance), ''transfers'' are not covered by Executive Order 13771. The E.O. 13771 Guidance also states that ''in some cases, [transfer rules] may impose requirements apart from transfers, or transfers may distort markets causing inefficiencies. In those cases, the actions would need to be offset to the extent they impose more than de minimis costs.'' SBA estimates that this rulemaking would impose only de minimis costs on small businesses and would result in negligible compliance costs. Thus, SBA has determined that this rulemaking is exempt from the requirements of Executive Order 13771. Details on the estimated costs of this proposed rule can be found in the Regulatory Impact Analysis above.

Regulatory Flexibility Act

According to the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, when an agency issues a rulemaking, it must prepare a regulatory flexibility analysis to address the impact of the rule on small entities.

This proposed rule, if adopted, may have a significant impact on a substantial number of small businesses in the industries covered by this proposed rule. As described above, this rule may affect small businesses seeking Federal contracts, loans under SBA's 7(a), 504 and Economic Injury Disaster Loan Programs, and assistance under other Federal small business programs.

Initial Regulatory Flexibility Analysis

Immediately below, SBA sets forth an initial regulatory flexibility analysis (IRFA) of this proposed rule addressing the following questions: (1) What are the need for and objective of the rule?; (2) What are SBA's description and estimate of the number of small businesses to which the rule will apply?; (3) What are the projected reporting, record keeping, and other compliance requirements of the rule?; (4) What are the relevant Federal rules that may duplicate, overlap, or conflict with the rule?; and (5) What alternatives will allow the Agency to accomplish its regulatory objectives while minimizing the impact on small businesses?

1. What are the need for and objective of the rule?

Changes in industry structure, technological changes, productivity growth, mergers and acquisitions, and updated industry definitions have changed the structure of many the industries covered by this proposed rule. Such changes can be enough to support revisions to current size standards for some industries. Based on the analysis of the latest data available, SBA believes that the revised standards in this proposed rule more appropriately reflect the size of businesses that need Federal assistance. The 2010 Jobs Act also requires SBA to review all size standards and make necessary adjustments to reflect market conditions.

2. What are SBA's description and estimate of the number of small businesses to which the rule will apply?

Based on data from the 2012 Economic Census, SBA estimates that there are about 1.1 million small firms covered by this rulemaking under industries with proposed changes to size standards. If the proposed rule is adopted in its present form, SBA

estimates that an additional 4,708 businesses will become small.

3.What are the projected reporting, record keeping and other compliance requirements of the rule?

The proposed size standard changes impose no additional reporting or record keeping requirements on small businesses. However, qualifying for Federal procurement and a number of other programs requires that businesses register in SAM and self-certify that they are small in that system frequently enough to ensure that their SAM registration is current, accurate, and complete with the submission of an offer for every new contract (FAR 52.204–7 and 52.204–8). For existing contracts, small business contractors are generally required to update their SAM registration at least annually (FAR 52.204–13). Therefore, businesses opting to participate in those programs must comply with SAM requirements. There are no costs associated with SAM registration or certification. Changing size standards alters the access to SBA's programs that assist small businesses but does not impose a regulatory burden because they neither regulate nor control business behavior.

4. What are the relevant Federal rules, which may duplicate, overlap or conflict with the rule?

Under section 3(a)(2)(C) of the Small Business Act, 15 U.S.C. 632(a)(2)(c), Federal agencies must use SBA's size standards to define a small business, unless specifically authorized by statute to do otherwise. In 1995, SBA published in the **Federal Register** a list of statutory and regulatory size standards that identified the application of SBA's size standards as well as other size standards used by Federal agencies (60 FR 57988 (November 24, 1995)). SBA is not aware of any Federal rule that would duplicate or conflict with establishing size standards.

However, the Small Business Act and SBA's regulations allow Federal agencies to develop different size standards if they believe that SBA's size standards are not appropriate for their programs, with the approval of SBA's Administrator (13 CFR 121.903). The Regulatory Flexibility Act authorizes an Agency to establish an alternative small business definition, after consultation with the Office of Advocacy of the U.S. Small Business Administration (5 U.S.C. 601(3)).

5. What alternatives will allow the Agency to accomplish its regulatory objectives while minimizing the impact on small entities?

By law, SBA is required to develop numerical size standards for establishing eligibility for Federal small business assistance programs. Other than varying size standards by industry and changing the size measures, no practical alternative exists to the systems of numerical size standards.

However, SBA considered two alternatives to its proposal to increase 70 size standards and maintain 75 size standards at their current levels. The first alternative SBA considered was adopting size standards based solely on the analytical results. In other words, the size standards of 70 industries for which the analytical results suggest raising size standards would be raised. However, the size standards of 63 industries for which the analytical results suggest lowering size standards would be lowered. This would cause a significant number of small businesses to lose their small business status. Under the second alternative, in view of the COVID–19 pandemic, SBA considered retaining all size standards at the current levels, even though the analytical results may suggest increasing 70 and decreasing 63 size standards. Retaining all size standards at their current levels would be more onerous for the small businesses than the option of adopting 70 increases and retaining the rest of size standards.

Executive Order 13563

Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. A description of the need for this regulatory action and benefits and costs associated with this action including possible distributional impacts that relate to Executive Order 13563 is included above in the Regulatory Impact Analysis under Executive Order 12866. Additionally, Executive Order 13563, section 6, calls for retrospective analyses of existing rules.

The review of size standards in the industries covered by this proposed rule is consistent with section 6 of Executive Order 13563 and the 2010 Jobs Act which requires SBA to review all size standards and make necessary adjustments to reflect market conditions. Specifically, the 2010 Jobs Act requires SBA to review at least one-third of all size standards during every 18-month period from the date of its enactment (September 27, 2010) and to review all size standards not less frequently than once every 5 years, thereafter. SBA had already launched a comprehensive review of size standards in 2007. In accordance with the Jobs Act, SBA completed the comprehensive review of the small business size standard for each industry, except those for agricultural enterprises previously set by Congress, and made appropriate adjustments to size standards for a number of industries to reflect current Federal and industry market conditions. The first comprehensive review was completed in 2015. Prior to 2007, the last time SBA conducted a comprehensive review of all size standards was during the late 1970s and early 1980s.

SBA issued a White Paper entitled ''Size Standards Methodology'' and published a notice in the April 11, 2019, edition of the **Federal Register** (84 FR 14587) to advise the public that the document is available for public review and comments. The ''Size Standards Methodology'' White Paper explains how SBA establishes, reviews, and modifies its receipts-based and employee-based small business size standards. SBA gave appropriate consideration to all input, suggestions, recommendations, and relevant information obtained from industry groups, individual businesses, and Federal agencies in developing size standards for those industries covered by this proposed rule.

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Executive Order 13132

For purposes of Executive Order 13132, SBA has determined that this proposed rule will not have substantial, direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, SBA has determined that this proposed rule has no federalism implications warranting preparation of a federalism assessment.

Paperwork Reduction Act

For the purpose of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA has determined that this rule will not impose any new reporting or record keeping requirements.

List of Subjects in 13 CFR Part 121

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

For the reasons set forth in the preamble, SBA proposes to amend 13 CFR part 121 as follows:

PART 121—SMALL BUSINESS SIZE REGULATIONS

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

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

■ 2. In § 121.201, amend the table ''Small Business Size Standards by NAICS Industry'' by revising entries ''611110'', ''611210'', ''611310'', ''611410'', ''611420'', ''611430'', ''611511'', ''611513'', ''611519'', ''611630'', ''611691'', ''611692'', ''611699'', ''611710'', ''621111'', ''621340'', ''621399'', ''621410'', ''621491'', ''621498'', ''621511'', ''621910'', ''621999'', ''623312'', ''623990'', ''624110'', ''624120'', ''624190'', ''624210'', ''624230'', ''624310'', ''624410'', ''711120'', ''711130'', ''711219'', ''711320'', ''711410'', ''712120'', ''712190'', ''713920'', ''713930'', ''713940'', ''713950'', ''721211'', ''721310'', ''722511'', ''722515'', ''811122'', ''811191'', ''811198'', ''811211'', ''811213'', ''811310'', ''812111'', ''812112'', ''812191'', ''812210'', ''812310'', ''812320'', ''812921'', ''812990'', ''813110'', ''813312'', ''813319'', ''813410'', ''813910'', ''813920'', ''813930'', ''813940'', and ''813990'' to read as follows:

§ 121.201 What size standards has SBA identified by North American Industry Classification System codes?

* * * * *

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
*	* * * * *	*	*
	Sector 61—Educational Services **Subsector 611—Educational Services**		
611110	Elementary and Secondary Schools	$17.5	
611210	Junior Colleges	28.5	
611310	Colleges, Universities and Professional Schools	30.5	
611410	Business and Secretarial Schools	18.0	
611420	Computer Training	14.0	
611430	Professional and Management Development Training	13.0	
611511	Cosmetology and Barber Schools	11.5	
*	* * * * *	*	*
611513	Apprenticeship Training	10.0	
611519	Other Technical and Trade Schools	18.5	
Except	Job Corps Centers[16]	[16] 41.5	
*	* * * * *	*	*
611630	Language Schools	18.0	
611691	Exam Preparation and Tutoring	11.0	
611692	Automobile Driving Schools	9.0	
611699	All Other Miscellaneous Schools and Instruction	14.5	
611710	Educational Support Services	$21.0	
	Sector 62—Health Care and Social Assistance **Subsector 621—Ambulatory Health Care Services**		
621111	Offices of Physicians (except Mental Health Specialists)	14.0	
*	* * * * *	*	*
621340	Offices of Physical, Occupational and Speech Therapists and Audiologists	11.0	
*	* * * * *	*	*
621399	Offices of All Other Miscellaneous Health Practitioners	9.0	
621410	Family Planning Centers	16.5	
*	* * * * *	*	*
621491	HMO Medical Centers	39.0	
*	* * * * *	*	*
621498	All Other Outpatient Care Centers	22.5	
621511	Medical Laboratories	$36.5	
*	* * * * *	*	*
621910	Ambulance Services	20.0	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
*	* * * * * *		*
621999	All Other Miscellaneous Ambulatory Health Care Services	18.0	
*	* * * * * *		*
	Subsector 623—Nursing and Residential Care Facilities		
*	* * * * * *		*
623312	Assisted Living Facilities for the Elderly	20.5	
623990	Other Residential Care Facilities	14.0	
	Subsector 624—Social Assistance		
624110	Child and Youth Services	13.5	
624120	Services for the Elderly and Persons with Disabilities	13.0	
624190	Other Individual and Family Services	14.0	
624210	Community Food Services	17.0	
*	* * * * * *		*
624230	Emergency and Other Relief Services	36.5	
624310	Vocational Rehabilitation Services	13.0	
624410	Child Day Care Services	8.5	
	Sector 71—Arts, Entertainment and Recreation **Subsector 711—Performing Arts, Spectator Sports and Related Industries**		
*	* * * * * *		*
711120	Dance Companies	16.0	
711130	Musical Groups and Artists	13.0	
*	* * * * * *		*
711219	Other Spectator Sports	14.5	
*	* * * * * *		*
711320	Promoters of Performing Arts, Sports and Similar Events without Facilities	19.5	
711410	Agents and Managers for Artists, Athletes, Entertainers and Other Public Figures	$15.5	
*	* * * * * *		*
	Subsector 712—Museums, Historical Sites and Similar Institutions		
*	* * * * * *		*
712120	Historical Sites	11.5	
*	* * * * * *		*
712190	Nature Parks and Other Similar Institutions	17.0	
	Subsector 713—Amusement, Gambling and Recreation Industries		
*	* * * * * *		*
713920	Skiing Facilities	31.0	
713930	Marinas	9.5	
713940	Fitness and Recreational Sports Centers	15.5	
713950	Bowling Centers	11.0	
*	* * * * * *		*
	Sector 72—Accommodation and Food Services **Subsector 721—Accommodation**		
*	* * * * * *		*
721211	RV (Recreational Vehicle) Parks and Campgrounds	9.0	

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NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
*	* * * * * *		*
721310	Rooming and Boarding Houses, Dormitories, and Workers' Camps	12.5	
	Subsector 722—Food Services and Drinking Places		
*	* * * * * *		*
722511	Full-Service Restaurants	10.0	
*	* * * * * *		*
722515	Snack and Nonalcoholic Beverage Bars	20.0	
	Sector 81—Other Services **Subsector 811—Repair and Maintenance**		
*	* * * * * *		*
811122	Automotive Glass Replacement Shops	15.5	
811191	Automotive Oil Change and Lubrication Shops	9.5	
*	* * * * * *		*
811198	All Other Automotive Repair and Maintenance	9.0	
811211	Consumer Electronics Repair and Maintenance	22.5	
*	* * * * * *		*
811213	Communication Equipment Repair and Maintenance	19.5	
*	* * * * * *		*
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance.	11.0	
*	* * * * * *		*
	Subsector 812—Personal and Laundry Services		
812111	Barber Shops	8.5	
812112	Beauty Salons	8.5	
*	* * * * * *		*
812191	Diet and Weight Reducing Centers	24.0	
*	* * * * * *		*
812210	Funeral Homes and Funeral Services	11.0	
*	* * * * * *		*
812310	Coin-Operated Laundries and Drycleaners	11.5	
812320	Dry cleaning and Laundry Services (except Coin-Operated)	7.0	
*	* * * * * *		*
812921	Photofinishing Laboratories (except One-Hour)	26.0	
*	* * * * * *		*
812990	All Other Personal Services	13.0	
	Subsector 813—Religious, Grantmaking, Civic, Professional and Similar Organizations		
813110	Religious Organizations	11.5	
*	* * * * * *		*
813312	Environment, Conservation and Wildlife Organizations	17.0	
813319	Other Social Advocacy Organizations	16.0	
813410	Civic and Social Organizations	8.5	
813910	Business Associations	13.5	
813920	Professional Organizations	20.5	
813930	Labor Unions and Similar Labor Organizations	14.5	
813940	Political Organizations	12.5	
813990	Other Similar Organizations (except Business, Professional, Labor, and Political Organizations).	12.0	

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY—Continued

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
*	* * * * *	*	*

Footnotes

16. NAICS code 611519—Job Corps Centers. For classifying a Federal procurement, the purpose of the solicitation must be for the management and operation of a U.S. Department of Labor Job Corps Center. The activities involved include admissions activities, life skills training, educational activities, comprehensive career preparation activities, career development activities, career transition activities, as well as the management and support functions and services needed to operate and maintain the facility. For SBA assistance as a small business concern, other than for Federal Government procurements, a concern must be primarily engaged in providing the services to operate and maintain Federal Job Corps Centers.

* * * * *

Jovita Carranza,

Administrator.

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