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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0271; Product Identifier 2017–SW–017–AD; Amendment 39–21259; AD 2020–20–03]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Helicopters Model AS350B2 helicopters. This AD requires performing a test of the main rotor RPM (NR) indicator, and depending on the results, altering the wiring. This AD was prompted by reports of some NR indicators displaying incorrect information. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD is effective November 3, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of November 3, 2020.

ADDRESSES: For service information identified in this final rule, 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 the 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–2020–0271.

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–2020–0271; 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 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: George Schwab, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *george.schwab@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Airbus Helicopters Model AS350B2 helicopters with a certain part-numbered NR sensor installed. The NPRM published in the **Federal Register** on March 23, 2020 (85 FR 16279). The NPRM proposed to require compliance with certain procedures described in the manufacturer's service bulletins. For Model AS350B2 helicopters with an NR sensor part number 704A37614007 installed, the NPRM proposed to require, before further flight, performing a test to determine if the NR indicator display changes or drops to zero when the emergency cut-out control is activated. If the NR display changes or drops to zero during the ground run, the NPRM proposed to require, before further flight, altering the NR sensor wiring.

The NPRM was prompted by EASA AD No. 2016–0260, dated December 21, 2016, 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 AS350B2 helicopters with a certain part-numbered NR sensor installed. EASA advises of several occurrences where the NR indicator has displayed incorrect data. According to EASA, an investigation determined that whenever the emergency cut-out control was activated, such as during a practice autorotation, electrical power to the NR indicator was lost. The EASA AD states that this condition, if not detected and corrected, could result in a significant increase in pilot workload, disruption of the autorotation training, and subsequent reduced control of the helicopter. To address this unsafe condition, the EASA AD requires a functional check of the NR indicator display, and, if required, altering the wiring to ensure a dual power supply to the NR indicator.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received one comment in support of the NPRM.

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 information provided by EASA and determining the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Differences Between This AD and the EASA AD

The EASA AD requires compliance within 75 flight hours, within 90 days, or before the next autorotation training flight, whichever occurs first. This AD requires compliance before further flight due to the critical nature of NR information for the pilot during an autorotation.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Airbus Helicopters Alert Service Bulletin No. AS350–63.00.27, Revision 0, dated May 17, 2016. This service information contains procedures for performing a functional check of the NR indicator, and, if necessary, altering the wiring to add a direct battery supply to the NR

indicator. Airbus Helicopters identifies this alteration as Modification 350A084886.00.

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

Costs of Compliance

The FAA estimates that this AD affects 352 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.

Performing a functional test of the NR indicator takes about 0.5 work-hours for an estimated cost of $43 per helicopter and $15,136 for the U.S. fleet.

If required, altering the NR sensor wiring takes about 2 work-hours, and parts cost about $154, for an estimated cost of $324 per helicopter.

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 helicopters 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 (AD):

2020–20–03 Airbus Helicopters: Amendment 39–21259; Docket No. FAA–2020–0271; Product Identifier 2017–SW–017–AD.

(a) Applicability

This AD applies to Airbus Helicopters Model AS350B2 helicopters, certificated in any category, with a main rotor RPM (NR) sensor part number 704A37614007 installed.

(b) Unsafe Condition

This AD defines the unsafe condition as loss of electrical power to the NR indicator when the emergency cutout control is activated. This condition could result in increased pilot workload and reduced helicopter control.

(c) Effective Date

This AD becomes effective November 3, 2020.

(d) 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.

(e) Required Actions

Before further flight, perform a ground run-up with the fuel flow control lever in the flight gate with the collective control in the down/locked position. While at flight NR speed, activate the emergency cut-out control and observe the NR indicator display value. If the NR indicator display changes or drops to zero, before further flight, do the following:

(1) Alter the NR indicator wiring as depicted in Figures 1 and 2 of Airbus Helicopters Alert Service Bulletin No. AS350–63.00.27, Revision 0, dated May 17, 2016; and,

Note 1 to paragraph (e)(1): Airbus Helicopters identifies the alteration of the wiring as Modification 350A084886.00.

(2) Conduct a continuity test to confirm correct alteration of the wiring.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: George Schwab, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, 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.

(g) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD No. 2016–0260, dated December 21, 2016. You may view the EASA AD on the internet at *https://www.regulations.gov* in Docket No. FAA–2020–0271.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6340, Main Rotor Drive Indicating System.

(i) Material Incorporated by Reference

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

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

(i) Airbus Helicopters Alert Service Bulletin No. AS350–63.00.27, Revision 0, dated May 17, 2016.

(ii) [Reserved]

(3) 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.*

(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 September 18, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21415 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0320; Project Identifier 2019–CE–011–AD; Amendment 39–21248; AD 2020–19–06]

RIN 2120–AA64

Airworthiness Directives; McCauley Propeller Systems

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain model McCauley Propeller Systems (McCauley) governors installed on airplanes. This AD was prompted by reports of an unapproved variant McCauley idler gear bearing, part number (P/N) A–20028, that could be installed in the affected governors. This AD requires replacing the governor with a governor that is eligible for installation. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 3, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 3, 2020.

ADDRESSES: For service information identified in this final rule, contact McCauley Propeller Systems, One Cessna Boulevard, P.O. Box 7704, Wichita, Kansas 67277; telephone: (800) 621–7767 or (316) 831–4021; email: *productsupport@txtav.com;* internet: *https://mccauley.txtav.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0320.

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–2020–0320; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations 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: Thomas Teplik, Aerospace Engineer, Wichita ACO Branch, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: (316) 946–4196; fax: (316) 946–4107; email: *thomas.teplik@faa.gov* or *Wichita-COS@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain model McCauley Propeller Systems (McCauley) governors installed on airplanes. The NPRM published in the **Federal Register** on April 7, 2020 (85 FR 19399). The NPRM was prompted by reports from McCauley that an unapproved variant idler gear bearing, P/N A–20028, was installed on certain governors during production between January 31, 2017, and September 27, 2018, and may have been installed on governors in service after January 31, 2017. The unapproved variant of the idler gear bearing does not conform to McCauley drawing requirements.

All models of McCauley governors have an idler gear bearing with P/N A–20028 installed; however, the unapproved variant of the bearing can be identified by part marking ''BA 59.'' The non-conforming idler gear bearing could have also been included in the idler gear assembly (idler gear and bearing), P/N A–20107, or the governor overhaul kit, P/N PL–20233 or PL–20234.

The non-conformity of the bearing may cause premature failure of the idler gear bearing. Early symptoms that the idler gear bearing may fail include inability of the governor to hold the selected RPM, hunting, surging, etc. An investigation identified 23 occurrences of airplane operation problems related to erratic governor behavior that may have resulted from the unapproved idler gear bearing.

The NPRM proposed to require replacing an affected governor with a governor eligible for installation. The FAA is issuing this AD to prevent failure of the idler gear bearing, which could result in failure of the governor, loss of propeller pitch control, engine and propeller over speed, engine oil contamination, and loss of airplane control.

Comments

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

Supportive Comments

The Civil Aviation Safety Authority (CASA) of Australia, David Paynter, and Chartair Pty Ltd supported the NPRM.

Request To Clarify the Applicability

CASA, David Paynter, and Chartair Pty Ltd requested the FAA clarify the applicability with respect to the idle gearing bearings affected by the unsafe condition.

CASA advised of similar incidents of premature failure in idler gear bearings identified by part marking ''SCE 59'' and asked whether the FAA has determined that the unsafe condition exists or can develop in idler gear bearings other than those identified with ''BA 59.'' David Paynter expressed concern with governors that have ''SCE 59'' bearings or bearings with ''BA 59'' that do not have any country of origin stamped on them. Chartair Pty Ltd stated it has experienced bearing failures outside of the range identified in the NPRM. David Paynter and Chartair Pty Ltd requested the FAA change the AD to include these additional bearings.

The FAA disagrees. The A–20028 bearing identified with ''BA 59'' is an unapproved bearing that does not conform to McCauley drawing requirements. Although the FAA is aware of failures of bearings other than those stamped with ''BA 59'', these bearings do not demonstrate the same unsafe condition as identified in this AD. The FAA will continue to monitor McCauley governor field reports for issues involving bearings other than those stamped with ''BA 59''.

The FAA did not make changes to this AD as a result of these comments.

Request To Clarify the Required Actions

The Aircraft Owners and Pilots Association (AOPA) requested the FAA clarify paragraph (f), Compliance, of the NPRM. AOPA stated that the proposed language in paragraph (f) of the proposed AD to replace the governor with a governor eligible for installation can be misleading and imply that the governor must be replaced with a new or overhauled governor regardless of the status of the existing governor.

The FAA disagrees. Paragraph (f) of this AD requires compliance, unless already done. Thus, the AD allows

operators to take credit for replacing the governor with a governor eligible for installation if done before the effective date of the AD. If the existing governor does not have an idler gear bearing with a part marking ''BA 59'', then compliance is already done.

No changes to this AD are necessary based on this comment.

Request To Clarify the Installation Prohibition

AOPA requested the FAA clarify the wording in paragraph (h), Parts Installation Prohibition, of the NPRM. AOPA stated the language does not convey whether replacing the affected idle gear bearing in the governor terminates the AD.

The FAA disagrees. This AD does not require repetitive actions; therefore, terminating action is inappropriate. The installation prohibition ensures that affected governors will not be replaced with a part that has the unsafe condition. Once the affected governor is replaced in accordance with the requirements of this AD, no further action is required. The FAA did not make changes to this AD as a result of this comment.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously. The FAA has determined that these changes:

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed McCauley Alert Service Bulletin No. ASB273C, dated January 30, 2019. The service bulletin contains model and serial number information to identify the affected governors. The service bulletin also contains procedures for removing the governor from the engine, inspecting the governor for the unapproved variant idler gear bearing, replacing the idler gear bearing or idler gear assembly if necessary, overhauling the governor if necessary, and installing a governor on the engine. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 2,500 governors as installed in airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Remove affected governor	1 work-hour × $85 per hour = $85	Not Applicable	$85	$212,500
Install a governor	1 work-hour × $85 per hour = $85	See table below	Variable	Unknown

An operator has the option to pay a service center to inspect their existing governor and replace the idler gear bearing if necessary or pay to have their existing governor overhauled. An operator has the option to purchase a factory new governor or an overhauled governor, a feathering/syncing governor or a non-feathering/syncing governor. The FAA has no way of knowing what option an operator may take to obtain a governor eligible for installation. Therefore, the FAA has no way of determining the parts cost on U.S. operators. The following represents the estimated parts cost associated with obtaining a governor.

COST FOR AN ELIGIBLE GOVERNOR

Type of governor	Cost of governor
Factory new non-feathering/non-syncing governor	2,000
Factory new feathering/syncing governor	9,000
Overhaul of existing non-feathering/non-syncing governor	1,000
Overhaul of existing feathering/syncing governor	3,000

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all costs in this cost estimate.

Authority for This Rulemaking

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

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 govement.

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 (AD):

2020–19–06 McCauley Propeller Systems: Amendment 39–21248; Docket No. FAA–2020–0320; Project Identifier 2019–CE–011–AD.

(a) Effective Date

This AD is effective November 3, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the McCauley Propeller Systems (McCauley) governors specified in paragraph (c)(1) or (2) of this AD and installed on airplanes, certificated in any category.

(1) Models listed in table 2 of McCauley Alert Service Bulletin No. ASB273C, dated January 30, 2019 (McCauley ASB273C) with a serial number from 170061 through 180501, excluding the serial numbers listed in table 1 of McCauley ASB273C; or

(2) Models listed in table 2 of McCauley ASB273C, with any serial number, that have an installation date after January 31, 2017, or an installation date that cannot be determined.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 61, Propellers.

(e) Unsafe Condition

This AD was prompted by reports of an unapproved variant idler gear bearing, McCauley part number (P/N) A–20028, installed on governors. All models of McCauley governors have a bearing with P/N A–20028 installed; however, the unapproved variant can be identified with the part marking ''BA 59.'' The FAA is issuing this AD to prevent failure of the idler gear bearing. This failure could result in failure of the governor, loss of propeller pitch control, engine and propeller over speed, engine oil contamination, and loss of control of the airplane.

(f) Compliance

Unless already done, within 50 hours time-in-service after the effective date of this AD or within 24 months after the effective date of this AD, whichever occurs first, replace the governor with a governor eligible for installation.

Note 1 to paragraph (f) of this AD: Any model McCauley governor that is stamped with the letter B, as specified in the Accomplishment Instructions in McCauley ASB273C, has already complied with the requirements of this AD.

(g) Definition

For the purposes of this AD, a governor eligible for installation is defined as a governor that does not have an idler gear bearing with a part marking ''BA 59'' installed.

(h) Parts Installation Prohibition

As of the effective date of this AD, do not install on any airplane a McCauley governor unless it is a governor eligible for installation.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD.

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

(j) Related Information

For more information about this AD, contact Thomas Teplik, Aerospace Engineer, Wichita ACO Branch, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: (316) 946–4196; fax: (316) 946–4107; email: *thomas.teplik@faa.gov* or *Wichita-COS@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 the AD specifies otherwise.

(i) McCauley Alert Service Bulletin No. ASB273C, dated January 30, 2019.

(ii) [Reserved]

(3) For McCauley Propeller Systems service information identified in this AD, contact McCauley Propeller Systems, One Cessna Boulevard, P.O. Box 7704, Wichita, Kansas 67277; telephone: (800) 621–7767 or (316) 831–4021; email: *productsupport@txtav.com;* internet: *https://mccauley.txtav.com.*

(4) You may view this service information at FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(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 September 4, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21440 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0203; Product Identifier 2019–NM–142–AD; Amendment 39–21256; AD 2020–19–13]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. This AD was prompted by a report that fast and easy access to the portable oxygen bottle may be prevented by the portable oxygen bottle installation's upper bracket latch assembly catching on the pressure gauge tube or on the pressure gauge bezel of the portable oxygen bottle. This AD requires a check to identify the manufacturer and part number of the portable oxygen bottle installation, and, if necessary, modification of the portable oxygen bottle installation. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 3, 2020.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of November 3, 2020.

ADDRESSES: For service information identified in this final rule, contact Bombardier, Inc., 200 Côte-Vertu Road West, Dorval, Québec H4S 2A3, Canada; North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; email *ac.yul@aero.bombardier.com;* internet *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. It is also available on the internet at

https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0203.

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–2020–0203; 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: Darren Gassetto, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7323; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2019–26, dated July 9, 2019 (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. 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–2020–0203.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. The NPRM published in the **Federal Register** on March 23, 2020 (85 FR 16284). The NPRM was prompted by a report that fast and easy access to the portable oxygen bottle may be prevented by the portable oxygen bottle installation's upper bracket latch assembly catching on the pressure gauge tube or on the pressure gauge bezel of the portable oxygen bottle. The NPRM proposed to require a check to identify the manufacturer and part number of the portable oxygen bottle installation, and, if necessary, modification of the portable oxygen bottle installation. The FAA is issuing this AD to address the portable oxygen bottle installation's upper bracket latch assembly catching on the pressure gauge tube or on the pressure gauge bezel of the portable oxygen bottle, which, if not detected and corrected, could prevent fast and easy access to the portable oxygen bottle in an emergency situation. See the MCAI for additional background information.

Comments

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

Support for the NPRM

An anonymous commenter had no objection to the NPRM.

Request To Revise or Clarify the Applicability of Paragraph (i) of the Proposed AD

NetJets requested that the FAA either revise the language in the first sentence of paragraph (i) of the proposed AD to clearly state that the paragraph applies to airplanes having a serial number of 6119 and below that is not listed in section 1.A. of the applicable Bombardier service information specified in figure 1 to paragraphs (g), (h), and (i) of the proposed AD, or that the FAA clarify paragraph (c)(3) of the proposed AD to state that all serial numbers are affected.

The FAA agrees to clarify. Paragraph (i) of the proposed AD is applicable to only airplanes having the serial numbers specified in paragraph (c) of this AD, but not listed in section 1.A. of the applicable Bombardier service information specified in figure 1 to paragraphs (g), (h), and (i) of this AD, and equipped with specified part numbers of Scott (Avox/Zodiac) 5500 or 5600 series 11 cubic foot portable oxygen bottle(s). As such, any serial number not specified in paragraph (c)(3) of this AD for Bombardier Inc. Model CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes, is not affected by paragraph (i) of this AD. The FAA has not changed this AD in this regard.

Conclusion

The FAA reviewed the relevant data, considered the comments 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

Bombardier has issued the following service information:

- Bombardier Service Bulletin 600–0772, dated June 29, 2018;
- Bombardier Service Bulletin 601–0646, dated June 29, 2018;
- Bombardier Service Bulletin 604–35–006, dated June 29, 2018;
- Bombardier Service Bulletin 605–35–005, dated June 29, 2018; and
- Bombardier Service Bulletin 650–35–001, dated June 29, 2018.

This service information describes procedures for a check to identify the manufacturer and part number of the portable oxygen bottle installation, and, if necessary, modification of the portable oxygen bottle installation. These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 188 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
3 work-hours × $85 per hour = $255 per installation	$1,530 per installation	$1,785 per installation	$335,580 per installation.

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 (AD):

2020–19–13 Bombardier, Inc.: Amendment 39–21256; Docket No. FAA–2020–0203; Product Identifier 2019–NM–142–AD.

(a) Effective Date

This AD is effective November 3, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Bombardier, Inc., airplanes identified in paragraphs (c)(1) through (3) of this AD, certificated in any category, equipped with Scott (Avox/Zodiac) 5500 or 5600 series 11 cubic foot portable oxygen bottle(s) with upper bracket part number (P/N) 36758–02, P/N 36758–12 or P/N H3–2091–1 installed at the neck of the bottle(s).

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

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

(3) Model CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes, serial numbers 5001 through 5194 inclusive, 5301 through 5665 inclusive, 5701 through 5988 inclusive, and 6050 through 6119 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen.

(e) Reason

This AD was prompted by a report that fast and easy access to the portable oxygen bottle may be prevented by the portable oxygen bottle installation's upper bracket latch assembly catching on the pressure gauge tube or on the pressure gauge bezel of the portable oxygen bottle. The FAA is issuing this AD to address this condition, which, if not detected and corrected, could prevent fast and easy access to the portable oxygen bottle in an emergency situation.

(f) Compliance

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

(g) Portable Oxygen Bottle Check

For airplanes with a serial number listed in Section 1.A. of the applicable Bombardier service information specified in figure 1 to paragraphs (g), (h), and (i) of this AD: Within 60 months after the effective date of this AD, check each portable oxygen bottle installation to determine the manufacturer and part number, in accordance with paragraph 2.B. of the Accomplishment Instructions of the applicable Bombardier service information specified in figure 1 to paragraphs (g), (h), and (i) of this AD.

Figure 1 to paragraphs (g), (h), and (i) – *Service Information References*

Airplane Model	Bombardier Service Information
Model CL-600-1A11	Bombardier Service Bulletin 600-0772, dated June 29, 2018
Model CL-600-2A12	Bombardier Service Bulletin 601-0646, dated June 29, 2018
Model CL-600-2B16	Bombardier Service Bulletin 601-0646, dated June 29, 2018
Model CL-600-2B16	Bombardier Service Bulletin 604-35-006, dated June 29, 2018
Model CL-600-2B16	Bombardier Service Bulletin 605-35-005, dated June 29, 2018
Model CL-600-2B16	Bombardier Service Bulletin 650-35-001, dated June 29, 2018

(h) Bracket Modifications

If, during the inspection specified in paragraph (g) of this AD, any portable oxygen bottle is found to be manufactured by Scott (Avox/Zodiac) and is a 5500 or 5600 series 11 cubic foot bottle, with upper bracket P/N 36758–02, 36758–12, or H3–2091–1 installed at the neck of the bottle: Modify the portable oxygen bottle brackets in accordance with paragraph 2.C. of the Accomplishment Instructions of the applicable Bombardier service information specified in figure 1 to paragraphs (g), (h), and (i) of this AD.

(i) Portable Oxygen Bottle Check and Corrective Actions for Airplanes Not Listed in the Service Information

For airplanes with a serial number that is not listed in section 1.A. of the applicable Bombardier service information specified in figure 1 to paragraphs (g), (h), and (i) of this AD: Within 60 months after the effective date of this AD, check each portable oxygen bottle installation to determine the manufacturer and part number and accomplish corrective actions in accordance with the procedures specified in paragraph (j)(2) of this AD.

(j) 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 local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 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 local flight standards district office/certificate holding district office.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, 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.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2019–26, dated July 9, 2019, 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–2020–0203.

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

(l) Material Incorporated by Reference

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

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

(i) Bombardier Service Bulletin 600–0772, dated June 29, 2018.

(ii) Bombardier Service Bulletin 601–0646, dated June 29, 2018.

(iii) Bombardier Service Bulletin 604–35–006, dated June 29, 2018.

(iv) Bombardier Service Bulletin 605–35–005, dated June 29, 2018.

(v) Bombardier Service Bulletin 650–35–001, dated June 29, 2018.

(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.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this 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 September 10, 2020.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21420 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0853; Project Identifier AD–2020–00588–E; Amendment 39–21260; AD 2020–20–04]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Corporation (Type Certificate Previously Held by Allison Engine Company) Turboprop Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Rolls-Royce Corporation (RRC) AE 2100D3 model turboprop engines. This AD requires revising the airworthiness limitations section (ALS) of the RRC AE 2100D3 Maintenance Manual and the operator's approved continuous airworthiness maintenance program. This AD was prompted by a report of a propeller gearbox (PGB) development test in which high vibration occurred due to a fatigue crack that initiated in the propeller shaft. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 14, 2020.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of October 14, 2020.

The FAA must receive comments on this AD by November 13, 2020.

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:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Rolls-Royce Corporation, 450 South Meridian Street, Mail Code NB–01–06, Indianapolis, IN 46225; phone: 317–230–1667; email: *CMSEindyOSD@rolls-royce.com;* internet: *www.rolls-royce.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0853.

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–2020–0853; 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 street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Kyri Zaroyiannis, Aerospace Engineer, Chicago ACO, FAA, 2300 E Devon Ave., Des Plaines, IL 60018; phone: (847) 294–7836; fax: (847) 294–7834; email: *kyri.zaroyiannis@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA was informed by the manufacturer that a PGB development test was stopped due to high vibration caused by a fatigue crack that initiated in the PGB shaft and carrier assembly. The fatigue crack initiated in a broach slot of the PGB shaft. The manufacturer determined the need to apply life limits to the PGB shaft and carrier assembly, which has not previously been a life-limited part. To track these parts, the manufacturer determined the need to assign usage hours to PGB shaft and carrier assemblies that already have time in service.

An examination by the manufacturer of Material Review Board records also identified two PGB shaft and carrier assemblies that were accepted with reduced material properties prior to their reclassification as a life limited part requiring reduced lives. The manufacturer applied reduced life limits to these PGB shaft and carrier assemblies. In addition, a review of shop repair records by the manufacturer identified a number of PGB shaft and carrier assemblies that received a keylock stud repair introducing unacceptable unused ''keyslots'' that can cause stress concentration and reduced life. The manufacturer requires either rework or removal of these PGB shaft and carrier assemblies.

The FAA determined that updating the ALS of the RRC AE 2100D3 Maintenance Manual and the continued airworthiness maintenance program for the affected RRC 2100D3 model turbofan engines is the most effective way to address the unsafe condition pertaining to fatigue cracks in the PGB shaft and carrier assembly. These ALS updates apply life limits to PGB shaft and carrier assemblies installed on RRC AE 2100D3 model turbofan engines. Certain part numbered PGB shaft and carrier assemblies with reduced material properties were assigned reduced life limits. To track these parts, the ALS updates require assignment of usage hours to the PGB shaft and carrier assembly no later than the next engine shop visit for all RRC AE model turboprop engines. Depending on the part and serial number of the PGB shaft and carrier assembly, the updates to the ALS requires reidentification or removal of the PGB shaft and carrier assembly.

This condition, if not addressed, could result in loss of the propeller, damage to the engine, and damage to the airplane. The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

The FAA is issuing 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.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Task 05–11–00–800–801, dated June 20, 2018 of the Airworthiness Limitations System Description Section-801, RRC AE 2100D3 Maintenance Manual (''Task 05–11–00–800–801'') and Task 05–12–11–800–802, dated June 1, 2020 of the Propeller Gearbox System Component Life Limits Systems Description Section-802, RRC AE 2100D3 Maintenance Manual (''Task 05–12–11–800–802'').

Task 05–11–00–800–801 specifies: (1) Assignment of usage hours to the PGB shaft and carrier assemblies; (2) reworking confirmed blind hole configured PGB shaft and carrier

assemblies to the through-hole controlled keyslot configuration; and (3) reidentifying through-hole PGB shaft and carrier assemblies to a new part number.

Task 05–12–11–800–802 specifies: (1) Assignment of new life limits to the PGB shaft and carrier assemblies; (2) decreasing the life limit for PGB shaft and carrier assemblies found to have reduced material properties; and (3) replacing PGB shaft and carrier assemblies that have received a keylock stud repair which introduced unacceptable unused keyslots.

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

Other Related Service Information

The FAA reviewed RRC Alert Service Bulletin (ASB) AE2100D3–A–72–256, Revision 3, dated January 15, 2018; AE 2100D3–A–72–313, Revision 1, dated May 28, 2018; RRC ASB AE 2100D3–A–72–314, Revision 0, dated January 15, 2018; RRC ASB AE 2100D3–A–72–315, Revision 2, dated July 13, 2018; RRC ASB AE 2100D3–A–72–324, Revision 0, dated November 26, 2019; and RRC ASB AE 2100D3–A–72–325, Revision 0, dated November 26, 2019.

RRC ASB AE2100D3–A–72–256, Revision 3, dated January 15, 2018, describes procedures for re-work of certain PGB shaft and carrier assemblies.

RRC ASB AE 2100D3–A–72–313 describes procedures for assigning usage hours to the PGB shaft and carrier assemblies.

RRC ASB AE 2100D3–A–72–314 describes procedures for reworking PGB shaft and carrier assemblies from the blind hole to the preferred through hole controlled keyslot configuration.

RRC ASB AE 2100D3–A–72–315 describes procedures for reidentifying PGB shaft and carrier assemblies which are of the preferred through hole controlled keyslot configuration.

RRC ASB AE 2100D3–A–72–324 establishes a decrease in life limit of 10,525 hours for PGB shaft and carrier assemblies, with (S/Ns) CU32063 and CU32071, which were found to have reduced material properties.

RRC ASB AE 2100D3–A–72–325 describes procedures for reworking or replacing PGB shaft and carrier assemblies, listed in Table 1 of RRC ASB AE 2100D3–72–A–325, that have received a keylock stud repair which introduced unacceptable unused keyslots.

AD Requirements

This AD requires revising the ALS of the AE 2100D3 Maintenance Manual and the operator's approved continuous airworthiness maintenance program.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C.) 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.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than 30 days, upon a finding of good cause.

The FAA has found the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because no domestic operators use this product. It is unlikely that the FAA will receive any adverse comments or useful information about this AD from U.S. operators. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reasons, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA–2020–0853 and Project Identifier AD–2020–00588–E at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule 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 FAA will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

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 final rule 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 final rule, 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 final rule. Submissions containing CBI should be sent to Kyri Zaroyiannis, Aerospace Engineer, Chicago ACO, FAA, 2300 E Devon Ave., Des Plaines, IL 60018. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 0 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Insert Task 05–12–11–800–801 into RRC AE 2100D3 Maintenance Manual.	0.5 work-hours × $85 per hour = $42.50.	$0	$42.50	$0

ESTIMATED COSTS—Continued

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Insert Task 05–12–11–800–802 into RRC AE 2100D3 Maintenance Manual.	0.5 work-hours × $85 per hour = $42.50.	0	42.50	0

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, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2020–20–04 Rolls-Royce Corporation (Type Certificate previously held by Allison Engine Company): Amendment 39–21260; Docket No. FAA–2020–0853; Project Identifier AD–2020–00588–E.

(a) Effective Date

This AD is effective October 14, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Rolls-Royce Corporation (RRC) AE 2100D3 model turboprop engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7210, Turbine Engine Reduction Gear.

(e) Unsafe Condition

This AD was prompted by a fatigue crack that initiated in the propeller shaft during a propeller gearbox (PGB) development test that induced high vibrations. The FAA is issuing this AD to prevent loss of the propeller. The unsafe condition, if not addressed, could result in damage to the engine and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) Within 30 days after the effective date of this AD, revise the RRC AE 2100D3 Maintenance Manual (''the Manual'') and the operator's existing approved continuous airworthiness maintenance program by inserting:

(i) Task 05–11–00–800–801, dated June 20, 2018, into Airworthiness Limitations System Description Section-801; and

(ii) Task 05–12–11–800–802, dated June 1, 2020, into Propeller Gearbox System Component Life Limits Systems Description Section-802 in the Manual.

(2) Thereafter, except as provided in paragraph (h) of this AD, no alternative replacement times or structural inspection intervals may be approved for this PGB shaft and carrier assembly.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Chicago ACO, 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 (i) of this AD.

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

(i) Related Information

For more information about this AD, contact or more information about this AD, contact Kyri Zaroyiannis, Aerospace Engineer, Chicago ACO, FAA, 2300 E. Devon Avenue, Des Plaines, IL 60018; phone: (847) 294–7836; fax: (847) 294–7834; email: *kyri.zaroyiannis@faa.gov*.

(j) Material Incorporated by Reference

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

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

(i) Task 05–11–00–800–801, dated June 20, 2018 of Airworthiness Limitations System Description Section-801, Rolls-Royce Corporation (RRC) AE 2100D3 Maintenance Manual.

(ii) Task 05–12–11–800–802, dated June 1, 2020 of Propeller Gearbox System Component Life Limits Systems Description Section-802, RRC AE 2100D3 Maintenance Manual.

(3) For RRC service information identified in this AD, contact Rolls-Royce Corporation, 450 South Meridian Street, Mail Code NB–01–06, Indianapolis, IN 46225; phone: 317–230–1667; email: *CMSEindyOSD@rolls-royce.com;* internet: *www.rolls-royce.com.*

(4) You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759.

(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 September 18, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21377 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0413; Product Identifier 2017–SW–018–AD; Amendment 39–21258; AD 2020–20–02]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Leonardo S.p.a. (Leonardo) Model A109E, A109S, and AW109SP helicopters. This AD requires inspecting each fire extinguisher bottle for a crack. This AD was prompted by a report of a cracked fire extinguisher bottle. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD is effective November 3, 2020.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of November 3, 2020.

ADDRESSES: For service information identified in this final rule, contact Leonardo, Emanuele Bufano, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate (Va) Italy; telephone +39–0331–225074; fax +39–0331–229046; or at *https://www.leonardocompany.com/en/home.* You may view the 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–2020–0413.

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–2020–0413; 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: Eric Haight, Aviation Safety Engineer, Regulations and Policy Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; *eric.haight@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Leonardo Model A109E, A109S, and AW109SP helicopters with a fire extinguisher bottle part number (P/N) 27300–1 installed. The NPRM published in the **Federal Register** on April 23, 2020 (85 FR 22686). The NPRM proposed to require repetitively inspecting the weld beads of each fire extinguisher bottle P/N 27300–1 assembly for a crack. If there is a crack, the NPRM proposed to require replacing the fire extinguisher bottle before further flight. The NPRM also proposed to prohibit the installation of a fire extinguisher bottle P/N 27300–1 on any helicopter unless it has met the requirements of this AD. The proposed requirements were intended to detect a crack on a fire extinguisher bottle bypass outlet assembly, which could result in failure of the fire extinguishing system in the event of a fire in the engine area and subsequent loss of control of the helicopter.

The NPRM was prompted by EASA AD No. 2016–0261R1, dated February 13, 2020, issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for Leonardo Model A109LUH, A109E, A109S, and AW109SP helicopters. EASA advises that a fractured bypass outlet assembly (assembly), which is a component of fire extinguishing bottle P/N 27300–1, was found during maintenance on a Model AW109SP helicopter. EASA states that this condition, if not detected and corrected, could affect the capability of the fire extinguishing system to extinguish a fire in the engine area, resulting in damage to the helicopter and injury to any occupants. To address this unsafe condition, the EASA AD requires repetitive inspections of the assembly, and if there is a crack, replacing the fire extinguisher bottle. Due to similarity of design, EASA advises other helicopter models may be subject to the same unsafe condition.

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 the same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Interim Action

The FAA considers this AD to be an interim action. If final action is later identified, the FAA might consider further rulemaking.

Differences Between This AD and the EASA AD

The EASA AD applies to Model A109LUH helicopters; this AD does not as that model helicopter is not type certificated in the U.S.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Leonardo Helicopters Bollettino Tecnico (BT) No. 109EP–152 for Model A109E helicopters, BT No. 109S–073 for Model A109S helicopters, and BT No. 109SP–108 for Model AW109SP helicopters, all dated December 15, 2016. The FAA also reviewed Leonardo Helicopters Alert Service Bulletin No. 109S–073, Revision A, dated November 23, 2018 for Model A109S helicopters. This service information contains procedures for inspecting the assembly for a crack and replacing the fire extinguishing bottle if there is a crack.

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

Costs of Compliance

The FAA estimates that this AD affects 107 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.

Inspecting both assemblies requires about 2 work-hours, for an estimated

cost of $170 per helicopter and $18,190 for the U.S fleet, per inspection cycle.

Replacing a fire extinguishing bottle requires about 3 work-hours and parts cost about $6,432, for an estimated cost of $6,687 per helicopter.

According to Leonardo's service information, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage by Leonardo. Accordingly, the FAA has included all costs in this cost estimate.

Authority for This Rulemaking

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

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 helicopters 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 (AD):

2020–20–02 Leonardo S.p.a.: Amendment 39–21258; Docket No. FAA–2020–0413; Product Identifier 2017–SW–018–AD.

(a) Applicability

This AD applies to Leonardo S.p.a. Model A109E, A109S, and AW109SP helicopters, certificated in any category, with a fire extinguisher bottle part number (P/N) 27300–1 installed.

Note 1 to paragraph (a): Fire extinguisher bottle P/N 27300–1 may be installed as part of fire extinguisher kit P/N 109–0811–39–103, P/N 109–0811–39–107, or P/N 109–0811–39–109.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack on a fire extinguisher bottle bypass outlet assembly. This condition could result in failure of the fire extinguishing system in the event of a fire in the engine area and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective November 3, 2020.

(d) 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.

(e) Required Actions

(1) Within 25 hours time-in-service (TIS) and thereafter at intervals not to exceed 200 hours TIS, using a mirror and a light, inspect the weld beads of each fire extinguisher bottle bypass outlet assembly for a crack in the areas depicted in Figure 2 of Leonardo Helicopters Bollettino Tecnico (BT) No. 109EP–152, BT No. 109S–073, or BT No. 109SP–108, each dated December 15, 2016, or Alert Service Bulletin No. 109S–073 Revision A, dated November 23, 2018, as applicable to your model helicopter. Pay particular attention to each circled area. If there is a crack, before further flight, replace the fire extinguisher bottle.

(2) After the effective date of this AD, do not install a fire extinguisher bottle P/N 27300–1 on any helicopter unless it has been inspected as required by paragraph (e)(1) of this AD.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to Eric Haight, Aviation Safety Engineer, Regulations and Policy Section, Rotorcraft Standards Branch, 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.

(g) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD No. 2016–0261R1, dated February 13, 2020. You may view the EASA AD on the internet at *https://www.regulations.gov* in Docket No. FAA–2020–0413.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 2620, Extinguishing System.

(i) 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) Leonardo Helicopters Alert Service Bulletin No. 109S–073, Revision A, dated November 23, 2018.

(ii) Leonardo Helicopters Bollettino Tecnico (BT) No. 109EP–152, dated December 15, 2016.

(iii) Leonardo Helicopters BT No. 109S–073, dated December 15, 2016.

(iv) Leonardo Helicopters BT No. 109SP–108, dated December 15, 2016.

(3) For service information identified in this AD, contact Leonardo, Emanuele Bufano, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate (Va) Italy; telephone +39–0331–225074; fax +39–0331–229046; or at *https://www.leonardocompany.com/en/home.*

(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 September 18, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21414 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0412; Product Identifier 2018–CE–030–AD; Amendment 39–21253; AD 2020–19–10]

RIN 2120–AA64

Airworthiness Directives; Piaggio Aero Industries S.p.A.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Piaggio Aero Industries S.p.A. Model P–180 airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as insufficient sealing of a steering select/bypass valve installed in the nose landing gear (NLG) manifold. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 3, 2020.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of November 3, 2020.

ADDRESSES: For service information identified in this final rule, contact Piaggio Aero Industries S.p.A, Airworthiness Office, Via Pionieri e Aviatori d'Italia snc, 16154 Genova, Italy; phone: +39 010 0998046; email: *airworthiness@piaggioaerospace.it;* and internet: *https://www.piaggioaerospace.it/en/customer-support.* You may review this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0412.

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–2019–0412; 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 Docket Operations, 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: Mike Kiesov, Aerospace Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; email: *mike.kiesov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Piaggio Aero Industries S.p.A. Model P–180 airplanes. The NPRM published in the **Federal Register** on June 5, 2019 (84 FR 26025). The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by the European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union. EASA issued AD No. 2017–0229, dated November 21, 2017 (referred to after this as ''the MCAI''), which states:

> An occurrence was reported of finding insufficient sealing of a Steering Select/Bypass Valve installed on the nose landing gear (NLG) Steering Manifold of a P.180 aeroplane.
>
> This condition, if not detected and corrected, could lead to uncommanded deflection of the NLG wheel, possibly resulting in reduced control of the aeroplane on the ground, with consequent damage to the aeroplane and injury to occupants.
>
> To address this potential unsafe condition, PAI issued Service Bulletin (SB) 80–0325 to provide inspection and rectification instructions.
>
> For the reason described above, this [EASA] AD requires a leak test of the NLG Steering Manifold and, depending on the finding(s), accomplishment of applicable corrective action(s). This [EASA] AD also requires amendment of the applicable Aircraft Flight Manual (AFM).

The MCAI further notes that airplanes with NLG steering manifold part number 72608 installed are known to include manufacturing serial numbers 1001, 3001, 3003, 3004, 3006, 3007, and 3008, and also include airplanes that have incorporated Piaggio Aerospace Service Bulletin No. 80–0425, Revision 0, dated March 30, 2017, and Piaggio Aerospace Service Bulletin No. 80–0454, Revision 0, March 6, 2017. You may examine the MCAI on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0412.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. No comments were received on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Piaggio Aerospace Service Bulletin No. 80–0325, Revision 0, dated August 10, 2017 (SB 80–0325), and Piaggio Aerospace P.180 AVANTI II/EVO Temporary Change No. 89, dated August 30, 2017 (Temporary Change 89), to the airplane flight manual (AFM). SB 80–0325 contains procedures for doing a NLG steering manifold leakage test. Temporary Change 89 contains emergency operating procedures for the pilot to follow if the NLG steering system fails. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

The FAA reviewed Piaggio Aerospace Service Bulletin No. 80–0425, Revision 0, dated March 30, 2017 (SB 80–0425); Piaggio Aerospace Service Bulletin No. 80–0454, Revision 0, March 6, 2017 (SB 80–0454); and Temporary Change No. 89 Errata Corrige, dated December 20, 2017 (Temporary Change 89EC). SB 80–0425 and SB 80–0454 both contain procedures for replacing the main landing gear and the NLG steering system on the applicable airplanes. Temporary Change 89EC revises the cover page of Temporary Change 89 to clarify the applicability of the change.

Costs of Compliance

The FAA estimates that this AD will affect 130 products of U.S. registry. The FAA also estimates that it will take about 2.5 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour.

Based on these figures, the FAA estimates the cost of this AD on U.S. operators to be $27,625, or $212.50 per product.

If necessary, the FAA estimates that replacing a NLG steering manifold would take about 10 work-hours and require parts costing $50,058, for a cost of $50,908 per product. The FAA has no way of determining the number of products that may need these actions.

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 (AD):

2020–19–10 Piaggio Aero Industries S.p.A.: Amendment 39–21253; Docket No. FAA–2019–0412; Product Identifier 2018–CE–030–AD.

(a) Effective Date

This AD is effective November 3, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Piaggio Aero Industries S.p.A. Model P–180 airplanes, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 32: Landing Gear.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as insufficient sealing of a steering select/bypass valve installed in the nose landing gear (NLG) manifold. The FAA is issuing this AD to detect and correct insufficient sealing of the steering select/bypass valve in the NLG steering manifold, which could lead to uncommanded NLG wheel turns with consequent lateral runway departure.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) through (3) of this AD.

(1) For airplanes with NLG steering manifold part number (P/N) 72608 installed: (i) Within 50 hours time-in service after the effective date of this AD, do a steering manifold pressure leakage test and, if there is steering actuator movement during the test, replace the NLG steering manifold and repeat the test by following the Accomplishment Instructions, procedure steps (1) through (24), in Piaggio Aerospace Service Bulletin No. 80–0325, Revision 0, dated August 10, 2017.

(ii) If steering actuator movement occurs during procedure step (9) or procedure step (15) of the leakage test required in paragraph (f)(1)(i) of this AD, replacing the NLG steering manifold and repeating the steering manifold pressure leakage test is required before further flight.

(2) For all airplanes, after the effective date of this AD, do not install NLG steering manifold P/N 72608 on any airplane unless it has been inspected as specified in paragraph (f)(1) of this AD and no steering actuator movement occurred.

(3) For all airplanes, within 30 days after the effective date of this AD, revise the airplane flight manual (AFM) by replacing certain pages in the Emergency Procedures section of the AFM by following the Instructions in Piaggio Aerospace P.180 AVANTI II/EVO Temporary Change No. 89, dated August 30, 2017.

(g) Alternative Methods of Compliance

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Mike Kiesov, Aerospace Engineer, FAA, General Aviation & Rotorcraft, International Validation Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; email: *mike.kiesov@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(g) Related Information

Refer to MCAI European Aviation Safety Agency AD No. 2017–0229, dated November 21, 2017, for related information. You may examine the MCAI on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0412.

(h) Material Incorporated by Reference

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

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

(i) Piaggio Aerospace Service Bulletin No. 80–0325, Revision 0, dated August 10, 2017 (SB 80–0325).

(ii) Piaggio Aerospace P.180 AVANTI II/EVO Temporary Change No. 89, dated August 30, 2017 (Temporary Change 89).

(3) For Piaggio Aerospace service information identified in this AD, contact Piaggio Aero Industries S.p.A, Airworthiness Office, Via Pionieri e Aviatori d'Italia snc, 16154 Genova, Italy; phone: +39 010 0998046; email: *airworthiness@piaggioaerospace.it;* and internet: *https://www.piaggioaerospace.it/en/customer-support.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call 816–329–4148. In addition, you can access this service information on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0412.

(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 September 10, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21392 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0555; Project Identifier AD–2020–00615–E; Amendment 39–21267; AD 2020–20–11]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain General Electric Company (GE) GEnx–1B64/P2, –1B67/P2, –1B70/P2, –1B70C/P2, –1B70/75/P2, –1B74/75/P2, –1B76/P2, –1B76A/P2, and GEnx–2B67/P model turbofan engines. This AD was prompted by the detection of melt-related freckles in the billet, which may reduce the life limits of certain high-pressure turbine (HPT) rotor stage 2 disks and a certain stages 6–10 compressor rotor spool. This AD requires the removal of certain HPT rotor stage 2 disk and the removal of a certain stages 6–10 compressor rotor spool before reaching their new life limits. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 3, 2020.

ADDRESSES: For service information identified in this final rule, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ae.ge.com;* website: *www.ge.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0555.

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–2020–0555; 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: Mehdi Lamnyi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7743; fax: 781–238–7199; email: *Mehdi.Lamnyi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain GE GEnx–1B64/P2, –1B67/P2, –1B70/P2, –1B70C/P2, –1B70/75/P2, –1B74/75/P2, –1B76/P2, –1B76A/P2, and GEnx–2B67/P model turbofan engines. The NPRM published in the **Federal Register** on June 8, 2020 (85 FR 35021). The NPRM was prompted by the detection of melt-related freckles in the billet, which may reduce the life limits of certain HPT rotor stage 2 disks and a certain stages 6–10 compressor rotor spool. The NPRM proposed to require the removal of certain HPT rotor stage 2 disk and the removal of a certain stages 6–10 compressor rotor spool before reaching their new life limits. The FAA is issuing this AD to address the unsafe condition on these products.

Comments

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

Request to List Part and Serial Numbers

GE requested that both the affected part and serial numbers be listed in the Applicability section of this AD instead of the affected engine serial numbers.

The FAA agrees. The FAA recognizes that affected HPT rotor stage 2 disks could be moved from one engine to another engine. The intent of this AD is to mandate the removal of the affected parts from service, regardless of the engine on which they are installed. The FAA is revising the Applicability section of this AD as suggested by the commenter. This change does not expand the scope of this AD because the number of affected engines installed on airplanes of U.S. registry remains the same in this final rule compared to what was published in the NPRM.

Support for the AD

The Air Line Pilots Association, International; the Boeing Company; and United Airlines Engineering expressed support for the AD as written.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and 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.

The FAA also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information

The FAA reviewed GE GEnx–1B Service Bulletin (SB) 72–0473 R00, dated April 14, 2020; GE GEnx–1B SB 72–0474 R00, dated April 14, 2020; and GE GEnx–2B SB 72–0416 R00, dated April 14, 2020. GE GEnx–1B SB 72–0473 R00 describes procedures for removing and replacing the HPT rotor stage 2 disks on GE GEnx–1B model engines. GE GEnx–1B SB 72–0474 R00 describes procedures for removing and replacing the stages 6–10 compressor rotor spool on GE GEnx–1B model engines. GE GEnx–2B SB 72–0416 R00 describes procedures for removing and replacing the HPT rotor stage 2 disks on GE GEnx–2B model engines.

Costs of Compliance

The FAA estimates that this AD affects two engines installed on airplanes of U.S. registry; one engine requires the HPT rotor stage 2 disk replacement and one engine requires the stages 6–10 compressor rotor spool replacement.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Removal and replacement of the HPT rotor stage 2 disk	1,500 work-hours × $85 per hour = $127,500.	$458,900	$586,400	$586,400
Removal and replacement of the stages 6–10 compressor rotor spool.	600 work-hours × $85 per hour = $51,000.	1,018,600	1,069,600	1,069,600

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2020–20–11 General Electric Company: Amendment 39–21267; Docket No. FAA–2020–0555; Project Identifier AD–2020–00615–E.

(a) Effective Date

This AD is effective November 3, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all General Electric Company (GE) GEnx–1B64/P2, –1B67/P2, –1B70/P2, –1B70C/P2, –1B70/75/P2, –1B74/75/P2, –1B76/P2, –1B76A/P2, and GEnx–2B67/P model turbofan engines with:

(1) a high-pressure turbine (HPT) rotor stage 2 disk, part number (P/N) 2383M86P02, having one of the following serial numbers (S/Ns): TMT18D6T, TMT18D6U, TMT18JC4, TMT18NGC, TMT1985C, TMT3UA34, TMT3UA55, TMT4CT46, or TMT4CT47, installed; or

(2) a stages 6–10 compressor rotor spool, P/N 2628M56G01, S/N GWN10ECM, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by the detection of melt-related freckles in the billet, which may reduce the life limits of certain HPT rotor stage 2 disks and a certain stages 6–10 compressor rotor spool. The FAA is issuing this AD to prevent failure of the HPT rotor stage 2 disk and stages 6–10 compressor rotor spool. The unsafe condition, if not addressed, could result in uncontained release of both the HPT rotor stage 2 disk and the stages 6–10 compressor rotor spool, damage to the engine, and damage to the aircraft.

(f) Compliance

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

(g) Required Actions

After the effective date of this AD, before the parts accumulate the cycles since new (CSN) threshold listed in Table 1 to paragraph (g) of this AD, remove the affected HPT rotor stage 2 disk and the stages 6–10 compressor rotor spool from service and replace with parts eligible for installation.

Table 1 to Paragraph (g) – Affected Parts and CSN Threshold

Part Name	Part P/N	Part S/N	CSN Threshold
HPT rotor stage 2 disk	2383M86P02	TMT18D6T	1,000
HPT rotor stage 2 disk	2383M86P02	TMT18D6U	1,000
HPT rotor stage 2 disk	2383M86P02	TMT18JC4	1,000
HPT rotor stage 2 disk	2383M86P02	TMT18NGC	1,000
HPT rotor stage 2 disk	2383M86P02	TMT1985C	1,000
HPT rotor stage 2 disk	2383M86P02	TMT3UA34	2,800
HPT rotor stage 2 disk	2383M86P02	TMT3UA55	2,800
HPT rotor stage 2 disk	2383M86P02	TMT4CT46	2,000
HPT rotor stage 2 disk	2383M86P02	TMT4CT47	2,000
Stages 6-10 compressor rotor spool	2628M56G01	GWN10ECM	6,500

(h) Installation Prohibition

After the effective date of this AD, do not install the affected HPT rotor stage 2 disks or the stages 6–10 compressor rotor spool identified in Table 1 to paragraph (g) of this AD on an engine.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. You may email your request to: *ANE-AD-AMOC@faa.gov.*

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

(j) Related Information

For more information about this AD, contact Mehdi Lamnyi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7743; fax: 781–238–7199; email: *Mehdi.Lamnyi@faa.gov.*

(k) Material Incorporated by Reference

None.

Issued on September 24, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21450 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0206; Product Identifier 2019–NM–202–AD; Amendment 39–21220; AD 2020–17–15]

RIN 2120–AA64

Airworthiness Directives; MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.) 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 MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440), CL–600–2C10 (Regional Jet Series 700, 701 & 702), CL–600–2C11 (Regional Jet Series 550), CL–600–2D15 (Regional Jet Series 705), CL–600–2D24 (Regional Jet Series 900), and CL–600–2E25 (Regional Jet Series 1000) airplanes. This AD was prompted by a determination that certain airplanes have outdated magnetic variation (MV) tables inside navigation systems. This AD requires revising the existing airplane flight manual (AFM) to update the Flight Management System (FMS), Inertial Reference System (IRS), and Attitude and Heading Reference System (AHRS) limitations. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 3, 2020.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of November 3, 2020.

ADDRESSES: For service information identified in this final rule, contact MHI RJ Aviation ULC, 12655 Henri-Fabre Blvd., Mirabel, Québec J7N 1E1 Canada; Widebody Customer Response Center North America toll-free telephone +1–844–272–2720 or direct-dial telephone +1–514–855–8500; fax +1–514–855–8501; email *thd.crj@mhirj.com;* internet *https://mhirj.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0206.

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–2020–0206; 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: Siddeeq Bacchus, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7362; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2019–40, dated November 1, 2019 (''Canadian AD CF–2019–40'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all MHI RJ Aviation ULC (type certificate previously held by Bombardier, Inc.) Model CL–600–2B19 (Regional Jet Series 100 & 440), CL–600–2C10 (Regional Jet Series 700, 701 & 702), CL–600–2C11 (Regional Jet Series 550), CL–600–2D15 (Regional Jet Series 705), CL–600–2D24 (Regional Jet Series 900), and CL–600–2E25 (Regional Jet Series 1000) 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–2020–0206.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440), CL–600–2C10 (Regional Jet Series 700, 701 & 702), CL–600–2C11 (Regional Jet Series 550), CL–600–2D15 (Regional Jet Series 705), CL–600–2D24 (Regional Jet Series 900), and CL–600–2E25 (Regional Jet Series 1000) airplanes. The NPRM published in the **Federal Register** on March 26, 2020 (85 FR 17036). The NPRM was prompted by a determination that certain airplanes have outdated MV tables inside navigation systems. The NPRM proposed to require revising the existing AFM to update the FMS, IRS, and AHRS limitations. The FAA is issuing this AD to address outdated MV 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 MV tables can lead to significantly inaccurate heading, course, and bearing calculations). See the MCAI for additional background information.

Comments

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

Support for the NPRM

The Airline Pilots Association, International stated its support for the NPRM.

Request To Refer to the Latest Service Information

Bombardier requested that the FAA refer to the latest service information in the NPRM. Bombardier noted that the proposed rule does not refer to the latest AFM revisions, but acknowledged that the proposed rule does refer to the AFM revisions that introduced changes to the MV tables in the limitations sections of the AFMs. Bombardier listed the current AFM revisions as of the time the comment was submitted.

The FAA does not agree. This AD does not directly mandate incorporating a specific revision level of the corresponding AFMs, but does require incorporating the information provided in the referenced AFM revisions in paragraph (g) of this AD. The language in paragraph (g) of this AD is designed to allow the incorporation of this information to be accomplished independent of the revision level of the AFM, under the condition that the incorporated information is identical to the information that is provided in the referenced AFM revisions specific in paragraph (g) of this AD. The FAA notes that when this comment was submitted, the information provided by the revisions of the AFMs listed by the commenter was identical to the information provided in the referenced AFM revisions in paragraph (g) of this AD. The FAA has not changed the AD in this regard.

Conclusion

The FAA reviewed the relevant data, considered the comments 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

Bombardier has issued the following service information, which describes procedures for updating, among other systems, the FMS, IRS, and AHRS. These documents are distinct since they apply to different airplane models.

- Section 02–09—Navigation System Limitations, of Chapter 2—LIMITATIONS, of the Bombardier CRJ Series Regional Jet Model CL–600–2B19 Airplane Flight Manual, CSP A–012, Volume 1, Revision 71A, dated April 26, 2019.
- Section 02–09—Navigation System Limitations, of Chapter 2—LIMITATIONS, of the Bombardier CRJ Series Regional Jet Model CL–600–2C10 (Series 700, 701, 702) Airplane Flight Manual, CSP B–012, Revision 26, dated March 1, 2019.
- Section 02–09—Navigation System Limitations, of Chapter 2—LIMITATIONS, of the Bombardier CRJ Series Regional Jet Model CL–600–2C10 (Series 700, 701, 702) and CL–600–2C11 (Series 550) Airplane Flight Manual, CSP B–012, Revision 28, dated September 18, 2019.
- Section 02–09—Navigation System Limitations, of Chapter 2—LIMITATIONS, of the Bombardier CRJ Series Regional Jet Model CL–600–2D24 (Series 900) and CL–600–2D15 (Series 705) Airplane Flight Manual, CSP C–012, Volume 1, Revision 21, dated March 29, 2019.
- Section 02–09—Navigation System Limitations, of Chapter 2—LIMITATIONS, of the Bombardier CRJ Series Regional Jet Model CL–600–2E25 (Series 1000) Airplane Flight Manual, CSP D–012, Revision 21, dated February 15, 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.

Costs of Compliance

The FAA estimates that this AD affects 1,072 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
1 work-hour × $85 per hour = $85	$0	$85	$91,120

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 (AD):

2020–17–15 MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.): Amendment 39–21220; Docket No. FAA–2020–0206; Product Identifier 2019–NM–202–AD.

(a) Effective Date

This AD is effective November 3, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to MHI RJ Aviation ULC (type certificate previously held by Bombardier, Inc.) Model CL–600–2B19 (Regional Jet Series 100 & 440), CL–600–2C10 (Regional Jet Series 700, 701 & 702), CL–600–2C11 (Regional Jet Series 550), CL–600–2D15 (Regional Jet Series 705), CL–600–2D24 (Regional Jet Series 900), and CL–600–2E25 (Regional Jet Series 1000) airplanes, certificated in any category, all serial numbers.

(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 (MV) tables inside navigation systems. The FAA is issuing this AD to address outdated MV 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 MV 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 30 days after the effective date of this AD, revise the existing AFM to incorporate the information specified in Section 02–09—Navigation System Limitations, of Chapter 2—LIMITATIONS, of the applicable Bombardier CRJ Series Regional Jet AFM specified in figure 1 to paragraph (g) of this AD.

Figure 1 to paragraph (g) – *AFM Revisions*

MHI RJ Aviation ULC Airplane Model	AFM Title	AFM Revision
CL-600-2B19	Bombardier CRJ Series Regional Jet Model CL-600-2B19 AFM, CSP A-012, Volume 1	Revision 71A, dated April 26, 2019
CL-600-2C10	Bombardier CRJ Series Regional Jet Model CL-600-2C10 (Series 700, 701, 702) AFM, CSP B-012	Revision 26, dated March 1, 2019
CL-600-2C11	Bombardier CRJ Series Regional Jet Model CL-600-2C10 (Series 700, 701, 702) and CL-600-2C11 (Series 550) AFM, CSP B-012	Revision 28, dated September 18, 2019
CL-600-2D15 and CL-600-2D24	Bombardier CRJ Series Regional Jet Model CL-600-2D24 (Series 900) and CL-600-2D15 (Series 705) AFM, CSP C-012, Volume 1	Revision 21, dated March 29, 2019
CL-600-2E25	Bombardier CRJ Series Regional Jet Model CL-600-2E25 (Series 1000) AFM, CSP D-012	Revision 21, dated February 15, 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 local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 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 local flight standards district office/certificate holding district office.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or MHI RJ Aviation ULC'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–2019–40, dated November 1, 2019, 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–2020–0206.

(2) For more information about this AD, contact Siddeeq Bacchus, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7362; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(j) 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) Section 02–09—Navigation System Limitations, of Chapter 2—LIMITATIONS, of the Bombardier CRJ Series Regional Jet Model CL–600–2B19 Airplane Flight Manual, CSP A–012, Volume 1, Revision 71A, dated April 26, 2019.

(ii) Section 02–09—Navigation System Limitations, of Chapter 2—LIMITATIONS, of the Bombardier CRJ Series Regional Jet Model CL–600–2C10 (Series 700, 701, 702) Airplane Flight Manual, CSP B–012, Revision 26, dated March 1, 2019.

Note 1 to paragraph (j)(2)(ii): Page 02–09–1 of this document is identified as Revision 22, dated September 15, 2017.

(iii) Section 02–09—Navigation System Limitations, of Chapter 2—LIMITATIONS, of the Bombardier CRJ Series Regional Jet Model CL–600–2C10 (Series 700, 701, 702) and CL–600–2C11 (Series 550) Airplane Flight Manual, CSP B–012, Revision 28, dated September 18, 2019.

Note 2 to paragraph (j)(2)(iii): Page 02–09–1 of this document is identified as Revision 22, dated September 15, 2017.

(iv) Section 02–09—Navigation System Limitations, of Chapter 2—LIMITATIONS, of the Bombardier CRJ Series Regional Jet Model CL–600–2D24 (Series 900) and CL–600–2D15 (Series 705) Airplane Flight Manual, CSP C–012, Volume 1, Revision 21, dated March 29, 2019.

Note 3 to paragraph (j)(2)(iv): Page 02–09–1 of this document is identified as Revision 17, dated October 13, 2017.

(v) Section 02–09—Navigation System Limitations, of Chapter 2—LIMITATIONS, of the Bombardier CRJ Series Regional Jet Model CL–600–2E25 (Series 1000) Airplane Flight Manual, CSP D–012, Revision 21, dated February 15, 2019.

Note 4 to paragraph (j)(2)(v): Page 02–09–1 of this document is identified as Revision 17, dated June 16, 2017.

(3) For service information identified in this AD, contact MHI RJ Aviation ULC, 12655 Henri-Fabre Blvd., Mirabel, Québec J7N 1E1 Canada; Widebody Customer Response Center North America toll-free telephone +1–844–272–2720 or direct-dial telephone +1–514–855–8500; fax +1–514–855–8501; email *thd.crj@mhirj.com;* internet *https://mhirj.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this 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 August 14, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21411 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

National Institutes of Standards and Technology

15 CFR Part 287

[Docket No.: 200813–0217]

RIN 0693–AB65

Guidance on Federal Conformity Assessment Activities

AGENCY: National Institute of Standards and Technology (NIST), United States Department of Commerce.

ACTION: Final rule.

SUMMARY: The National Institute of Standards and Technology (NIST) announces revisions to regulations updating guidance on Federal agency use of conformity assessment that reflects advancement in conformity assessment concepts, and the evolution in Federal agency strategies and coordination in using and relying on conformity assessment. The provisions are solely intended to be used as guidance for agencies in their use and reliance on conformity assessment to meet agency requirements and do not preempt the agency authority and responsibility to make decisions authorized by statute or required in establishing regulatory, procurement, or programmatic activities.

DATES: This rule is effective October 29, 2020.

FOR FURTHER INFORMATION CONTACT: Mr. Gordon Gillerman via email at *15CFR287@nist.gov,* or by phone at (301) 975–4000.

SUPPLEMENTARY INFORMATION:

I. Purpose of This Guidance

The guidance outlines Federal agencies' responsibilities for using conformity assessment to meet respective agency requirements in an efficient and cost-effective manner for the agency and its stakeholders. To reduce unnecessary complexity and make productive use of Federal resources, this guidance emphasizes that agencies should consider coordinating conformity assessment activities with those of other appropriate government agencies (Federal, State, and local) and with those in the private sector. This guidance does not preempt agency authority and responsibility to make decisions authorized by statute or required in establishing regulatory, procurement, or program activities. This guidance also does not preempt agency authority and responsibility in determining or implementing procurement, regulatory, or programmatic requirements.

II. Background

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 directs NIST to ''coordinate technical standards activities and conformity assessment activities of Federal, State, and local governments with private sector technical standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures'' (15 U.S.C. 272(b)(13)). NIST originally issued the guidance found in 15 CFR part 287 (this Guidance) on August 10, 2000, in response to Office of Management and Budget (OMB) Circular A–119 (February 10, 1998) directing the Secretary of Commerce to issue guidance to Federal agencies to ensure effective coordination of Federal conformity assessment activities (65 FR 48894). The January 2016 revision to OMB Circular A–119 re-emphasizes NIST's role in issuing guidance to agencies as well as Federal agencies responsibilities with respect to conformity assessment. NIST is revising this guidance to reflect progression in conformity assessment concepts and evolution in Federal agency strategies and coordination in using and relying on conformity assessment.

This guidance is one of several activities undertaken by the NIST Standards Coordination Office to update its guidance, training, and other artifacts that help agencies develop and use conformity assessment. As a first activity, NIST provided significant input to the conformity assessment related policies of OMB Circular A–119. NIST released two NIST Special Publications (SPs) in September 2018. NIST SP 2000–01, *ABCs of Conformity Assessment,* serves as a primer for the topic of conformity assessment, and NIST SP 2000–02, *Conformity Assessment Considerations for Federal Agencies,* provides agencies with a path to follow in considering the development, use or improvement of conformity assessment to meet their requirements. The revisions to 15 CFR part 287 represent NIST's most recent effort to provide Federal agencies with up-to-date tools for effective use of conformity assessment.

Summary of Changes Between the Proposed Rule and Final Rule

On February 7, 2020, NIST published a notice of proposed rulemaking (NPRM) in the **Federal Register** (85 FR 7258) requesting public comments on proposed revisions to regulations updating policy guidance on Federal agency use of conformity assessment that reflects advancement in conformity assessment concepts, and the evolution in Federal agency strategies and coordination in using and relying on conformity assessment. Nine (9) entities submitted comments, including two (2) accreditation bodies, one (1) conformity assessment body, two (2) individuals, three (3) industry associations, and one (1) regional government. The following is a summary and analysis of the comments received during the public comment period, and NIST's responses including the recommendations and issues considered in the development of the CFR.

1. *Comment:* Commenters indicated that definitions should be updated to include new terminology and definitions for state agency, local agency, state standards executive, and local standards executive. In addition, commenters indicated changes to the definition of conformity assessment were necessary to ensure consistency between NIST conformity assessment publications and this guidance.

Response: NIST agrees with the need for consistency of definitions and has aligned the definitions in 15 CFR 287.2, Definitions, with those in OMB Circular

A–119. NIST does not have the authority to define roles for a state standards executive or a local standards executive. The definition of NIST as an acronym has been removed from this guidance. During the rulemaking process, NIST realized this definition was unnecessary and that its removal does not result in substantive changes.

2. *Comment:* Commenters supported removal of examples (*i.e.,* conformity assessment organizations by name and specific standards) from the NPRM. Other comments were received that support continued inclusion of examples.

Response: NIST reviewed the impact of the comments and has removed the examples. While they may be valuable as a learning vehicle, the use of examples may lead agencies to believe there are limited ways to address specific needs. In addition, the inclusion of some examples, (and exclusion of others) may be perceived as an endorsement or criticism by NIST.

3. *Comment:* Commenters responded that they were concerned changes reflected a reduction in NIST's role working with agencies and indicated that a central coordination role should be included to guide, collect, and disseminate Federal, State, and local conformity assessment activities.

Response: The roles and responsibilities of Federal agencies, including NIST, with respect to conformity assessment are stated in the National Technology Transfer and Advancement Act (NTTAA) and OMB Circular A–119. NIST does not interpret its statutory coordination role under the NTTAA with respect to State and local agencies to include the collection and dissemination of conformity assessment information from State and local agencies, as the explicit purpose of the relevant provision is limited to eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures.

4. *Comment:* Commenters responded that greater emphasis was placed on the role of the Interagency Committee for Standards Policy (ICSP), including coordination of conformity assessment activities through this committee in the proposed revisions to the regulations than the original CFR.

Response: NIST has clarified language in 15 CFR 287.3(c) regarding the role of the ICSP by adding the phrase, ''and other means,'' so that the new provision will indicate that NIST intends to ''work with agencies through the ICSP and other means to coordinate Federal, State and local conformity assessment activities with private sector conformity assessment activities.'' NIST utilizes the ICSP to exchange information, provide direction to Federal agencies, and provide opportunities for coordination. The ICSP provides a conduit for sharing conformity assessment information across agencies.

5. *Comment:* Commenters requested the use of Federal agency viewpoints in the development of voluntary consensus standards related to conformity assessment. In addition, commenters indicated that the term ''voluntary consensus conformity assessment related standards'' is not defined and may cause industry confusion.

Response: NIST has revised 15 CFR 287.4(g) to clarify the role of agencies in development of voluntary consensus standards as well as development of voluntary consensus standards related to conformity assessment. In addition, NIST intends to revise the term ''voluntary consensus conformity assessment related standard'' to ''voluntary consensus standards related to conformity assessment.''

6. *Comment:* Commenters indicated that NIST should not extend the review period of the effectiveness of this guidance from three to five years. Commenters expressed the need for frequent review due to the complex and dynamic nature of conformity assessment in addition to transparency and openness.

Response: NIST has kept the proposed language and maintained the five-year review of the effectiveness of the guidance consistent with the review periodicity of OMB Circular A–119.

7. *Comment:* Commenters indicated a need for state and local government conformity assessment coordination in addition to coordination within the Federal Government in 15 CFR 287.3, NIST Responsibilities, and 15 CFR 287.4, Federal Agency Responsibilities.

Response: NIST has retained the language as written in the CFR. The proposed language is consistent with the statutory authority in NTTAA as well as OMB Circular A–119. NIST does not have the authority to expand the role of other Federal agencies regarding coordination of state and local conformity assessment activities.

III. Applicability of This Guidance

This guidance applies to all agencies, which set policy for, manage, operate, or use conformity assessment activities and results. ''Agency'' means any Executive Department, independent commission, board, bureau, office, government-owned or controlled corporation, or other establishment of the Federal Government. It also includes any regulatory commission or board, except for independent regulatory commissions insofar as they are subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment activities. It does not include the legislative or judicial branches of the Federal Government although those branches may use this guidance to inform their own use of conformity assessment.

IV. Classification

Executive Order 12866

This rulemaking is not a significant regulatory action under Executive Order 12866.

Executive Order 13771

This rule is not subject to the requirements of Executive Order 13771, because its likely impact is *de minimis.*

Executive Order 13132

This rule does not contain policies with federalism implications as defined in Executive Order 13132.

Regulatory Flexibility Act

The Chief Counsel for Regulation for the Department of Commerce certified at the proposed rule stage to the Chief Counsel for Advocacy of the Small Business Administration under the provisions of the Regulatory Flexibility Act, 5 U.S.C. 605(b), that this rule, if adopted, would not have a significant economic impact on a substantial number of small business entities. No comments were received on this certification, so no Final Regulatory Flexibility Analysis is required, and none has been prepared.

Paperwork Reduction Act

This rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

National Environmental Policy Act

This rule will not significantly affect the quality of the human environment. Therefore, neither an environmental assessment nor an Environmental Impact Statement is required to be prepared under the National Environmental Policy Act of 1969.

List of Subjects in 15 CFR Part 287

Conformity assessment, Procurement, Trade agreements, Voluntary standards.

■ For the reasons stated in the preamble, the National Institute of Standards and Technology revises 15 CFR part 287 to read as follows:

PART 287—GUIDANCE ON FEDERAL CONFORMITY ASSESSMENT

Sec.
287.1 Purpose and scope of this part.
287.2 Definitions.
287.3 Responsibilities of the National Institute of Standards and Technology.
287.4 Responsibilities of Federal agencies.
287.5 Responsibilities of Agency Standards Executives.

Authority: 15 U.S.C. 272.

§ 287.1 Purpose and scope of this part.

(a) This part outlines Federal agencies' responsibilities for using conformity assessment to meet respective agency requirements in an efficient and cost-effective manner for the agency and its stakeholders. To reduce unnecessary complexity and make productive use of Federal resources, this part emphasizes that agencies should consider coordinating conformity assessment activities with those of other appropriate government agencies (Federal, State, and local) and with those in the private sector.

(b) Using conformity assessment in a manner consistent with this part supports U.S. Government efforts to meet trade obligations and demonstrate good regulatory practices, which reduces unnecessary obstacles to international trade and improves market access for products and services.

(c) This part applies to all agencies which set policy for, manage, operate, or use conformity assessment. This part does not preempt the agencies' authority and responsibility to make decisions authorized by statute or required to meet regulatory, procurement, or programmatic objectives and requirements. These decision-making activities include: determining the level of acceptable regulatory or procurement risk; setting the level of protection; balancing risk, cost, and availability of technology and technical resources (where statutes permit) in establishing regulatory, procurement, and program requirements.

(d) Each agency retains broad discretion in its selection and use of conformity assessment activities and may elect not to use or recognize alternative conformity assessment approaches if the agency deems the alternatives to be inappropriate, inadequate, or inconsistent with statutory criteria or programmatic objectives and requirements. Nothing contained in this part shall give any party any claim or cause of action against the Federal Government or any agency thereof. Each agency remains responsible for representation of the agency's views on conformity assessment in matters under its jurisdiction. Each agency also remains the primary point of contact for information on the agency's regulatory, procurement, or programmatic conformity assessment actions.

§ 287.2 Definitions.

For the purposes of this part:

Agency means any Executive Department, independent commission, board, bureau, office, government-owned or controlled corporation, or other establishment of the Federal Government. It also includes any regulatory commission or board, except for independent regulatory commissions insofar as they are subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment. It does not include the legislative or judicial branches of the Federal Government.

Agency Standards Executive means an official designated by an agency as its representative on the Interagency Committee for Standards Policy (ICSP) and delegated the responsibility for agency implementation of Office of Management and Budget (OMB) Circular A–119 and the guidance in this part.

Conformity assessment is a demonstration, whether directly or indirectly, that specified requirements relating to a product, process, system, person, or body are fulfilled. Requirements for products, services, systems, persons, and organizations are those defined by law or regulation, by an agency in regulatory or procurement actions, or an agency programmatic policy. Conformity assessment does not include mandatory administrative procedures (such as registration notification) for granting permission for a good or service to be produced, marketed, or used for a stated purpose or under stated conditions. Conformity assessment related terminology and concepts, including a discussion of the value and benefits of conformity assessment, are contained in NIST Special Publication 2000–01, *ABCs of Conformity Assessment* (2018) found free of charge at: *https://doi.org/10.6028/NIST.SP.2000-01* and *NIST Special Publication 2000–02, Conformity Assessment Considerations for Federal Agencies,* found at: *https://doi.org/10.6028/NIST.SP.2000-02.* The definitions of conformity assessment related terminology included in these documents are based on voluntary consensus standards. See OMB Circular A–119 for a description of voluntary consensus standards and recommendations for their development and use by Federal agencies.

§ 287.3 Responsibilities of the National Institute of Standards and Technology.

(a) Coordinate issues related to agency conformity assessment program development, use, and implementation and issue guidance, training material, and other material to assist Federal agencies in understanding and applying conformity assessment to meet their requirements. Material is available at *https://www.standards.gov.*

(b) Chair the Interagency Committee on Standards Policy (ICSP); encourage participation in the ICSP; as well as provide resource support to the ICSP and its working groups related to conformity assessment issues, as needed.

(c) Work with agencies through the ICSP and other means to coordinate Federal, State, and local conformity assessment activities with private sector conformity assessment activities.

(d) Participate in the development of voluntary consensus standards, recommendations, and guidelines related to conformity assessment to ensure that Federal viewpoints are represented.

(e) Increase awareness of the importance of public and private sector conformity assessment through development and publication of conformity assessment resources. Material is available at *https://www.standards.gov.*

(f) To the extent that resources are available and upon request by a state government agency, work with that state agency to reduce duplication and complexity in state conformity assessment activities.

(g) Review, within five years from October 29, 2020, the effectiveness of the guidance in this part and recommend modifications to the Secretary as needed.

§ 287.4 Responsibilities of Federal agencies.

Each agency should:

(a) Implement the policies contained in the guidance in this part. Agencies may rely on NIST Special Publication 2000–02 *Conformity Assessment Considerations for Federal Agencies* found free of charge at *https://doi.org/10.6028/NIST.SP.2000-02.*

(b) Develop and implement conformity assessment in a manner that meets regulatory, procurement, and programmatic objectives; reduces unnecessary complexity for stakeholders; makes productive use of Federal resources; and meets international trade agreement obligations.

(c) Provide a rationale for its use of specified conformity assessment in

rulemaking, procurement actions, and agency programs to the extent feasible. Further, when notice and comment rulemaking is otherwise required, each agency should provide the opportunity for public comment on the rationale for the agency's conformity assessment decision.

(d) Work with other Federal agencies to avoid unnecessary duplication and complexity in Federal conformity assessment activities.

(e) Consider leveraging the activities and results of other governmental agency and private sector programs in lieu of creating government-unique programs or to enhance the effectiveness of proposed new and existing conformity assessment.

(f) Give a preference for using voluntary consensus standards, guides, and recommendations related to conformity assessment in agency operations. Each agency retains responsibility for determining which, if any, of these documents are relevant to its needs. See OMB Circular A–119 for a description of voluntary consensus standards and recommendations for their development and use by Federal agencies.

(g) Participate, as needed, representing agency and Federal viewpoints, in efforts to develop voluntary consensus standards, guideline, and recommendations related to conformity assessment.

(h) Participate, as needed, representing agency and Federal viewpoints in efforts designed to improve coordination among governmental and private sector conformity assessment activities.

(i) Work with NIST, other Federal agencies, ICSP members, and the private sector to coordinate U.S. conformity assessment needs, practices, and requirements in support of the efforts of the U.S. Government and U.S. industry to increase international trade of U.S. products and services.

(j) Assign an Agency Standards Executive the responsibility for coordinating agency-wide implementation of the guidance in this part who is situated in the agency's organizational structure such that the Agency Standards Executive is kept regularly apprised of the agency's regulatory, procurement, and other mission-related activities, and has sufficient authority within the agency to ensure implementation of the guidance in this part.

§ 287.5 Responsibilities of Agency Standards Executives.

Each Agency Standards Executive should:

(a) Carry out the duties in OMB Circular A–119 related to conformity assessment activities.

(b) Encourage effective use of agency conformity assessment related resources.

(c) Provide ongoing assistance and policy guidance to the agency on significant issues in conformity assessment.

(d) Contribute to the development and dissemination of:

(1) Internal agency policies related to conformity assessment issues; and

(2) Agency positions on conformity assessment related issues that are in the public interest.

(e) Work with other parts of the agency to develop and implement improvements in agency conformity assessment activities.

(f) Participate in the Interagency Committee on Standards Policy (ICSP) as the agency representative and member.

(g) Promote agency participation in ICSP working groups related to conformity assessment issues, as needed.

(h) Encourage agency participation in efforts related to the development of voluntary consensus standards, recommendations, and guidelines related to conformity assessment consistent with agency missions, authorities, priorities, and resources.

(i) Establish an ongoing process for reviewing the agency's conformity assessment programs and identify areas where efficiencies can be achieved through coordination within the agency and among other agencies and private sector conformity assessment activities.

Kevin A. Kimball,

Chief of Staff.

[FR Doc. 2020–18745 Filed 9–28–20; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 75

[Docket No. FR–6085–N–04]

Section 3 Benchmarks for Creating Economic Opportunities for Low- and Very Low-Income Persons and Eligible Businesses

AGENCY: Office of the Assistant Deputy Secretary for Field Policy and Management, HUD.

ACTION: Notification of benchmarks.

SUMMARY: Section 3 of the Housing and Urban Development Act of 1968, as amended by the Housing and Community Development Act of 1992 (Section 3), contributes to the establishment of stronger, more sustainable communities by ensuring that employment and other economic opportunities generated by Federal financial assistance for housing and community development programs are, to the greatest extent feasible, directed toward low- and very low-income persons, particularly those who are recipients of government assistance for housing. HUD is statutorily charged with the authority and responsibility to implement and enforce Section 3. Elsewhere in this issue of the **Federal Register**, HUD published a final rule that would amend the Section 3 regulations to, among other things, increase Section 3's impact, and streamline and update HUD's reporting and tracking requirements. The final rule includes a requirement that HUD set Section 3 benchmarks by publishing a notification, subject to public comment, in the **Federal Register**. If a recipient complies with the statutory priorities regarding effort and meets the outcome benchmarks in this document, HUD will presume the recipient is following Section 3 requirements, absent evidence to the contrary.

DATES: *Effective Date.* October 29, 2020.

FOR FURTHER INFORMATION CONTACT: Alastair W. McFarlane, Director, Economic Development and Public Finance Division, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street SW, Room 8216, Washington, DC 20410; telephone 202–402–5845 (voice/TDD) (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, toll-free at, 800–877–8339. General email inquiries regarding Section 3 may be sent to: *section3@hud.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 3 of the Housing and Urban Development Act of 1968 (Pub. L. 90–448, approved August 1, 1968) (Section 3) (12 U.S.C. 1701u) was enacted to ensure, to the greatest extent feasible, that economic opportunities generated by certain HUD financial assistance expenditures are directed to low- and very low-income persons, particularly those who receive Federal financial assistance for housing and those residing in communities where the financial assistance is expended.

In accordance with statutory authority, HUD is charged with the responsibility to implement and enforce

Section 3. HUD's regulations implementing the requirements of Section 3 have not been updated since 1994 and are not as effective as HUD believes they could be. Furthermore, significant legislation has been enacted that affects HUD programs that are subject to Section 3 and that are not adequately addressed in the current Section 3 regulations. On April 4, 2019, HUD proposed a rule to update the Section 3 regulations. *See* 84 FR 13177. The proposed rule incorporated a change from tracking the number of Section 3 qualified new hires in public housing financial assistance and Section 3 projects, to tracking the total labor hours worked. In connection with the proposed rule, HUD issued a proposed benchmark notification. *See* 84 FR 13199. The proposed benchmark notification included a proposed benchmark number and the methodology for determining the benchmarks.

Benchmarks

For public housing financial assistance, the proposed benchmark notification provided that PHAs and other recipients would meet the safe harbor in the new § 75.13 by certifying to the prioritization of effort in the new § 75.9 and meeting or exceeding Section 3 benchmarks for total number of labor hours worked by Section 3 workers and by Targeted Section 3 workers. (See the definitions of these two categories of workers at the end of Section II of this preamble, below.) The benchmark for Section 3 workers was set at 25 percent or more of the total number of labor hours worked by all workers employed with public housing financial assistance in the PHA's or other recipient's fiscal year. The benchmark for Targeted Section 3 workers was set at 5 percent or more of the total number of labor hours worked by all workers employed with public housing financial assistance in the PHA's or other recipient's fiscal year.

For Section 3 projects, the proposed benchmark notification set the same benchmarks but with regards to the project itself rather than the recipient's fiscal year. The proposed benchmark notification provided that recipients would meet the safe harbor in the new § 75.23 by certifying to the prioritization of effort in the new § 75.19 and meeting or exceeding Section 3 benchmarks for total number of labor hours worked by Section 3 workers and by Targeted Section 3 workers. The benchmark for Section 3 workers was set at 25 percent or more of the total number of labor hours worked by all workers on a Section 3 project. The benchmark for Targeted Section 3 workers was set at 5 percent or more of the total number of labor hours worked by all workers on a Section 3 project.

Methodology

To determine these benchmarks, HUD looked at the total hours worked on a construction or development project, the total number of workers that would likely qualify as Section 3 workers, and the potential pool of Targeted Section 3 workers. In order for the Section 3 employment goal to be attainable, HUD determined a labor-hour threshold that is congruent with the labor market for low-income workers by examining the lower end of the wage distribution of the relevant industries. Based on the wage distribution data for on-site construction and building services, HUD set the threshold for Section 3 labor hours at 25 percent of all labor hours to encourage recipients, subrecipients, contractors, and subcontractors to hire more Section 3 workers for construction. For the Targeted Section 3 benchmarks, HUD estimated the number of residents of public housing or Section 8-assisted housing, of current YouthBuild participants, and of workers employed by Section 3 business concerns. HUD also examined commuting times based on U.S. Census data. Finally, HUD reviewed Community Development Block Grant program (CDBG) and HOME Investment Partnerships Program (HOME) projects to estimate the number of potential Targeted Section 3 workers available for Section 3 projects. Based on these data, HUD determined that 5 percent of all labor hours, or, in other words, 20 percent of the Section 3 labor hour threshold, was a reasonable goal for both public housing financial assistance and for Section 3 projects.

HUD sought public comment on both the proposed rule and benchmark notification and received 187 public comments, 163 public comments on the proposed rule and 24 public comments on the proposed benchmark notification. Comments on the proposed rule and notification covered both content on the rule and the benchmark numbers. Therefore, all public comments received on both the proposed rule and the proposed benchmark notification are addressed in HUD's Section 3 final rule.

II. Section 3 Final Rule

The Section 3 final rule creates new Section 3 regulations in 24 CFR part 75; the public can find the final rule issued elsewhere in today's **Federal Register**. The Section 3 final rule aims to make Section 3 goals and reporting more meaningful and more aligned with statutory requirements. The final rule, consistent with HUD's Section 3 proposed rule, includes new metrics for compliance safe harbors and provides that these benchmarks will be set by notification in the **Federal Register**. The final rule separates out the new requirements and benchmarks by the type of funding, as follows:

(1) *Public housing program:* Subpart B, Additional Provisions for Public Housing Financial Assistance, covers development assistance provided pursuant to section 5 of the U.S. Housing Act of 1937 (1937 Act) and Operating Fund and Capital Fund assistance provided pursuant to section 9 of the 1937 Act, collectively; these are defined as public housing financial assistance in the proposed rule.

(2) *Other HUD programs:* Subpart C, Additional Provisions for Section 3 Projects, covers housing rehabilitation, housing construction, and other public construction projects assisted under HUD programs that provide housing and community development financial assistance when the amount of assistance to the project exceeds a threshold of $200,000, and is defined as a Section 3 project. A $100,000 project threshold applies to grants under HUD's Lead Hazard Control and Healthy Homes programs.

As for new metrics, the final rule provides, consistent with the Section 3 proposed rule, that HUD will establish the Section 3 benchmarks, through a **Federal Register** notification. The final rule provides that HUD may establish a single nationwide benchmark for work performed by Section 3 workers and a single nationwide benchmark for work performed by Targeted Section 3 workers, or may establish multiple benchmarks based on geography, the type of public housing financial assistance, or other variables. The final rule also provides, in establishing the benchmarks, that HUD may consider the industry averages worked by specific categories of workers or in different localities or regions; prior Section 3 reports by recipients; and any other factors HUD deems important. In establishing the Section 3 benchmarks, HUD would exclude professional services, which would be defined as non-construction services that require an advanced degree or professional licensing, including, but not limited to, contracts for legal services, financial consulting, accounting services, environmental assessment, architectural services, and civil engineering services. Lastly, HUD commits to updating the benchmarks no less frequently than once every three years through notice,

subject to public comment, in the **Federal Register**.

HUD created the Section 3 worker and Targeted Section 3 worker concepts so that HUD could track and set benchmarks to target selected categories of workers and to recognize the statutory requirements pertaining to contracting opportunities for business concerns employing low- and very-low income persons.

In the final Section 3 rule, HUD defines a Section 3 worker for both public housing financial assistance and Section 3 projects as a worker that meets one of the following requirements:

- The worker's income is below the income limit established by HUD.
- The worker is employed by a Section 3 business concern.
- The worker is a YouthBuild participant.

HUD defines a Targeted Section 3 worker differently for public housing financial assistance and Section 3 projects. For § 75.11, public housing financial assistance, a Targeted Section 3 worker includes any worker who is employed by a Section 3 business concern or is a:

- Resident of public housing or Section 8-assisted housing;
- Resident of another project managed by the PHA that is expending assistance; or
- YouthBuild participant.

For § 75.21, Section 3 projects, a Targeted Section 3 worker includes any worker who is employed by a Section 3 business concern or is a Section 3 worker who is:

- Living within the service area or neighborhood of the project; or
- A YouthBuild participant.

HUD defines a Section 3 business concern as a business concern that meets one of the following requirements:

- It is at least 51 percent owned by low- or very low-income persons;
- Over 75 percent of the labor hours performed for the business are performed by low- or very low-income persons; or
- It is a business at least 51 percent owned by current public housing residents or residents who currently live in Section 8-assisted housing.

For more information about the final rule, HUD refers readers to the final rule published elsewhere in this issue of the **Federal Register**.

III. Section 3 Benchmarks

This document finalizes the benchmarks with regards to labor hours for both public housing financial assistance and Section 3 projects without changes from what was included in the proposed benchmark notification. In the final rule, HUD is not adopting the new hires formula as proposed as an alternative in the proposed rule, so the new hires formula is accordingly not reflected in this document. HUD is finalizing the same benchmarks for all public housing financial assistance and Section 3 projects. The methodology in determining the Section 3 benchmarks, as discussed above in the Background section, did not change from what was described in the proposed benchmark notification because the definitions of Section 3 Workers, Targeted Section 3 Workers, and Section 3 Business concerns provided in the proposed rule and adopted in the Section 3 final rule were not substantially different. Once HUD has more data, it may determine whether different benchmarks are appropriate. Please see the above summary in the Background section of this document and the proposed benchmark notification for more information.

The following benchmarks apply to recipients subject to Section 3 upon the effective date in the Section 3 final rule:

Public Housing Financial Assistance

For meeting the safe harbor in § 75.13, PHAs and other recipients that certify to following the prioritization of effort in § 75.9 and meet or exceed the following Section 3 benchmarks will be considered to have complied with requirements in proposed 24 CFR part 75, subpart B, in the absence of evidence to the contrary:

(1) Twenty-five (25) percent or more of the total number of labor hours worked by all workers employed with public housing financial assistance in the PHA's or other recipient's fiscal year are Section 3 workers;

$$\frac{\text{Section 3 Labor Hours}}{\text{Total Labor Hours}} = 25\%$$

and

(2) Five (5) percent or more of the total number of labor hours worked by all workers employed with public housing financial assistance in the PHA's or other recipient's fiscal year are Targeted Section 3 workers, as defined at § 75.11.

$$\frac{\text{Targeted Section 3 Labor Hours}}{\text{Total Labor Hours}} = 5\%$$

Section 3 Project

For meeting the safe harbor in § 75.23, recipients that certify to following the prioritization in § 75.19 and meet or exceed the following Section 3 benchmarks will be considered to have complied with requirements in proposed 24 CFR part 75, subpart C, in the absence of evidence to the contrary:

(1) Twenty-five (25) percent or more of the total number of labor hours worked by all workers on a Section 3 project are Section 3 workers;

$$\frac{\text{Targeted Section 3 Labor Hours}}{\text{Total Labor Hours}} = 25\%$$

and

(2) Five (5) percent or more of the total number of labor hours worked by all workers on a Section 3 project are Targeted Section 3 workers, as defined at § 75.21.

$$\frac{\text{Targeted Section 3 Labor Hours}}{\text{Total Labor Hours}} = 5\%$$

IV. Environmental Impact

This document involves the establishment of new Section 3 benchmarks for creating economic opportunities for low- and very low-income persons and eligible businesses, and does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction; or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this document is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Benjamin S. Carson, Sr.,

Secretary.

[FR Doc. 2020–19183 Filed 9–28–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9901]

RIN 1545–BO55

Deduction for Foreign-Derived Intangible Income and Global Intangible Low-Taxed Income; Correcting Amendment

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to Treasury Decision 9901, which was published in the **Federal Register** on Wednesday, July 15, 2020. The Treasury Decision provided guidance regarding the deduction for foreign derived intangible income (FDII) and global intangible low-taxed income (GILTI).

DATES: These corrections are effective on September 29, 2020.

Applicability Date: For date of applicability, see § 1.250–1(b).

FOR FURTHER INFORMATION CONTACT: Brad McCormack at (202) 317–6911 and Lorraine Rodriguez at (202) 317–6726; (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9901) that are the subject of this correction are issued under section 250 of the Internal Revenue Code.

Need for Correction

As published July 15, 2020 (85 FR 43042), the final regulations (TD 9901) contain errors that need to be corrected.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.250–0 is amended by revising the entry for § 1.250(b)–6 (d)(3)(ii) to read as follows:

§ 1.250–0 Table of contents.

* * * * *

§ 1.250(b)–6 *Related party transactions.*

* * * * *

(d) * * *

(3) * * *

(ii) Rules for allocating the benefits provided by and price paid to the renderer of a related party service.

* * * * *

■ **Par. 3.** Section 1.250(b)–2 is amended by revising the second sentence of paragraph (d)(4)(ii)(C) to read as follows:

§ 1.250(b)–2 Qualified business asset investment (QBAI).

* * * * *

(d) * * *

(4) * * *

(ii) * * *

(C) * * * Therefore, under paragraph (d)(3) of this section, DC's dual use ratio with respect to the machine for the taxable year is 80 percent, which is DC's depreciation with respect to the machine that is capitalized to inventory of Product A, the gross income or loss from the sale of which is taken into account in determining DC's DEI for the taxable year ($320x), divided by DC's depreciation with respect to the machine that is capitalized to inventory, the gross income or loss from the sale of which is taken into account in determining DC's income for Year 1 ($400x). * * *

* * * * *

■ **Par. 4.** Section 1.250(b)–4 is amended by revising the paragraph heading for paragraph(d)(2)(iv)(B)(*13)* to read as follows:

§ 1.250(b)–4 Foreign-derived deduction eligible income (FDDEI) sales.

* * * * *

(d) * * *

(2) * * *

(iv) * * *

(B) * * *

(*13*) *Example 13: License of intangible property used in research and development of other intangible property—** * *

* * * * *

■ **Par. 5.** Section 1.250(b)–5 is amended by revising the second sentence of paragraph (e)(2)(iii) to read as follows:

§ 1.250(b)–5 Foreign-derived deduction eligible income (FDDEI) services.

* * * * *

(e) * * *

(2) * * *

(iii) * * * If it cannot be determined whether the location is within or outside the United States (such as where the location of access cannot be reliably determined using the location of the IP address of the device used to receive the service), and the gross receipts from all services with respect to the business recipient are in the aggregate less than $50,000 for the renderer's taxable year, the operations of the business recipient that benefit from the service provided by the renderer are deemed to be located at the recipient's billing address; otherwise, the operations of the business recipient that benefit are deemed to be located in the United States. * * *

* * * * *

■ **Par. 6.** Section 1.250(b)–6 is amended by:

■ 1. Revising the second sentence of paragraph (d)(4)(ii)(B)(*2*)(*i*).

■ 2. Revising the third sentence of paragraph (d)(4)(ii)(C)(*2*)(*i*).

The revisions read as follows:

§ 1.250(b)–6 Related party transactions.

* * * * *

(d) * * *

(4) * * *

(ii) * * *

(B) * * *

(*2*) * * *

(*i*) * * * However, because 90 percent of R's operations that will benefit from FC's service are located outside the United States under paragraph (d)(3)(i) of this section, only 10 percent of the benefits of FC's service are conferred on persons located within the United States. * * *

* * * * *

(C) * * *

(*2*) * * *

(*i*) * * * Accordingly, because 10 percent of R's operations that will benefit from FC's services are located within the United States, persons located within the United States are treated as paying $10x ($100x × 0.10) for FC's services for purposes of applying the test in paragraph (d)(2)(ii) of this section.

* * * * *

§ 1.1502–12 [Corrected]

■ **Par. 7.** On page 43112, in the third column, amendatory instruction 18 under § 1.1502–12, is corrected to read as ''Redesignating newly designated paragraphs (c)(7)(ii)(Q)(a) through (c) as paragraphs (c)(7)(ii)(Q)(*1*) through (*3*)''.

Crystal Pemberton,

Senior Federal Register Liaison, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2020–19333 Filed 9–28–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 272

[Docket ID: DOD–2019–OS–0007]

RIN 0790–AK51

Administration and Support of Basic Research by the Department of Defense

AGENCY: Under Secretary of Defense (Research and Engineering), Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: This final rule removes DoD's regulation concerning the

administration and support of basic research by the Department of Defense, because the content of this part is internal to the Department. Therefore, this CFR part can be removed.

DATES: This rule is effective September 29, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Orlando, Basic Research Office, telephone 571–372–6413.

SUPPLEMENTARY INFORMATION: The DoD rule at 32 CFR part 272, last updated on September 23, 2005 (70 FR 55726), is internal to the DoD and does not need to be codified in the CFR. Based on a recommendation from the DoD Regulatory Reform Task Force, this part is removed. It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest since it is based on removing DoD internal policies and procedures that are publicly available on the Department's issuance website. DoD internal guidance concerning administration and support of basic research by the DoD will continue to be updated and maintained in DoD Instruction 3210.1, ''Administration and Support of Basic Research by the Department of Defense,'' last updated on October 15, 2018 (available at *http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321001p.pdf*).

This rule is not significant under Executive Order (E.O.) 12866, ''Regulatory Planning and Review.'' Therefore, E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' does not apply.

List of Subjects in 32 CFR part 272

Grant programs-science and technology, Research.

PART 272—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 272 is removed.

Dated: September 25, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–21612 Filed 9–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0606]

RIN 1625–AA00

Safety Zone; I–5 Bridge Construction Project, Columbia River, Vancouver, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of the Columbia River. This action is necessary to provide for the safety of life on these navigable waters around the Northbound I–5 Interstate Bridge at Columbia River Mile 106.5. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Columbia River.

DATES: This rule is effective with actual notice from 12:01 a.m. on September 27, 2020, through September 29, 2020. It is effective without actual notice from September 29, 2020 through 11:59 p.m. on October 12, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0247 in the ''SEARCH'' box and click ''SEARCH.'' To view the Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Dixon Whitley, Waterways Management Division, Marine Safety Unit Portland, U.S. Coast Guard; telephone 503–240–9319, email *msupdxwwm@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Oregon Department of Transportation notified the Coast Guard that they will be replacing bridge components at the south end of the Northbound I–5 Interstate Bridge over the Columbia River at River Mile 106.5 beginning September 6, 2020, through September 26, 2020. In response, on June 22, 2020, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; I–5 Bridge Construction Project, Columbia River, Vancouver, WA (85 FR 37397). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this construction project. During the comment period that ended July 22, 2020, we did not receive any relevant comments. On September 24, 2020, the Oregon Department of Transportation notified the Coast Guard that the work was not finished, and will not be completed until October 12, 2020. In response, the Coast Guard is publishing this Temporary final rule to further establish the temporary safety zone until all work is complete.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Oregon Department of Transportation did not submit notice to the Coast Guard with sufficient time to publish an NPRM before the previous safety zone expires and the public is exposed to the dangers associated with this bridge construction work. Delaying the effective date of this rule to wait for a comment period to run would be impracticable and contrary to the public interest by inhibiting the Coast Guard's ability to protect mariners and vessels from the hazards associated with this bridge construction work.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30-day notice period to run would be impracticable and contrary to the public interest.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of Port Sector Columbia River has determined that the potential hazards associated with the construction project would be a safety concern for anyone within the designated area of the I–5 bridge

construction project. The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within the designated area of the I–5 bridge construction project.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no relevant comments on our NPRM published June 22, 2020. This TFR is substantially the same to the one published in conjunction with that TFR (Docket No. USCG–2020–0247,) just with different effective dates.

This rule establishes a safety zone from 12:01 a.m. on September 27, 2020, through 11:59 p.m. on October 12, 2020. The safety zone will cover all navigable waters of the Columbia River, directly below the lifting span of the I–5 bridge from the Washington shoreline to the edge of the lifting span (approx. 800 ft.), and approximately 400 ft. both east and west of the bridge. The duration of the zone is intended to ensure the safety of vessels and these navigable waters while the bridge construction is underway. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-year of the safety zone. Vessel traffic would be able to safely transit around this safety zone, which would only impact a small designated area of the Columbia River, during the bridge construction project. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the safety zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule's predecessor under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. That rule involved enforcing a safety zone for 20 days that prohibits vessel traffic from transiting underneath the lift span of the I–5 Bridge during bridge repair and construction operations. It was, and by extension this TFR is, categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A 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.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T13–0247 to read as follows:

§ 165.T13–0247 Safety Zone[s]; Safety Zone; I–5 Bridge Construction Project, Columbia River, Vancouver, WA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Columbia River, surface to bottom, encompassed by a line connecting the following points beginning at the shoreline at 45°37′17.7″ N/122°40′31.4″ W, southwest to 45°37′12.1″ N/122°40′35.0″ W, southeast to 45°37′08.8″ N 122°40′22.1″ W, thence northeast to 45°37′15.0″ N/122°40′18.3″ W, and along the shoreline back to the beginning point.

(b) *Definitions.* As used in this section, *designated representative* means any Coast commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Columbia River (COTP) to act on his behalf, or a Federal, State, and local officer designated by or assisting the Captain of the Port Columbia River in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) Vessel operators desiring to enter or operate within the safety zone may contact the COTP's on-scene designated representative by calling 503–209–2468 or the Sector Columbia River Command Center on Channel 16 VHF–FM. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section is in effect from 12:01 a.m. on September 27, 2020, through 11:59 p.m. on October 12, 2020. It will be subject to enforcement this entire period unless the Captain of the Port, Columbia River determines it is no longer needed. The Coast Guard will inform mariners of any change to this period of enforcement via Broadcast Notice to Mariners.

Dated: September 24, 2020.

J.C. Smith,

Captain, U.S. Coast Guard, Captain of the Port Columbia River.

[FR Doc. 2020–21614 Filed 9–28–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 254

RIN 0596–AD41

Conveyance of Small Tracts

AGENCY: Forest Service, USDA.

ACTION: Final rule.

SUMMARY: The United States Department of Agriculture (USDA), Forest Service is issuing this final rule to implement certain changes to the Small Tracts Act, which was enacted in the Agriculture Improvement Act of 2018, also known as the 2018 Farm Bill. These statutory changes create two new categories of lands eligible for conveyance outside of the National Forest System under the Small Tracts Act: parcels 40 acres or less that are physically isolated, inaccessible, or have lost National Forest System character; and parcels of ten acres or less that are not eligible for conveyance under previous eligibility conditions and are encroached on by a permanent habitable improvement for which there is no evidence that the encroachment was intentional or negligent.

DATES: This final rule is effective October 29, 2020.

ADDRESSES: Information on this final rule may be obtained via written request addressed to the Director, Lands and Realty Management, USDA Forest Service, 201 14th Street Southwest, Washington, DC 20250–1124 or by email to *SM.FS.WO_LandStaff@usda.gov.*

FOR FURTHER INFORMATION CONTACT: Brad Tait, Lands Staff, by phone at 971–806–2199, or via email at *bradley.tait@usda.gov.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

Public Law 97–465, commonly known as the Small Tracts Act (16 U.S.C. 521c-521i), was enacted in 1983 to help the Forest Service resolve land disputes and boundary management problems for parcels that generally were small in scale (less than ten acres) with land values that did not exceed $150,000. Eligible lands for sale, exchange, or interchange included National Forest System lands encumbered by an encroachment like a house or fence; roads or road rights-of-way in excess of Forest Service transportation needs; and ''mineral survey fractions,'' or small parcels of National Forest System lands interspersed with or adjacent to lands transferred out of Federal ownership under mining laws.

Discussion of Amendments to the Small Tracts Act

The Small Tracts Act was amended by Section 8621 of the Agriculture Improvement Act of 2018, also known as the 2018 Farm Bill (Pub. L. 115–334). The changes to the Small Tracts Act required by the Agriculture Improvement Act of 2018 are being implemented in two phases. The first phase, implementing statutory revisions that did not entail the exercise of agency discretion, was accomplished by revisions to 36 CFR part 254 by the final rule published in the **Federal Register** without notice and comment on February 13, 2020 (85 FR 8180). The second phase, implementing changes that may entail an exercise of agency discretion, is accomplished by this final rule.

The Agriculture Improvement Act of 2018 added two new paragraphs to the Small Tracts Act Section 3 (16 U.S.C. 521e) to resolve by conveyance certain encroachment, trespass, and boundary management problems: paragraph (4) (16 U.S.C. 521e(4)), adding a limited conveyance authority for parcels of 40 acres or less that are determined by the Secretary of Agriculture (hereafter ''Secretary'') to be physically isolated

from other Federal lands, to be inaccessible, or to have lost National Forest character; and paragraph (5) (16 U.S.C. 521e(5)), addressing encroachments by permanent habitable improvements on parcels of 10 acres or less. This final rule implements paragraph (4) by adding a new 36 CFR 254.37, and implements paragraph (5) by adding a new paragraph (b) to 36 CFR 254.32. These amendments to the Small Tracts Act are expected to provide the Forest Service with more flexibility for resolving property conflicts with private landowners, reduce the time and expense arising from a protracted boundary dispute, and alleviate management burden and expense to the Forest Service.

Rulemaking is required for these specific amendments because Section 6 of the Small Tracts Act (16 U.S.C. 521(h)) provides that ''[t]he Secretary shall issue regulations to carry out the provisions of this Act, including specification of . . . criteria which shall be used in making the determination as to what constitutes the public interest.'' The public interest determination in § 254.36 will apply to the new paragraph 254.32(b) and new § 254.37 created by this final rule.

A previous rule published on February 13, 2020 (85 FR 8180), added a new paragraph (c) to 36 CFR 254.32. As noted above, this final rule published September 29, 2020 revises 36 CFR 254.32 to add a new paragraph (b); accordingly, it redesignates existing paragraph (b) as paragraph (c), which in turn redesignates paragraph (c), added by the previous rule, as paragraph (d). The previous rule also added 36 CFR 254.38. This final rule published September 29, 2020 revises the citations to other rule provisions in 36 CFR 254.38(a) from 36 CFR 254.32(c) to 36 CFR 254.32(d), consistent with the revisions to § 254.32 made by this final rule, and revises 36 CFR 254.38(b) to add a subparagraph (3).

Summary of Public Comments and Responses

Overview

On February 26, 2020, the Forest Service published a proposed rule implementing provisions within Section 8621 of the Agriculture Improvement Act of 2018 in the **Federal Register** (85 FR 11041) with a 60-day comment period ending April 27, 2020. The agency received 18 comments, with approximately half of the respondents expressing support of the proposed rule and half expressing criticism. Comments in support of the rule tended to be general in nature: Some respondents described specific scenarios in which they would like to see the rule applied to resolve a management issue, or alternative ways to spend funds received from eligible conveyances. Several critical comments also were general in nature, or raised philosophical, rather than substantive, issues with the rule. Some critical comments did raise substantive concerns regarding specific applications of the rule that the Forest Service plans to address in directives instructing field-level personnel in how to implement this rule.

General Comments

Comment: One respondent expressed concern that the regulations place no limitations on the number of conveyances to a single landowner. There were also concerns that a single parcel that is too large to qualify could be divided into smaller qualifying parcels.

Response: These concerns are currently addressed in 36 CFR 254.35(g), which limits the area conveyed to the ''minimum necessary to resolve encroachment or land management problems.''

Comment: One respondent took issue with the acreage limitations contained in the rule, stating that the limitations do not take into account small acreage discrepancies that could disqualify otherwise eligible parcels.

Response: Congress set clear acreage limitations within the 2018 Farm Bill amendments to the Small Tracts Act, which the Forest Service is required to follow.

Comment: One respondent supported the expanded conveyance categories, but preferred that the money generated go towards deferred maintenance rather than new land acquisition.

Response: Congress made clear that money generated from eligible conveyances be deposited into a Sisk Act account, which limits expenditures to the acquisition of land within the same State the funds were generated.

Comment: One respondent raised concerns that the rule would encourage squatting, or adverse possession, on Forest Service land in order eventually to gain ownership.

Response: Squatting or other types of adverse possession are generally not applicable against the Federal government. While the Small Tracts Act provides an avenue for private landowners to gain ownership of Federal land underlying encroachments, Forest Service officials are required to consider ''factual evidence of claim of title or color of title'' in reaching a conveyance decision, among other factors and considerations.

Comment: One respondent raised an issue with the maximum parcel sizes allowable for conveyance under the Small Tracts Act.

Response: While the Small Tracts Act does specify parcel sizes for some of its conveyance categories, those acreage amounts represent the maximum allowable acreage for such transactions. Actual acreage will be determined on a case-by-case basis in accordance with factual and record evidence provided by the private landowner and will often be smaller than the maximum allowable acreage.

Comment: One respondent took issue with the inclusion of the terms ''shed'' and ''hunting blind'' in the definition of ''permanent habitable improvement'' because of the ability to move these structures easily.

Response: The Forest Service has removed the terms ''shed'' and ''hunting blind'' from the definition of ''permanent habitable improvement'' in section 254.31 of this final rule, based on the non-permanent and non-habitable nature of such structures.

Comment: One respondent generally supported the rule but encouraged the Forest Service to apply the public interest criteria at 36 CFR 254.36 when considering conveyances of parcel 40 acres or less that are physically isolated, inaccessible, or have lost National Forest character.

Response: Pursuant to 36 CFR 254.36(b), the Forest Service will apply the public interest criteria at 36 CFR 254.36 to all potential conveyances under the Small Tracts Act.

Comment: One respondent stated that the Forest Service should not apply an existing categorical exclusion (CE) under the National Environmental Policy Act (NEPA) that excludes from further analysis in an environmental assessment or environmental impact statement the ''sale or exchange of land or interests in land and resources where the resulting land uses remain essentially the same'' to the new category for parcels 40 acres or less that are physically isolated, inaccessible, or have lost National Forest character. The respondent offered three reasons for this: (1) The CE was enacted prior to this 40-acre category and could not take into account properly its environmental effects; (2) the Forest Service has no basis to support a conclusion that the size and scope of the new 40-acre conveyance category will not have significant impacts on the human environment; and (3) the discretion afforded to agency officials to determine whether a parcel has lost National

Forest character is too broad to remove it from analysis under NEPA. The respondent also requests that the agency provide more guidance to officials tasked with determining whether a parcel is isolated, inaccessible, or has lost National Forest character.

Response: The final rule does not make any changes to the NEPA process. Each conveyance proposed under this new 40-acre category will be examined and subject to an appropriate level of NEPA analysis. Generally, the public will have an opportunity to provide input.

Regarding the request to provide more guidance to officials on what qualifies as isolated, inaccessible, or having lost National Forest character, the agency intends to amend its directives implementing the Small Tracts Act to include guidelines for agency officials to consider when determining whether a parcel meets any of these categories.

Comment: One respondent expressed concern that the expansion of categories offered under the Farm Bill amendment to the Small Tracts Act will result in a ''death by a thousand paper-cuts'' scenario where public forest land is converted to private use at too great of a scale.

Response: The Small Tracts Act is considered a relief authority, only to be used in specific instances to resolve specific title claims, innocent encroachments, and management inefficiencies (*see* Forest Service Handbook 5509.11, ch. 21.1). Since 2007, the Forest Service has conveyed less than 500 acres using the Small Tracts Act, which is greatly offset by the number of acres it acquires under authorities such as the Land and Water Conservation Fund. Public interest determinations indicate most land conveyed to private entities under the Small Tracts Act no longer meets the mission and purpose of the agency, ultimately guiding public resources towards more suitable lands and resources. Moreover, the use of the conveyance authority in the Small Tracts Act is discretionary and subject to public interest considerations contained in the Act and 36 CFR 254.36.

Regulatory Certifications

Executive Order 12866

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this final rule is not significant.

Executive Order 13771

The final rule has been reviewed in accordance with E.O. 13771 on reducing regulation and controlling regulatory costs, and is considered an E.O. deregulatory action.

Congressional Review Act

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

Regulatory Flexibility Act Analysis

The Agency has considered the final rule under the requirements of the Regulatory Flexibility Act (5 U.S.C. 602 *et seq.*). This final rule will not have any direct effect on small entities as defined by the Regulatory Flexibility Act. The final rule will not impose recordkeeping requirements on small entities; will not affect their competitive position in relation to large entities; and will not affect their cash flow, liquidity, or ability to remain in the market. Therefore, the Department has determined that this final rule would not have a significant economic impact on a substantial number of small entities pursuant to the Regulatory Flexibility Act.

Federalism

The Department has considered this final rule under the requirements of E.O. 13132, *Federalism.* The Department has concluded that the final rule conforms with the federalism principles set out in this executive order; will not impose any compliance costs on the States; and will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, nor on the distribution of power and responsibilities among the various levels of government. Therefore, the Department concludes that this final rule does not have federalism implications.

Consultation With Tribal Governments

Tribal consultation is not required for the revisions to the Small Tracts Act regulations effected in this final rule. Tribal consultation on individual proposed projects and local notification requirements to Tribes and other individuals for land adjustment activities will occur as required.

No Takings Implications

The Department has analyzed this final rule in accordance with the principles and criteria found in E.O. 12630, *Governmental Actions and Interference With Constitutionally Protected Property Rights,* and has determined that the rule does not pose the risk of a taking of protected private property.

Controlling Paperwork Burdens on the Public

This final rule does not contain any recordkeeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 that are not already required by law, or are not already approved for use, and therefore imposes no additional paperwork burden on the public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), and its implementing regulations at 5 CFR part 1320, do not apply.

National Environmental Policy Act

Agency regulations at 36 CFR 220.6(d)(2) (73 FR 43093) exclude from documentation in an environmental assessment or impact statement ''rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instructions.'' The Department has concluded that the revisions to regulations effected in this final rule fall within this category of actions and that no extraordinary circumstances exist which would require preparation of an environment assessment or environmental impact statement.

Energy Effects

This final rule has been reviewed under E.O. 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.'' The Department has determined that this final rule does not constitute a significant energy action as defined in E.O. 13211.

Civil Justice Reform

The Department has analyzed this rule in accordance with the principles and criteria of Executive Order 12988, *Civil Justice Reform.* The Department has not identified any State or local laws or regulations that conflict with this regulation or that would impede full implementation of this rule. Nevertheless, in the event that such conflicts were to be identified, the final rule, if implemented, will preempt the State or local laws or regulations found to be in conflict. However, in that case, (1) no retroactive effect will be given to this final rule; and (2) the USDA will not require the use of administrative proceedings before parties could file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Department has assessed the effects of this final rule on State, local, and Tribal governments and

the private sector. This final rule does not compel the expenditure of $100 million or more by any State, local, or Tribal governments, or anyone in the private sector. Therefore, statements as described under sections 202 and 205 of the Act are not required.

List of Subjects in 36 CFR Part 254

Community facilities, National forests.

Therefore, for the reasons set forth in the preamble, the Forest Service is amending part 254 of title 36 of the Code of Federal Regulations as follows:

PART 254 LANDOWNERSHIP ADJUSTMENT

Subpart C—Conveyance of Small Tracts

■ 1. The authority citation for part 254, subpart C continues to read:

Authority: Public Law 97–465; 96 Stat. 2535.

■ 2. Amend § 254.31 by adding, in alphabetical order, the definition of ''Permanent Habitable Improvement'' to read as follows:

§ 254.31 Definitions.

Permanent Habitable Improvement means a dwelling, improvement, house, or other structure presently being used as a residence or domicile for a lasting or indefinite period of time.

■ 3. Revise § 254.32 to read as follows:

§ 254.32 Encroachments and other improvements.

(a) This subpart allows conveyance of parcels of 10 acres or less, which will resolve encroachments by persons on National Forest System lands:

(1) To whom no advance notice was given that the improvements encroached or would encroach, and

(2) Who in good faith relied on an erroneous survey, title search, or other land description which did not reveal such encroachment.

(b) This subpart also allows conveyance of parcels of 10 acres or less that are not eligible for conveyance under subsection (a) but are encroached on by a permanent habitable improvement for which there is no evidence that the encroachment was intentional or negligent.

(c) Forest Service officials shall consider the following factors when determining whether to convey lands upon which encroachments exist under subsections (a) and (b):

(1) The location of the property boundaries based on historical location and continued acceptance and maintenance,

(2) Factual evidence of claim of title or color of title,

(3) Notice given to persons encroaching on National Forest System lands,

(4) Degree of development in the encroached upon area, and

(5) Creation of an uneconomic remnant.

(d) This subpart also allows conveyance of parcels that are used as a cemetery (including a parcel of not more than one acre adjacent to the parcel used as a cemetery), a landfill, or a sewage treatment plant under a special use authorization issued or otherwise authorized by a Forest Service official.

■ 4. Add § 254.37 to read as follows:

§ 254.37 Conveyance of parcels 40 acres or less that no longer meet National Forest System objectives.

(a) This subpart allows conveyance of parcels of 40 acres or less that are determined by Forest Service officials to:

(1) be physically isolated from other Federal land; or

(2) be inaccessible; or

(3) have lost National Forest character.

(b) [Reserved]

■ 5. Amend § 254.38 by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

(a) The net proceeds derived from any sale or exchange of parcels in § 254.32(b) and (d) and § 254.37 shall be deposited in the fund commonly known as the ''Sisk Act'' account.

(b) * * *

(3) Reimbursement for costs incurred in preparing a sale conducted under § 254.37 if the sale is a competitive sale.

James E. Hubbard,

Undersecretary, Natural Resources and Environment.

[FR Doc. 2020–21258 Filed 9–28–20; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 211 and 252

[Docket DARS–2020–0006]

RIN 0750–AK60

Defense Federal Acquisition Regulation Supplement: Repeal of DFARS Clause ''Substitutions for Military or Federal Specifications and Standards'' (DFARS Case 2019–D023)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to remove internal agency guidance and a clause that is no longer necessary pursuant to action taken by the DoD Regulatory Reform Task Force.

DATES: Effective October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Moore, telephone 571–372–6093.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 85 FR 19722 on April 8, 2020, to remove DFARS subpart 211.273, Substitutions for Military or Federal Specifications and Standards, and DFARS clause 252.211–7005, Substitutions for Military of Federal Specifications, from the DFARS, because the guidance and clause are no longer necessary. One public comment was received in response to the proposed rule. The public comment was outside the scope of this case and no changes were made to the rule, as a result of public comment.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule only removes obsolete internal guidance and the clause at DFARS 252.211–7005 from the DFARS. This rule does not impose any new requirements on contracts at or below the simplified acquisition threshold, or commercial items, including commercially available off-the-shelf items.

III. Executive Orders 12866 and 13563

E.O.s 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Executive Order 13771

This rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

V. Regulatory Flexibility Act

DoD does not expect this rule to have a significant economic impact on a substantial number of small businesses within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the rule is not creating any new requirements for contractors or changing any existing policies or practices. However, a final regulatory flexibility analysis has been prepared and is summarized as follows:

The Department of Defense is amending the Defense Federal Acquisition Regulation Supplement (DFARS) to repeal DFARS subpart 211.273, Substitutions for Military or Federal Specifications of Standards, and DFARS clause 252.211–7005, Substitutions for Military or Federal Specifications of Standards, as the guidance and clause are no longer necessary. The objective of this rule is to remove outdated guidance from the DFARS and reduce regulatory burden on the public. This repeal is pursuant to action taken by the DoD Regulatory Reform Task Force established under Executive Order 13777, Enforcing the Regulatory Reform Agenda.

No public comments were received in response to the initial regulatory flexibility analysis.

DoD does not collect data on the number of small businesses that proposed an Single Process Initiative (SPI) process in lieu of military of Federal specifications or standards cited in the solicitation. Instead, DoD subject matter experts estimate that approximately 10 contractors participate in SPI and that each participant will respond to one solicitation per year. Based on the information available, DoD does not anticipate that this rule will significantly impact small business entities.

This rule does not include any new reporting, recordkeeping, or other compliance requirements for small businesses.

There are no known alternative to the rule that will meet the stated objectives or minimize the impact on of the rule on small entities.

VI. Paperwork Reduction Act

This rule removes the burden associated with DFARS 252.211–7005 from the information collection requirement currently approved under 0704–0398, entitled DFARS Part 211, Describing Agency Needs, and Related Clause at DFARS 252.211. This reduction is reflected in the revision to and extension of the information collection, as published in the **Federal Register** on February 27, 2020, at 85 FR 11351, and May 28, 2020, at 85 FR 32019.

List of Subjects in 48 CFR Parts 211 and 252

Government procurement.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 211 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 211 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 211—DESCRIBING AGENCY NEEDS

211.273 [Removed and Reserved]

■ 2. Remove and reserve section 211.273.

211.273–1 through 211.273–4 [Removed]

■ 3. Remove sections 211.273–1 through 211.273–4.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.211–7005 [Removed and Reserved]

■ 4. Remove and reserve section 252.211–7005.

[FR Doc. 2020–21248 Filed 9–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 211 and 252

[Docket DARS–2019–0056]

RIN 0750–AK59

Defense Federal Acquisition Regulation Supplement: Repeal of DFARS Provision ''Alternate Preservation, Packaging, and Packing'' (DFARS Case 2019–D022)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to remove a provision that is no longer necessary pursuant to action taken by the DoD Regulatory Reform Task Force.

DATES: Effective October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Moore, telephone 571–372–6093.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 85 FR 19721 on April 8, 2020, to remove the provision at DFARS 252.211–7004, Alternate Preservation, Packaging, and Packing, and the associated prescription from the DFARS, because the provision is no longer necessary. No public comments were received in response to the proposed rule. No changes were made to the rule, as proposed.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule only removes the obsolete solicitation provision at DFARS 252.211–7004, Alternate Preservation, Packaging, and Packing. This rule does not impose any new requirements on contracts at or below the simplified acquisition threshold, or commercial items, including commercially available off-the-shelf items.

III. Executive Orders 12866 and 13563

E.O.s 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Executive Order 13771

This rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

V. Regulatory Flexibility Act

DoD does not expect this rule to have a significant economic impact on a substantial number of small businesses within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the rule is not creating any new

requirements for contractors or changing any existing policies or practices. However, a final regulatory flexibility analysis has been prepared and is summarized as follows:

The Department of Defense is amending the Defense Federal Acquisition Regulation Supplement (DFARS) to repeal DFARS provision 252.211–7004, Alternate Preservation, Packaging, and Packing, as the provision is no longer necessary. The objective of this rule is to reduce regulatory burden on the public. This repeal is pursuant to action taken by the Regulatory Reform Task Force established under Executive Order (E.O.) 13777, Enforcing the Regulatory Reform Agenda.

No public comments were received in response to the initial regulatory flexibility analysis.

DoD does not collect data on the number of small businesses that respond to a solicitation that includes DFARS clause 252.211–7004 or the number of small businesses responding to such a solicitation with alternative preservation, packaging, or packing methods. Instead, DoD subject matter experts advise that approximately 375 solicitations are issued each year that contain military preservation, packaging, or packing requirements where commercial or industrial methods may also be acceptable. DoD estimates that it receives 1.5 responses to each solicitation, for a total of 563 offers received in response to these solicitation. This total estimated number of responses does not delineate between the business size of the offerors or those offerors that did and did not propose alternative methods for preservation, packaging, or packing in lieu of military specifications. Based on the information available, DoD does not anticipate that this rule will significantly impact small business entities.

This rule does not include any new reporting, recordkeeping, or other compliance requirements for small businesses.

There are no known alternative to the rule that will meet the stated objectives or minimize the impact on of the rule on small entities.

VI. Paperwork Reduction Act

This rule removes the burden associated with DFARS 252.211–7004 from the information collection requirement currently approved under 0704–0398, entitled DFARS Part 211, Describing Agency Needs, and Related Clause at DFARS 252.211. This reduction is reflected in the revision to and extension of the information collection, as published in the **Federal Register** on February 27, 2020, at 85 FR 11351, and May 28, 2020, at 85 FR 32019.

List of Subjects in 48 CFR Parts 211 and 252

Government procurement.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore 48 CFR parts 211 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 211 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 211—DESCRIBING AGENCY NEEDS

211.272 [Removed and Reserved]

■ 2. Remove and reserve section 211.272.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.211–7004 [Removed and Reserved]

■ 3. Remove and reserve section 252.211–7004.

[FR Doc. 2020–21247 Filed 9–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 244, and 252

[Docket DARS–2019–0052]

RIN 0750–AK66

Defense Federal Acquisition Regulation Supplement: Treatment of Certain Items as Commercial Items (DFARS Case 2019–D029)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement several sections of the National Defense Authorization Act for Fiscal Year 2017 that address treatment of commingled items purchased by contractors and services provided by nontraditional defense contractors as commercial items.

DATES: Effective October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 84 FR 65322 on November 27, 2019, to implement sections 877 and 878 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017 (Pub. L. 114–328) and further implement section 848 of the NDAA for FY 2018 (Pub. L. 115–91). Section 877, Treatment of Commingled Items Purchased by Contractors as Commercial Items, adds 10 U.S.C. 2380b. Section 878, Treatment of Services Provided by Nontraditional Contractors as Commercial Items, amends 10 U.S.C. 2380a. Section 848 modifies 10 U.S.C. 2380(b) to provide that a contract for an item using FAR part 12 procedures shall serve as a prior commercial item determination, unless the appropriate official determines in writing that the use of such procedures was improper or that it is no longer appropriate to acquire the item using commercial item acquisition procedures. Two respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

A. Summary of Significant Changes From the Proposed Rule

Further implementation of section 848 of the NDAA for FY 2018 (Pub. L. 115–91) has been removed from the final rule under this case. DoD plans to publish a new proposed rule under a separate case (DFARS Case 2020–D033).

B. Analysis of Public Comments

1. Treatment of commingled items as commercial items (section 877 of the NDAA for FY 2017).

a. Strike ''when purchased'' from proposed DFARS 244.402(S–70) and the proposed clause at DFARS 252.244–7000(c).

Comment: One respondent suggested removal of the words ''when purchased,'' which were added as a clarification to the statutory text in the proposed rule, suggesting that the addition ''serves only to erode the purpose of the law, and will increase administrative burden of identifying comingled items.''

Response: The statutory change adding a new section 10 U.S.C. 2380b is titled, ''Treatment of commingled items purchased contractors as commercial items.'' The statute is intended to

address the common situation in which a contractor purchases items in bulk, intending to use the items for its general business, as distinguished from a specific subcontract, identifiable at the time of purchase with a specific prime contract. This is consistent with the legislative history quoted by the respondent with regard to cases where contractors often place orders with subcontractors for material, supplies, and parts that may be applicable to several Government programs in advance of any Government contract or RFP. The text of the enactment is fully consistent with this interpretation: ''items . . . that are *purchased by a contractor for use in the performance of multiple contracts* with the Department of Defense and other parties and are not identifiable to any particular contract.'' The language ''when purchased'' was added to avoid a possible application to items that were in fact purchased for specific purposes, as subcontracts subject to the wide range of contract terms that the purchaser might be required to ''flow down'' to the particular subcontracts. Many of those ''flow down'' clauses are required by other laws, or otherwise reflect important procurement policies, and any exceptions must be applied narrowly. It is contrary to the intent of the underlying laws if those items are to be ''treated as commercial items'' on the sole basis that after acquisition, the prime contractor commingles them with other materials in inventory, whether by policy or in error, so that they lose their ''identification.''

b. Clarify that items are not ''identifiable to any particular contract'' if they are not specifically identified, are indistinguishable, and are not serialized (DFARS 244.402(S–70)).

Comment: In connection with this issue, one respondent suggested that DoD define the term ''identifiable to any particular contract'' as stated. The respondent argued that this is ''in the Government's best interest'' on the basis of an example in which the prime contractor purchases items in bulk, apparently ''for use in the performance of multiple contracts with the Department of Defense and other parties.'' In the example, the items are ''identifiable to any particular contract'' only to the extent that DPAS ratings are ''flowed down'' to the supplier as to a small proportion of the total quantity purchased. On this basis, the respondent suggests, while the subcontract order did not identify any particular items as designated for the DPAS-rated prime contract; the items are physically indistinguishable from each other; and they will be commingled in inventory; yet because the *costs* of the few items will be allocable to the particular prime contract, they will be considered ''identifiable to [the] particular contract'' and thus effectively excluded from the coverage of 10 U.S.C. 2380b unless the suggested amendment is adopted.

Response: This clarification is unnecessary. The Congressional intent to allow contractors to buy relatively low-value items in bulk, for various customers, appears to be directly applicable to the described situation. There is no single definition of the term ''identifiable,'' as used in the NDAA, but the statute is written in regard to items, not the cost of the items. DoD does not consider that unspecified items procured as part of a bulk purchase for multiple customers are ''identifiable to [a] particular contract'' on the sole basis that a related portion of the cost is allocable to the contract.

There may, however, be other bases on which particular items or subdivisions of a single purchase may be identifiable with a particular contract, and creating a criterion that the items must be identifiable by individual serial number is not warranted.

c. Strike ''The Contractor shall ensure that any such items to be used in performance of this contract meet all terms and conditions of this contract that are applicable to commercial items'' from the clause at 252.244–7000(c).

Comment: One respondent suggested that the quoted language ''would require specific clauses to be applied 'after the fact' in direct conflict with Section 877 and negate its intent.''

Response: Section 877 only specifies that the items shall be treated as commercial items. It is not in conflict with section 877 to state that items treated as commercial items must comply with requirements that are applicable to commercial items. The respondent is apparently concerned that because the items are not purchased for a specific Government contract, that the contractor will not have imposed Government requirements upon the suppliers. The proposed language simply clarifies that if certain items are to be ''treated as commercial items'' pursuant to the first sentence and 10 U.S.C. 2380b, on the basis that they are ''valued under $10,000 and [were] purchased by a contractor for use in the performance of multiple contracts with the Department of Defense and other parties and are not identifiable to any particular contract,'' then in place of clauses that might otherwise apply, the items must comply with the clauses that apply to commercial items. If the respondent is suggesting that section 877, by providing that the items are to be ''treated as commercial items,'' was intended to further excuse a contractor from compliance with the clauses identified in FAR 52.244–6(c) (and any authorized agency supplements), DoD disagrees. One of the criteria for an acceptable purchasing system requires the contractor to ensure that all applicable purchase orders and subcontracts contain all flowdown clauses . . . needed to carry out the requirements of the prime contract (DFARS 252.244–7001(c)(2)).

d. Clarify what is meant by ''treatment as'' a commercial item (DFARS 244.402(S–70)).

Comment: One respondent suggested that the term ''shall be treated as commercial items'' be supplemented by adding language to the effect that ''treatment'' of an item as a commercial item under the authority provided in 10 U.S.C. 2380b means that FAR part 12 applies, as it would apply under the proposed rule applicable to 41 U.S.C. 1903, Special Emergency Procurement Authority, and 10 U.S.C. 2380a, Treatment of Services Provided by Nontraditional Contractors as Commercial Items.

Response: 41 U.S.C. 1903 provides that in defined circumstances in which its ''special emergency procurement authority'' applies, an executive agency ''may treat the property or service as a commercial item for the purpose of carrying out the procurement.'' 10 U.S.C. 2380a provides the same ''treatment'' by an agency for items and services provided by nontraditional defense contractors. Both of these provisions apply to acquisitions by an agency. To the extent that an agency ''may treat the property or service as a commercial item for the purpose of carrying out the procurement,'' this logically implies application of FAR part 12 procedures. 10 U.S.C. 2380b, however, applies to purchases by a contractor. The requirements of FAR part 12 do not apply to purchases by a contractor, it would be extremely burdensome on contractors to make its requirements applicable, and DoD did not propose to do so.

Comment: The respondent further suggested that language be added to specify that when 10 U.S.C. 2380b applies, ''a commercial item determination is not required.''

Response: By the proposed language, contractors are entitled to treat items as commercial items when they are ''purchased by a contractor for use in the performance of multiple contracts'' and meet the other criteria of the

section. The following has been added: '', even though the items *may* not meet the definition of ''commercial item'' at FAR 2.101 and do not require a commercial item *determination*.

e. Retain existing language at DFARS 244.402(a).

Comment: One respondent questioned why the wording at DFARS 244.402 was changed from ''Contractors shall determine whether a particular subcontract item meets the definition of a commercial item'' to ''Contractors are required to determine whether a particular subcontract item meets the definition of a commercial item.''

Response: This change is to conform to the DFARS drafting convention that provisions and clauses are the appropriate place to direct contractors to do something. The text of the DFARS that is not a provision or a clause is directed to the contracting officer. Therefore, DFARS 244.402(a) should not tell the contractor that it shall do something, but should inform the contracting officer of a requirement applicable to contractors.

f. Need to add Government checks on industry's new responsibility to treat certain items as commercial items.

Comment: One respondent stated that even the DAR Council's proposed rule itself says there are checks to be made on industry in determining an item is commingled. The respondent requests that the administrative contracting officer (ACO) to be given the authority to examine industry's rationale against the Council's stated stipulations, by assigning this responsibility to the ACO and adding contractual requirement for the contractor to provide the requested documentation. Specifically, the respondent requested the following:

- DFARS 244.303(a)—Add the requirement, as part of the Contractors' Purchasing System Review, to review the adequacy of rationale documenting how items were purchased for use in the performance of multiple contracts with the Department of Defense and other parties and were not identifiable to any particular contract when purchased.

Response: The contracting officer already has the authority to request and review contractor supporting documentation. Those performing a CPSR or audit may adjust their requests to ensure that ''treated as commercial'' items are included in their reviews.

- FARS 252.244–7001, Contractor Purchasing System Administration, paragraph (b)—Add a new subparagraph to require the following: ''Upon request by the Contracting Officer, the Contractor shall provide rationale documenting commercial item determinations to ensure compliance with the definition of 'commercial item' in FAR 2.101. In addition, the Contractor shall provide rationale documenting how it determined items were purchased for use in the performance of multiple contracts with the Department of Defense and other parties and were not identifiable to any particular contract when purchased.''

Response: This change does not fit in this clause on Contractor Purchasing System Administration. Paragraph (b) addresses the general requirement to establish and maintain an acceptable purchasing system. Paragraphs (a) and (c) provide applicable definitions and the criteria for an acceptable system. This change would duplicate requirements in other clauses. The contractor has the obligation to document and justify purchasing commingled items under this authority.

2. Treatment of services provided by nontraditional contractors as Commercial Items (section 878 of the NDAA for FY 2017).

a. Authorize prime contractors to treat supplies and services from nontraditional contractors as commercial items.

Comment: One respondent recommended that authorizing prime contractors to utilize 10 U.S.C. 2380a (a) and (b) in their subcontracts and treating the supplies and services as commercial items, will help attract nontraditional defense contractors to do business with DOD. The file documentation proposed under DFARS 212.102(iv)(C) to use either authority would be a representation by the subcontractor in accordance with DFARS 252.215–7013, and the prime contractor should be able to rely on such.

Response: Both the permissive authority of 10 U.S.C. 2380a(a) and the mandatory treatment of 10 U.S.C. 2380a(b) apply only on the Government (prime contract) level. The statute does not allow DoD to flow down the authority.

Comment: One respondent commented that additional direction is needed for certain nontraditional services that shall be treated as commercial items.

Response: The DFARS final text includes DFARS 212.102(a)(iii)(B), which provides sufficient direction.

b. Retain existing language at DFARS 212.102(a)(iii).

Comment: One respondent recommended retention of the existing language at DFARS 212.102(a)(iii), which states explicitly that the decision to apply commercial item procedures to the procurement of supplies and services from nontraditional defense contractors does not require a commercial item determination and does not mean that the item is commercial.

Response: Concur.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule proposes to modify the clause at DFARS 252.244,7000, Subcontracts for Commercial Items, but does not modify its applicability. The clause is applicable to all solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items and solicitations and contracts valued at or below the simplified acquisition threshold. However, the amendment to DFARS 252.244–7000 proposed by this rule does not impose any burdens on contractors, but allows treatment of certain items as commercial items, that do not otherwise meet the definition of ''commercial item'' in FAR part 2.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq*. The FRFA is summarized as follows:

This final rule is issued in order to implement sections 877 and 878 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017 (10 U.S.C. 2380a and 10 U.S.C. 2380b). The objective of this rule is to address the

treatment as commercial items of services provided by nontraditional defense contractors and certain items purchased by a contractor for use in the performance of multiple contracts. The legal basis for the rule is the NDAA section cited as the reasons for the action.

There were no significant issues raised by the public comments in response to the initial regulatory flexibility analysis.

Based on FY 2018 data from the Federal Procurement Data System (FPDS), awards of commercial contracts were made to 15,231 nontraditional defense contractors that were also small entities. It is unknown how many of those entities might provide services that use the same pool of employees used for commercial customers and are priced using methodology similar to the methodology used for commercial pricing.

Also based on FPDS data for FY 2018, DoD awarded 110,000 contracts for the purchase of supplies, commercial or noncommercial, exceeding $10,000, to 13,892 unique small entities. This rule will affect an unknown number of those 13,892 small entities, if such small entities purchase noncommercial items valued at less than $10,000 per item that are not identifiable to any particular contract when purchased and are for use in the performance of multiple contracts with DoD and other parties.

This rule does not impose any new reporting, recordkeeping, or other compliance requirements. The rule does remind the contractor of the responsibility to ensure that items treated as commercial items pursuant to section 877 of the NDAA for FY 2017 that are to be used in the performance of the DoD contract meet all terms and conditions of the contract that are applicable to commercial items.

DoD did not identify any significant alternatives that would minimize or reduce the significant economic impact on small entities, because there is no significant impact on small entities. Any impact is expected to be beneficial.

VII. Paperwork Reduction Act

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

List of Subjects in 48 CFR Parts 212, 244, and 252

Government procurement.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 244, and 252 are amended as follows:

■ 1. The authority citation for parts 212, 244, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 2. Amend section 212.102 by revising paragraph (a)(iii) to read as follows:

212.102 Applicability.

(a)(i) * * *

(iii) *Nontraditional defense contractors.* In accordance with 10 U.S.C. 2380a, contracting officers—

(A) Except as provided in paragraph (a)(iii)(B) of this section, may treat supplies and services provided by nontraditional defense contractors as commercial items. This permissive authority is intended to enhance defense innovation and investment, enable DoD to acquire items that otherwise might not have been available, and create incentives for nontraditional defense contractors to do business with DoD. It is not intended to recategorize current noncommercial items; however, when appropriate, contracting officers may consider applying commercial item procedures to the procurement of supplies and services from business segments that meet the definition of ''nontraditional defense contractor'' even though they have been established under traditional defense contractors. The decision to apply commercial item procedures to the procurement of supplies and services from nontraditional defense contractors does not require a commercial item determination and does not mean the item is commercial;

(B) Shall treat services provided by a business unit that is a nontraditional defense contractor as commercial items, to the extent that such services use the same pool of employees as used for commercial customers and are priced using methodology similar to methodology used for commercial pricing; and

(C) Shall document the file when treating supplies or services from a nontraditional defense contractor as commercial items in accordance with paragraph (a)(iii)(A) or (B) of this section.

* * * * *

PART 244—SUBCONTRACTING POLICIES AND PROCEDURES

■ 3. Amend section 244.402 by—

■ a. In paragraph (a) removing ''shall'' and adding ''are required to'' in its place; and

■ b. Adding a new paragraph (S–70).

The addition reads as follows:

244.402 Policy requirements.

* * * * *

(S–70) In accordance with 10 U.S.C. 2380b, items that are valued at less than $10,000 per item that are purchased by a contractor for use in the performance of multiple contracts with the Department of Defense and other parties and are not identifiable to any particular contract when purchased shall be treated as commercial items, even though the items may not meet the definition of ''commercial item'' at FAR 2.101 and do not require a commercial item determination.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Amend section 252.244–7000 by—

■ a. Removing the clause date of ''(JUN 2013)'' and adding ''(SEP 2020)'' in its place;

■ b. Redesignating paragraph (c) as (d);

■ c. In the newly redesignated paragraph (d), removing ''(c)'' and adding ''(d)'' in its place; and

■ c. Adding a new paragraph (c).

The addition reads as follows:

252.244–7000 Subcontracts for Commercial Items.

* * * * *

(c)(1) In accordance with 10 U.S.C. 2380b, the Contractor shall treat as commercial items any items valued at less than $10,000 per item that were purchased by the Contractor for use in the performance of multiple contracts with the Department of Defense and other parties and are not identifiable to any particular contract when purchased.

(2) The Contractor shall ensure that any items to be used in performance of this contract, that are treated as commercial items pursuant to paragraph (c)(1) of this clause, meet all terms and conditions of this contract that are applicable to commercial items in accordance with the clause at Federal Acquisition Regulation 52.244–6 and paragraph (a) of this clause.

* * * * *

[FR Doc. 2020–21249 Filed 9–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 216

[Docket DARS–2020–0032]

RIN 0750–AL02

Defense Federal Acquisition Regulation Supplement: Modification of Determination Requirement for Certain Task- or Delivery-Order Contracts (DFARS Case 2020–D016)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2020 that revises contract file documentation requirements when awarding a task- or delivery order-contract in excess of $100 million to a single source.

DATES: Effective October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Moore, telephone 571–372–6093.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is issuing a final rule amending the DFARS to implement section 816 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020 (Pub. L. 116–92). Section 816 amends 10 U.S.C. 2304a to permit the award of a DoD task- or delivery-order contract estimated to exceed $100 million (including all options) to a single source without a written determination by the head of the agency, if the head of the agency made a written determination that other than competitive procedures were authorized for the award of such contract.

The requirement for the written determination required by 10 U.S.C. 2304a is implemented at Federal Acquisition Regulation (FAR) 16.504(c)(1)(ii)(D), which prohibits the award of a task- or delivery-order contract in excess of $100 million to a single source, unless the head of the agency makes a written determination that the acquisition meets one of four specific circumstances that necessitate an award to a single source.

To implement 10 U.S.C. 2304a, as amended by section 816, this final rule amends DFARS section 216.504 to advise DoD contracting officers that the determination from the head of the agency pursuant to FAR 16.504(c)(1)(ii)(D)(*1*) is no longer required for a single-award task- or delivery-order contract valued at greater than $100 million, if a justification for the use of other than full and open competition has been executed in accordance with FAR subpart 6.3 and DFARS subpart 206.3.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not create new provisions or clauses or impact any existing provisions or clauses.

III. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the FAR is Office of Federal Procurement Policy statute (codified at title 41 of the United States Code). Specifically, 41 U.S.C. 1707(a)(1) requires that a procurement policy, regulation, procedure, or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because DoD is not issuing a new regulation; rather, this rule is updating internal operating procedures that require contracting officers to obtain certain internal documentation and authorizations prior to awarding a contract under certain acquisitions.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 41 U.S.C. 1707(a)(1) (see section III. of this preamble), the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

VII. Paperwork Reduction Act

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

List of Subjects in 48 CFR Part 216

Government procurement.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, DoD is amending 48 CFR part 216 as set forth below:

PART 216—TYPES OF CONTRACTS

■ 1. The authority citation for 48 CFR part 216 continues to read as follows:

Authority: 10 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Amend section 216.504 by adding new paragraph (c)(1)(ii)(D)(*3*)(*i*) to read as follows:

216.504 Indefinite-quantity contracts.

(c) * * *

(1) * * *

(ii) * * *

(D) * * *

(*3*)(*i*) In accordance with section 816 of the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116–92), the determination at FAR 16.504(c)(1)(ii)(D) is not required if a justification has been executed, in accordance with FAR subpart 6.3 and subpart 206.3.

[FR Doc. 2020–21250 Filed 9–28–20; 8:45 am]

BILLING CODE 5001–06–P

Proposed Rules

Federal Register
Vol. 85, No. 189
Tuesday, September 29, 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 ENERGY

10 CFR Part 431

[EERE–2017–BT–STD–0022]

RIN 1904–AE47

Energy Conservation Program: Energy Conservation Standards for Certain Commercial and Industrial Equipment; Early Assessment Review; Automatic Commercial Ice Makers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Request for information.

SUMMARY: The U.S. Department of Energy (''DOE'') is undertaking an early assessment review for amended energy conservation standards for automatic commercial ice makers (''ACIM'') to determine whether to amend applicable energy conservation standards for this equipment. Specifically, through this request for information (''RFI''), DOE seeks data and information that could enable the agency to determine whether DOE should propose a ''no-new-standard'' determination because a more-stringent standard: Would not result in a significant savings of energy; is not technologically feasible; is not economically justified; or any combination of the foregoing. DOE welcomes written comments from the public on any subject within the scope of this document (including those topics not specifically raised in this RFI), as well as the submission of data and other relevant information concerning this early assessment review.

DATES: Written comments and information are requested and will be accepted on or before December 14, 2020.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2017–BT–STD–0022, by any of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email:* to *ACIM2017STD0022@ee.doe.gov.* Include the docket number EERE–2017–BT–STD–0022 in the subject line of the message.

3. *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, Suite 600, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section III of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *http://www.regulations.gov.* All documents in the docket are listed in the *http://www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at: *http://www.regulations.gov/#!docketDetail;D=EERE-2017-BT-STD-0022.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section III for information on how to submit comments through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Dr. Stephanie Johnson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1943. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Amelia Whiting, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–2588. Email: *Amelia.Whiting@hq.doe.gov.*

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

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I. Introduction

DOE has established an early assessment review process to conduct a more focused analysis of a specific set of facts or circumstances that would allow DOE to determine, based on one or more statutory criteria, a new or amended energy conservation standard is not warranted. The purpose of this review is to limit the resources, from both DOE and stakeholders, committed to rulemakings that will not satisfy the requirements in the Energy Policy and Conservation Act, as amended (''EPCA''),[1] that a new or amended energy conservation standard save a significant amount of energy, and be economically justified and technologically feasible. *See* 85 FR 8626, 8653–8654 (Feb. 14, 2020).

As part of the early assessment, DOE publishes an RFI in the **Federal Register**, announcing that DOE is considering initiating a rulemaking proceeding and soliciting comments, data, and information on whether a new or amended energy conservation standard would save a significant amount of energy and be technologically feasible and economically justified. Based on the information received in response to the RFI and DOE's own

[1] All references to EPCA in this document refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115–270 (Oct. 23, 2018).

analysis, DOE will determine whether to proceed with a rulemaking for a new or amended energy conservation standard.

If DOE makes an initial determination based upon available evidence that a new or amended energy conservation standard would not meet the applicable statutory criteria, DOE would engage in notice and comment rulemaking before issuing a final determination that new or amended energy conservation standards are not warranted. Conversely, if DOE makes an initial determination that a new or amended energy conservation standard would satisfy the applicable statutory criteria or DOE's analysis is inconclusive, DOE would undertake the preliminary stages of a rulemaking to issue a new or amended energy conservation standard. Beginning such a rulemaking, however, would not preclude DOE from later making a determination that a new or amended energy conservation standard cannot satisfy the requirements in EPCA, based upon the full suite of DOE's analyses. *See* 85 FR 8626, 8654 (Feb. 14, 2020).

A. Authority

EPCA, among other things, authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C [2] of EPCA, added by Public Law 95–619, Title IV, section 441(a) (42 U.S.C. 6311–6317, as codified), established the Energy Conservation Program for Certain Industrial Equipment. This equipment includes ACIM, the subject of this document. (42 U.S.C. 6311(1)(F))

Under EPCA, DOE's energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6311), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6313), and the authority to require information and reports from manufacturers (42 U.S.C. 6316).

Federal energy efficiency requirements for covered equipment established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6316(a); 42 U.S.C. 6297(a)–(c)) DOE may, however, grant waivers of Federal preemption in limited instances for particular State laws or regulations, in accordance with the procedures and other provisions set forth under EPCA. (42 U.S.C. 6316(a); 42 US.C. 6297(d))

EPCA prescribed the initial energy and water conservation standards for ACIMs. (42 U.S.C. 6313(d)(1)) EPCA also authorizes DOE to establish new standards for ACIMs not covered by the statutory standards. (42 U.S.C. 6313(d)(2)) Not later than January 1, 2015, with respect to the standards established under 42 U.S.C. 6313(d)(1), and, with respect to the standards established under 42 U.S.C. 6313(d)(2), not later than 5 years after the date on which the standards take effect, EPCA required DOE to issue a final rule to determine whether amending the applicable standards is technologically feasible and economically justified. (42 U.S.C. 6313(d)(3)(A)) Not later than 5 years after the effective date of any amended standards under 42 U.S.C. 6313(d)(3)(A) or the publication of a final rule determining that amending the standards is not technologically feasible or economically justified, DOE must issue a final rule to determine whether amending the standards established under 42 U.S.C. 6313(d)(1) or the amended standards, as applicable, is technologically feasible or economically justified. (42 U.S.C. 6313(d)(3)(B)) A final rule issued under 42 U.S.C. 6313(d)(2) or (3) must establish standards at the maximum level that is technically feasible and economically justified, as provided in 42 U.S.C. 6295(o) and (p). (42 U.S.C. 6313(d)(4))

B. Rulemaking History

On October 18, 2005, DOE published a final rule codifying in the Code of Federal Regulations (''CFR'') the energy conservation standards and water conservation standards prescribed by EPCA in 42 U.S.C. 6313(d)(1) for certain automatic commercial ice makers manufactured on or after January 1, 2010. 70 FR 60407, 60415–60416. The codified statutory standards consisted of maximum energy use and maximum condenser water use, if applicable, to produce 100 pounds (''lb.'') of ice for ACIM with harvest rates between 50 and 2,500 lb. ice per 24 hours. *Id.* at 70 FR 60416. Most recently on January 28, 2015, in satisfaction of the first rulemaking cycle required by EPCA, DOE published a final rule adopting more-stringent energy conservation standards for certain classes of ACIM and establishing energy conservation standards for other classes of ACIM not previously subject to standards. 80 FR 4646 (the ''January 2015 Final Rule''). The current energy conservation standards are located in 10 CFR 431.136(c) and (d), and specify the maximum energy use, in terms of kilowatt-hours (''kWh'') per 100 lb. of ice produced, and maximum condenser water use, in terms of gallons (''gal'') per 100 lb. of ice produced. The currently applicable DOE test procedures for ACIM appear at 10 CFR 431.134.

II. Request for Information

DOE is publishing this RFI to collect data and information during the early assessment review to inform its decision, consistent with its obligations under EPCA, as to whether the Department should proceed with an energy conservation standards rulemaking. Accordingly, in the following sections, DOE has identified specific issues on which it seeks input to aid in its analysis of whether an amended standard for ACIM would not save a significant amount of energy or be technologically feasible or economically justified. In particular, DOE is interested in any information indicating that there has not been sufficient technological or market changes since DOE last conducted an energy conservation standards rulemaking analysis for ACIM to suggest a more-stringent standard could satisfy these criteria. DOE also welcomes comments on other issues relevant to its early assessment that may not specifically be identified in this document.

A. Significant Savings of Energy

The energy conservation standards for ACIM established by DOE in the January 2015 Final Rule are expected to result in 0.064 quads of site energy savings, representing an 8 percent reduction in site energy use, relative to the base case without amended standards over a 30-year period.[3] *See* 80 FR 4646, 4649; and the January 2015 Final Rule Technical Support Document (''TSD'').[4] Additionally, in the January 2015 Final Rule, DOE estimated that an energy conservation standard established at an energy use level equivalent to that achieved using the maximum available

[2] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated Part A–1.

[3] This estimate of 0.064 quads reflects site energy savings. The January 2015 Final Rule presented the 30-year energy savings estimate as 0.18 quads, reflecting full-fuel-cycle (''FFC'') energy savings. The FFC measure includes point-of-use (site) energy; the energy losses associated with generation, transmission, and distribution of electricity; and the energy consumed in extracting, processing, and transporting or distributing primary fuels.

[4] The January 2015 Final Rule TSD is available on *http://www.regulations.gov* in docket number EERE–2010–BT–STD–0037, document number 136. The docket also includes the spreadsheet used to conduct the national impact analysis, document number 131, as described in chapter 10 of the January 2015 Final Rule TSD.

technology (''max-tech'') would have resulted in 0.051 additional quads of site energy savings.[5] *See* 80 FR 4646, 4736; and the January 2015 Final Rule TSD. This represents a 7 percent reduction in energy use compared to the estimated national energy use at the established energy conservation standard level. If DOE determines that a more-stringent energy conservation standard would not result in an additional 0.3 quad of site energy savings or an additional 10-percent reduction in site energy use over a 30-year period, DOE would propose to make a no-new-standards determination. DOE seeks comment on energy savings that could be expected from more-stringent standards for ACIM.

While DOE's request for information is not limited to the following issues, DOE is particularly interested in comment, information, and data on the following.

Issue 1: DOE seeks information on whether the max-tech level analysis from the January 2015 Final Rule is applicable to the current ACIM market and on whether the previous estimates of energy savings at the max-tech level represent the savings that would be realized were DOE to establish future amended energy conservation standards at the max-tech level.

Issue 2: DOE seeks information on the January 2015 Final Rule analysis resulting in the energy savings estimates discussed in this section. Specifically, DOE requests comment and data on updates to the relevant analysis inputs, including stock of ACIMs, shipments since 2010, efficiency distributions, and the incorporation of various refrigerants in the models available on the market. DOE also requests data on market share by equipment class and refrigerant.

B. Technological Feasibility

During the January 2015 Final Rule, DOE considered a number of technology options that manufacturers could use to reduce energy consumption in ACIM. DOE seeks comment on any changes to these technology options that could affect whether DOE could propose a ''no-new-standards'' determination, such as an insignificant increase in the range of efficiencies and performance characteristics of these technology options. DOE also seeks comment on whether there are any other technology options that DOE should consider in its analysis.

While DOE's request for information is not limited to the following issues, DOE is particularly interested in comment, information, and data on the following.

Issue 3: DOE requests feedback on whether the use of alternative refrigerants could impact: ACIM efficiencies, the viability or efficiency of other technology options incorporated into the equipment (*e.g.,* refrigeration system components, additional sensing/safety components), the availability of equipment features, or consumer utility.

Issue 4: DOE is aware that the range of available ACIM efficiencies has changed since the January 2015 Final Rule analysis. DOE requests comment and data regarding which design options are incorporated in equipment that may achieve higher efficiencies than those considered in the previous rulemaking analysis, including at a potentially updated max-tech efficiency level, and how any such design options or combinations of design options may impact the availability of equipment features or consumer utility. Additionally, DOE seeks information on any alternative approaches for achieving potential reductions in energy usage for ACIMs.

C. Economic Justification

In determining whether a proposed energy conservation standard is economically justified, DOE analyzes, among other things, the potential economic impact on consumers, manufacturers, and the Nation. DOE seeks comment on whether there are economic barriers to the adoption of more-stringent energy conservation standards. DOE also seeks comment and data on any other aspects of its economic justification analysis from the January 2015 Final Rule that may indicate whether a more-stringent energy conservation standard would not be economically justified or cost effective.

While DOE's request for information is not limited to the following issues, DOE is particularly interested in comment, information, and data on the following.

Issue 5: DOE seeks input on whether frequency of repair differs for the design options that underlie max-tech efficiency levels when compared to baseline efficiency levels, and if and how installation costs would be affected by the presence of such design options in equipment.

Issue 6: DOE seeks input on whether 8.5 years, as estimated in the January 2015 Final Rule analysis (*see* 80 FR 4646, 4700–4701), is an appropriate lifetime for use in the economic analyses for all equipment classes.

III. Submission of Comments

DOE invites all interested parties to submit in writing by December 14, 2020, comments and information on matters addressed in this notice and on other matters relevant to DOE's early assessment of whether more-stringent energy conservation standards are not warranted for ACIM.

Submitting comments via http://www.regulations.gov. The *http://www.regulations.gov* web page requires you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. If this instruction is followed, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *http://www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to

[5] This estimate of 0.051 additional quads of site energy savings reflects the difference in the cumulative national energy savings between the max-tech efficiency levels and the energy conservation standards established in the January 2015 Final Rule, when converted from full-fuel-cycle energy savings to site energy savings.

several weeks. Please keep the comment tracking number that *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or postal mail. Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to *http://www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. Faxes will not be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

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, postal mail, or hand delivery/courier two well-marked copies: 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. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE considers public participation to be a very important part of the process for developing test procedures and energy conservation standards. DOE actively encourages the participation and interaction of the public during the comment period in each stage of this process. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in the process. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about this process should contact Appliance and Equipment Standards Program staff at (202) 287–1445 or via email at *ApplianceStandardsQuestions@ee.doe.gov.*

Signing Authority

This document of the Department of Energy was signed on September 17, 2020, by Alexander N. Fitzsimmons, Deputy Assistant Secretary for Energy Efficiency, 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 September 17, 2020.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2020–20925 Filed 9–28–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 162

[Docket No. USCG–2020–0521]

RIN 1625–AA11

Connecting Waters From Lake Huron to Lake Erie; Traffic Rules

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to amend the navigation regulations between the Great Lakes. Specifically, this proposed amendment would allow a vessel to overtake another vessel that has slowed its speed to await berth availability or to make the turn for Rouge River and the overtaking vessel has so advised the Canadian Coast Guard Marine communications and Traffic Services Centre located in Sarnia, Ontario. Currently, the regulation only permits vessels to overtake vessels engaged in towing between the west end of Belle Isle and Peche Island Light. We invite your comments on this proposed rulemaking.

DATES: Comments and related materials must reach the Coast Guard on or before October 29, 2020.

ADDRESSES: You may submit comments identified by docket number USCG–2020–0521 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 on this proposed rule, call or email Tracy Girard, Sector Detroit, Coast Guard; telephone (313) 568–9564, email *Tracy.M.Girard@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

The purpose of this rulemaking is to update the navigation rule in § 162.134(a)(4) to improve traffic efficiency on the river while maintaining safety. The Canadian Coast

Guard has modified their traffic rules to reflect this change and the Lake Carriers Association has endorsed this change. This proposed rule would provide consistency on the river, and would apprise the public in a timely manner through permanent publication in Title 33 of the Code of Federal Regulations.

III. Discussion of Proposed Rule

This proposed modification to the rule will allow a vessel to overtake another vessel that has slowed its speed to await berth availability or to make the turn for Rouge River and the overtaking vessel has so advised the Canadian Coast Guard Marine Communications and Traffic Services Centre located in Sarnia, Ontario. This will improve traffic efficiency on the river while maintaining safety. Currently 33 CFR 162.134(a)(4) states, ''Between the west end of Belle Isle and Peche Island Light, vessels may only overtake vessels engaged in towing.'' We propose to replace 33 CFR 162.134(a)(4) with ''Between the west end of Belle Isle and Peche Island Light, vessels may overtake vessels if the vessel to be overtaken is engaged in towing or has slowed its speed to await berth availability or to make the turn for Rouge River, and the overtaking vessel has so advised the Canadian Coast Guard Marine Communications and Traffic Services Centre located in Sarnia, Ontario.''

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

B. Impact on Small Entities

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

While some owners or operators of vessels intending to transit the regulated areas 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 contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, 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 navigation rules. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. 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. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your

message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and 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 *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects 33 CFR Part 162

Navigation (water), Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 162 as follows:

PART 162—INLAND WATERWAYS NAVIGATION REGULATIONS

■ 1. The authority citation for part 162 continues to read as follows:

Authority: 33 U.S.C. 1231; Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 162.134, revise paragraph (a)(4) to read as follows:

§ 162.134 Connecting waters from Lake Huron to Lake Erie; traffic rules.

(a) * * *

(4) Between the west end of Belle Isle and Peche Island Light, vessels may overtake vessels if the vessel to be overtaken is engaged in towing or has slowed its speed to await berth availability or to make the turn for Rouge River, and the overtaking vessel has so advised the Canadian Coast Guard Marine Communications and Traffic Services Centre located in Sarnia, Ontario.

* * * * *

Dated: August 26, 2020.

Brad. W. Kelly,

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

[FR Doc. 2020–19238 Filed 9–28–20; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2020–0300; FRL–10014–58–Region 6]

Air Plan Approval; Texas; Reasonable Further Progress Plan for the Houston-Galveston-Brazoria Ozone Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is proposing to approve revisions to the Texas State Implementation Plan (SIP) to meet the Reasonable Further Progress (RFP) requirements for the Houston-Galveston-Brazoria (HGB) serious ozone nonattainment area for the 2008 ozone National Ambient Air Quality Standard (NAAQS). Specifically, EPA is proposing to approve the RFP demonstration and associated motor vehicle emission budgets, contingency measures should the area fail to make RFP emissions reductions or attain the 2008 ozone NAAQS by the applicable attainment date, and a revised 2011 base year emissions inventory for the HGB area.

DATES: Written comments must be received on or before October 29, 2020.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2020–0300, at *https://www.regulations.gov* or via email to *paige.carrie@epa.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact Carrie Paige, 214–665–6521, *paige.carrie@epa.gov.* 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.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov.* While all documents in the docket are listed in the index, some information may not be publicly available due to docket file size restrictions or content (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Carrie Paige, EPA Region 6 Office, Infrastructure & Ozone Section, 214–665–6521, *paige.carrie@epa.gov.* Out of an abundance of caution for members of the public and our staff, the EPA Region 6 office may be closed to the public to reduce the risk of transmitting COVID–19. We encourage the public to submit comments via *https://www.regulations.gov,* as there may be a delay in processing mail and courier or hand deliveries may not be accepted. Please call or email the contact listed above if you need alternative access to material indexed but not provided in the docket.

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

I. Introduction

On May 13, 2020, the Texas Commission on Environmental Quality (TCEQ or State) submitted to EPA a SIP revision addressing RFP requirements for the 2008 8-hour ozone NAAQS for the two serious ozone nonattainment areas in Texas (''the TCEQ submittal''). These two areas are the HGB and the Dallas-Fort Worth (DFW) areas. The TCEQ submittal also establishes motor vehicle emissions budgets (MVEBs) for the year 2020 and includes contingency measures for each of the HGB and DFW areas, should the areas fail to make reasonable further progress, or to attain

the NAAQS by the applicable attainment date.

In this rulemaking action, we are addressing only that portion of the TCEQ submittal that refers to the HGB area. We are proposing to approve the RFP demonstration and associated contingency measures for RFP or failure-to-attain and MVEBs for the HGB area. We are also proposing to approve a revised 2011 base year emissions inventory (EI) for the HGB area. The portion of the TCEQ submittal that refers to the DFW area will be addressed in a separate rulemaking action.

II. Background

In 2008, we revised the 8-hour ozone primary and secondary NAAQS to a level of 0.075 parts per million (ppm) to provide increased protection of public health and the environment (73 FR 16436, March 27, 2008).[1] The HGB area was classified as a marginal ozone nonattainment area for the 2008 ozone NAAQS [2] and initially given an attainment date of no later than December 31, 2015 (77 FR 30088 and 77 FR 30160, May 21, 2012). The HGB area consists of Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery and Waller counties.

On December 23, 2014, the D.C. Circuit Court issued a decision rejecting, among other things, our attainment deadlines for the 2008 ozone nonattainment areas, finding that we did not have statutory authority under the CAA to extend those deadlines to the end of the calendar year. *NRDC* v. *EPA*, 777 F.3d 456, 464–69 (D.C. Cir. 2014). Consistent with the court's decision we modified the attainment deadlines for all nonattainment areas for the 2008 ozone NAAQS and set the attainment deadline for all 2008 ozone marginal nonattainment areas, including the HGB area as July 20, 2015 (80 FR 12264, March 6, 2015). The HGB area qualified for a 1-year extension of the attainment date and we revised the attainment date to July 20, 2016 (81 FR 26697, May 4, 2016). The HGB area did not meet the revised attainment deadline and we reclassified the area to moderate with an attainment date no later than July 20, 2018 (81 FR 90207, December 14, 2016). Subsequently, the HGB area did not meet the moderate attainment date and was reclassified as a serious ozone nonattainment area (84 FR 44238, August 23, 2019).[3] Accordingly, the State was required to submit revisions to the HGB SIP to meet serious area requirements.

The CAA requires that areas designated as nonattainment for ozone and classified as moderate or worse demonstrate RFP by reducing emissions of ozone precursors (nitrogen oxides or NO_X and volatile organic compounds or VOC).[4] On March 6, 2015 (80 FR 12264), EPA published the final rule to implement the 2008 ozone standard (the ''SIP Requirements Rule'' or ''SRR'') that addressed, among other things, the RFP control and planning obligations as they apply to areas designated nonattainment for the 2008 ozone standard. In the SRR, RFP was defined (for the purposes of the 2008 ozone standard) as meaning the progress reductions required under sections 172(c)(2) and 182(b)(1) and (c)(2)(B) and (c)(2)(C) of the CAA (80 FR 12264, 12313).[5] RFP plans must also include a MVEB, which provides the allowable on-road mobile emissions an area can produce and continue to demonstrate RFP (57 FR 13498, 13558, April 16, 1992).

The RFP plan for the HGB moderate ozone nonattainment area for the 2008 ozone NAAQS was approved on February 13, 2019 (84 FR 3708) and it demonstrated required emissions reductions through the end of calendar year 2017. Because the HGB area was reclassified as a serious ozone nonattainment area, pursuant to CAA section 182(c)(2) and 40 CFR 51.1110, the RFP SIP for the HGB area must demonstrate NO_X and/or VOC emissions reductions of at least an average of 3 percent per year for the calendar years 2018, 2019, and 2020 for a total of 9 percent and an additional 3 percent for contingency measures in 2021, should the area fail to meet RFP or fail to attain the 2008 ozone NAAQS by the July 20, 2021 attainment date. Finally, the emissions reductions must occur within the HGB area.

III. EPA's Evaluation of the TCEQ Submittal

We reviewed the TCEQ submittal for consistency with the requirements of the CAA and EPA regulations and guidance. A summary of our analysis and findings are provided below. For a more detailed discussion of our evaluation, please see our TSD in the docket for this rulemaking action.

A. Revised 2011 Base Year Emissions Inventory

An emissions inventory (EI) is a collection of data that lists, by source, the amount of air pollutants discharged into the atmosphere, during a year or other time period. The EI includes estimates of the emissions associated with the air quality problems in the area (in this case, NO_X and VOC) from various pollution sources. The State submitted a 2011 base year EI for the 2008 ozone NAAQS, which we approved for the HGB area (80 FR 9204).[6] The State later revised the 2011 base year EI for the HGB area, which we approved (84 FR 3708). In the TCEQ submittal, the State further refined the 2011 base year EI for the HGB area. Pursuant to 40 CFR 51.1110(b), the values in the submitted 2011 base year EI are actual ozone season day emissions. Pursuant to CAA sections 172(c)(3) and 182(b)(1), the submitted 2011 base year EI consists of NO_X and VOC emissions from all sources inside the nonattainment area. Compared with that approved at 84 FR 3708, the submitted 2011 base year NO_X emissions decrease by 17.02 tons per day (tpd) and VOC emissions increase by 3.66 tpd. The revised 2011 base year EI was developed using EPA-approved guidelines for point, mobile, and area emission sources. Point source emissions data for 2011 were pulled from the State of Texas Air Reporting System (STARS) database—these data also include all authorized/planned Startup, Shutdown and Maintenance emissions.[7] On-road and nonroad mobile source emissions were calculated using the EPA's MOVES2014a model [8] combined with

[1] On October 1, 2015, the EPA promulgated a more protective 8-hour ozone standard of 0.070 ppm (80 FR 65292, October 26, 2015). On April 30, 2018, the EPA promulgated designations under the 2015 ozone standard (83 FR 25776, June 4, 2018) and in that action, the EPA designated Brazoria, Chambers, Fort Bend, Galveston, Harris, and Montgomery counties as a marginal ozone nonattainment area. The RFP plan is not required for a marginal nonattainment area under the 2015 ozone standard. The TCEQ submittal does not specifically address the 2015 ozone standard, but provides progress toward attaining the new standard. For more information on ozone, see our Technical Support Document (TSD) in the docket for this rulemaking and visit *https://www.epa.gov/ground-level-ozone-pollution.*

[2] Throughout this document, we refer to the 2008 8-hour ozone NAAQS as the ''2008 ozone NAAQS.''

[3] For more on the history of ozone in the HGB area, see our TSD in the docket for this rulemaking and visit *https://www.tceq.texas.gov/airquality/sip/hgb/hgb-ozone-history.*

[4] See CAA sections 172(c)(2) and 182(b)(1) and 40 CFR 51.1110.

[5] See 40 CFR 51.1110.

[6] See also the EI regulations at 40 CFR 51.1115.

[7] States are not obligated to include malfunction emissions in the base year inventory for RFP plans. See the discussion beginning on page 83 of Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards (NAAQS) and Regional Haze Regulations EPA–454/B–17–003, available at *https://www.epa.gov/sites/production/files/2017-07/documents/ei_guidance_may_2017_final_rev.pdf* (hereinafter referred to as ''EPA's EI Guidance'') (July 2017).

[8] EPA's Motor Vehicle Emission Simulator (MOVES) is a state-of-the-science emission

Continued

local activity inputs including vehicle miles traveled (VMT) and average speed data, as well as local fleet, age distribution, and fuels information. Area sources include many categories of emissions. The EPA finds that these sources were adequately accounted for in the revised 2011 base year EI. The methodology used to calculate emissions for each respective category followed relevant EPA EI guidance [9] and was sufficiently documented in the TCEQ Submittal.[10] We are proposing to approve the revised 2011 base year EI. Table 1 summarizes the revised EI for the HGB area. See our TSD for more detail.

TABLE 1—HGB RFP 2011 BASE YEAR EI

2011 Base year inventory, reported in tpd				
Source type	NO_X		VOC	
	Approved at 84 FR 3708	Revised inventory	Approved at 84 FR 3708	Revised inventory
Point	108.33	108.33	95.99	95.97
Area	21.15	21.15	304.90	308.53
Non-road Mobile	142.44	144.84	49.78	50.11
On-road Mobile	188.02	168.60	80.73	80.45
Total	459.94	442.92	531.40	535.06

B. Reasonable Further Progress Demonstration

To calculate the required RFP emission reductions, CAA section 182 and 40 CFR 51.1110(b) require that the percent reduction be calculated from the base year EI. The required reductions are then subtracted from the 2011 base year EI to provide the RFP emissions target numbers. See our TSD and the TCEQ submittal for more detail. The RFP calculations are shown in Table 2.

TABLE 2—CALCULATION OF RFP TARGET EMISSION REDUCTIONS THROUGH 2020

[tpd]

Description	NO_X	VOC
a. 2011 Emissions Inventory (totals from Table 1)	442.92	535.06
b. Percent of NO_X and VOC to meet 15% reduction [11] (percentages must total 15, and 10 + 5 = 15)	10.0%	5.0%
c. Percent of NO_X and VOC to meet 9% reduction (percentages must total 9, and 6.2 + 2.8 = 9)	6.2%	2.8%
d. 15% NO_X and VOC reduction, 2011–2017 (row a multiplied by row b) (442.92 × 0.1 = 44.29) and (535.06 × 0.05 = 26.75)	44.29	26.75
e. 9% NO_X and VOC reduction, 2018–2020 (row a multiplied by row c) (442.92 × 0.062 = 27.46) and (535.06 × 0.028 = 14.98)	27.46	14.98
f. Total emissions reductions for 2011–2020 (row d plus row e)	71.75	41.73
g. 2020 Target Level of Emissions (row a minus row f)	371.17	493.33

To determine whether the area is able to meet the RFP target, the State must establish the future year (2020) EI and subtract any control measures that will be applied to sources in the HGB area. Section 182(b)(1)(A) of the Act requires that states provide sufficient control measures in their RFP plans to offset growth in emissions. The controls identified by the State to achieve RFP are listed in Table 3. For more detail on these controls, see our TSD and the TCEQ submittal.

TABLE 3—HGB AREA CONTROL MEASURES AND PROJECTED EMISSION REDUCTIONS (tpd), 2011–2020

Control strategy description	NO_X	VOC
Federal Motor Vehicle Control Program (FMVCP)	561.84	245.62
Reformulated Gasoline (RFG) [12]/Low Sulfur Gasoline/Ultra-Low Sulfur Diesel (ULSD)	101.55	16.96
Inspection and Maintenance (I/M) (66 FR 57261, 11/14/2001)	5.13	7.39
On-road Texas Low-Emission Diesel (TxLED) [13]	2.39	0.00
Tier I and II locomotive NO_X standards	21.02	0.81
Small non-road spark-ignition (SI) engines (Phase I)	−3.17	25.60
Heavy duty non-road engines	26.71	13.71
Tiers 2 and 3 non-road diesel engines	30.22	2.62
Small non-road SI engines (Phase II)	2.22	23.67
Large non-road SI and recreational marine	37.37	16.51
Non-road TxLED	1.36	0.00

modeling system that estimates emissions for mobile sources at the national, county, and project level for criteria air pollutants, greenhouse gases, and air toxics. See *https://www.epa.gov/moves.*

[9] In addition to EPA's EI Guidance, see MOVES2014 and MOVES2014a Technical Guidance: Using MOVES to Prepare Emission Inventories for State Implementation Plans and Transportation Conformity, EPA–420–B–15–093, available at *https://nepis.epa.gov/Exe/ZyPDF.cgi/P100NN9L.PDF?Dockey=P100NN9L.pdf* (Nov. 2015).

[10] See our TSD and the TCEQ submittal with appendices in the docket for this rulemaking.

[11] To account for the reductions required and taken under the moderate area RFP plan, we reduce emissions by 15% between 2011 and 2017. See 84 FR 3708.

TABLE 3—HGB AREA CONTROL MEASURES AND PROJECTED EMISSION REDUCTIONS (tpd), 2011–2020—Continued

Control strategy description	NO_X	VOC
Non-road RFG	0.01	0.73
Tier 4 non-road diesel engines	17.70	0.78
Small SI (Phase III)	2.16	15.43
Drilling rigs: Federal engine standards and TxLED	0.43	0.09
Commercial Marine Vessel engine certification standards and fuel programs	14.76	0.12
Total Projected Emission Reductions	821.70	370.04

To determine whether the area will meet the RFP targets, we subtract the projected emission reductions (Table 3) from the projected EI of uncontrolled emissions for 2020. This projected EI will reflect emissions resulting from anticipated changes in activity from 2011 to 2020, such as emissions increases due to growth in population and VMT. NO_X emissions from sites with equipment applicable to the Mass Emissions Cap and Trade (MECT) Program were projected using the MECT cap. Major stationary sources of VOC emissions were projected by adding emissions growth allowed under the nonattainment New Source Review NSR major modification thresholds. The projected EI was also adjusted to account for available (unused) emissions credits.[14] For more detail on the projected EI, please see our TSD and the TCEQ submittal. The methodology used to forecast the 2020 emissions for each respective category followed relevant EPA EI guidance and was sufficiently documented in the TCEQ submittal. The projected EI data in Table 4 are labeled as ''uncontrolled'' emissions. To achieve RFP, the amount of emissions remaining after subtracting the emissions reductions from the control measures must be equal to or less than the target inventories calculated in Table 2.

TABLE 4—SUMMARY OF RFP DEMONSTRATION FOR THE HGB AREA THROUGH 2020

[tpd]

Description	NO_X	VOC
a. 2020 Uncontrolled emissions	1,165.66	854.65
b. Projected emissions reductions through 2020 (total from Table 3)	821.70	370.04
c. Projected Emissions after Reductions (subtract line b from line a)	343.96	484.61
d. 3% reductions reserved for prior (2017–2018) RFP milestone contingency measures	13.29	.....
e. Projected emissions, including prior contingency requirement (add lines c and d)	357.25	484.61
f. 2020 Target (from Table 2)	371.17	493.33
If the projected emissions (line e) are less than the RFP target (line f), the area demonstrates RFP. Is line e less than line f?	Yes	Yes
g. Subtract line e from line f for surplus	13.92	8.72

In Table 4, we see that the projected emissions in row e, after accounting for reductions from controls and the 2017–2018 contingency measures, are less than the 2020 RFP target emissions and thus, demonstrate RFP. We are proposing that the emissions reductions projected for 2020 are sufficient to meet the 2020 RFP targets.

C. Contingency Measures

As noted earlier, RFP plans for moderate and above nonattainment areas must include contingency measures, which, consistent with CAA section 172(c)(9), ''shall provide for the implementation of specific measures to be undertaken if the area fails to make reasonable further progress, or to attain the national primary ambient air quality standard by the attainment date applicable under this part.'' EPA has long interpreted the contingency measures provision to allow states to rely on measures already in place and implemented so long as those reductions are beyond those relied on for purposes of the attainment or RFP planning SIP.[15] In addition, the April 16, 1992 General Preamble provided the following guidance: ''States must show that their contingency measures can be implemented with minimal further action on their part and with no additional rulemaking actions such as public hearings or legislative review. In general, EPA will expect all actions needed to affect full implementation of the measures to occur within 60 days after EPA notifies the State of its failure.'' (57 FR 13512).

While the CAA does not specify the type of measures or quantity of emissions reductions required, EPA interprets the CAA to mean that implementation of these contingency measures would provide additional emissions reductions of up to 3 percent of the adjusted base year inventory (or a lesser percentage that will make up the identified shortfall) in the year following the missed milestone, whether it be RFP or attainment.[16]

The TCEQ submittal provides NO_X reductions for the HGB contingency measures. These contingency measure reductions for the HGB area are not

[12] The RFG program is implemented in all 8 counties identified elsewhere in this proposal as the HGB area. For more information on the RFG program, visit *https://www.epa.gov/gasoline-standards/reformulated-gasoline.*

[13] The TxLED fuel rules apply to highway (on-road) and non-road vehicles and were approved into the Texas SIP on November 14, 2001 (66 FR 57196). Subsequent revisions were approved April 6, 2005 (70 FR 17321), October 6, 2005 (70 FR 58325), October 24, 2008 (73 FR 63378), and May 6, 2013 (78 FR 26255).

[14] Emissions credits are banked emissions reductions that may return to the air shed in the future when these emissions credits are used either to modify existing facilities, construct new facilities, or demonstrate compliance with source-specific emissions limit obligations where provided for in Texas SIP rules.

[15] This interpretation has been upheld by the Fifth Circuit Court of Appeals (and the State of Texas is within the Fifth Circuit jurisdiction). *See LEAN* v. *EPA,* 382 F.3d 575 (5th Cir. 2004).

[16] See the April 16, 1992 General Preamble section III.A.3.c (57 FR 13498 at 13511).

relied upon for RFP or for attainment. The TCEQ submittal includes but is not limited to surplus emissions reductions from the 2020 RFP demonstration (see Table 4, line g) for the HGB area contingency measure demonstration. The TCEQ submittal also includes emission reductions that will take place during calendar year 2021 for the HGB area contingency measure demonstration—these contingency measures consist of State mobile source measures that are already approved in the SIP (I/M, RFG, and TxLED) [17] and federal measures (FMVCP and ULSD). Thus, the contingency measures for 2021 are reliable, permanent, and enforceable. The contingency measures are listed in Table 5.

TABLE 5—DEMONSTRATION FOR 2021 FOR THE HGB AREA RFP CONTINGENCY MEASURES

[tpd]

	NO_X	VOC
Description		
a. 2011 Base year Emissions Inventory (from Table 1)	442.92	535.06
b. Percent of NO_X and VOC to meet contingency measure requirement (total must equal 3%)	3%	0
c. 3% NO_X reduction for 2021 (row a multiplied by row b) (442.92 × 0.03 = 13.29)	13.29	0
Excess reductions to meet contingency requirement		
d. Surplus RFP reductions (from Table 4)	13.92	8.72
e. Subtract 2020 RFP MVEB safety margin [18]	−8.21	−5.49
f. 2020 to 2021 emission reductions (FMVCP, I/M, RFG, 2017 low sulfur gasoline standard on-road TxLED, and ULSD)	24.19	13.05
g. 2020 to 2021 emission reductions (federal non-road mobile new vehicle certification standards, non-road RFG, and non-road TxLED)	4.59	2.29
h. Total projected emissions, accounting for contingency measures (add lines d, e, f, and g)	34.49	18.57
Total surplus or shortfall		
Line h is greater than line c. Subtract line c from line h for surplus	21.20	18.57
Is the contingency measure requirement met?	Yes	Yes

In Table 5, we see that the contingency measures provided for the HGB area, after accounting for the MVEB safety margin, are more than sufficient to meet the 3 percent contingency requirement. Indeed, if the HGB area relied only on the contingency measures scheduled for implementation during 2021 (Table 5, lines f and g), after accounting for the MVEB safety margin, those contingency measures alone would be adequate to meet the 3 percent contingency requirement. In addition, the contingency measures that occur from 2020 to 2021 are State and Federal measures that are already approved into the Texas SIP and as such are expected to be implemented with no further action by the State and with no additional rulemaking actions. Our evaluation of these contingency measures finds that the full implementation of such measures within 60 days after EPA notifies the State of its failure is achievable as, the contingency measures that occur from 2020 to 2021 are State and Federal measures already approved into the Texas SIP and as such are expected to be implemented with no further action by the State. We are proposing to approve the contingency measures for the HGB area.

D. Motor Vehicle Emission Budgets

The MVEB is the mechanism to determine if future transportation plans conform to the SIP. Transportation conformity is required by CAA section 176(c) and mandates that future transportation plans must not produce new air quality violations, worsen existing violations, delay RFP milestones, or delay timely attainment of the NAAQS. Thus, pursuant to CAA section 176(c), the RFP plan must include MVEBs for transportation conformity purposes. The MVEB is the maximum amount of emissions allowed in the SIP for on-road motor vehicles. The HGB RFP SIP contains VOC and NO_X MVEBs for RFP milestone year 2020 (see Table 6). On-road emissions must be shown in future transportation plans to be less than the MVEBs for 2020 and subsequent years.

EPA is evaluating the adequacy of the submitted MVEBs in parallel to this proposed approval action. Once EPA finds the submitted MVEBs are adequate for transportation conformity purposes, those MVEBs must be used by State and Federal agencies in determining whether proposed transportation projects conform to the SIP as required by section 176(c) of the CAA. EPA's criteria for determining adequacy of a MVEB are set out in 40 CFR 93.118(e)(4). The process for determining adequacy is described in our TSD.

EPA intends to make its determination on the adequacy of the 2020 RFP MVEBs for the HGB area for transportation conformity purposes soon, by completing the adequacy process that was started on June 3, 2020.[19] After EPA finds the 2020 MVEBs adequate or approves them, the new MVEBs for NO_X and VOC must be used for future transportation conformity determinations. For required regional emissions analysis years 2020 and beyond, the applicable budgets will be the new 2020 MVEBs. We are proposing to approve the 2020 MVEBs for the HGB area.

[17] As noted earlier in this rulemaking, the I/M program was approved into the SIP in 2001 (66 FR 57261). See footnotes 14 and 15 regarding approval of RFG and TxLED in the SIP.

[18] The safety margin allows for unanticipated growth in vehicle miles traveled, changes, and uncertainty in vehicle mix assumptions, etc., that will influence the emission estimates.

[19] On June 3, 2020, EPA posted the HGB area NO_X and VOC MVEBs on EPA's website for the purpose of soliciting public comments, as part of the adequacy process. The comment period closed on July 3, 2020, and we received no comments. For more information, visit *https://www.epa.gov/state-and-local-transportation/state-implementation-plans-sip-submissions-currently-under-epa#houston-texas-rea.*

TABLE 6—RFP MOTOR VEHICLE EMISSIONS BUDGETS FOR HGB

[tpd]

Year	NO_X	VOC
2020	87.69	57.70

III. Proposed Action

We are proposing to approve revisions to the Texas SIP that address the RFP requirements for the HGB serious ozone nonattainment area for the 2008 ozone NAAQS. Specifically, we are proposing to approve the RFP demonstration and associated MVEBs, contingency measures for RFP or failure-to-attain, and the revised 2011 base year EI for the HGB area. Further, as part of today's action, EPA is describing the status of its adequacy determination for the NO_X and VOC MVEBs for 2020 in accordance with 40 CFR 93.118(f)(2). Within 24 months from the effective date of EPA's adequacy determination for the MVEBs or the publication date for the final rule for this action, whichever is earlier, the transportation partners will need to demonstrate conformity to the new NO_X and VOC MVEBs pursuant to 40 CFR 93.104(e)(3).

IV. Statutory and Executive Order Reviews

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

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

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Volatile organic compounds.

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

Dated: September 16, 2020.

Kenley McQueen,

Regional Administrator, Region 6.

[FR Doc. 2020–20849 Filed 9–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2015–0699; FRL–10015–10–Region 5]

Air Plan Approval; Ohio; Attainment Plan for the Muskingum River SO_2 Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Ohio State Implementation Plan (SIP) submitted on April 3, 2015 and October 13, 2015, and supplemented on June 23, 2020, by the Ohio Environmental Protection Agency (Ohio EPA), consisting of its plan for attaining the 1-hour sulfur dioxide (SO_2) primary national ambient air quality standard (NAAQS) for the Muskingum River, Ohio SO_2 nonattainment area. This plan (herein called a ''nonattainment plan'') includes Ohio's attainment demonstration and other elements required under the Clean Air Act (CAA). In addition to an attainment demonstration, the plan addresses the requirements for meeting reasonable further progress (RFP) toward attainment of the NAAQS, reasonably available control measures (RACM) and reasonably available control technology (RACT), enforceable emission limitations and control measures, base-year and projection-year emission inventories, and contingency measures. EPA proposes to conclude that Ohio has appropriately demonstrated that the plan provisions provide for attainment of the 2010 1-hour primary SO_2 NAAQS in the Muskingum River, Ohio nonattainment area and that the plan meets the other applicable requirements under the CAA.

DATES: Comments must be received on or before October 29, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2015–0699 at *http://www.regulations.gov,* or via email to *aburano.douglas@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted,

comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Gina Harrison, Environmental Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–6956, *harrison.gina@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

SUPPLEMENTARY INFORMATION: Throughout this document, whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This state submittal addressed Ohio's Lake County, Muskingum River, and Steubenville OH-WV SO_2 nonattainment areas. EPA is proposing action on only the Muskingum River portion of Ohio's submittal at this time; the Lake County and Steubenville portions were addressed in prior rulemaking actions. The following outline is provided to aid in locating information regarding EPA's proposed action on Ohio's Muskingum River SO_2 nonattainment plan.

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I. Why was Ohio required to submit an SO_2 plan for the Muskingum River area?

On June 22, 2010, EPA promulgated a new 1-hour primary SO_2 NAAQS of 75 parts per billion (ppb), which is met at an ambient air quality monitoring site when the 3-year average of the annual 99th percentile of the daily maximum 1-hour average concentrations does not exceed 75 ppb, as determined in accordance with appendix T of 40 CFR part 50. *See* 75 FR 35520, codified at 40 CFR 50.17(a)–(b). The 3-year average of the annual 99th percentile of daily maximum 1-hour concentrations is called the air quality monitor's SO_2 ''design value.'' For the 3-year period 2009–2011, the design value at the Muskingum River SO_2 monitor in Morgan County, Ohio (39–115–004) was 180 ppb, which is a violation of the SO_2 NAAQS. On August 5, 2013, EPA designated a first set of 29 areas of the country as nonattainment for the 2010 SO_2 NAAQS, including the Muskingum River nonattainment area. Muskingum River's SO_2 designation was based upon the monitored design value at this location for this three-year period. The Muskingum River nonattainment area is defined to include part of Morgan County (Center Township) and part of Washington County (Waterford Township). *See* 78 FR 47191, codified at 40 CFR part 81, subpart C. This area designation was effective on October 4, 2013.

Section 191(a) of the CAA directs states to submit SIPs for areas designated as nonattainment for the SO_2 NAAQS to EPA within 18 months of the effective date of the designation; in this case, by no later than April 4, 2015. These SIPs are required by CAA section 192(a) to demonstrate that their respective areas will attain the NAAQS as expeditiously as practicable, but no later than 5 years from the effective date of designation. The SO_2 attainment deadline for Muskingum River was October 4, 2018. EPA is proposing to approve this plan in accordance with a court-ordered deadline of October 30, 2020 for final action on the SIP.[1]

In response to the SO_2 nonattainment plan submittal requirement, Ohio submitted a nonattainment plan for the Muskingum River nonattainment area on April 3, 2015,[2] submitted revisions on October 13, 2015, and submitted a supplement specific to the Muskingum River area on June 23, 2020. The June 23, 2020 supplement contains the core features of the attainment plan. The remainder of this document describes the requirements that such plans must meet in order to obtain EPA approval, provides a review of the state's plan with respect to these requirements, and describes EPA's proposed action on the plan.

II. Requirements for SO_2 Nonattainment Area Plans

Nonattainment SIPs must meet the applicable requirements of the CAA, and specifically CAA sections 110, 172, 191 and 192. EPA's regulations governing nonattainment SIPs are set forth at 40 CFR part 51, with specific procedural requirements and control strategy requirements residing at subparts F and G, respectively. Soon after Congress enacted the 1990 Amendments to the CAA, EPA issued comprehensive guidance on SIPs, in a document entitled the ''General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' published at 57 FR 13498 (April 16, 1992) (General Preamble). Among other things, the General Preamble addressed SO_2 SIPs and fundamental principles for SIP control strategies. *Id.,* at 13545–13549, 13567–13568. On April 23, 2014, EPA issued recommended guidance for meeting the statutory requirements in SO_2 SIPs, in a document entitled, ''Guidance for 1-Hour SO_2 Nonattainment Area SIP Submissions,'' available at *https://www.epa.gov/sites/production/files/2016-06/documents/20140423guidance_nonattainment_sip.pdf.* In this guidance, referred to in this document as the 2014 SO_2 guidance, EPA described the statutory requirements for a complete nonattainment area SIP,

[1] In a November 26, 2019, order issued in *Center for Biological Diversity, et al.* v. *Wheeler,* No. 4:18–cv–03544 (N.D. Cal.), the court ordered EPA to take action on certain aspects of Ohio's SIP submittal, including the attainment demonstration for the Muskingum River area, by October 30, 2020.

[2] For a number of areas, EPA published a final rule on March 18, 2016 that the pertinent states had failed to submit the required SO_2 nonattainment plan by this submittal deadline. *See* 81 FR 14736. However, because Ohio EPA had submitted its SO_2 nonattainment plan before that date, EPA did not make such a finding with respect to Ohio's submittal for Muskingum River.

which includes an accurate emissions inventory of current emissions for all sources of SO_2 within the nonattainment area; an attainment demonstration; demonstration of RFP; implementation of RACM/RACT; enforceable emission limitations and control measures; NSR; and adequate contingency measures for the affected area.

In order for EPA to fully approve a SIP as meeting the requirements of CAA sections 110, 172 and 191–192, and EPA's regulations at 40 CFR part 51, the SIP for the affected area needs to demonstrate to EPA's satisfaction that each of the aforementioned requirements have been met. Under CAA sections 110(l) and 193, EPA may not approve a SIP that would interfere with any applicable requirement concerning NAAQS attainment and RFP, or any other applicable requirement, and no requirement in effect (or required to be adopted by an order, settlement, agreement, or plan in effect before November 15, 1990) in any area which is a nonattainment area for any air pollutant, may be modified in any manner unless it ensures equivalent or greater emission reductions of such air pollutant.

III. Attainment Demonstration and Longer Term Averaging

CAA section 172(c)(1) directs states with areas designated as nonattainment to demonstrate that the submitted plan provides for attainment of the NAAQS. The regulations at 40 CFR part 51, subpart G further delineate the control strategy requirements that SIPs must meet. EPA has long required that all SIPs and control strategies reflect four fundamental principles of quantification, enforceability, replicability, and accountability. *See* General Preamble, at 13567–13568. SO_2 attainment plans must consist of two components: (1) Emission limits and other control measures that ensure implementation of permanent, enforceable and necessary emission controls, and (2) a modeling analysis which meets the requirements of 40 CFR part 51, appendix W which demonstrates that these emission limits and control measures provide for timely attainment of the primary SO_2 NAAQS as expeditiously as practicable, but by no later than the attainment date for the affected area. In all cases, the emission limits and control measures must be accompanied by appropriate methods and conditions to determine compliance with the respective emission limits and control measures and must be quantifiable (*i.e.,* a specific amount of emission reduction can be ascribed to the measures), fully enforceable (specifying clear, unambiguous and measurable requirements for which compliance can be practicably determined), replicable (the procedures for determining compliance are sufficiently specific and non-subjective so that two independent entities applying the procedures would obtain the same result), and accountable (source specific limits must be permanent and must reflect the assumptions used in the SIP demonstrations).

EPA's 2014 SO_2 guidance recommends that emission limits be expressed as short-term average limits (*e.g.,* addressing emissions averaged over one or three hours), but also describes an option to utilize emission limits with longer averaging times of up to 30 days so long as the state meets various suggested criteria. *See* 2014 SO_2 guidance, pp. 22 to 39. Should states and sources utilize longer averaging times, the guidance recommends that the longer term average limit be set at an adjusted level that reflects a stringency comparable to the 1-hour average limit that the plan otherwise would have set at the critical emission value (CEV) shown to provide for attainment.

The 2014 SO_2 guidance provides an extensive discussion of EPA's rationale for concluding that appropriately set, comparably stringent limitations based on averaging times as long as 30 days can be found to provide for attainment of the 2010 SO_2 NAAQS. In evaluating this option, EPA considered the nature of the standard, conducted detailed analyses of the impact of use of 30-day average limits on the prospects for attaining the standard, and carefully reviewed how best to achieve an appropriate balance among the various factors that warrant consideration in judging whether a state's plan provides for attainment. *Id.* at pp. 22 to 39. *See* also *id.* at appendices B, C, and D.

EPA considered that the 1-hour primary SO_2 NAAQS, as specified in 40 CFR 50.17(b), is met at an ambient air quality monitoring site when the 3-year average of the annual 99th percentile of daily maximum 1-hour average concentrations is less than or equal to 75 ppb. In a year with 365 days of valid monitoring data, the 99th percentile would be the fourth highest daily maximum 1-hour value. The 2010 SO_2 NAAQS, including this form of determining compliance with the standard, was upheld by the U.S. Court of Appeals for the District of Columbia Circuit in *Nat'l Envt'l Dev. Ass'n's Clean Air Project* v. *EPA,* 686 F.3d 803 (D.C. Cir. 2012). Because the standard has this form, a single hourly exceedance of the 75 ppb NAAQS level does not create a violation of the standard. Therefore, an emission limit which allows some operational flexibility or emission variability may still be protective of the standard.

At issue is whether a source operating in compliance with a properly set longer term average could cause exceedances of the NAAQS level, and if so, what are the resulting frequency and magnitude of such exceedances. Specifically, EPA must determine with reasonable confidence whether a properly set longer term average limit will provide that the 3-year average of the annual fourth highest daily maximum 1-hour value will be at or below 75 ppb. A synopsis of EPA's review of how to judge whether such plans provide for attainment in light of the NAAQS' form, based on modeling of projected allowable emissions for determining attainment at monitoring sites, is given below.

For SO_2 plans based on 1-hour emission limits, the standard approach is to conduct modeling using fixed emission rates. The maximum emission rate that would be modeled to result in attainment (*i.e.,* in an ''average year'' [3] shows three, not four days with maximum hourly levels exceeding 75 ppb) is labeled the ''critical emission value'' or ''CEV.'' The modeling process for identifying this CEV inherently considers the numerous variables that affect ambient concentrations of SO_2, such as meteorological data, background concentrations, and topography. In the standard approach, the state would then provide for attainment by setting a continuously applicable 1-hour emission limit at this CEV.

EPA recognizes that some sources have highly variable emissions, for example due to variations in fuel sulfur content and operating rate, that can make it extremely difficult, even with a well-designed control strategy, to ensure in practice that emissions for any given hour do not exceed the CEV. EPA also acknowledges the concern that longer term emission limits can allow short periods with emissions above the CEV, which, if coincident with meteorological conditions conducive to high SO_2 concentrations, could in turn create the possibility of a NAAQS

[3] An ''average year'' is used to mean a year with average air quality. While 40 CFR 50 appendix T provides for averaging three years of 99th percentile daily maximum hourly values (*e.g.,* the fourth highest maximum daily hourly concentration in a year with 365 days with valid data), this discussion and an example below uses a single ''average year'' in order to simplify the illustration of relevant principles.

exceedance occurring on a day when an exceedance would not have occurred if emissions were continuously controlled at the level corresponding to the CEV. However, for several reasons, EPA believes that the approach recommended in its guidance document suitably addresses this concern. First, from a practical perspective, EPA expects the actual emission profile of a source subject to an appropriately set longer term average limit to be similar to the emission profile of a source subject to an analogous 1-hour average limit. EPA expects this similarity because it has recommended that the longer term average limit be set at a level that is comparably stringent to the otherwise applicable 1-hour limit (reflecting a downward adjustment from the CEV) and that takes the source's emissions profile into account. As a result, EPA expects either form of emission limit to yield comparable air quality.

Second, from a more theoretical perspective, EPA has compared the likely air quality with a source having maximum allowable emissions under an appropriately set longer term limit, as compared to the likely air quality with the source having maximum allowable emissions under the comparable 1-hour limit. In this comparison, in the 1-hour average limit scenario, the source is presumed at all times to emit at the CEV level, and in the longer term average limit scenario, the source is presumed occasionally to emit more than the CEV level but on average, and presumably at most times, to emit well below the CEV. In an ''average year,'' compliance with the 1-hour limit is expected to result in three exceedance days (*i.e.,* three days with maximum hourly values above 75 ppb) and a fourth day with a maximum hourly value at 75 ppb. By comparison, with the source complying with a longer term limit, it is possible that additional hourly exceedances would occur that would not occur in the 1-hour limit scenario (if emissions exceed the CEV at times when meteorology is conducive to poor air quality). However, this comparison must also factor in the likelihood that hourly exceedances that would be expected in the 1-hour limit scenario would not occur in the longer term limit scenario. This result arises because the longer term limit requires lower emissions most of the time (because the limit is set well below the CEV), so a source complying with an appropriately set longer term limit is likely to have lower emissions at critical times than would be the case if the source were emitting as allowed with a 1-hour limit.

As a hypothetical example to illustrate these points, suppose a source that always emits 1,000 pounds of SO_2 per hour (lb/hr), which results in air quality at the level of the NAAQS (*i.e.,* results in a design value of 75 ppb). Suppose further that in an ''average year,'' these emissions cause the 5 highest daily maximum 1-hour average concentrations to be 100 ppb, 90 ppb, 80 ppb, 75 ppb, and 70 ppb. Then suppose that the source becomes subject to a 30-day average emission limit of 700 lb/hr. It is theoretically possible for a source meeting this limit to have emissions that occasionally exceed 1,000 lb/hr, but with a typical emissions profile emissions would much more commonly be between 600 and 800 lb/hr. In this simplified example, assume a zero background concentration, which allows one to assume a linear relationship between emissions and air quality. (A nonzero background concentration would make the mathematics more difficult but would give similar results.) Air quality will depend on what emissions happen on what critical hours, but suppose that emissions at the relevant times on these 5 days are 800 pounds/hour, 1,100 lb/hr, 500 lb/hr, 900 lb/hr, and 1,200 lb/hr, respectively. (This is a conservative example because the average of these emissions, 900 lb/hr, is well over the 30-day average emission limit.) These emissions would result in daily maximum 1-hour average concentrations of 80 ppb, 99 ppb, 40 ppb, 67.5 ppb, and 84 ppb. In this example, the fifth day would have an exceedance of the NAAQS level that would not otherwise have occurred, but the third day would not have an exceedance that otherwise would have occurred, and the fourth day would have been below, rather than at, 75 ppb. In this example, the fourth highest maximum daily concentration under the 30-day average would be 67.5 ppb.

This simplified example illustrates the findings of a more complicated statistical analysis that EPA conducted using a range of scenarios using actual plant data. As described in appendix B of EPA's April 2014 SO_2 guidance, EPA found that the requirement for lower average emissions is highly likely to yield better air quality than is required with a comparably stringent 1-hour limit. Based on analyses described in appendix B of its April 2014 SO_2 guidance, EPA expects that an emission profile with maximum allowable emissions under an appropriately set comparably stringent 30-day average limit is likely to have the net effect of having a *lower* number of NAAQS exceedances and better air quality than an emission profile with maximum allowable emissions under a 1-hour emission limit at the CEV. This result provides a compelling policy rationale for allowing the use of a longer averaging period in appropriate circumstances where the facts indicate that a result of this type might occur.[4]

The question then becomes whether this approach—which is likely to produce no more overall NAAQS exceedances even though it may produce some unexpected exceedances above the CEV—meets the requirements in sections 110(a)(1), 172(c)(1), and 172(c)(6) for emission limitations in state implementation plans to ''provide for attainment'' of the NAAQS. For SO_2, as for other pollutants, it is generally impossible to design a nonattainment plan in the present that will guarantee that attainment will occur in the future. A variety of factors can cause a well-designed plan to fail and unexpectedly not result in attainment, for example if meteorological conditions occur that are more conducive to poor air quality than was anticipated in the plan. Therefore, in determining whether a plan meets the requirement to provide for attainment, EPA's task is commonly to judge not whether the plan provides absolute certainty that attainment will in fact occur, but rather whether the plan provides an adequate level of confidence of prospective NAAQS attainment.

From this perspective, in evaluating use of a 30-day average limit, EPA must weigh the likely net effect on air quality. Such an evaluation must consider the risk that occasions with meteorological conditions conducive to high concentrations will have elevated emissions leading to exceedances of the NAAQS level that would not otherwise have occurred, and must also weigh the likelihood that the requirement for lower emissions on average will result in days not having exceedances that would have been expected with emissions at the CEV. Additional policy considerations, such as in this case the desirability of accommodating real

[4] See also work done to supplement the work described in appendix B. This supplemental work, done to address a comment on rulemaking for the Southwest Indiana SO_2 nonattainment area objecting that the appendix B analysis is not comparable to an assessment of air quality with a 1-hour emission limit, provides further evidence that longer term limits that are appropriately determined can be expected to achieve comparable air quality as comparably stringent 1-hour limits. Documentation of this supplemental work is available in the docket for the Southwest Indiana rulemaking, at *https://www.regulations.gov/document?D=EPA-R05-OAR-2015-0700-0023,* as discussed in the associated rulemaking at 85 FR 49969–49971 (August 17, 2020).

world emissions variability without significant risk of NAAQS violations, are also appropriate factors for EPA to weigh in judging whether a plan provides a reasonable degree of confidence that the plan will lead to attainment. Based on these considerations, especially given the high likelihood that a continuously enforceable limit averaged over as long as 30 days, determined in accordance with EPA's guidance, will result in attainment, EPA believes as a general matter that such limits, if appropriately determined, can reasonably be considered to provide for attainment of the 2010 SO_2 NAAQS.

The 2014 SO_2 guidance offers specific recommendations for determining an appropriate longer term average limit. The recommended method starts with determination of the 1-hour emission limit that would provide for attainment (*i.e.,* the CEV), and applies an adjustment factor to determine the (lower) level of the longer term average emission limit that would be estimated to have a stringency comparable to the otherwise necessary 1-hour emission limit. This method uses a database of continuous emission data reflecting the type of control that the source will be using to comply with the SIP emission limits, which (if compliance requires new controls) may require use of an emission database from another source. The recommended method involves using these data to compute a complete set of emission averages, computed according to the averaging time and averaging procedures of the prospective emission limitation. In this recommended method, the ratio of the 99th percentile among these longer term averages to the 99th percentile of the 1-hour values represents an adjustment factor that may be multiplied by the candidate 1-hour emission limit to determine a longer term average emission limit that may be considered comparably stringent.[5] The guidance also addresses a variety of related topics, such as the potential utility of setting supplemental emission limits, such as mass-based limits, to reduce the likelihood and/or magnitude of elevated emission levels that might occur under the longer term emission rate limit.

EPA anticipates that most modeling used to develop longer term average emission limits and to prepare full attainment demonstrations will be performed using one of EPA's preferred air quality models. Preferred air quality models for use in regulatory applications are described in appendix A of EPA's *Guideline on Air Quality Models* (40 CFR part 51, appendix W).[6] In 2005, EPA promulgated AERMOD as the Agency's preferred near-field dispersion modeling for a wide range of regulatory applications addressing stationary sources (for example in estimating SO_2 concentrations) in all types of terrain based on extensive developmental and performance evaluation. Supplemental guidance on modeling for purposes of demonstrating attainment of the SO_2 standard is provided in appendix A to the 2014 SO_2 nonattainment area SIP guidance document referenced above. Appendix A provides extensive guidance on the modeling domain, the source inputs, assorted types of meteorological data, and background concentrations. Consistency with the recommendations in this guidance is generally necessary for the attainment demonstration to offer adequately reliable assurance that the plan provides for attainment.

As stated previously, attainment demonstrations for the 2010 1-hour primary SO_2 NAAQS must demonstrate future attainment and maintenance of the NAAQS in the entire area designated as nonattainment (*i.e.,* not just at the violating monitor) by using air quality dispersion modeling (*see* appendix W to 40 CFR part 51) to show that the mix of sources and enforceable control measures and emission rates in an identified area will not lead to a violation of the SO_2 NAAQS. For a short-term (*i.e.,* 1-hour) standard, EPA believes that dispersion modeling, using allowable emissions and addressing stationary sources in the affected area (and in some cases those sources located outside the nonattainment area which may affect attainment in the area) is technically appropriate, efficient and effective in demonstrating attainment in nonattainment areas because it takes into consideration combinations of meteorological and emission source operating conditions that may contribute to peak ground-level concentrations of SO_2.

The meteorological data used in the analysis should generally be processed with the most recent version of AERMET. Estimated concentrations should include ambient background concentrations, should follow the form of the standard, and should be calculated as described in section 2.6.1.2 of the August 23, 2010 clarification memo on ''Applicability of appendix W Modeling Guidance for the 1-hr SO_2 National Ambient Air Quality Standard'' (EPA, 2010).

IV. Review of Modeled Attainment Plan

As part of its SIP development process, Ohio used EPA's regulatory dispersion model, AERMOD, to help determine the SO_2 emission limit revisions that would be needed to bring the Muskingum River area into attainment of the 2010 SO_2 NAAQS. Ohio evaluated the two highest-emitting facilities in the Muskingum River area—the Muskingum River Power Plant and the Globe Metallurgical, Inc. facility (Globe). According to Ohio's submittal, 99 percent of the Muskingum River area's 2011 SO_2 emissions were attributable to the Muskingum River Power Plant, with the Globe facility accounting for 1,203 tons of SO_2, which comprised the remaining 1 percent that year. On May 31, 2015, all coal fired boilers at the Muskingum River Power Plant were permanently shut down. Subsequently, the ambient monitor which had been showing violations of the NAAQS no longer recorded violations. Nevertheless, for purposes of assuring attainment and maintenance of the NAAQS, Ohio determined that, in addition to the permanent retirement of the Muskingum River Power Plant, a reduction in allowable emissions at the remaining source, the Globe facility, was warranted. Ohio performed air quality modeling and analysis and issued Director's Final Findings and Orders (DFFOs) to the Globe facility establishing 24-hour average SO_2 emission limits at the facility. Ohio submitted the DFFOs to EPA as a supplement its original SIP submission. These DFFOs were issued on June 23, 2020, and have a compliance deadline of September 15, 2020.

The following paragraphs evaluate various features of the most recent modeling analysis that Ohio performed for its attainment demonstration, as supplemented by the DFFOs.

A. Model Selection and General Model Inputs

For the Muskingum River attainment demonstration, Ohio used the AERMOD model, version 19191. AERMOD is EPA's preferred model for this type of application and version 19191 is the current version. The AERMOD model was run using the regulatory default mode.

AERMOD requires land use to be characterized to determine how pollutants are dispersed in the atmosphere. The state used urban dispersion coefficients to represent the proposed heat island generated by the facility operations. Beyond the facility

[5] For example, if the CEV is 1,000 pounds of SO_2 per hour, and a suitable adjustment factor is determined to be 70 percent, the recommended longer term average limit would be 700 lb/hr.

[6] EPA published revisions to the *Guideline on Air Quality Models* on January 17, 2017.

industrial region, the area is best classified as rural.

EPA's Guideline on Air Quality Models (40 CFR part 51 appendix W) acknowledges that larger industrial facilities can impact turbulence and dispersion in the vicinity of the facility, similar to overnight impacts on turbulence in cities.

The Globe facility analysis used two approaches to examine and justify whether the heat released from the facility was significant enough to influence dispersion. They first used satellite thermal images to estimate the urban-rural temperature difference. Twelve images from the Advanced Spaceborne Thermal Emission and Reflection radiometer satellite system were identified, with 8 images without cloud interference, to estimate the difference in temperature between warm facility areas and cooler rural areas. The average difference between the industrial area temperatures and the rural temperatures was 8.7 degrees Celsius.

The second analysis used formulas from the AERMOD Formulation Document to relate heat flux to temperature differences between urban and rural areas. Another formula relates the temperature difference to population. The temperature difference using the Formulation Document equation results in a value of 8.5 degrees Celsius. This compares well with the 8.7 degree value determined from thermal satellite images. Ultimately the calculated heat release and temperature difference information can be used to calculate an estimated population. AERMOD uses a population value to represent the strength of the urban impact. The population used in the Globe analysis is 108,000, which reflects a relatively modest industrial heat island effect.

The state used a set of nested grids of receptors centered on the Globe facility. The analysis included a total of 5,049 receptors. Receptors were placed every 25 meters (m) along the ambient air boundary out to 350 m; 50 m out to 1 km; 100 m spacing out to 2 km, and 200 m spacing out to 5 km. The facility is in the process of purchasing property to the north. This property will be non-ambient air and does not have receptors in the current modeling. A fence runs around the entire Globe facility with adjacent property protected through surveillance and patrols. EPA finds that Ohio's submitted modeling results, based on modeling without receptors on fenced plant property and surveilled and patrolled property currently under purchase, are adequate to demonstrate that no such violations of the 1-hour SO_2 NAAQS are occurring.

Ohio used the AERMAP terrain preprocessor, version 18081, with USGS Digital Elevation Data to include terrain heights at the receptor locations. The Globe facility is in the Muskingum River valley. Terrain rises about 50–60 m within a kilometer to the east and north of the facility. Similar terrain increases also occur about 2–3 km in the westerly and southern directions. EPA finds the model selection and these modeling options appropriate.

B. Meteorological Data

Ohio used five years (2014–2018) of National Weather Service (NWS) meteorological data from the Parkersburg, West Virginia Airport (Station 03804) with upper air data from Pittsburgh, Pennsylvania (Station 94823). One-minute wind data was processed using AERMINUTE version 15272 with a 0.5 m/s minimum wind speed threshold option. Surface parameters of the Bowen ratios (a measure of surface moisture) were developed using monthly precipitation data compared to climatological averages. The Parkersburg NWS station is at the Regional Airport located about 10 km northeast of Parkersburg, and about 35 km southeast of the Globe facility. The station is up out of the Ohio River valley on the elevated terrain. The Pittsburgh upper air station is at the International Airport and is roughly 140 km from the Globe facility. The prevailing winds in southeast Ohio are from the south and west. The Parkersburg NWS wind roses illustrate a predominantly southwesterly flow. Both the surface and upper air station are considered reasonably representative of surface and upper air meteorological conditions, respectively, impacting the area around the Globe facility. EPA finds that the meteorological data and the procedure for determining surface characteristics are acceptable.

C. Modeled Emissions Data

The Globe facility consists of two electric arc furnace shops. The main sources of SO_2 emissions are two baghouses, which collect emissions at the two shops from the electric arc furnaces and ancillary equipment, respectively. Emissions from each baghouse exit through a roof monitor. The Globe facility modeled emissions from the roof monitors using point source release characteristics that allowed for capturing building downwash impacts while also preserving the total buoyancy of the emission releases. Neither of these features would have been represented had the sources been modeled as volume sources. Volume source characterization does not include plume buoyancy or building downwash impacts. The baghouse stack characterizations include a stack height equal to the height of the roof monitor. The exit velocities were calculated to match the actual flow rates from each baghouse roof monitor. Additionally, one of the baghouses (Baghouse 1) has a roof monitor that releases emissions horizontally rather than vertically. Consequently, the POINTHOR AERMOD option was used for this source to more accurately characterize its release.

Fugitive emissions released from the roof of the furnace shops were modeled using volume source parameters. A series of seven alternate volume sources were placed at the height of the roof monitor at furnace shop 1, and a series of 4 alternate volume sources were placed at the height of furnace shop 2. All were aligned evenly along monitor openings. Volume source model inputs were developed based on recommendations in the AERMOD User's Guide, Table 3–2.

Ohio modeled 26 different scenarios reflecting 26 different combinations of emissions from the two baghouses. Each of the 26 scenarios was specifically modeled for attainment of the 1-hr SO_2 NAAQS. Each of the 26 different scenarios also included an assumption that 2 percent of the total emissions were being released as fugitive emissions from the furnace shop. The 2 percent fugitive value was based on a capture efficiency analysis document prepared for the Globe facility and included in Ohio's submittal.

Ohio EPA's attainment demonstration only modeled emission units associated with the Globe facility. An examination of National Emissions Inventory data shows there are no other SO_2 sources of significance in the area near the Globe facility, specifically that no other sources within 25 km emit over 5 tons per year (tpy).

D. Emission Limits

An important prerequisite for approval of a nonattainment plan is that the emission limits that provide for attainment be quantifiable, fully enforceable, replicable, and accountable. *See* General Preamble at 13567–68. Ohio issued DFFOs to Globe on June 23, 2020, which set forth new emission limits for the facility on the basis of a matrix of CEVs for the two baghouses, where each combination was modeled to demonstrate attainment and maintenance of the standard. As part of this proposed approval of Ohio's

supplemented attainment plan for this area, EPA is proposing to approve Ohio's June 23, 2020 DFFOs for the Globe facility into the SIP, which include these new CEV combinations as emission limits. *See* Table 1.

TABLE 1

SO_2 emission limit sets	Calendar day (24-hour) emission limits	
	BH1 (lbs/hr)	BH2 (lbs/hr)
1	195.3	0.0
2	190.6	55.8
3	186.0	74.4
4	181.3	102.3
5	176.7	116.2
6	172.0	130.2
7	167.4	144.1
8	162.7	158.1
9	158.1	167.4
10	153.4	176.7
11	148.8	186.0
12	144.1	190.6
13	139.5	195.3
14	134.8	199.9
15	130.2	204.6
16	125.5	213.9
17	120.9	218.5
18	116.2	223.2
19	111.6	223.2
20	106.9	227.8
21	88.3	232.5
22	74.4	237.1
23	60.4	241.8
24	41.8	246.4
25	27.9	251.1
26	0.0	260.4

As described in the DFFOs, compliance with the emission limit sets is determined through mass balance calculations, as implemented through a compliance assurance plan (CAP). Compliance with the emission limits will also be determined through periodic compliance performance testing.

Ohio EPA stated in its June 2020 attainment plan supplement that it plans to adopt and submit a state rule that incorporates the emission limits for the Globe facility, and associated requirements, into its regulations (Ohio Administrative Code Chapter 3745–18). Ohio believes that its DFFOs provide enforceable limits and specification of the procedures that will be used to determine compliance with these limits such that the DFFOs provide sufficient enforceable requirements for EPA to rely on these DFFOs as enforceable measures that provide for attainment, if incorporated as permanent measures into the SIP. Any future submittal of rules to replace the DFFOs in the SIP will be addressed in separate future rulemaking, subject to the requirements of CAA section 110(l).

Because the limits set forth in the DFFOs are expressed as 24-hour average limits, part of the review of Ohio's nonattainment plan must address the use of these limits, both with respect to the general suitability of using such limits for this purpose and with respect to whether the particular limits included in the plan have been suitably demonstrated to provide for attainment. The first subsection that follows addresses the overall enforceability of the emission limits in Ohio's plan, and the second subsection that follows addresses the 24-hour average limits.

The DFFOs also require that validation testing be performed to verify the accuracy of the mass balance calculations. In addition, a Capture Evaluation conducted by a third party is required to be performed during the validation testing. This Capture Evaluation will include observations of emissions capture during the validation testing period, an evaluation of emissions capture performance, and, if appropriate, recommendations for measures to improve capture, as well as operational parameter(s) and ranges that could serve as an indicator of ongoing performance of the capture system.

1. Enforceability

Ohio's supplemented nonattainment plan for the Muskingum River area relies on the permanence of the Muskingum River Power Plant retirement and on revised emission limits for the Globe facility as discussed above (in section D. Emission Limits). As of April 2015, the entire Muskingum River Power Plant was shut down and all coal fired boilers were permanently retired. This facility is no longer authorized to operate its coal-fired boilers, and cannot reinstate them without obtaining a new permit under Ohio's New Source Review program. Therefore, the reductions in SO_2 emissions from the Muskingum River Power Plant retirement can be considered permanent, enforceable reductions.

Ohio's June 2020 DFFOs issued to Globe, in addition to establishing new emission limits, also provide specific measures and requirements that add stringency to the required emission control requirements. Specifically, the DFFOs require that Globe conduct validation testing and perform a Capture Evaluation at the facility's two baghouses to validate the mass balance calculation, and that Globe submit a CAP to be approved by Ohio EPA in consultation with EPA. The DFFOs require that the Capture Evaluation be performed by a third party in a manner designed to identify improvements and other measures, if any, that may aid in the capture of SO_2 emissions, and operational parameters that could serve as a reasonable indicator of ongoing performance of the capture systems. The CAP will include specific monitoring data and techniques used to perform the mass balance calculations, associated recordkeeping and reporting to demonstrate compliance with the emission limits, parameters to be monitored to ensure adequate performance of the capture system, and reporting from the Capture Evaluation.

To provide an additional level of assurance that air quality standards are being met in the area, Ohio's new DFFOs require Globe to install an ambient SO_2 monitor. This monitor will be located across the Muskingum River in the vicinity of the Globe facility near an expected area of maximum impact as approved by Ohio EPA.

2. Longer Term Average Limits

Ohio's SIP submittal includes emission limits for the Globe facility which require compliance based on 24-hour average emission rates. *See* Table 1. Ohio's primary method for determining compliance is a mass balance method, in which the emissions are assessed by determining the sulfur content of the raw materials, determining the sulfur content of the product and the process by-products, and assuming that the difference between these quantities of sulfur is all converted to SO_2 and emitted to the atmosphere. Ohio adopted a 24-hour limit to provide a more practical frequency of conducting this compliance determination.

In accordance with EPA's recommendations, Ohio adopted its limits at levels that were adjusted to account for the effect on stringency of adopting the limits on a 24-hour average basis. The Globe facility does not have the continuous emissions monitoring system (CEMS) data necessary to determine an appropriate site-specific adjustment factor. Therefore, Ohio applied a national average adjustment factor from appendix D of EPA's 2014 guidance. Specifically, Ohio applied an adjustment factor of 0.93, appropriate for establishment of 24-hour average SO_2 limits for sources without SO_2 emissions control equipment. Since EPA anticipates that the Globe facility will meet its limits through careful management of the sulfur content of its feed materials, EPA considers this selection of an adjustment factor to be acceptable.

Ohio calculated the Globe facility's emission limits in accordance with EPA's recommended method. *See*

section III. Ohio used dispersion modeling to determine 26 combinations of 1-hour CEVs for each unit that would provide for attainment of the NAAQS. Ohio then applied the above adjustment factor to determine, for each combination, the level of the longer term average emission limit for each unit that would be estimated to have a stringency comparable to the critical 1-hour emission values for each combination. EPA finds this acceptable.

E. Background Concentrations

The modeled attainment demonstration for a nonattainment area specifically includes the maximum allowable emissions and the individual dispersion characteristics of the most significant emission source in the area. To ensure that the demonstration also represents the cumulative impacts of additional sources which are individually too small or too distant to be expected to show a significant concentration gradient within the modeling domain, a background concentration is added to the modeled results. Data from a nearby air quality monitor can be used to determine a background value which approximates the diffuse impacts of these sources within the modeling domain. For the Globe emissions assessment, Ohio used background contributions on a season/hour-of-day basis using values from the Hackney monitor, located approximately 5.5 km to the north of the Globe facility. In order to avoid double counting of impacts from Globe, hourly values in a 90 degree sector representing winds from the south were removed from the monitoring data and replaced with the average of those hourly values prior to determining season/hour-of-day values. Values ranged from 6.32 micrograms per cubic meter ($\mu g/m^3$) to 13.09 $\mu g/m^3$. EPA finds the background values used in the Globe assessment to be acceptable.

F. Summary of Results

Ohio's attainment modeling analyses resulted in a predicted 1-hour design value of 196.0 $\mu g/m^3$, or 74.8 ppb, which is below the SO_2 NAAQS of 75 ppb/196.4 $\mu g/m^3$. This modeled value, which includes the background concentration, occurred at the northern boundary of the Globe facility, less than 200 meters from the emission units.

EPA policy also requires that one facility must not cause or contribute to exceedances of the NAAQS on another facility's property. Ohio's modeling only excludes receptors from the Globe facility. Consequently, EPA agrees that the modeling shows that no facility is causing or contributing to violations within another facility's property.

The emission releases from the Globe facility are difficult to characterize. Ohio considered various options for characterizing the release of fugitive emissions from the baghouses and the furnace shops before concluding that the characterizations described above were warranted. While no direct means of assessing the efficiency at capturing the emissions of the furnace are available, the requirements of the DFFOs, particularly the requirement to implement recommendations of the Capture Evaluation, help make the plan's estimate of 98 percent capture a reasonable estimate. Therefore, despite the uncertainties inherent in modeling this source, EPA finds that Ohio has submitted an appropriate analysis of the impact of this source. In addition, EPA finds that the ambient SO_2 monitoring that Globe and Ohio are undertaking will provide a further assessment of the reliability of this modeling and thereby will provide further assurance that air quality in this area is attaining the 1-hour SO_2 NAAQS.

Based on its review of Ohio's analysis, EPA finds that the emission limits for the Globe facility set forth in the DFFOs, in combination with other measures identified in the state's plan, will provide for attainment and maintenance of the 2010 SO_2 NAAQS, and proposes to approve the DFFOs into the SIP.

V. Review of Other Plan Requirements

A. Emissions Inventory

The emissions inventory and source emission rate data for an area serve as the foundation for air quality modeling and other analyses that enable states to: (1) Estimate the degree to which different sources within a nonattainment area contribute to violations within the affected area; and (2) assess the expected improvement in air quality within the nonattainment area due to the adoption and implementation of control measures. As noted above, the state must develop and submit to EPA a comprehensive, accurate and current inventory of actual emissions from all sources of SO_2 emissions in each nonattainment area, as well as any sources located outside the nonattainment area which may affect attainment in the area. *See* CAA section 172(c)(3).

Ohio prepared an emissions inventory[7] using 2011 as the base year and 2018, the SO_2 NAAQS attainment year, as the future year. The inventories were prepared for six categories: Electrical generating units (EGU), non-electrical generating units (non-EGU), non-road mobile sources, on-road mobile sources, area sources, and marine, air and rail sources. The 2011 base year inventory totaled 105,317.67 tpy for all six categories. Reflecting growth and known, planned, point source emission reductions, the 2018 future year inventory projection totaled 1,204.18 tpy. Emissions from the Globe facility were projected to remain constant between 2011 and 2018. The EGU category of this emissions inventory only contains the Muskingum River Power Plant's six emission sources (six coal-fired boilers). The 2018 inventory submitted by Ohio accounted for the closure of the Muskingum River Power Plant. As of April 2015, the Muskingum River Power Plant retired its coal-fired boilers, which resulted in projected 2018 EGU emissions of 0.0 tpy (104,113.16 tpy reduction from 2011), and thus would reduce Ohio's total six-category 2018 projected year inventory to 1,204.18 tpy. Ohio's emissions inventory indicates that SO_2 emissions were significantly and permanently reduced in the Muskingum River area of the SO_2 NAAQS attainment year.

B. RACM/RACT and Emissions Limitations and Control Measures

Section 172(c)(1) of the CAA requires states to adopt and submit all RACM, including RACT, as needed to attain the standards as expeditiously as practicable. Section 172(c)(6) requires the SIP to contain enforceable emission limitations and control measures necessary to provide for timely attainment of the standard. Ohio EPA's initial plan for attaining the 1-hour SO_2 NAAQS in the Muskingum River area was based only on emission reductions resulting from the Muskingum River Power Plant. Following discussions with EPA, Ohio determined that a combination of the permanent retirement of the Muskingum River Power Plant and additional emission limitations and emission reduction strategies implemented at the Globe facility will result in attainment of the NAAQS. Redevelopment of the Muskingum River Power Plant site would require new source review analysis and potentially additional emission controls to maintain SO_2

[7] The Emissions Modeling Clearinghouse (EMCH) provides emissions model input formatted inventories based on the latest versions of the NEI databases as well as the projection of these emissions. For Ohio's inventory, Ohio used 2011 and projected 2018 county level emissions data for area (non-point), on-road, marine/air/rail (MAR), and non-road sources from the 2011 NEI version 1-based Emissions Modeling Platform (2011v6) (*http://ftp.epa.gov/EmisInventory/2011v6/v1platform/*).

attainment in the Muskingum River area. Therefore, EPA concludes that the Muskingum River Power Plant's SO_2 emissions are currently zero and RACT requirements are satisfied at this source.

The initial Globe facility RACM evaluation and subsequent supplemental RACM evaluation[1] determined that RACM for control of SO_2 emissions from the electric arc furnaces (EAFs) at the Globe facility is pollution prevention through the use of low sulfur coal and low sulfur coke. In its evaluation of whether Ohio satisfied the requirement for RACM, in accordance with EPA guidance, EPA evaluated whether Ohio had provided for sufficient control to provide for attainment.

Ohio's plan includes new emission limits at the Globe facility and requires timely compliance with such limits and other control measures required by the June 23, 2020 DFFOs. Ohio has determined that these measures suffice to provide for timely attainment. EPA concurs and proposes to find that the state has satisfied the requirements in sections 172(c)(1) and 172(c)(6) to adopt and submit all RACM and enforceable limitations and control measures as are needed to attain the standards as expeditiously as practicable.

C. New Source Review (NSR)

Section 172 of the CAA requires the state to have an adequate new source review program. EPA approved Ohio's nonattainment new source review rules on January 22, 2003 (68 FR 2909). Ohio's new source review rules, codified at OAC 3745–31, provide for appropriate new source review for SO_2 sources undergoing construction or major modification in the Muskingum River area without need for modification of the approved rules. The latest revisions to OAC Chapter 3745–31 were approved into Ohio's SIP on February 20, 2013 (78 FR 11748). EPA concludes that this requirement has been met for this area.

D. RFP

Section 172 of the CAA requires Ohio's Muskingum River nonattainment SIP to provide for reasonable further progress toward attainment. For SO_2 SIPs, which address a small number of affected sources, requiring expeditious compliance with attainment emission limits can address the RFP requirement. EPA concludes that the state's revised limits and required additional control strategy measures for the Globe facility and the 2015 retirement of the Muskingum River Power Plant represent implementation of control measures as expeditiously as practicable. Accordingly, EPA proposes to find that Ohio's plan provides for RFP.

E. Contingency Measures

Section 172 of the CAA requires that nonattainment plans include additional measures which will take effect if an area fails to meet RFP or fails to attain the standard by the attainment date. As noted above, EPA guidance describes special features of SO_2 planning that influence the suitability of alternative means of addressing the requirement in section 172(c)(9) for contingency measures for SO_2. An appropriate means of satisfying this requirement is for the state to have a comprehensive enforcement program that identifies sources of violations of the SO_2 NAAQS and for the state to undertake aggressive follow-up for compliance and enforcement. Ohio's plan provides for satisfying the contingency measure requirement in this manner. EPA concurs and proposes to approve Ohio's plan for meeting the contingency measure requirement in this manner.

VI. EPA's Proposed Action

EPA is proposing to approve Ohio's SIP submission for attaining the 2010 1-hour SO_2 NAAQS and for meeting other nonattainment area planning requirements for the Muskingum River SO_2 nonattainment area. This SO_2 nonattainment plan includes Ohio's revised emission limits and attainment demonstration for the Muskingum River nonattainment area as submitted on June 23, 2020, and addresses the CAA requirements for reasonable further progress, RACM/RACT, base-year and projection-year emission inventories, and contingency measures. In conjunction with this proposed plan approval, EPA is also proposing to approve the DFFOs issued by Ohio to Globe on June 23, 2020, and submitted to EPA as a supplement to the original SIP submission.

EPA concludes that Ohio has appropriately demonstrated that the plan provisions provide for attainment of the 2010 1-hour primary SO_2 NAAQS in the Muskingum River nonattainment area and that the plan meets the other applicable requirements of section 172 of the CAA. EPA therefore is proposing to approve Ohio's nonattainment plan for the Muskingum River nonattainment area.

VII. Incorporation by Reference

In this rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference the Ohio Director's Final Findings and Orders for the Globe facility, issued on June 23, 2020. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov,* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VIII. Statutory and Executive Order Reviews

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

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

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

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

List of Subjects in 40 CFR Part 52

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

Dated: September 24, 2020.

Kurt Thiede,

Regional Administrator, Region 5.

[FR Doc. 2020–21560 Filed 9–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2010–0037; FRL–10014–72–Region 5]

Air Plan Approval; Minnesota; Revision to Taconite Federal Implementation Plan; Notice of Public Hearing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is announcing that a virtual public hearing will be held on the proposed action titled, ''Air Plan Approval; Minnesota; Revision to Taconite Federal Implementation Plan,'' which was published in the **Federal Register** on February 4, 2020. The hearing will be held on October 14, 2020.

DATES: Comments must be received on or before November 13, 2020. EPA will hold a virtual public hearing on October 14, 2020. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information on the public hearing and the submission of written comments.

ADDRESSES: You may submit comments, identified by Docket ID No. EPA–R05–OAR–2010–0037, at *http://www.regulations.gov* or via email to *aburano.douglas@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Virtual Public Hearing. The virtual public hearing will be held on October 14, 2020. The hearing will convene at 9:00 a.m. Central Daylight Time (CDT) and will conclude at 1:00 p.m. CDT, or 15 minutes after the last pre-registered presenter in attendance has presented if there are no additional presenters. EPA will announce further details on the virtual public hearing website at *https://www.epa.gov/mn/revision-taconite-federal-implementation-plan.* Refer to the **SUPPLEMENTARY INFORMATION** section below for additional information.

FOR FURTHER INFORMATION CONTACT: Abigail Teener, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, 312–353–7314, *Taconite-FIP-Revision@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

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

On February 6, 2013, EPA promulgated a Federal implementation plan (FIP) that included BART limits for certain taconite furnaces in Minnesota and Michigan (2013 Taconite FIP; 78 FR 8706). On February 4, 2020, EPA proposed to revise the 2013 Taconite FIP with respect to the nitrogen oxides (NO_X) best available retrofit technology (BART) emission limitations and compliance schedules for the United States Steel Corporation's (U.S. Steel's) Minntac taconite facility (''Minntac'' or ''Minntac facility'') located in Mt. Iron, Minnesota (85 FR 6125). Specifically, EPA proposed that an aggregate emission limit of 1.6 pounds NO_X per million British Thermal Units (lbs NO_X/MMBTU), based on a 30-day rolling average, averaged across Minntac's five production lines, represents NO_X BART for the Minntac facility. An explanation of the Clean Air Act (CAA) requirements, a detailed analysis of how these requirements apply to Minntac, and EPA's bases for proposing the revised limit and compliance schedule were provided in the notice of proposed rulemaking. The public comment period for this proposed rule ended on March 5, 2020.

One commenter stated that EPA did not provide information regarding a public hearing and did not ask the public if they were interested in a public hearing in accordance with CAA section 307(d)(5). The commenter also stated that EPA did not demonstrate that the agency consulted with Federal Land Managers (FLMs) regarding the proposed FIP revision.

To address these comments, EPA is holding a virtual public hearing and reopening the comment period consistent with CAA section 307(d)(5). Further, EPA has engaged with the FLMs on the proposed revision to the taconite FIP for Minntac. The FLMs have indicated that they have no comments on the proposed FIP revision.

Participation in virtual public hearing. In order to comply with current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders, for social distancing to limit the spread of COVID–19, EPA is holding a virtual public hearing to provide interested parties the opportunity to present data, views, or arguments concerning the proposal.

EPA will begin pre-registering presenters and attendees for the hearing upon publication of this document in the **Federal Register**. EPA will provide information on participating in the virtual public hearing at *https://www.epa.gov/mn/revision-taconite-federal-implementation-plan.* To pre-register to attend or present at the virtual public hearing, please use the online registration form available at

https://www.epa.gov/mn/revision-taconite-federal-implementation-plan or contact Abigail Teener at 312–353–7314 or by email at *Taconite-FIP-Revision@epa.gov.* The last day to pre-register to present at the hearing will be October 9, 2020. On October 13, 2020, EPA will post a general agenda for the hearing that will list pre-registered presenters in approximate order at: *https://www.epa.gov/mn/revision-taconite-federal-implementation-plan.* Additionally, requests to present will be taken on the day of the hearing as time allows.

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. Each commenter will have 5 minutes to provide oral testimony. EPA encourages commenters to provide EPA with a copy of their oral testimony electronically by including it in the registration form or emailing it to *Taconite-FIP-Revision@epa.gov.* 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 virtual public hearing.

EPA is asking all hearing attendees to pre-register, even those who do not intend to present. This will help EPA prepare for the virtual hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/mn/revision-taconite-federal-implementation-plan.* While EPA expects the hearing to go forward as set forth above, please monitor our website or contact Abigail Teener at 312–353–7314 to determine if there are any updates. 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/closed captioning, please pre-register for the hearing with Abigail Teener at 312–353–7314 or *Taconite-FIP-Revision@epa.gov* and describe your needs by October 6, 2020. EPA may not be able to arrange accommodations without advance notice.

How can I get copies of the proposed action and other related information?

EPA has established the official public docket for the proposed action under Docket ID No. EPA–R05–OAR–2010–0037. A copy of the proposed action is also available at *https://www.govinfo.gov/content/pkg/FR-2020-02-04/pdf/2020-01321.pdf,* and any detailed information related to the proposed action will be available in the public docket prior to the public hearing. Verbatim transcripts of the hearing and written statements will be included in the rulemaking docket.

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

Dated: September 14, 2020.

Kurt Thiede,

Regional Administrator, Region 5.

[FR Doc. 2020–20611 Filed 9–28–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 225, and 252

[Docket DARS–2020–0036]

RIN 0750–AL03

Defense Federal Acquisition Regulation Supplement: Source Restrictions on Auxiliary Ship Components (DFARS Case 2020–D017)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a statute that requires certain auxiliary ship components to be procured from a manufacturer in the national technology and industrial base.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before November 30, 2020, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2019–D017, using any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Search for ''DFARS Case 2020–D017'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select ''Comment Now'' and follow the instructions provided to submit a comment. Please include ''DFARS Case 2020–D017'' on any attached documents.
- *Email: osd.dfars@mail.mil.* Include DFARS Case 2020–D017 in the subject line of the message.
- *Mail:* Defense Acquisition Regulations System, Attn: Ms. Kimberly Bass, OUSD (A&S) DPC/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Bass, telephone 571–372–6174.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to amend the DFARS to implement section 853 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020. Section 853 amends 10 U.S.C. 2534, Miscellaneous limitations on the procurement of goods other than United States goods, to establish limitations on the procurement of large medium-speed diesel engines for contracts awarded for new construction of an auxiliary ship, unless the engines are manufactured in the national technology and industrial base, which includes the United States, Australia, Canada, and the United Kingdom.

II. Discussion and Analysis

This proposed rule addresses the restrictions related to auxiliary ship components in DFARS section 225.7010, which already restricts contracting officers from acquiring certain components of naval vessels, to the extent they are unique to marine applications, unless the components are from the national industrial base. Paragraph 225.7010–1(b) is added to include limitations on large medium-speed diesel engines for auxiliary ships for contracts awarded by the Secretary of a military department for new construction of an auxiliary ship using funds available for National Defense Sealift Fund programs or Shipbuilding and Conversion, Navy.

Language is added at DFARS 225.7010–2, Exceptions, to state that the newly added restriction at 225.7010–1(b) does not apply to contracts or subcontracts that do not exceed the simplified acquisition threshold or to large medium-speed diesel engines for icebreakers or special mission ships.

The waiver criteria at DFARS 225.7008 apply to the restrictions; therefore, a conforming change is made to DFARS 225.7010–3, Waiver, to add a pointer to the restrictions at 225.7010–1. An editorial change is also made to

DFARS 225.7010–4 to add cross-references to 225.7010–1(a).

A new clause, DFARS 252.225–70XX, Restriction on Acquisition of Large Medium-Speed Diesel Engines, is added. The clause applies to acquisitions greater than the simplified acquisition threshold and to contracts using FAR part 12 procedures for the acquisition of commercial items that require large medium-speed diesel engines for new construction of auxiliary ships using funds available for National Defense Sealift Fund programs or Shipbuilding and Conversion, Navy. The restriction does not apply to large medium-speed diesel engines for icebreakers or special mission ships. DFARS 212.301 is amended to reflect that the clause will apply to commercial item acquisitions.

DoD seeks public input and feedback on the content of the proposed rule and specifically in regard to a clarifying definition for ''large medium-speed diesel engines'' for auxiliary ships using funds available for National Defense Sealift Fund programs or Shipbuilding and Conversion, Navy. As noted in the statute, the term ''auxiliary ship'' does not include an icebreaker or a special mission ship.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule proposes to create a new DFARS clause, 252.225–70XX, Restriction on Acquisition of Large Medium-Speed Diesel Engines. DoD does not intend to apply the requirements of section 853 of the NDAA for FY 2020 to contracts at or below the simplified acquisition threshold (SAT). Section 853 amends 10 U.S.C. 2534(a) to provide a limitation on components for auxiliary ships. 10 U.S.C. 2534 does not apply to a contract or subcontract for an amount that does not exceed the SAT (see paragraph (g)). Therefore this clause will not apply to acquisitions at or below the SAT. However the rule proposes to apply the clause to contracts for the acquisition of commercial items, including commercially available off-the-shelf (COTS) items.

A. Applicability to Contracts for the Acquisition of Commercial Items, Including COTS Items

10 U.S.C. 2375 governs the applicability of laws to DoD contracts for the acquisition of commercial items, including COTS items, and is intended to limit the applicability of laws to contracts and subcontracts for the acquisition of commercial items, including COTS items. 10 U.S.C. 2375 provides that if a provision of law contains criminal or civil penalties, or if the Under Secretary of Defense for Acquisition and Sustainment (USD(A&S)) makes a written determination that it is not in the best interest of the Federal Government to exempt commercial item contracts, the provision of law will apply to contracts for the acquisition of commercial items unless—

- The provision of law—
  - Provides for criminal or civil penalties;
  - Requires that certain articles be bought from American sources pursuant to 10 U.S.C. 2533a or that strategic materials critical to national security be bought from American sources pursuant to 10 U.S.C. 2533b; or
  - Specifically refers to 10 U.S.C. 2375 and states that it shall apply to contracts and subcontracts for the acquisition of commercial items (including COTS items); or
- USD (A&S) determines in writing that it would not be in the best interest of the Government to exempt contracts or subcontracts for the acquisition of commercial items from the applicability of the provision.

This authority has been delegated to the Principal Director, Defense Pricing and Contracting (DPC).

B. Applicability

Section 853 of the NDAA for FY 2020 does not apply to contracts at or below the SAT and is silent on applicability to contracts and subcontracts for the acquisition of commercial items. Also, the statute does not provide for civil or criminal penalties. Therefore, it does not apply to contracts or subcontracts for the acquisition of commercial items unless the Principal Director, DPC, makes a written determination as provided in 10 U.S.C. 2375.

DoD intends to determine that it is in the best interest of the Federal Government to apply the rule to contracts and subcontracts for the acquisition of commercial items, including COTS items, as defined at FAR 2.101. Not applying this rule to contracts and subcontracts for the acquisition of commercial items, including COTS items, would exclude contracts intended to be covered by this rule and undermine the overarching purpose of the rule to restrict the purchase of large medium-speed diesel engines for auxiliary ships, unless the engines are manufactured in the national technology and industrial base, which includes the United States, Australia, Canada, and the United Kingdom.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This rule is not expected to be subject to E.O. 13771, because this rule is not significant under E.O. 12866.

VI. Regulatory Flexibility Act

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Nevertheless, an initial regulatory flexibility analysis has been performed and summarized as follows:

The rule amends the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a statute that requires certain auxiliary ship components to be procured from a manufacturer in the national technology and industrial base, which includes the United States, Australia, Canada, and the United Kingdom, subject to exceptions.

The objective and legal basis for the rule is to implement section 853 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020, which amends 10 U.S.C. 2534, Miscellaneous limitations on the procurement of goods other than United States goods. Section 853 establishes limitations on procurement of large medium-speed diesel engines for contracts awarded by the Secretary of a military department using funds available for National Defense Sealift Fund programs or Shipbuilding and Conversion, Navy for new construction of an auxiliary ship using funds available for National Defense Sealift Fund programs or Shipbuilding and Conversion, Navy, unless manufactured

in the United States, Australia, Canada, or the United Kingdom.

DoD reviewed Federal Procurement Data System (FPDS) data for fiscal years (FY) 2017, 2018, and 2019 (excluding contracts or subcontracts that do not exceed the simplified acquisition threshold or acquisitions of spare or repair parts needed to support naval vessels manufactured outside the United States; and large medium-speed diesel engines specifically for icebreakers or special mission ships). The FPDS data reflected that there were a total of 241 awards, of which 121 were made to small businesses, a median of 50 percent awarded to unique small entities over the last three fiscal years.

It is expected that this rule will benefit small businesses. The rule will provide small businesses the opportunity to participate in the manufacture of auxiliary ship components in support of the national technology and industrial base.

This rule does not include any new reporting, recordkeeping, or other compliance requirements for small businesses. The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known significant alternative approaches to the rule that would meet the requirements of the statute.

DoD invites comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2020–D017), in correspondence.

VII. Paperwork Reduction Act

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

List of Subjects in 48 CFR Parts 212, 225, and 252

Government procurement.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 225, and 252 is proposed to be amended as follows:

■ 1. The authority citation for 48 CFR parts 212, 225, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 12—ACQUISITION OF COMMERCIAL ITEMS

■ 2. Amend section 212.301 by adding paragraph (f)(ix)(GG) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

* * * * *

(f) * * *

(ix) * * *

(GG) Use the clause at 252.225–70XX, Restriction on Acquisition of Large Medium-Speed Diesel Engines, as prescribed in 225.7010–5, to comply with 10 U.S.C. 2534(a)(6).

PART 225—FOREIGN ACQUISITION

■ 3. Revise the section 225.7010 heading to read as follows:

225.7010 Restrictions on certain naval vessel and auxiliary ship components.

■ 4. Revise section 25.7010–1 to read as follows:

225.7010–1 Restrictions.

In accordance with 10 U.S.C. 2534, unless manufactured in the United States, Australia, Canada, or the United Kingdom, do not acquire—

(a) The following components of naval vessels, to the extent they are unique to marine applications:

(1) Gyrocompasses.

(2) Electronic navigation chart systems.

(3) Steering controls.

(4) Pumps.

(5) Propulsion and machinery control systems.

(6) Totally enclosed lifeboats.

(b) Large medium-speed diesel engines for auxiliary ships using funds available for National Defense Sealift Fund programs or Shipbuilding and Conversion, Navy.

■ 5. Revise section 225.7010–2 to read as follows:

225.7010–2 Exceptions.

(a) The restriction at 225.7010–1(a) does not apply to—

(1) Contracts or subcontracts that do not exceed the simplified acquisition threshold; or

(2) Acquisition of spare or repair parts needed to support components for naval vessels manufactured outside the United States. Support includes the purchase of spare gyrocompasses, electronic navigation chart systems, steering controls, pumps, propulsion and machinery control systems, or totally enclosed lifeboats, when those from alternate sources are not interchangeable.

(b) The restriction at 225.7010–1(b) does not apply to—

(1) Contracts or subcontracts that do not exceed the simplified acquisition threshold; or

(2) Large medium-speed diesel engines for icebreakers or special mission ships.

■ 6. Revise 225.7010–3 to read as follows:

225.7010–3 Waiver.

The waiver criteria at 225.7008 apply to the restrictions at 225.7010–1.

■ 7. Amend section 225.7010–4 by—

■ a. Revising the section heading; and

■ b. In paragraphs (a) and (b), removing ''this restriction'' and adding ''the restriction at 225–7010–1(a)'' in both places.

The revision reads as follows:

225.7010–4 Implementation of restriction on certain naval vessel components.

* * * * *

■ 8. Add section 225.7010–5 to read as follows:

225.7010–5 Contract clause.

Use the clause at 252.225–70XX, Restriction on Acquisition of Large Medium-Speed Diesel Engines, in solicitations and contracts that exceed the simplified acquisition threshold, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items, that require large medium-speed diesel engines for new construction of auxiliary ships using funds available for National Defense Sealift Fund programs or Shipbuilding and Conversion, Navy unless—

(a) An exception at 225.7010–2(b)(2) applies; or

(b) A waiver has been granted.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 9. Add section 252.225–7038 to read as follows:

252.225–7038 Restriction on Acquisition of Large Medium-Speed Diesel Engines.

As prescribed in 225.7010–5, use the following clause:

Restriction on Acquisition of Large Medium-Speed Diesel Engines (Date)

Unless otherwise specified in its offer, the Contractor shall deliver under this contract large medium-speed diesel engines manufactured in the United States, Australia, Canada, or the United Kingdom.

(End of clause)

[FR Doc. 2020–21251 Filed 9–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

RIN 0648–XG809

Notification of Receipt of a Supplemental Petition To Ban Imports of All Fish and Fish Products From New Zealand That Do Not Satisfy the Marine Mammal Protection Act

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

ACTION: Receipt of supplemental petition to ban imports through emergency rulemaking; request for comments.

SUMMARY: NMFS announces receipt of a supplemental petition for emergency rulemaking under the Administrative Procedure Act. Sea Shepherd Legal, Sea Shepherd New Zealand Ltd., and Sea Shepherd Conservation Society petitioned the U.S. Department of Commerce and other relevant Departments to initiate emergency rulemaking under the Marine Mammal Protection Act (MMPA), to ban importation of commercial fish or products from fish that have been caught with commercial fishing technology that results in incidental mortality or serious injury of Māui dolphin in excess of United States standards.

DATES: Written comments must be received by 5 p.m. Eastern Time on October 9, 2020.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2019–0013, by the following method:

1. *Electronic Submissions:* Submit all electronic comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2019-0013,* click the ''Comment Now!'' icon, complete the required fields and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *http://www.regulations.gov without change.* All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Anyone who is unable to comment through *http://www.regulations.gov* may contact the **FOR FURTHER INFORMATION CONTACT** below to discuss potential alternatives for submitting comments.

Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe portable document file (PDF) formats only. The complete text of the petition is available via the internet at the following web address: *http://www.nmfs.noaa.gov/ia/.* In addition, copies of this petition may be obtained by contacting NMFS at the above address.

FOR FURTHER INFORMATION CONTACT: Nina Young, NMFS F/IASI at *Nina.Young@noaa.gov* or 301–427–8383.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(2) of the Marine Mammal Protection Act (MMPA), 16 U.S.C. 1371(a)(2), states that the Secretary of the Treasury shall ban the importation of commercial fish or products from fish which have been caught with commercial fishing technology, which results in the incidental kill or incidental serious injury of ocean mammals in excess of United States standards. In August 2016, NMFS published a final rule (81 FR 54390; August 15, 2016) implementing the fish and fish product import provisions in section 101(a)(2) of the MMPA. This rule established conditions for evaluating a harvesting nation's regulatory programs to address incidental and intentional mortality and serious injury of marine mammals in fisheries operated by nations that export fish and fish products to the United States. In that rule's preamble, NMFS stated that it may consider emergency rulemaking to ban imports of fish and fish products from an export or exempt fishery having or likely to have an immediate and significant adverse impact on a marine mammal stock.

Information on the Petition

On February 6, 2019, NMFS received a petition from Sea Shepherd Legal, Sea Shepherd New Zealand Ltd, and Sea Shepherd Conservation Society to the Department of Homeland Security, the Department of the Treasury, and the Department of Commerce to carry out non-discretionary duties under section 101(a)(2) of the MMPA (16 U.S.C. 1371(a)(2)), to ban the importation of commercial fish or products from fish sourced in a manner that results in the incidental kill or incidental serious injury of Māui dolphins in excess of United States standards. The petition requested that the relevant Secretary immediately ban all fish and fish products originating from fisheries in the Māui dolphin's range that employ either gillnets or trawls, unless affirmatively identified as having been caught with a gear type other than set nets or trawls or affirmatively identified as caught outside the Māui dolphin's range.

NMFS reviewed the petition, supporting documents, New Zealand's previous risk assessments and Threat Management Plans (TMP). On June 18, 2019, NMFS denied the petition, stating that: (1) New Zealand is implementing a regulatory program comparable in effectiveness to the United States; (2) New Zealand has in place an existing regulatory program to reduce Māui dolphin bycatch; and (3) New Zealand was in the process of proposing additional regulatory measures that would further reduce the risk to Māui dolphins. (See 84 FR 32853, July 10, 2019.)

Petitioners filed a lawsuit against the relevant Departments in the United States Court of International Trade (CIT) on May 21, 2020. On August 13, 2020, the CIT remanded Sea Shepherd's February 2019 petition at NMFS' request, because New Zealand had announced its final regulatory program. NMFS proposed, and the court agreed, that the petitioners should have the opportunity to supplement their petition.

On August 27, 2020, NMFS received the supplemental petition, which both maintains the grounds for action outlined in the original petition and includes facts that arose after submission of the original petition. The supplemental petition directs attention to the following new information: (1) The receipt of data from the New Zealand government noting sightings of Māui dolphins on the east coast of the North Island; (2) the issuance of the 2019 Draft TMP; (3) the final TMP announced on June 24, 2020; and (4) the 2020 draft List of Foreign Fisheries.

NMFS will consider public comments received in its evaluation of the supplemental information received from the petitioners.

Dated: September 24, 2020.

Paul N. Doremus,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 2020–21526 Filed 9–28–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 200911–0242]

RIN 0648–XT038

Atlantic Highly Migratory Species; 2021 Atlantic Shark Commercial Fishing Year

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

ACTION: Proposed rule; request for comments.

SUMMARY: This proposed rule would adjust quotas and retention limits and establish the opening date for the 2021 fishing year for the Atlantic commercial shark fisheries. Quotas would be adjusted as required or allowable based on any overharvests and/or underharvests experienced during the 2020 fishing year. NMFS proposes the opening date and commercial retention limits to provide, to the extent practicable, fishing opportunities for commercial shark fishermen in all regions and areas. The proposed measures could affect fishing opportunities for commercial shark fishermen in the northwestern Atlantic Ocean, the Gulf of Mexico, and the Caribbean Sea.

DATES: Written comments must be received by October 29, 2020.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2020–0108, by electronic submission. Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0108,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of this proposed rule and supporting documents are available from the HMS Management Division website at *https://www.fisheries.noaa.gov/topic/atlantic-highly-migratory-species* or by contacting Lauren Latchford (*lauren.latchford@noaa.gov*) by phone at 301–427–8503.

FOR FURTHER INFORMATION CONTACT: Lauren Latchford (*lauren.latchford@noaa.gov*), Guy Eroh (*guy.eroh@noaa.gov*), or Karyl Brewster-Geisz (*karyl.brewster-geisz@noaa.gov*) at 301–427–8503.

SUPPLEMENTARY INFORMATION:

Background

The Atlantic commercial shark fisheries are managed under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The 2006 Consolidated Atlantic Highly Migratory Species (HMS) Fishery Management Plan (FMP) and its amendments are implemented by regulations at 50 CFR part 635. For the Atlantic commercial shark fisheries, the 2006 Consolidated Atlantic HMS FMP and its amendments established default commercial shark retention limits, commercial quotas for species and management groups, and accounting measures for underharvests and overharvests. Regulations also include provisions allowing flexible opening dates for the fishing year and inseason adjustments to shark trip limits, which provide management flexibility in furtherance of equitable fishing opportunities, to the extent practicable, for commercial shark fishermen in all regions and areas.

2021 Proposed Commercial Shark Quotas

NMFS proposes adjusting the quota levels for the different shark stocks and management groups for the 2021 Atlantic commercial shark fishing year based on overharvests and underharvests that occurred during the 2020 fishing year, consistent with existing regulations at 50 CFR 635.27(b). Overharvests and underharvests are accounted for in the same region, sub-region, and/or fishery in which they occurred the following year, except that large overharvests may be spread over a number of subsequent fishing years up to a maximum of five years. If a sub-regional quota is overharvested, but the overall regional quota is not, no subsequent adjustment is required. Unharvested quota may be added to the quota for the next fishing year, but only if NMFS knows the status of all species in the management group, none of the species in the group are overfished, and there is no overfishing in the group. No more than 50 percent of a base annual quota may be carried over from a previous fishing year.

Based on 2020 harvests to date, and after considering catch rates and landings from previous years, NMFS proposes to adjust the 2021 quotas for certain management groups as shown in Table 1. All of the 2021 proposed quotas for the respective stocks and management groups will be subject to further adjustment in the final rule after NMFS considers the dealer reports through mid-October. NMFS anticipates that dealer reports received after that time will be used to adjust 2021 quotas, as appropriate, noting that in some circumstances, NMFS re-adjusts quotas in the subject year.

Because the Gulf of Mexico blacktip shark management group and smoothhound shark management groups in the Gulf of Mexico and Atlantic regions are not overfished, and overfishing is not occurring, available underharvest (up to 50 percent of the base annual quota) from the 2020 fishing year for these management groups may be added to the respective 2021 base quotas. NMFS proposes to account for any underharvest of Gulf of Mexico blacktip sharks by dividing underharvest between the eastern and western Gulf of Mexico sub-regional quotas based on the sub-regional quota split percentage implemented in Amendment 6 to the 2006 Consolidated Atlantic HMS FMP (80 FR 50073; August 18, 2015).

For the sandbar shark, aggregated large coastal shark (LCS), hammerhead shark, non-blacknose small coastal shark (SCS), blacknose shark, blue shark, porbeagle shark, and pelagic shark (other than porbeagle or blue sharks) management groups, the 2020 underharvests cannot be carried over to the 2021 fishing year because those stocks or management groups are overfished, are experiencing overfishing, or have an unknown status. With the exception of the sub-regional western Gulf of Mexico overharvest of the aggregated LCS quota, which will be discussed below, there are no overharvests to account for in these management groups to date. Thus, NMFS proposes that quotas for these

management groups be equal to the annual base quota without adjustment, although the ultimate decision will be based on current data at the time of the final rule.

The proposed 2021 quotas by species and management group are summarized in Table 1; the description of the calculations for each stock and management group can be found below. All quotas and landings are dressed weight (dw), in metric tons (mt), unless specified otherwise. Table 1 includes landings data as of July 10, 2020; final quotas are subject to change based on landings as of October 2020. 1 mt = 2,204.6 lb.

TABLE 1—2021 PROPOSED QUOTAS AND OPENING DATE FOR THE ATLANTIC SHARK MANAGEMENT GROUPS

Region or sub-region	Management group	2020 Annual quota (A)	Preliminary 2020 landings [1] (B)	Adjustments [2] (C)	2021 Base annual quota (D)	2021 Proposed annual quota (D + C)	Season opening dates
Western Gulf of Mexico	Blacktip Sharks [3]	347.2 mt dw (765,392 lb dw).	204.4 mt dw (450,612 lb dw).	115.7 mt dw (255,131 lb dw).	231.5 mt dw (510,261 lb dw).	347.2 mt dw (765,392 lb dw).	January 1, 2021.
	Aggregated [4] Large Coastal Sharks.	72.0 mt dw (158,724 lb dw).	78.9 mt dw (173,959 lb dw).	.....	72.0 mt dw (158,724 lb dw).	72.0 mt dw (158,724 lb dw).	
	Hammerhead Sharks	11.9 mt dw (26,301 lb dw).	<2.3 mt dw (<5,000 lb dw).	.....	11.9 mt dw (26,301 lb dw).	11.9 mt dw (26,301 lb dw).	
Eastern Gulf of Mexico	Blacktip Sharks [3]	37.7 mt dw (83,158 lb dw).	3.5 mt dw (7,726 lb dw).	12.6 mt dw (27,719 lb dw).	25.1 mt dw (55,439 lb dw).	37.7 mt dw (83,158 lb dw).	January 1, 2021.
	Aggregated Large Coastal Sharks.	85.5 mt dw (188,593 lb dw).	50.9 mt dw (112,266 lb dw).	.....	85.5 mt dw (188,593 lb dw).	85.5 mt dw (188,593 lb dw).	
	Hammerhead Sharks	13.4 mt dw (29,421 lb dw).	<2.7 mt dw (<6,000 lb dw).	.....	13.4 mt dw (29,421 lb dw).	13.4 mt dw (29,421 lb dw)).	
Gulf of Mexico	Non-Blacknose Small Coastal Sharks.	112.6 mt dw (248,215 lb dw).	25.2 mt dw (55,563 lb dw).	.....	112.6 mt dw (248,215 lb dw).	112.6 mt dw (248,215 lb dw).	
	Smoothhound Sharks	504.6 mt dw (1,112,441 lb dw).	1.4 mt dw (3,144 lb dw).	168.2 mt dw (370,814 lb dw).	336.4 mt dw (741,627 lb dw).	504.6 mt dw (1,112,441 lb dw).	
Atlantic	Aggregated Large Coastal Sharks.	168.9 mt dw (372,552 lb dw).	36.8 mt dw (81,217 lb dw).	.....	168.9 mt dw (372,552 lb dw).	168.9 mt dw (372,552 lb dw).	January 1, 2021
	Hammerhead Sharks	27.1 mt dw (59,736 lb dw).	10.6 mt dw (23,340 lb dw).	.....	27.1 mt dw (59,736 lb dw).	27.1 mt dw (59,736 lb dw).	
	Non-Blacknose Small Coastal Sharks.	264.1 mt dw (582,333 lb dw).	44.0 mt dw (96,939 lb dw).	.....	264.1 mt dw (582,333 lb dw).	264.1 mt dw (582,333 lb dw).	
	Blacknose Sharks (South of 34° N lat. only).	17.2 mt dw (37,921 lb dw).	2.6 mt dw (5,753 lb dw).	.....	17.2 mt dw (37,921 lb dw).	17.2 mt dw (37,921 lb dw).	
	Smoothhound Sharks	1,802.6 mt dw (3,971,587 lb dw).	121.1 mt dw (266,965 lb dw).	600.9 mt dw (1,323,862 lb dw).	1,201.7 mt dw (2,649,268 lb dw).	1,802.6 mt dw (3,971,587 lb dw).	
No regional quotas	Non-Sandbar LCS Research.	50.0 mt dw (110,230 lb dw).	<2.5 mt dw (<5,500 lb dw).	.....	50.0 mt dw (110,230 lb dw).	50.0 mt dw (110,230 lb dw).	January 1, 2021.
	Sandbar Shark Research.	90.7 mt dw (199,943 lb dw).	<4.5 mt dw (<10,000 lb dw).	.....	90.7 mt dw (199,943 lb dw).	90.7 mt dw (199,943 lb dw).	
	Blue Sharks	273.0 mt dw (601,856 lb dw).	0 mt dw (0 lb dw)	.....	273.0 mt dw (601,856 lb dw).	273.0 mt dw (601,856 lb dw).	
	Porbeagle Sharks	1.7 mt dw (3,748 lb dw).	0 mt dw (0 lb dw)	.....	1.7 mt dw (3,748 lb dw).	1.7 mt dw (3,748 lb dw).	
	Pelagic Sharks Other Than Porbeagle or Blue.	488.0 mt dw (1,075,856 lb dw).	28.8 mt dw (63,485 lb dw).	.....	488.0 mt dw (1,075,856 lb dw).	488.0 mt dw (1,075,856 lb dw).	

[1] Landings are from January 1, 2020, through July 10, 2020, and are subject to change.
[2] Underharvest adjustments can only be applied to stocks or management groups that are not overfished and have no overfishing occurring. Also, the underharvest adjustments cannot exceed 50 percent of the base annual quota.
[3] This adjustment accounts for underharvest in 2020. This proposed rule would increase the overall Gulf of Mexico blacktip shark quota by 128.3 mt dw (282,850 lb dw). Since any underharvest would be divided based on the sub-regional quota percentage split, the western Gulf of Mexico blacktip shark quota would be increased by 115.7 mt dw, or 90.2 percent of the quota adjustment, while the eastern Gulf of Mexico blacktip shark quota would be increased by 12.6 mt dw, or 9.8 percent of the quota adjustment.
[4] While there is an overharvest of the western Gulf of Mexico Aggregated LCS sub-regional quota in 2020, NMFS does not expect the full Gulf of Mexico regional quota to be filled, and is thus proposing to maintain the full baseline quota in 2021. However, if the Gulf of Mexico regional quota is filled or exceeded, the sub-regional quota would be adjusted accordingly.

1. Proposed 2021 Quotas for the Gulf of Mexico Region Shark Management Groups

The 2021 proposed commercial quota for blacktip sharks in the western Gulf of Mexico sub-region is 347.2 mt dw (765,392 lb dw) and the eastern Gulf of Mexico sub-region is 37.7 mt dw (83,158 lb dw; Table 1). As of July 10, 2020, preliminary reported landings for blacktip sharks in the western Gulf of Mexico sub-region were at 59 percent (204.4 mt dw) of their 2020 quota levels (347.2 mt dw), and blacktip sharks in the eastern Gulf of Mexico sub-region were at 9 percent (3.5 mt dw) of the sub-regional 2020 quota levels (37.7 mt dw). Reported landings in both sub-regions have not exceeded the 2020 quota to date. Gulf of Mexico blacktip sharks are not overfished, are not experiencing overfishing, and do not have an unknown status. Pursuant to § 635.27(b)(2)(ii), underharvests for blacktip sharks within the Gulf of Mexico region therefore may be applied to the 2020 quotas, up to 50 percent of the base annual quota. Additionally, any underharvest would be divided between the two sub-regions, based on the percentages that are allocated to each sub-region, which are set forth in § 635.27(b)(1)(ii)(C). To date, the overall Gulf of Mexico blacktip shark management group is underharvested by 177.0 mt dw (390,212 lb dw). Accordingly, NMFS proposes to increase the western Gulf of Mexico blacktip shark quota by 115.7 mt dw or 90.2 percent of the quota adjustment, while the eastern Gulf of Mexico blacktip shark sub-regional quota would increase by 12.6 mt dw, or 9.8 percent of the quota adjustment (Table 1). Thus, the proposed western sub-regional Gulf of Mexico blacktip shark commercial quota is 347.2 mt dw (765,392 lb dw), and the proposed eastern sub-regional Gulf of Mexico blacktip shark commercial quota is 37.7 mt dw (83,158 lb dw).

The 2021 proposed commercial quota for aggregated LCS in the western Gulf of Mexico sub-region is 72.0 mt dw (158,724 lb dw), and the eastern Gulf of Mexico sub-region is 85.5 mt dw (188,593 lb dw; Table 1). As of July 10, 2020, preliminary reported landings for aggregated LCS in the western Gulf of Mexico sub-region were at 110 percent (78.9 mt dw) of the 2020 quota (72.0 mt dw), while the aggregated LCS in the eastern Gulf of Mexico sub-region were at 60 percent (50.9 mt dw) of the 2020 quota levels (85.5 mt dw). While the aggregated LCS management group

landings have been exceeded in the western Gulf of Mexico sub-region, the current combined catch rates for both sub-regions (82 percent; 129.8 mt dw) indicate that the overall regional 2020 quota is not likely to be exceeded before the end of the fishing year. NMFS will continue to monitor these landings for the remainder of the 2020 fishing year. If the combined aggregated LCS quotas are exceeded, then the 2020 quota would be adjusted to account for any overharvest.

The 2021 proposed commercial quotas for hammerhead sharks in the eastern Gulf of Mexico sub-region and western Gulf of Mexico sub-region are 11.9 mt dw (26,301 lb dw) and 13.4 mt dw (29,421 lb dw), respectively (Table 1). As of July 10, 2020, preliminary reported landings for hammerhead sharks in the western Gulf of Mexico sub-region were less than 20 percent (<2.3 mt dw) of the 2020 quota levels (11.9 mt dw), while landings of hammerhead sharks in the eastern Gulf of Mexico sub-region were at less than 20 percent (<2.7 mt dw) of the 2020 quota levels (13.4 mt dw). Reported landings from both Gulf of Mexico and Atlantic regions have not exceeded the 2020 overall hammerhead quota to date. Given the overfished status of the scalloped hammerhead shark, the hammerhead shark quota cannot be adjusted for any underharvests. Therefore, based on both preliminary estimates and catch rates from previous years and the fact that the 2020 overall hammerhead shark quota has not been overharvested to date, and consistent with the current regulations at § 635.27(b)(2)(ii), NMFS proposes that the 2021 quotas for hammerhead sharks in the western Gulf of Mexico and eastern Gulf of Mexico sub-regions be equal to their annual base quotas without adjustment.

The 2021 proposed commercial quota for non-blacknose SCS in the Gulf of Mexico region is 112.6 mt dw (248,215 lb dw). As of July 10, 2020, preliminary reported landings of non-blacknose SCS were at 22 percent (25.2 mt dw) of their 2020 quota level (112.6 mt dw) in the Gulf of Mexico region. Reported landings have not exceeded the 2020 quota to date. Given the unknown status of bonnethead sharks within the Gulf of Mexico non-blacknose SCS management group, underharvests cannot be carried forward, pursuant to § 635.27(b)(2)(ii). Based on both preliminary estimates and catch rates from previous years, and because there have not been any overharvests, NMFS proposes that the 2021 quota for non-blacknose SCS in the Gulf of Mexico region be equal to the annual base quota without adjustment.

The 2021 proposed commercial quota for smoothhound sharks in the Gulf of Mexico region is 504.6 mt dw (1,112,441 lb dw). As of July 10, 2020, preliminary reported landings of smoothhound sharks were less than 1 percent (1.4 mt dw) in the Gulf of Mexico region. Gulf of Mexico smoothhound sharks are not overfished, are not experiencing overfishing, and do not have an unknown status. Pursuant to § 635.27(b)(2)(ii), underharvests for smoothhound sharks within the Gulf of Mexico region therefore could be added to the 2021 quotas up to 50 percent of the base annual quota. Accordingly, NMFS proposes to increase the 2021 Gulf of Mexico smoothhound shark quota to adjust for anticipated underharvests in 2020 to the full extent allowed. The proposed 2021 adjusted base annual quota for Gulf of Mexico smoothhound sharks is 504.6 mt dw (336.4 mt dw annual base quota + 168.2 mt dw 2020 underharvest = 504.6 mt dw 2021 adjusted annual quota).

2. Proposed 2021 Quotas for the Atlantic Region Shark Management Groups

The 2021 proposed commercial quota for aggregated LCS in the Atlantic region is 168.9 mt dw (372,552 lb dw). As of July 10, 2020, the aggregated LCS fishery in the Atlantic region is still open, and preliminary landings indicate that only 22 percent (36.8 mt dw) of the quota has been harvested. Given the unknown status of some of the shark species within the Atlantic aggregated LCS management group, underharvests cannot be carried over pursuant to § 635.27(b)(2)(ii). Therefore, based on both preliminary estimates and catch rates from previous years, and consistent with current regulations at § 635.27(b)(2), NMFS proposes that the 2021 quota for aggregated LCS in the Atlantic region be equal to the annual base quota without adjustment, because there have not been any overharvests, and underharvests cannot be carried over due to stock status.

The 2021 proposed commercial quota for hammerhead sharks in the Atlantic region is 27.1 mt dw (59,736 lb dw). Currently, the hammerhead shark fishery in the Atlantic region is still open and preliminary landings as of July 10, 2020, indicate that 39 percent (10.6 mt dw) of the Atlantic regional quota has been harvested. Reported landings from both Gulf of Mexico and Atlantic regions have not exceeded the 2020 overall hammerhead quota to date. Given the overfished status of hammerhead sharks, underharvests cannot be carried forward pursuant to § 635.27(b)(2)(ii). Therefore, based on both preliminary estimates and catch rates from previous years, and consistent with the current regulations at § 635.27(b)(2), NMFS proposes that the 2021 quota for hammerhead sharks in the Atlantic region be equal to the annual base quota without adjustment.

The 2021 proposed commercial quota for non-blacknose SCS in the Atlantic region is 264.1 mt dw (582,333 lb dw). As of July 10, 2020, preliminary reported landings of non-blacknose SCS were at 17 percent (44.0 mt dw) of the 2020 quota level in the Atlantic region. Reported landings have not exceeded the 2020 quota to date. Given the unknown status of bonnethead sharks within the Atlantic non-blacknose SCS management group, underharvests cannot be carried forward pursuant to § 635.27(b)(2)(ii). Therefore, based on preliminary estimates of catch rates from previous years, and consistent with the current regulations at § 635.27(b)(2), NMFS proposes that the 2021 quota for non-blacknose SCS in the Atlantic region be equal to the annual base quota without adjustment.

The 2021 proposed commercial quota for blacknose sharks in the Atlantic region is 17.2 mt dw (37,921 lb dw). This quota is available in the Atlantic region only for those vessels operating south of 34° N latitude. North of 34° N latitude, retention, landing, or sale of blacknose sharks is prohibited. NMFS is not proposing any adjustments to the blacknose shark quota at this time. As of July 10, 2020, preliminary reported landings of blacknose sharks were at 15 percent (2.6 mt dw) of the 2020 quota levels in the Atlantic region. Reported landings have not exceeded the 2020 quota to date. Pursuant to § 635.27(b)(2), because blacknose sharks have been declared to be overfished with overfishing occurring in the Atlantic region, NMFS could not carry forward the remaining underharvest. Therefore, NMFS proposes that the 2021 Atlantic blacknose shark quota be equal to the annual base quota without adjustment.

The 2021 proposed commercial quota for smoothhound sharks in the Atlantic region is 1,802.6 mt dw (3,973,902 lb dw). As of July 10, 2020, preliminary reported landings of smoothhound sharks were at 6.7 percent (121.1 mt dw) of their 2020 quota levels in the Atlantic region. Atlantic smoothhound sharks have not been declared to be overfished, to have overfishing occurring, or to have an unknown status. Pursuant to § 635.27(b)(2)(ii), underharvests for smoothhound sharks within the Atlantic region therefore could be applied to the 2021 quotas up to 50 percent of the base annual quota. Accordingly, NMFS proposes to increase the 2021 Atlantic smoothhound shark quota to adjust for

anticipated underharvests in 2020 as allowed. The proposed 2021 adjusted base annual quota for Atlantic smoothhound sharks is 1,802.6 mt dw (1,201.7 mt dw annual base quota + 600.9 mt dw 2019 underharvest = 1,802.6 mt dw 2021 adjusted annual quota).

3. Proposed 2021 Quotas for Shark Management Groups With No Regional Quotas

The 2021 proposed commercial quotas within the shark research fishery are 50 mt dw (110,230 lb dw) for research LCS and 90.7 mt dw (199,943 lb dw) for sandbar sharks. Within the shark research fishery, as of July 10, 2020, preliminary reported landings of research LCS were at less than 5 percent (<2.5 mt dw) of the 2020 quota, and sandbar shark reported landings were at less than 5 percent (<4.5 mt dw) of their 2020 quota. Under § 635.27(b)(2)(ii), because sandbar sharks and scalloped hammerhead sharks within the research LCS management group are either overfished or overfishing is occurring, underharvests for these management groups cannot be carried forward. Therefore, based on preliminary estimates, and consistent with the regulations at § 635.27(b)(2), NMFS proposes that the 2021 quota in the shark research fishery be equal to the annual base quota without adjustment because there have not been any overharvests, and because underharvests cannot be carried over due to stock status.

The 2021 proposed commercial quotas for blue sharks, porbeagle sharks, and pelagic sharks (other than porbeagle or blue sharks) are 273.0 mt dw (601,856 lb dw), 1.7 mt dw (3,748 lb dw), and 488.0 mt dw (1,075,856 lb dw), respectively. As of July 10, 2020, there were no preliminary reported landings of blue sharks or porbeagle sharks, and landings of pelagic sharks (other than porbeagle and blue sharks) were at 5.9 percent (28.8 mt dw) of the 2020 quota level (488.0 mt dw). Given that these pelagic species are overfished, have overfishing occurring, or have an unknown status, underharvests cannot be carried forward pursuant to § 635.27(b)(2)(ii). Therefore, based on preliminary estimates and consistent with the current regulations at § 635.27(b)(2), NMFS proposes that the 2021 quotas for blue sharks, porbeagle sharks, and pelagic sharks (other than porbeagle and blue sharks) be equal to their annual base quotas without adjustment, because there have not been any overharvests and because underharvests cannot be carried over due to stock status.

Proposed Opening Date and Retention Limits for the 2021 Atlantic Commercial Shark Fishing Year

In proposing the commercial shark fishing season opening dates for all regions and sub-regions, NMFS considers regulatory criteria listed at § 635.27(b)(3) and other relevant factors such as the available annual quotas for the current fishing season, estimated season length and average weekly catch rates from previous years, length of the season and fishery participation in past years, impacts to accomplishing objectives of the 2006 Consolidated Atlantic HMS FMP and its amendments, temporal variation in behavior or biology of target species (*e.g.,* seasonal distribution or abundance), impact of catch rates in one region on another, and effects of delayed openings.

In analyzing the criteria, NMFS examines the overharvests and underharvests of the different management groups in the 2020 fishing year to determine the likely effects of the proposed commercial quotas for 2021 on shark stocks and fishermen across regional and sub-regional fishing areas. NMFS also examines the potential season length and previous catch rates to ensure, to the extent practicable, that equitable fishing opportunities be provided to fishermen in all areas. Lastly, NMFS examines the seasonal variation of the different species/management groups and the effects on fishing opportunities. At the start of each fishing year, the default commercial retention limit is 45 LCS other than sandbar sharks per vessel per trip in the eastern and western Gulf of Mexico sub-regions and in the Atlantic region, unless NMFS determines otherwise and files with the Office of the Federal Register for publication notification of an inseason adjustment. NMFS may adjust the retention limit from zero to 55 LCS other than sandbar sharks per vessel per trip if the respective LCS management group is open under §§ 635.27 and 635.28, after considering the six ''inseason trip limit adjustment criteria'' listed at § 635.24(a)(8). Those criteria are: The amount of remaining shark quota in the relevant area, region, or sub-region, to date, based on dealer reports; the catch rates of the relevant shark species/complexes in the region or sub-region, to date, based on dealer reports; the estimated date of fishery closure based on when the landings are projected to reach 80-percent of the quota given the realized catch rates and whether they are projected to reach 100 percent before the end of the fishing season; effects of the adjustment on accomplishing the objectives of the 2006 Consolidated Atlantic HMS FMP and its amendments; variations in seasonal distribution, abundance, or migratory patterns of the relevant shark species based on scientific and fishery-based knowledge; and/or effects of catch rates in one part of a region precluding vessels in another part of that region from having a reasonable opportunity to harvest a portion of the relevant quota.

After considering all these criteria, NMFS is proposing to open the 2021 Atlantic commercial shark fishing season for all shark management groups in the northwestern Atlantic Ocean, including the Gulf of Mexico and the Caribbean Sea, on January 1, 2021, after the publication of the final rule for this action (Table 2). NMFS proposes to open the season on January 1, 2021, but recognizes that the actual opening date is contingent on publication in the **Federal Register**, and may vary accordingly. NMFS is also proposing to start the 2021 commercial shark fishing season with the commercial retention limit of 45 LCS other than sandbar sharks per vessel per trip in both the eastern and western Gulf of Mexico sub-regions, and a commercial retention limit of 36 LCS other than sandbar sharks per vessel per trip in the Atlantic region (Table 2). Proposed retention limits could change as a result of public comments as well as updated catch rates and landings information available when drafting the final rule.

TABLE 2—QUOTA LINKAGES, SEASON OPENING DATES, AND COMMERCIAL RETENTION LIMIT BY REGIONAL OR SUB-REGIONAL SHARK MANAGEMENT GROUP

Region or sub-region	Management group	Quota linkages	Season opening date	Commercial retention limits for directed shark limited access permit holders (inseason adjustments are possible)
Western Gulf of Mexico	Blacktip Sharks ..... Aggregated Large Coastal Sharks. Hammerhead Sharks.	Not Linked ..... Linked.	January 1, 2021	45 LCS other than sandbar sharks per vessel per trip.

TABLE 2—QUOTA LINKAGES, SEASON OPENING DATES, AND COMMERCIAL RETENTION LIMIT BY REGIONAL OR SUB-REGIONAL SHARK MANAGEMENT GROUP—Continued

Region or sub-region	Management group	Quota linkages	Season opening date	Commercial retention limits for directed shark limited access permit holders (inseason adjustments are possible)
Eastern Gulf of Mexico	Blacktip Sharks Aggregated Large Coastal Sharks. Hammerhead Sharks.	Not Linked Linked.	January 1, 2021	45 LCS other than sandbar sharks per vessel per trip.
Gulf of Mexico	Non-Blacknose Small Coastal Sharks.	Not Linked	January 1, 2021	N/A.
	Smoothhound Sharks	Not Linked	January 1, 2021	N/A.
Atlantic	Aggregated Large Coastal Sharks. Hammerhead Sharks	Linked	January 1, 2021	36 LCS other than sandbar sharks per vessel per trip. If quota is landed quickly (*e.g.,* if approximately 40 percent of quota is caught at the beginning of the year), NMFS anticipates considering an inseason reduction (*e.g.,* to 3 or fewer LCS other than sandbar sharks per vessel per trip), then an inseason increase to 36 LCS other than sandbar sharks per vessel per trip around July 15, 2021.[1]
	Non-Blacknose Small Coastal Sharks.	Linked (South of 34° N lat. only).	January 1, 2021	N/A.
	Blacknose Sharks (South of 34° N lat. only).			8 Blacknose sharks per vessel per trip (applies to directed and incidental permit holders).
	Smoothhound Sharks	Not Linked	January 1, 2021	N/A.
No regional quotas	Non-Sandbar LCS Research. Sandbar Shark Research.	Linked	January 1, 2021	N/A.
	Blue Sharks Porbeagle Sharks. Pelagic Sharks Other Than Porbeagle or Blue.	Not Linked	January 1, 2021	N/A.

[1] NMFS is proposing changing the percent of quota harvested at which it considers adjusting the retention limit. Rather than 35 percent, NMFS would consider adjustment to 40 percent to allow fishermen in the Atlantic region to more fully utilize the quota.

In the eastern and western Gulf of Mexico sub-regions, NMFS proposes opening the fishing season on January 1, 2021, for the aggregated LCS, blacktip sharks, and hammerhead shark management groups, with the commercial retention limits of 45 LCS other than sandbar sharks per vessel per trip for directed shark permits. This opening date and retention limit combination would provide, to the extent practicable, equitable opportunities across the fisheries management sub-regions. This opening date takes into account all the season opening criteria listed in § 635.27(b)(3), and particularly the criteria that require NMFS to consider the length of the season for the different species and/or management groups in the previous years (§ 635.27(b)(3)(ii) and (iii)) and whether fishermen were able to participate in the fishery in those years (§ 635.27(b)(3)(v)). The proposed commercial retention limits take into account the criteria listed in § 635.24(a)(8), and particularly the criterion that requires NMFS to consider the catch rates of the relevant shark species/complexes based on dealer reports to date (§ 635.24(a)(8)(ii)). NMFS may also adjust the retention limit in the Gulf of Mexico region throughout the season to ensure fishermen in all parts of the region have an opportunity to harvest aggregated LCS, blacktip sharks, and hammerhead sharks (see the criteria listed at § 635.27(b)(3)(v) and § 635.24(a)(8)(ii), (v), and (vi)). For both the eastern and western Gulf of Mexico sub-regions combined, dealer reports received through July 10, 2020, indicate that 58 percent (200.4 mt dw), 110 percent (78.9 mt dw), and less than 15 percent (<0.5 mt dw) of the available blacktip, aggregated LCS, and hammerhead shark quotas, respectively, has been harvested. Therefore, for 2021, NMFS is considering opening both the western and eastern Gulf of Mexico sub-regions with a commercial retention limit of 45 sharks other than sandbar sharks, per vessel per trip.

In the Atlantic region, NMFS proposes opening the aggregated LCS and hammerhead shark management groups on January 1, 2021. This opening date also takes into account all the criteria listed in § 635.27(b)(3), and particularly the criterion that NMFS consider the effects of catch rates in one part of a region precluding vessels in another part of that region from having a reasonable opportunity to harvest a portion of the different species and/or management quotas (§ 635.27(b)(3)(v)). The 2020 data indicates that an opening date of January 1, coupled with inseason adjustments to the retention limit, provided a reasonable opportunity for fishermen in every part of each region to harvest a portion of the available quotas (§ 635.27(b)(3)(i)), while accounting for variations in seasonal distribution of the different species in the management groups (§ 635.27(b)(3)(iv)). Because the quotas we propose for 2021 are the same as the quotas in 2020, NMFS proposes that the season lengths, and therefore, the participation of various fishermen throughout the region, would be similar in 2021 (§ 635.27(b)(3)(ii) and (iii)). Based on the recent performance of the fishery, the January 1 opening date appears to meet the objectives of the 2006 Consolidated Atlantic HMS FMP and its amendments (§ 635.27(b)(3)(vi)). NMFS' review of the landings data from 2016 to the present has shown a decrease in landings over time in the aggregated LCS and hammerhead management groups. In the Final Rule to Establish Adjusted Base Annual Quotas, Opening Dates, and Retention Limits for the 2020 Atlantic Shark Commercial Fishing Year (84 FR 65690; November 29, 2019), NMFS increased the starting retention limit from 25 to 36, and the percentage threshold from 20 to 35 percent. NMFS proposes to follow the same trip adjustment criteria in 2021, but because landings continue to remain low, NMFS is proposing to change the percent of quota harvested at which it

considers adjusting the retention limit from 35 to 40 percent. Changing the percent of quota harvested could allow fishermen in the Atlantic region to more fully utilize the quota. Changing the percentage of quota harvested is a management benchmark NMFS has used (and announced as part of the rulemaking process) in previous seasons to help determine at which point it will consider an inseason action to adjust the retention limits.

In addition, for the aggregated LCS and hammerhead shark management groups in the Atlantic region, NMFS proposes opening the fishing year with the commercial retention limit for directed shark limited access permit holders of 36 LCS other than sandbar sharks per vessel per trip. This retention limit should allow fishermen to harvest some of the 2021 quota at the beginning of the year when sharks are more prevalent in the South Atlantic area (see the criteria at § 635.24(a)(3)(i), (ii), (v), and (vi)). As was done in 2020, if it appears that the quota is being harvested too quickly to allow directed fishermen throughout the entire region an opportunity to fish and ensure enough quota remains until later in the year, NMFS would consider either reducing the commercial retention limits to incidental levels (3 LCS other than sandbar sharks per vessel per trip), or setting another level calculated to reduce the harvest of LCS in accordance with the opening commercial fishing season criteria listed in § 635.27(b)(3) and the inseason trip limit adjustment criteria listed in § 635.24(a)(8). If the quota continues to be harvested quickly, NMFS could consider reducing the retention limit to 0 LCS other than sandbar sharks per vessel per trip to ensure enough quota remains until later in the year. If either situation occurs, NMFS would publish in the **Federal Register** notification of any inseason adjustments of the retention limit. NMFS will consider increasing the commercial retention limits per trip at a later date, after considering the appropriate inseason adjustment criteria, if necessary to provide fishermen in the northern portion of the Atlantic region an opportunity to retain aggregated LCS and hammerhead sharks. Similarly, at some point later in the year, NMFS may consider increasing the retention limit to a higher retention limit of aggregated LCS other than sandbar sharks per vessel per trip, as deemed appropriate, after considering the inseason trip limit adjustment criteria. If the quota is being harvested too quickly or too slowly, NMFS could adjust the retention limit appropriately to ensure the fishery remains open most of the rest of the year.

All of the shark management groups would remain open until December 31, 2021, or until NMFS determines that the landings for any shark management group are projected to reach 80 percent of the quota given the realized catch rates and whether they are projected to reach 100 percent before the end of the fishing season, or when the quota-linked management group is closed. If NMFS determines that a non-linked shark species or management group must be closed, then, consistent with § 635.28(b)(2) for non-linked quotas (*e.g.,* eastern Gulf of Mexico blacktip, western Gulf of Mexico blacktip, Gulf of Mexico non-blacknose SCS, pelagic sharks, or the Atlantic or Gulf of Mexico smoothhound sharks), NMFS will publish in the **Federal Register** a notice of closure for that shark species, shark management group, region, and/or sub-region that will be effective no fewer than four days from the date of filing (This is pursuant to 50 CFR part 635, as most recently amended by the July 9, 2018, final rule (83 FR 31677) revising Atlantic highly migratory species shark fishery closure regulations). For the blacktip shark management group, regulations at § 635.28(b)(5)(i) through (v) authorize NMFS to close the management group before landings have reached or are projected to reach 80 percent of applicable available overall, regional, and/or sub-regional quota and are projected to reach 100 percent of the relevant quota by the end of the fishing season, after considering the following criteria and other relevant factors: Season length based on available sub-regional quota and average sub-regional catch rates; variability in regional and/or sub-regional seasonal distribution, abundance, and migratory patterns; effects on accomplishing the objectives of the 2006 Consolidated Atlantic HMS FMP and its amendments; amount of remaining shark quotas in the relevant sub-region; and regional and/or sub-regional catch rates of the relevant shark species or management groups. The fisheries for the shark species or management group would be closed (even across fishing years) from the effective date and time of the closure until NMFS announces, via the publication of a notice in the **Federal Register**, that additional quota is available and the season is reopened.

If NMFS determines that a linked shark species or management group must be closed, then, consistent with § 635.28(b)(3) for linked quotas and the Final Rule to Revise Atlantic Highly Migratory Species Shark Fishery Closure Regulations (83 FR 31677; July 9, 2018), NMFS will publish in the **Federal Register** a notice of closure for all of the species and/or management groups in a linked group that will be effective no fewer than four days from the date of filing. In that event, from the effective date and time of the closure until NMFS announces that the season is reopened and additional quota is available (via the publication of another notice in the **Federal Register**), the fisheries for all linked species and/or management groups will be closed, even across fishing years. The linked quotas of the species and/or management groups are Atlantic hammerhead sharks and Atlantic aggregated LCS; eastern Gulf of Mexico hammerhead sharks and eastern Gulf of Mexico aggregated LCS; western Gulf of Mexico hammerhead sharks and western Gulf of Mexico aggregated LCS; and Atlantic blacknose and Atlantic non-blacknose SCS south of 34° N latitude.

Request for Comments

Comments on this proposed rule may be submitted via *www.regulations.gov.* NMFS solicits comments on this proposed rule by October 29, 2020 (see **DATES** and **ADDRESSES**).

Classification

The NMFS Assistant Administrator has determined that the proposed rule is consistent with the 2006 Consolidated Atlantic HMS FMP and its amendments, the Magnuson-Stevens Act, and other applicable laws, subject to further consideration after public comment.

These proposed specifications are exempt from review under Executive Order 12866.

NMFS determined that the final rules to implement Amendment 2 to the 2006 Consolidated Atlantic HMS FMP (June 24, 2008, 73 FR 35778; corrected on July 15, 2008, 73 FR 40658), Amendment 5a to the 2006 Consolidated Atlantic HMS FMP (78 FR 40318; July 3, 2013), Amendment 6 to the 2006 Consolidated Atlantic HMS FMP (80 FR 50073; August 18, 2015), and Amendment 9 to the 2006 Consolidated Atlantic HMS FMP (80 FR 73128; November 24, 2015) are consistent to the maximum extent practicable with the enforceable policies of the approved coastal management program of coastal states on the Atlantic, including the Gulf of Mexico and the Caribbean Sea, as required under the Coastal Zone Management Act. Pursuant to 15 CFR 930.41(a), NMFS provided the Coastal Zone Management Program of each coastal state a 60-day period to review the consistency determination and to advise NMFS of their concurrence. NMFS received concurrence with the

consistency determinations from several states and inferred consistency from those states that did not respond within the 60-day time period. This proposed action to establish an opening date and adjust quotas for the 2021 fishing year for the Atlantic commercial shark fisheries does not change the framework previously consulted upon. Therefore, no additional consultation is required.

An initial regulatory flexibility analysis (IRFA) was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. The IRFA analysis follows.

Section 603(b)(1) of the RFA requires agencies to explain the purpose of the rule. This rule, consistent with the Magnuson-Stevens Act and the 2006 Consolidated Atlantic HMS FMP and its amendments, would adjust quotas and retention limits and establish the opening date for the 2021 Atlantic commercial shark fishing year, consistent with regulations at 50 CFR 635.27(b).

Section 603(b)(2) of the RFA requires agencies to explain the rule's objectives. The objectives of this rule are to: Adjust the base quotas for all shark management groups based on any overharvests and/or underharvests from the previous fishing year(s); establish the opening dates of the various shark fishery management groups; and establish the retention limits for the blacktip shark, aggregated large coastal shark, and hammerhead shark management groups in order to provide, to the extent practicable, equitable opportunities across the fishing management regions and/or sub-regions while also considering the ecological needs of the different shark species.

Section 603(b)(3) of the RFA requires agencies to provide an estimate of the number of small entities to which the rule would apply. The Small Business Administration (SBA) has established size criteria for all major industry sectors in the United States, including fish harvesters. SBA's regulations include provisions for an agency to develop its own industry-specific size standards after consultation with SBA and providing an opportunity for public comment (see 13 CFR 121.903(c)). Under this provision, NMFS may establish size standards that differ from those established by the SBA Office of Size Standards, but only for use by NMFS and only for the purpose of conducting an analysis of economic effects in fulfillment of the agency's obligations under the RFA. To utilize this provision, NMFS must publish such size standards in the **Federal Register**, which NMFS did on December 29, 2015 (80 FR 81194; 50 CFR 200.2). In this final rule effective on July 1, 2016, NMFS established a small business size standard of $11 million in annual gross receipts for all businesses in the commercial fishing industry (NAICS 11411) for RFA compliance purposes. NMFS considers all HMS permit holders to be small entities because they had average annual receipts of less than $11 million for commercial fishing.

As of July 10, 2020, the proposed rule would apply to the approximately 218 directed commercial shark permit holders, 263 incidental commercial shark permit holders, 159 smoothhound shark permit holders, and 104 commercial shark dealers. Not all permit holders are active in the fishery in any given year. Active directed commercial shark permit holders are defined as those with valid permits that landed one shark based on HMS electronic dealer reports. Of the 481 directed and incidental commercial shark permit holders, only 18 permit holders landed sharks in the Gulf of Mexico region, and only 85 landed sharks in the Atlantic region. Of the 159 smoothhound shark permit holders, only 61 permit holders landed smoothhound sharks in the Atlantic region, and none landed smoothhound sharks in the Gulf of Mexico region. NMFS has determined that the proposed rule would not likely affect any small governmental jurisdictions.

This proposed rule does not contain any new reporting, recordkeeping, or other compliance requirements (5 U.S.C. 603(b)(4)) or a collection-of-information requirement subject to the Paperwork Reduction Act. Similarly, this proposed rule would not conflict, duplicate, or overlap with other relevant Federal rules (5 U.S.C. 603(b)(5)). Fishermen, dealers, and managers in these fisheries must comply with a number of international agreements as domestically implemented, domestic laws, and FMPs. These include, but are not limited to, the Magnuson-Stevens Act, the Atlantic Tunas Convention Act, the Marine Mammal Protection Act, the Endangered Species Act, the National Environmental Policy Act, and the Coastal Zone Management Act.

Section 603(c) of the RFA requires each IRFA to contain a description of any significant alternatives to the proposed rule, which would accomplish the stated objectives of applicable statutes and minimize any significant economic impact of the proposed rule on small entities. Additionally, the RFA (5 U.S.C. 603(c)(1)–(4)) lists four general categories of significant alternatives that would assist an agency in the development of significant alternatives. These categories of alternatives are: (1) Establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) use of performance rather than design standards; and (4) exemptions from coverage of the rule for small entities. In order to meet the objectives of this proposed rule, consistent with the Magnuson-Stevens Act, NMFS cannot exempt small entities or change the reporting requirements only for small entities, because all of the entities affected are considered small entities. For similar reasons, there are no alternatives discussed that fall under the first, second, and fourth categories described above. NMFS does not know of any performance or design standards that would satisfy the aforementioned objectives of this rulemaking while, concurrently, complying with the Magnuson-Stevens Act; therefore, there are no alternatives considered under the third category.

This rulemaking would implement previously adopted and analyzed measures with adjustments, as specified in the 2006 Consolidated Atlantic HMS FMP and its amendments and the Environmental Assessment (EA) that accompanied the 2011 shark quota specifications rule (75 FR 76302; December 8, 2010). NMFS proposes to adjust quotas established and analyzed in the 2006 Consolidated Atlantic HMS FMP and its amendments by subtracting the underharvest or adding the overharvest as allowable. NMFS has limited flexibility to otherwise modify the quotas in this rule. In addition, the impacts of the quotas (and any potential modifications) were analyzed in previous regulatory flexibility analyses (RFAs), including the RFA that accompanied the 2011 shark quota specifications rule.

Based on the 2019 ex-vessel price (Table 3), fully harvesting the unadjusted 2021 Atlantic shark commercial base quotas could result in total fleet revenues of $9,997,263. For the Gulf of Mexico blacktip shark management group, NMFS is proposing to adjust the base sub-regional quotas upward due to underharvests in 2020. The increase for the western Gulf of Mexico blacktip shark management group could result in a $241,691 gain in total revenues for fishermen in that sub-region, while the increase for the eastern Gulf of Mexico blacktip shark

management group could result in a $27,645 gain in total revenues for fishermen in that sub-region. For the Gulf of Mexico and Atlantic smoothhound shark management groups, NMFS is proposing to increase the base quotas due to the underharvest in 2020. This would cause a potential gain in revenue of $393,063 for the fleet in the Gulf of Mexico region, and a potential gain in revenue of $1,112,680 for the fleet in the Atlantic region.

All of these changes in gross revenues are similar to the gross revenues analyzed in the 2006 Consolidated Atlantic HMS FMP and Amendments 2, 3 5a, 6, and 9 to the 2006 Consolidated Atlantic HMS FMP. The final RFAs for those amendments concluded that the economic impacts on these small entities from adjustments such as those contemplated in this action are expected to be minimal. In accordance with the 2006 Consolidated Atlantic HMS FMP, as amended, and consistent with NMFS' statements in rule implementing Amendments 2, 3 5a, 6, and 9, and in the EA for the 2011 shark quota specifications rule, NMFS now conducts annual rulemakings in which NMFS considers the potential economic impacts of adjusting the quotas for underharvests and overharvests.

TABLE 3—AVERAGE EX-VESSEL PRICES PER LB DW FOR EACH SHARK MANAGEMENT GROUP, 2019

Region	Species	Average ex-vessel meat price	Average ex-vessel fin price
Western Gulf of Mexico	Blacktip Shark	$0.70	$9.16
	Aggregated LCS	0.73	15.81
	Hammerhead Shark	0.52	12.00
Eastern Gulf of Mexico	Blacktip Shark	0.75	8.00
	Aggregated LCS	0.56	12.00
	Hammerhead Shark	0.50	13.43
Gulf of Mexico	Non-Blacknose SCS	0.59	5.81
	Smoothhound Shark	1.06	.....
Atlantic	Aggregated LCS	0.99	3.51
	Hammerhead Shark	0.46	.....
	Non-Blacknose SCS	1.02	4.60
	Blacknose Shark	1.27	.....
	Smoothhound Shark	0.78	1.68
No Region	Shark Research Fishery (Aggregated LCS)	0.86	15.15
	Shark Research Fishery (Sandbar only)	0.68	.....
	Blue shark	.....	.....
	Porbeagle shark	0.36	2.51
	Other Pelagic sharks	1.35	7.60

For this rule, NMFS also reviewed the criteria at § 635.27(b)(3) to determine when opening each fishery would provide equitable opportunities for fishermen, to the extent practicable, while also considering the ecological needs of the different species. The opening date of the fishing year could vary depending upon the available annual quota, catch rates, and number of fishing participants during the year. For the 2021 fishing year, NMFS is proposing to open all of the shark management groups on the effective date of the final rule for this action (which is expected to be January 1). The direct and indirect economic impacts would be neutral on a short- and long-term basis, because NMFS is not proposing to change the opening date of these fisheries from the status quo.

For all of the reasons explained above, this action, if implemented, will not have a significant economic impact on a substantial number of small entities.

Authority: 16 U.S.C. 971 *et seq.;* 16 U.S.C. 1801 *et seq.*

Dated: September 14, 2020.

Samuel D. Rauch, III,

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

[FR Doc. 2020–20573 Filed 9–28–20; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 85, No. 189
Tuesday, September 29, 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–20–0067]

United States Standards for Split Peas

AGENCY: Agricultural Marketing Service, USDA

ACTION: Notice and request for comments

SUMMARY: The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) is proposing a revision to the method of interpretation for determining ''whole peas,'' in the Pea and Lentil Inspection Handbook, as it pertains to the class ''Split Peas,'' in the U.S. Standards for Split Peas under the United States Agricultural Marketing Act (AMA). Stakeholders in the pea processing/handling industry requested AMS to amend the interpretation of whole peas in the Split Pea inspection instructions by increasing the percent requirement for the factor whole peas. To ensure that the Split Pea class standard remains relevant, AMS invites interested parties to comment on whether revising the inspection instruction facilitates the marketing of Split Peas. This action does not revise or amend the Grade and Grade Requirements for the class Split Peas in the U.S. Standard for Split Peas.

DATES: We will consider comments we receive by October 29, 2020.

ADDRESSES: Submit comments or notice of intent to submit comments by any of the following methods:

To submit Comments: Go to *Regulations.gov* (*http://www.regulations.gov*). Instructions for submitting and reading comments are detailed on the site. Interested persons are invited to submit written comments concerning this notice. All comments must be submitted through the Federal e-rulemaking portal at *http://www.regulations.gov* and should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Loren Almond, USDA AMS; Telephone: (816) 891–0422; Email: *Loren.L.Almond@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of the AMA (7 U.S.C. 1621–1627), as amended, AMS establishes and maintains a variety of quality and grade standards for agricultural commodities that serve as a fundamental starting point to define commodity quality in the domestic and global marketplace. Standards developed under the AMA include those for rice, whole dry peas, split peas, feed peas, lentils, and beans. The U.S. standards for whole dry peas, split peas, feed peas, lentils and beans no longer appear in the Code of Federal Regulations but are now maintained by USDA-AMS-Federal Grain Inspection Service. The U.S. standards for split peas are voluntary and widely used in private contracts, government procurement, marketing communication, and for some commodities, consumer information.

The split pea standards facilitate pea marketing and define U.S. pea quality in the domestic and global marketplace. The standards define commonly used industry terms; contain basic principles governing the application of standards such as the type of sample used for a particular quality analysis; the basis of determination; and specify grades and grade requirements. Official procedures for determining grading factors are provided in the Pea and Lentil Inspection Handbook. Together, the grading standards and testing procedures allow buyers and sellers to communicate quality requirements, compare pea quality using equivalent forms of measurement, and assist in price discovery.

AMS engages in outreach with stakeholders to ensure commodity standards maintain relevance to the modern market. Stakeholders, including the U.S. Dry Pea and Lentil Council (USDPLC), requested AMS to revise the split pea criteria for whole peas in the class Split Peas. Whole Peas are dry peas which are not split. The current definition of a ''whole pea'' is any pea which is 55 percent or more of a whole pea. The current tolerances for whole peas in split peas are determined on approximately 250 grams. AMS–FGIS proposes to revise the split pea inspection criteria in the Pea and Lentil Inspection Handbook by amending the definition for whole peas in the Split Pea class from 55 percent or more, to 60 percent or more.

Split Pea Tolerances for Whole Peas

Representatives of pea industry stakeholders contacted AMS–FGIS to discuss ongoing issues with Split Peas, which grow predominately in Montana and North Dakota. Stakeholders told AMS that customers are looking for improved grading tools to measure the quality of products. Further, pea stakeholders told AMS that in 2019 shipments of split peas grading Number 1 at the processor subsequently graded less than Number 1, after packaging for Section 32/Food Distribution Programs. Stakeholders stated the current whole pea factor tolerance makes meeting contract specifications difficult due to the interpretation of a whole pea. During meetings and discussions, pea stakeholders communicated the need to revise the Pea and Lentil Inspection Handbook by revising the whole pea definition.

The current tolerances for whole peas in split peas are determined on a percent basis of 55 percent or more of a whole pea in 250 grams. Pea industry stakeholders recommended the tolerance be increased to 60 percent or more of a whole pea. This would assist in moving the U.S. Split Pea market towards fewer quality complaints and serve to ensure consistent grading results across the nation. AMS views this action as noncontroversial and anticipates no adverse public comment.

AMS grading and inspection services, provided through a network of federal, state, and private laboratories, conduct tests to determine the quality and condition of Split Peas. These tests are conducted in accordance with applicable standards using approved methodologies and can be applied at any point in the marketing chain. Furthermore, the tests yield rapid, reliable, and consistent results. The U.S.

Standards for Split Peas and the affiliated grading and testing services offered by AMS verify that a seller's Split Peas meet specified requirements and ensure that customers receive the quality purchased.

In order for U.S. standards and grading procedures for split peas to remain relevant, AMS is issuing this request for information to invite interested parties to submit comments on the proposal to amend the whole pea interpretation for the class Split Peas. These changes do not revise or amend the Grade and Grade Requirements for the class Split Peas in the U.S. Standard for Split Peas.

Proposed AMS Action

Based on input from stakeholder organizations in the pea industry, AMS proposes 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.

AMS will solicit comments for 30 days. All comments received within the comment period will be made part of the public record maintained by AMS, will be available to the public for review, and will be considered by AMS before a final action is taken on this proposal.

Authority: 7 U.S.C. 1621–1627.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–21434 Filed 9–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc No. AMS–FGIS–20–0066]

United States Standards for Lentils

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) is proposing a revision to the method of interpretation for the determining the special grade ''Green,'' in the Pea and Lentil Inspection Handbook, as it pertains to the class ''Lentils,'' in the U.S. Standards for Lentils under the United States Agricultural Marketing Act (AMA). Stakeholders in the lentil processing/handling industry requested AMS to amend the definition of the special grade ''Green'' to allow for the inclusion of mottled lentils. To ensure that the Lentil standards remain relevant, AMS invites interested parties to comment on whether revising the inspection instructions facilitate the marketing of Lentils. This action will revise or amend the Grade and Grade Requirements for Lentils in the U.S. Standard for Lentils.

DATES: We will consider comments we receive by October 29, 2020.

ADDRESSES: Submit comments or notice of intent to submit comments by any of the following methods:

To submit Comments: Go to *Regulations.gov* (*http://www.regulations.gov*). Instructions for submitting and reading comments are detailed on the site. Interested persons are invited to submit written comments concerning this notice. All comments must be submitted through the Federal e-rulemaking portal at *http://www.regulations.gov* and should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Loren Almond, USDA AMS; Telephone: (816) 891–0422; Email: *Loren.L.Almond@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of the AMA (7 U.S.C. 1621–1627), as amended, AMS establishes and maintains a variety of quality and grade standards for agricultural commodities that serve as a fundamental starting point to define commodity quality in the domestic and global marketplace. Standards developed under the AMA include those for rice, whole dry peas, split peas, feed peas, lentils, and beans. The U.S. standards for whole dry peas, split peas, feed peas, lentils and beans no longer appear in the Code of Federal Regulations, but are now maintained by USDA–AMS–Federal Grain Inspection Service. The U.S. standards for lentils are voluntary and widely used in private contracts, government procurement, marketing communication, and for some commodities, consumer information. The lentil standards were last revised in 2017 (82 FR 31550).

The lentil standards facilitate lentil marketing and define U.S. lentil quality in the domestic and global marketplace. The standards define commonly used industry terms; contain basic principles governing the application of standards such as the type of sample used for a particular quality analysis; the basis of determination; and specify grades and grade requirements. Official procedures for determining grading factors are provided in the Pea and Lentil Inspection Handbook. Together, the grading standards and testing procedures allow buyers and sellers to communicate quality requirements, compare lentil quality using equivalent forms of measurement, and assist in price discovery.

AMS engages in outreach with stakeholders to ensure commodity standards maintain relevance to the modern market. Stakeholders, including the U.S. Dry Pea and Lentil Council (USDPLC), requested AMS to revise the lentil criteria for the special grade ''Green'' in the class Lentils. Currently, Green Lentils are clear seeded (Non-Mottled) lentils possessing a natural, uniformly green color. This criteria for ''Green'' Lentils is determined on the sample as a whole, after the removal of dockage, but before the removal of defects and must be equal to or better than the depiction on the Interpretive Line Print (ILP) to quality for the special grade ''Green Lentils''. AMS–FGIS proposes to revise the lentil inspection criteria in the U.S. Standards for Lentils and the Pea and Lentil Inspection Handbook by amending the definition and criteria requirements for ''Green'' in lentils.

Special Grade ''Green'' Criteria in Lentils

When special grade ''Green'' was added to the lentil standard in 2017, stakeholders did not intend the interpretation of the definition to exclude all mottled lentils. Representatives of lentil industry stakeholders contacted AMS–FGIS to discuss ongoing issues with Lentils, which are predominately grown in Montana and North Dakota. Stakeholders stated in 2019 that most shipments of lentils did not achieve the special grade ''Green'' as the current definition and interpretation make it difficult to meet the special grade criteria. During meetings and discussions, lentil stakeholders communicated the need to revise the standard by changing definition of special grade ''Green'' and changing the inspection criteria in the Pea and Lentil Inspection Handbook to include a percentage of allowable mottled lentils.

Stakeholders recommended the definition of ''Green'' be revised in the lentil standard to read ''Clear seeded (green) lentils possessing a natural,

uniformly green color''. Further, stakeholders recommended the instruction in the Pea and Lentil Inspection Handbook be amended to read: ''The portion size of, approximately 60 grams for small seeded lentils and 125 grams for large seeded lentils, must contain less than 0.5 percent mottled lentils before the removal of defects, and must be equal to or better than depicted on the interpretive line print after the removal of dockage.'' AMS regards this action as noncontroversial and anticipates no adverse public comment.

AMS grading and inspection services, provided through a network of federal, state, and private laboratories, conduct tests to determine the quality and condition of Lentils. These tests are conducted in accordance with applicable standards using approved methodologies and can be applied at any point in the marketing chain. Furthermore, the tests yield rapid, reliable, and consistent results. The U.S. Standards for Lentils and the affiliated grading and testing services offered by AMS verify that a seller's Lentils meet specified requirements and ensure that customers receive the quality purchased.

In order for U.S. standards and grading procedures for lentils to remain relevant, AMS is issuing this request for information to invite interested parties to submit comments on the proposal to amend the definition and inspection instruction of special grade ''Green'' in the class Lentils.

Proposed AMS Action

Based on input from stakeholder organizations in the lentil industry, AMS proposes to amend U.S. Standards for Lentils by revising the definition of the special grade ''Green'' in Section 609 to read:

609 Special grades and requirements.

* * *

(c) Green lentils. Clear seeded (green) lentils possessing a natural, uniformly green color.

* * * * *

AMS will amend the Pea and Lentil Inspection Handbook by revising the inspection instruction for determining the special grade ''Green'', as stated above.

AMS will solicit comments for 30 days. All comments received within the comment period will be made part of the public record maintained by AMS, will be available to the public for review, and will be considered by AMS before a final action is taken on this proposal.

(Authority: 7 U.S.C. 1621–1627)

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–21435 Filed 9–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc No. AMS–FGIS–20–0065]

United States Standards for Beans

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) is proposing a revision to the method of interpretation for determining ''sample grade criteria,'' in the Bean Inspection Handbook, as it pertains to the class ''Blackeye beans,'' in the U.S. Standards for Beans under the United States Agricultural Marketing Act (AMA). Stakeholders in the dry bean processing/handling industry requested that AMS amend the definition of sample grade in the Blackeye bean inspection instructions by revising the unit of measurement for the factor Insect Webbing or Filth and removing clean-cut weevil-bore as a sample grade factor. Clean-cut weevil-bore will be considered a damage factor only. To ensure that the Blackeye bean class standard remains relevant, AMS invites interested parties to comment on whether revising the inspection instructions facilitate the marketing of Blackeye beans. This action does not revise or amend the Grade and Grade Requirements for the class Blackeye Beans in the U.S. Standard for Beans.

DATES: We will consider comments we receive by October 29, 2020.

ADDRESSES: Submit comments or notice of intent to submit comments by any of the following methods:

To submit Comments: Go to *Regulations.gov* (*http://www.regulations.gov*). Instructions for submitting and reading comments are detailed on the site. Interested persons are invited to submit written comments concerning this notice. All comments must be submitted through the Federal e-rulemaking portal at *http://www.regulations.gov* and should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Loren Almond, USDA AMS; Telephone: (816) 891–0422; Email: *Loren.L.Almond@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of the AMA (7 U.S.C. 1621–1627), as amended, AMS establishes and maintains a variety of quality and grade standards for agricultural commodities that serve as a fundamental starting point to define commodity quality in the domestic and global marketplace.

Standards developed under the AMA include those for rice, whole dry peas, split peas, feed peas, lentils, and beans. The U.S. standards for whole dry peas, split peas, feed peas, lentils and beans no longer appear in the Code of Federal Regulations but are now maintained by USDA–AMS-Federal Grain Inspection Service. The U.S. standards for beans are voluntary and widely used in private contracts, government procurement, marketing communication, and for some commodities, consumer information.

The bean standards facilitate bean marketing and define U.S. bean quality in the domestic and global marketplace. The standards define commonly used industry terms; contain basic principles governing the application of standards such as the type of sample used for a particular quality analysis; the basis of determination; and specify grades and grade requirements. Official procedures for determining grading factors are provided in the Bean Inspection Handbook. Together, the grading standards and testing procedures allow buyers and sellers to communicate quality requirements, compare bean quality using equivalent forms of measurement, and assist in price discovery.

AMS engages in outreach with stakeholders to ensure commodity standards maintain relevance to the modern market. Stakeholders including the U.S. Dry Bean Council (USDBC); California Dry Bean Advisory Board; California Bean Shippers Association; and Cal Bean and Grain requested AMS to revise the sample grade tolerance for Insect Webbing or Filth (IWOF), only in the class Blackeye beans, to align with the CODEX Standard for Certain Pulses (CODEX Standard 171–1989). The current sample grade tolerances for IWOF in all classes of beans are determined on a count basis of two or more beans in 1,000 grams. AMS–FGIS

proposes to revise the Blackeye bean inspection criteria by amending the Bean Inspection Handbook to change the sample grade tolerance for IWOF in the Blackeye bean class only, from a count of two or more beans in 1,000 grams, to more than 0.10 percent on the basis of the representative sample as a whole, and remove clean-cut weevil-bore as a sample grade factor.

Blackeye Bean Sample Grade Tolerances for Insect Webbing or Filth

Representatives of dry bean industry stakeholders contacted AMS–FGIS to discuss ongoing issues with Blackeye beans, which grow predominately in California and Texas. The bean stakeholders told AMS the type of insect filth found in the Blackeye bean is not due to storage practices, but originates in the field, brought on by years of drought, and is the result of challenges associated with applying aerial pesticides. These elements have contributed to an increase of IWOF (beans and pieces of beans which contain webbing, refuse, excreta, dead insects, larvae, or eggs) in the Blackeye bean crops for years. With the current sample grade factor tolerance, difficulty in meeting contract specifications is problematic. During meetings and discussions, bean stakeholders communicated the need to revise the Bean Inspection Handbook by changing Blackeye bean sample grade tolerances for IWOF from count to percent. This would assist in moving the U.S. Blackeye bean market towards fewer quality complaints. The current sample grade tolerances for IWOF in all classes of beans are determined on a count basis of two or more beans in 1,000 grams. This change will increase the actual count to at least three beans, and in some cases possibly four beans, depending on the variety size. These changes were recommended to AMS by the stakeholder organizations identified in the background section of this notice to facilitate the current marketing practices. AMS views this action as noncontroversial and anticipates no adverse public comment.

Removing Clean Cut Weevil Bore as a Sample Grade Factor

Dry bean representatives also discussed issues with the Blackeye bean determination of clean-cut weevil-bore (CCWB) beans as a sample grade factor. Currently, two or more clean-cut weevil-bored (beans and pieces of beans from which weevils have emerged, leaving a clean-cut open cavity free from any webbing, refuse, excreta, dead insect, larvae, or eggs) are considered sample grade/weevily in 1,000 grams. AMS proposes to remove clean-cut weevil-bored as a sample grade criteria. This results in clean-cut weevil-bored beans considered only for damage and removes the weevily and sample grade determination based on the count of clean-cut weevil-bored beans for blackeye beans.

AMS grading and inspection services are provided through a network of federal, state, and private laboratories that conduct tests to determine the quality and condition of Blackeye beans. These tests are conducted in accordance with applicable standards using approved methodologies and can be applied at any point in the marketing chain. Furthermore, the tests yield rapid, reliable, and consistent results. The U.S. Standards for Beans and the affiliated grading and testing services offered by AMS verify that a seller's Blackeye beans meet specified requirements and ensure that customers receive the quality purchased.

In order for U.S. standards and grading procedures for Blackeye beans to remain relevant, AMS is issuing this request for information to invite interested parties to submit comments on the proposal to amend the sample grade interpretation for the class Blackeye beans. These changes do not revise or amend the Grade and Grade Requirements for the class Blackeye Beans in the U.S. Standard for Beans.

Proposed AMS Action

Based on input from stakeholder organizations in the Blackeye bean industry, AMS proposes to amend the Bean Inspection Handbook by revising the sample grade tolerances for Blackeye beans such that clean cut weevil bore is no longer a sample grade determining factor, and changing the Insect Webbing or Filth determination from a count to a percent basis.

AMS will solicit comments for 30 days. All comments received within the comment period will be made part of the public record maintained by AMS, will be available to the public for review, and will be considered by AMS before a final action is taken on this proposal.

Authority: 7 U.S.C. 1621–1627.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–21436 Filed 9–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0091]

General Conference Committee of the National Poultry Improvement Plan

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of renewal.

SUMMARY: We are giving notice that the Secretary of Agriculture has renewed the charter of the General Conference Committee of the National Poultry Improvement Plan (Committee) for a 2-year period. The Secretary of Agriculture has determined that the Committee is necessary and in the public interest.

FOR FURTHER INFORMATION CONTACT: Dr. Elena Behnke, Senior Coordinator, National Poultry Improvement Plan, VS, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094; (770) 922–3496.

SUPPLEMENTARY INFORMATION: The purpose of the General Conference Committee of the National Poultry Improvement Plan (Committee) is to maintain and ensure industry involvement in Federal administration of matters pertaining to poultry health.

The Committee Chairperson and the Vice Chairperson shall be elected by the Committee from among its members. There are seven members on the Committee. The poultry industry elects the members of the Committee. The members represent six geographic areas with one member-at-large.

Done in Washington, DC, this 24th day of September 2020.

Cikena Reid,

Committee Management Officer, USDA.

[FR Doc. 2020–21516 Filed 9–28–20; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Child Nutrition Database

AGENCY: Food and Nutrition Service (FNS), U.S. Department of Agriculture.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection.

This is a revision of a currently approved collection. This collection is the voluntary submission of data including nutrient data from the food industry to update and expand the Child Nutrition (CN) Database in support of the Child Nutrition Act of 1966. The CN Database is required in nutrient analysis software approved by USDA for use in the school meal programs. The software allows schools participating in the National School Lunch Program (NSLP) and School Breakfast Program (SBP) to analyze meals and measure the compliance of their menus with established nutrition goals and standards specified under these programs.

DATES: Written comments must be received on or before November 30, 2020.

ADDRESSES: Comments may be sent to: Natalie Partridge, Nutritionist, Nutrition, Education, Training and Technical Assistance Division, Child Nutrition Programs, Food and Nutrition Service, United States Department of Agriculture, 1320 Braddock Place, 4th Floor, Alexandria, VA 22314. Comments may also be submitted via email to the attention of Natalie Partridge at *cndb-inbox@usda.gov* with ''CN Database Comments'' in the subject line. Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be directed to Natalie Partridge at (703) 457–6803, or *natalie.partridge@usda.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Child Nutrition Database.

Form Number: FNS–710.

OMB Number: 0584–0494.

Expiration Date: January 31, 2021.

Type of Request: Revision of currently approved collection.

Abstract: The development of the Child Nutrition (CN) Database is regulated by the United States Department of Agriculture (USDA), Food and Nutrition Service. This database is designed to be incorporated in USDA-approved nutrient analysis software and provide an accurate source of nutrient data. The software allows schools participating in the National School Lunch Program (NSLP) and School Breakfast Program (SBP) to analyze meals and measure the compliance of their menus with established nutrition goals and standards specified in 7 CFR 210.10 for the NSLP and 7 CFR 220.8 for the SBP. The information collection for the CN Database is conducted using an outside contractor. The CN Database is updated annually with brand name or manufactured foods commonly used in school food service. To update and expand the CN Database, collection of this information is accomplished by form FNS–710, *CN Database Qualification Report.* The Food and Nutrition Service's contractor collects this data from the food industry through a spreadsheet version of the FNS–710. The online web tool and paper version have been deleted from the collection because they are no longer used. The online web tool was discontinued due to outdated technology. The paper form was discontinued because no data was submitted by industry using the paper form for many years. The spreadsheet was edited to update terminology and instructions. These changes do not affect the burden for the collection. However, FNS has changed how the frequency and the estimated time per response are determined. Previously the frequency of response (or total annual responses per respondent) was defined as each food item reported (n=1,120) and the hours per response represented the amount of time to report 1 food item (n=2 hours). The current burden defines the frequency of response as the number of times a manufacturer responds per year (1) with the hours adjusted to represent the total hours for the submission (estimated number of food items per manufacturer [35] × 2 hours per food item). As a result, the number of responses for this collection have changed; however, the total overall burden remains the same (estimated 32 manufacturers × 1 response per year × 35 items per manufacturer × 2 hours per item). The submission of data from the food industry will be strictly voluntary, and based on analytical, calculated, or nutrition facts label sources. FNS is currently researching options for modernizing the Child Nutrition Database, including the data collection, compilation, and dissemination of data. FNS is exploring the use of existing data sets and processes to collect nutrient data for food products marketed to schools. The current process is needed until the new process is finalized and in place.

Affected Public: Business or other for-profit (Manufacturers of food produced for schools).

Estimated Number of Respondents: The total estimated number of respondents is 32.

Estimated Number of Responses per Respondent: The estimated number of responses per respondent is 1. Respondents will provide new and updated data on an annual basis.

Estimated Total Annual Responses: 32.

Estimated Time per Response: The estimated time per response 70.0 hours, which represents 2 hours each for an average of 35 food items, and includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Estimated Total Annual Burden on Respondents: The estimated total annual burden on respondents is 2,240 hours. See the table below for estimated total annual burden for each type of respondent.

Respondent category	Type of respondents (optional)	Instruments	Form	Number of respondents	Frequency of response	Total annual responses	Hours per response	Annual burden (hours)
Business (or other for profit).	Manufacturers of food produced for schools.	CN Database Qualification Report (spreadsheet).	FNS–710	32	1	32	70	2,240.0

Respondent category	Type of respondents (optional)	Instruments	Form	Number of respondents	Frequency of response	Total annual responses	Hours per response	Annual burden (hours)
Total	.....	.....	.....	32	1	32	70	2,240

Pamilyn Miller,

Administrator, Food and Nutrition Service.

[FR Doc. 2020–21491 Filed 9–28–20; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

[Docket Number: RUS–20–WATER–0031]

Information Collection Activity; Comment Request

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the United States Department of Agriculture's Rural Utilities Service (RUS), invites comments on this information collection for which the Agency intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by November 30, 2020.

FOR FURTHER INFORMATION CONTACT: Kimble Brown, Innovation Center, Regulations Management Division, USDA, 1400 Independence Avenue SW, Room 5225–S, Washington, DC 20250–1522. Telephone: (202) 720–6780, Facsimile: (202) 720–8435, email: *Kimble.Brown@usda.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that the Agency is submitting to OMB for extension. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) The accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) Ways to enhance the quality, utility and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to: Kimble Brown, Innovation Center, Regulations Management Division, USDA, 1400 Independence Avenue SW, Room 5225–S, Washington, DC 20250–1522. Telephone: (202) 720–6780, Facsimile: (202) 720–8435, email: *Kimble.Brown@usda.gov.*

Title: 7 CFR part 1776, ''Household Water Well System Grant Program''.

OMB Control Number: 0572–0139.

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

Abstract: The Rural Utilities Service supports the sound development of rural communities and the growth of our economy without endangering the environment. RUS provides financial and technical assistance to help communities bring safe drinking water and sanitary, environmentally sound waste disposal facilities to rural Americans in greatest need.

The Household Water Well System (HWWS) Grant Program makes grants to qualified private non-profit organizations which will help homeowners finance the cost of private wells. As the grant recipient, non-profit organizations will establish a revolving loan fund lending program to provide water well loans to individuals who own or will own private wells in rural areas. The individual loan recipients may use the funds to construct, refurbish, and service their household well systems for an existing home.

The collection of information consists of the materials to file a grant application with the agency, including forms, certifications and required documentation.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 5.12 hours per response.

Respondents: Non-profit institutions.

Estimated Number of Respondents: 6.

Estimated Total Annual Responses: 130.

Estimated Number of Responses per Respondent: 23.

Estimated Total Annual Burden on Respondents: 666 Hours.

Copies of this information collection can be obtained from Lynn Gilbert, Management Analyst, Innovation Center, Regulations Management Division, at (202) 690–2682; 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.

Chad Rupe,

Administrator, Rural Utilities Service.

[FR Doc. 2020–21425 Filed 9–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Small Business Pulse Survey

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on May 19, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau.

Title: Small Business Pulse Survey.

OMB Control Number: 0607–1014.

Form Number(s): None.

Type of Request: Regular Submission, Request for a Revision of a Currently Approved Collection.

Number of Respondents: 738,000 (We anticipate receiving 20,500 responses per week for up to 36 weeks of collection each year).

Average Hours per Response: 6 minutes.

Burden Hours: 73,920 (73,800 + 120 hours for cognitive testing).

Needs and Uses: On April 22, 2020, the Office of Management and Budget authorized clearance of an emergency

Information Collection Request (ICR) to the U.S. Department of Commerce, U.S. Census Bureau to conduct the Small Business Pulse Survey. The emergency clearance enabled the Census Bureau to collect urgently needed data on the experiences of American small businesses as the coronavirus pandemic prompted business and school closures and widespread stay-at-home orders.

The emergency clearance for the Small Business Pulse Survey will expire on October 31, 2020. In anticipation of a continuing need for Small Business Pulse Survey data, the Census Bureau is putting forward this request through normal (non-emergency) clearance channels for the purposes of continuing the survey beyond the emergency clearance expiration.

The continuation of the Small Business Pulse Survey is responsive to stakeholder requests for high frequency data that measure the effect of changing business conditions during the Coronavirus pandemic on small businesses. While the ongoing monthly and quarterly economic indicator programs provide estimates of dollar volume outputs for employer businesses of all size, the Small Business Pulse Survey captures the effects of the pandemic on operations and finances of small, single location employer businesses. As the pandemic continues, the Census Bureau is best poised to collect this information from a large and diverse sample of small businesses.

It is hard to know a priori when a shock will result in economic activity changing at a weekly, bi-weekly, or monthly frequency. Early in the pandemic, federal, state, and local policies were moving quickly so it made sense to have a weekly collection. The problem is that while we are in the moment, we cannot accurately forecast the likelihood of policy action. In addition, we are not able to forecast a change in the underlying cause of policy actions: The effect of the Coronavirus pandemic on the economy. We cannot predict changes in the severity of the pandemic (*e.g.,* will it worsen in flu season?) nor future developments that will alleviate the pandemic (*e.g.,* vaccines or treatments). In a period of such high uncertainty, the impossibility of forecasting these inflection points underscore the benefits of having a weekly survey. For these reasons, the Census Bureau will proceed with a weekly collection.

For the purposes of referencing prior ICRs, we refer to the initial approval by OMB to conduct the Small Business Pulse Survey as ''Phase 1'' (April–June 2020), and the second approved clearance as ''Phase 2'' (August–October, 2020). This ICR requests regular (non-emergency) approval to conduct ''Phase 3'', starting November 2020.

Phase 1 of the Small Business Pulse Survey was launched on April 26, 2020 as an effort to produce and disseminate high-frequency, geographic- and industry-detailed experimental data about the economic conditions of small businesses as they experience the coronavirus pandemic. It is a rapid response endeavor that leverages the resources of the federal statistical system to address emergent data needs. Given the rapidly changing dynamics of this situation for American small businesses, the Small Business Pulse Survey has been successful in meeting an acute need for information on changes in revenues, business closings, employment and hours worked, disruptions to supply chains, and expectations for future operations. In addition, the Small Business Pulse Survey provided important estimates of federal program uptake to key survey stakeholders.

In Phase 1, the Census Bureau worked in collaboration with the Bureau of Economic Analysis (BEA), Bureau of Labor Statistics (BLS), Federal Reserve Board (FRB), International Trade Administration (ITA), Minority Business Development Agency (MBDA), and the Small Business Administration (SBA) to develop questionnaire content. Subsequently, the Census Bureau was approached by the Bureau of Transportation Statistics (BTS), National Telecommunications and Information Administration (NTIA), and the Office of Tax Analysis (OTA) with requests to include additional content to the Small Business Pulse Survey for Phase 2. Understanding that information needs are changing as the pandemic continues, the Census Bureau proposed a revised questionnaire to ensure that the data collected continue to be relevant and broadly useful. Also in Phase 2, the Census Bureau refined its strategies for contacting businesses in a clear and effective manner while motivating their continued participation.

Anticipating that businesses will continue to be affected by the pandemic, and as new developments are expected later this year and into 2021 (including the continuation of government assistance programs that target small businesses; policy shifts including the loosening or tightening of restrictions on businesses or customers; changing weather or seasons on businesses that rely on serving customers outdoors; and new research, vaccines, and/or medications or treatments for the coronavirus), the Census Bureau will move forward with a Phase 3 as proposed in this ICR. The questionnaire used in Phase 2 will continue to be used in this next phase. Acknowledging that circumstances may evolve and information needs on specific topics may intensify, change or diminish over time, the Census Bureau may propose revisions to the questionnaire via the Non-Substantive Change process. These plans also will be made available for public comment through notice in the **Federal Register**.

Phase 3 of the Small Business Pulse Survey will continue in cooperation with other federal agencies to produce near real-time experimental data to understand how changes due to the response to the COVID–19 pandemic are affecting American small businesses and the U.S. economy.

The Phase 3 survey will carry forward questionnaire content from Phase 2. Content has been provided by the Census Bureau, SBA, FRB, MBDA, OTA, BTS, NTIA, and ITA. Domains include business closings, changes in employment and hours, disruptions to supply chain, changes in capacity, finances, and expectations for future operations.

The historical circumstances of the pandemic and uncertainty about how it may or may not continue to affect businesses over the period of Phase 3 drives the need for flexibility in Phase 3 of the SBPS. If required, the Census Bureau would seek approval from OMB through the Non-Substantive Change Review Process to revise, remove or add questionnaire content during this phase to remain relevant in guiding the nation's response and recovery.

All results from the Small Business Pulse Survey will continue to be disseminated as U.S. Census Bureau Experimental Data Products (*https://portal.census.gov/pulse/data/*). This and additional information on the Small Business Pulse Survey are available to the public on *census.gov*.

Affected Public: Business or other for-profit organizations.

Frequency: Small business will be selected once to participate in a 6-minute survey.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Sections 131 and 182.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the

following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–1014.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–21424 Filed 9–28–20; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA515]

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permit; Correction

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

ACTION: Notice; request for comments; correction.

SUMMARY: NMFS is correcting a notice that informed the public that the Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit application contains all of the required information and warrants further consideration. The catch estimates provided in kilograms in Table 1 were incorrect. The table also erroneously included nudibranch in the list of federally managed species.

DATES: Comments must be received on or before October 1, 2020.

ADDRESSES: You may submit written comments by either of the following methods:

- *Email: nmfs.gar.efp@noaa.gov.* Include in the subject line ''Comments on CFRF Beam Trawl Survey EFP.''
- *Mail:* Michael Pentony, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on CFRF Beam Trawl Survey EFP.''

FOR FURTHER INFORMATION CONTACT: Maria Fenton, Fishery Management Specialist, 978–281–9196, *Maria.Fenton@noaa.gov.*

SUPPLEMENTARY INFORMATION: On September 16, 2020, NMFS published a notice that informed the public that the Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit (EFP) application contains all of the required information and warrants further consideration. The catch estimates provided in kilograms in Table 1 were incorrect. The table also erroneously included nudibranch in the list of federally managed species. This correction does not change the scope or impact of the proposed EFP. This correction is necessary to provide interested parties the opportunity to comment on the application with correct and complete information.

Correction

In the **Federal Register** of September 16, 2020, in FR Doc 2020–20389, on page 57835, Table 1 is corrected to read as follows:

TABLE 1—ESTIMATED CATCH OF FEDERALLY REGULATED SPECIES PER SURVEY TRIP, AND TOTAL ESTIMATED CATCH

Common name	Scientific name	Estimated catch per trip	Estimated total survey catch
Little skate	*Leucoraja erinacea*	976.9 lb (443.1 kg)	23,444.8 lb (10,634.4 kg)
Sea scallop	*Placopectin magellanicus*	754.0 lb (342.0 kg)	18,095.5 lb (8,208.0 kg)
Winter skate	*Leucoraja ocellata*	484.4 lb (219.7 kg)	11,624.5 lb (5,272.8 kg)
Leucoraja spp. skates (immature)	*Leucoraja spp.*	132.5 lb (60.1 kg)	3,179.9 lb (1,442.4 kg)
Winter flounder	*Pseudopleuronectes americanus*	108.9 lb (49.4 kg)	2,613.8 lb (1,185.6 kg)
Monkfish	*Lophius americanus*	96.1 lb (43.6 kg)	2,306.9 lb (1,046.4 kg)
Spiny dogfish	*Squalus acanthias*	54.0 lb (24.5 kg)	1,296.3 lb (588.0 kg)
Clearnose skate	*Raja eglanteria*	53.1 lb (24.1 kg)	1,275.2 lb (578.4 kg)
Ocean quahog	*Arctica islandica*	34.0 lb (15.4 kg)	814.8 lb (369.6 kg)
Yellowtail flounder	*Pleuronectes ferruginea*	29.3 lb (13.3 kg)	703.7 lb (319.2 kg)
Barndoor skate	*Raja laevis*	29.1 lb (13.2 kg)	698.4 lb (316.8 kg)
Summer flounder	*Paralichthys dentatus*	29.1 lb (13.2 kg)	698.4 lb (316.8 kg)
Windowpane flounder	*Scophthalmus aquosus*	23.8 lb (10.8 kg)	571.4 lb (259.2 kg)
Silver hake	*Merluccius bilinearis*	15.9 lb (7.2 kg)	381.0 lb (172.8 kg)
Red hake	*Urophycis chuss*	12.1 lb (5.5 kg)	291.0 lb (132.0 kg)
American lobster	*Homarus americanus*	11.5 lb (5.2 kg)	275.1 lb (124.8 kg)
Witch flounder	*Glyptocephalus cynoglossus*	10.6 lb (4.8 kg)	254.0 lb (115.2 kg)
Ocean pout	*Macrozdarces americanus*	9.5 lb (4.3 kg)	227.5 lb (103.2 kg)
Longfin inshore squid	*Doryteuthis pealeii*	5.3 lb (2.4 kg)	127.0 lb (57.6 kg)
Scup	*Stenotomus chrysops*	5.3 lb (2.4 kg)	127.0 lb (57.6 kg)
Butterfish	*Peprilus triacanthus*	1.5 lb (0.7 kg)	37.0 lb (16.8 kg)
Surf clam	*Spisula solidissima*	1.5 lb (0.7 kg)	37.0 lb (16.8 kg)
Black sea bass	*Centropristis striata*	0.4 lb (0.2 kg)	10.6 lb (4.8 kg)
Haddock	*Melanogrammus aeglefinus*	0.4 lb (0.2 kg)	10.6 lb (4.8 kg)

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

Dated: September 23, 2020.

Jennifer M. Wallace,

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

[FR Doc. 2020–21402 Filed 9–28–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA417]

2021 Annual Determination To Implement the Sea Turtle Observer Requirement

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

ACTION: Notice.

SUMMARY: The National Marine Fisheries Service (NMFS) is providing notification that the agency will not identify additional fisheries to observe on the 2021 Annual Determination (AD), pursuant to its authority under the Endangered Species Act (ESA or Act). Through the AD, NMFS identifies U.S. fisheries operating in the Atlantic Ocean, Gulf of Mexico, and Pacific Ocean that will be required to take observers upon NMFS' request. The purpose of observing identified fisheries is to learn more about sea turtle bycatch in a given fishery, evaluate measures to prevent or reduce sea turtle bycatch, and implement the prohibition against sea turtle takes. Fisheries identified on the 2018 and 2020 ADs (see Table 1) remain on the AD for a 5-year period and are required to carry observers upon NMFS' request until December 31, 2022, and September 29, 2025 respectively.

ADDRESSES: Chief, Marine Mammal and Sea Turtle Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Jaclyn Taylor, Office of Protected Resources, 301–427–8402; Ellen Keane, Greater Atlantic Region, 978–282–8476; Dennis Klemm, Southeast Region, 727–824–5312; Dan Lawson, West Coast Region, 206–526–4740; Irene Kelly, Pacific Islands Region, 808–725–5141. Individuals who use a telecommunications device for the hearing impaired may call the Federal Information Relay Service at 800–877–8339 between 8 a.m. and 4 p.m. Eastern time, Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION:

Purpose of the Sea Turtle Observer Requirement

Under the ESA, 16 U.S.C. 1531 *et seq.,* NMFS has the responsibility to implement programs to conserve marine life listed as endangered or threatened. All sea turtles found in U.S. waters are listed as either endangered or threatened under the ESA. Kemp's ridley (*Lepidochelys kempii*), loggerhead (*Caretta caretta;* North Pacific distinct population segment), leatherback (*Dermochelys coriacea*), green (*Chelonia mydas;* Central West Pacific and Central South Pacific distinct population segments), and hawksbill (*Eretmochelys imbricata*) sea turtles are listed as endangered. Loggerhead (*Caretta caretta;* Northwest Atlantic Ocean distinct population segment), green (*Chelonia mydas;* North Atlantic, South Atlantic, Central North Pacific, and East Pacific distinct population segments), and olive ridley (*Lepidochelys olivacea*) sea turtles are listed as threatened, except for breeding colony populations of olive ridleys on the Pacific coast of Mexico, which are listed as endangered. Due to the inability to distinguish between populations of olive ridley turtles away from the nesting beach, NMFS considers these turtles endangered wherever they occur in U.S. waters. While some sea turtle populations have shown signs of recovery, many populations continue to decline.

Bycatch in fishing gear is the primary anthropogenic source of sea turtle injury and mortality in U.S. waters. Section 9 of the ESA prohibits the take (defined to include harassing, harming, pursuing, hunting, shooting, wounding, killing, trapping, capturing, or collecting or attempting to engage in any such conduct), including incidental take, of endangered sea turtles. Pursuant to section 4(d) of the ESA, NMFS has issued regulations extending the prohibition of take, with exceptions, to threatened sea turtles (50 CFR 223.205 and 223.206). Section 11 of the ESA provides for civil and criminal penalties for anyone who violates the Act or a regulation issued to implement the Act. NMFS may grant exceptions to the take prohibitions with an incidental take statement or an incidental take permit issued pursuant to ESA section 7 or 10, respectively. To do so, NMFS must determine that the activity that will result in incidental take is not likely to jeopardize the continued existence of the affected listed species. For some Federal fisheries and most state fisheries, NMFS has not granted an exception for incidental takes of sea turtles primarily because we lack information about fishery-sea turtle interactions.

The most effective way for NMFS to learn more about bycatch in order to implement the take prohibitions and prevent or minimize take is to place observers aboard fishing vessels. In 2007, NMFS issued a regulation (50 CFR 222.402) establishing procedures to annually identify, pursuant to specified criteria and after notice and opportunity for comment, those fisheries in which the agency intends to place observers (72 FR 43176; August 3, 2007). These regulations specify that NMFS may place observers on U.S. fishing vessels, commercial or recreational, operating in U.S. territorial waters, the U.S. exclusive economic zone, or on the high seas, or on vessels that are otherwise subject to the jurisdiction of the United States. Failure to comply with the requirements under this regulation may result in civil or criminal penalties under the ESA.

NMFS will pay the direct costs for vessels to carry the required observers. These include observer salary and insurance costs. NMFS may also evaluate other potential direct costs, should they arise. Once selected, a fishery will be required to carry observers, if requested, for a period of 5 years without further action by NMFS. This will enable NMFS to develop appropriate observer coverage and sampling protocol to investigate whether, how, when, where, and under what conditions sea turtle bycatch is occurring; to evaluate whether existing measures are minimizing or preventing bycatch; and to implement ESA take prohibitions and conserve and recover turtles.

2021 Annual Determination

Pursuant to 50 CFR 222.402(a), NOAA's Assistant Administrator for Fisheries, in consultation with Regional Administrators and Fisheries Science Center Directors, annually identifies fisheries for inclusion on the AD based on the extent to which:

(1) The fishery operates in the same waters and at the same time as sea turtles are present;

(2) The fishery operates at the same time or prior to elevated sea turtle strandings; or

(3) The fishery uses a gear or technique that is known or likely to result in incidental take of sea turtles based on documented or reported takes in the same or similar fisheries; and

(4) NMFS intends to monitor the fishery and anticipates that it will have the funds to do so.

NMFS is providing notification that the agency is not identifying additional fisheries to observe on the 2021 AD, pursuant to its authority under the ESA. NMFS is not identifying additional fisheries at this time given lack of dedicated resources to implement new observer programs or expand existing observer programs to focus on sea turtles. The two fisheries identified on the 2018 AD (see Table 1) will remain on the AD for a 5-year period and are therefore required to carry observers upon NMFS' request until December 31, 2022. The four fisheries identified on the 2020 AD (see Table 1) will remain on the AD for a 5-year period and are therefore required to carry observers upon NMFS' request until September 29, 2025.

TABLE 1—STATE AND FEDERAL COMMERCIAL FISHERIES INCLUDED ON THE 2018 AND 2020 ANNUAL DETERMINATIONS

Fishery	Years eligible to carry observers
Trawl Fisheries	
Southeastern U.S. Atlantic, Gulf of Mexico shrimp trawl	2020–2025
Gulf of Mexico mixed species fish trawl	2020–2025
Gillnet Fisheries	
Mid-Atlantic gillnet	2018–2022
Chesapeake Bay inshore gillnet	2020–2025
Long Island inshore gillnet	2020–2025
Pound Net/Weir/Seine Fisheries	
Gulf of Mexico menhaden purse seine	2018–2022

Dated: September 23, 2020.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2020–21468 Filed 9–28–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; International Design Applications (Hague Agreement)

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of an information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), in accordance with the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0075 (International Design Applications (Hague Agreement)). The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before November 30, 2020.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email: InformationCollection@uspto.gov.* Include ''0651–0075 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Rafael Bacares, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–3276; or by email to *Rafael.Bacares@uspto.gov* with ''0651–0075 comment'' in the subject line. Additional information about this information collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The Patent Law Treaties Implementation Act of 2012 (PLTIA) amends the patent laws to implement the provisions of the Geneva Act of the Hague Agreement Concerning International Registration of Industrial Designs (hereinafter ''Hague Agreement'') in title 1, and the Patent Law Treaty (PLT) in title 2. The Hague Agreement is an international agreement that enables an applicant to file a single international design application which may have the effect of an application for protection for the design(s) in countries and/or intergovernmental organizations that are Parties to the Hague Agreement (the ''Contracting Parties'') designated in the applications. The United States is a Contracting Party to the Hague Agreement, which took effect with respect to the United States on May 13, 2015. The Hague Agreeement is administered by the International Bureau (IB) of World Intellectual Property Organization (WIPO) located in Geneva, Switzerland.

This collection covers information filed by U.S. applicants for the prosecution of international design applications ''indirectly'' through the United States Patent and Trademark Office (USPTO), which will forward the applications to the IB or ''directly'' with the IB. The IB ascertains whether the international design application complies with formal requirements, registers the international design in the International register, and publishes the international registration in the International Designs Bulletin. The international registration contains all of the data of the international application, any reproduction of the industrial design, date of the international registration, number of the international registration, and relevant class of the International Classification.

The IB will provide a copy of the publication of the international registration to each Contracting party designated by the applicant. A designated Contracting Party may perform a substantive examination of the design application. The USPTO will perform a substantive examination for patentability of the international design application, as in the case of regular U.S. design applications. The industrial design or designs will be eligible for protection in all the Contracting Parties designated by applicants.

In addition, this collection covers the various fees related to the processing of International design applications, such as the: (1) Basic fee; (2) standard designation fee(s); (3) individual designation fee(s); and (4) publication fee. Also, an additional fee is required where the applications contain a description that exceeds 100 words, and a transmittal fee is required for

international design applications filed through an office of indirect filing. The fees required by the IB may be paid either directly to the IB or through the USPTO as an office of indirect filing in the amounts specified on the WIPO website. If applicants want to pay the required fees through USPTO as an office of indirect filing, the fees must be paid no later than the date of payment of the transmittal fee. The fees will then be forwarded to the IB.

The Hague Agreement enables applicants from Contracting Parties to obtain protection of their designs with minimal formalities and expenses in multiple countries and/or regions. The Hague Agreement is administered by the IB, which simplifies the management of an industrial design registration. For example, through the IB, applicants can record changes of their representatives or changes in ownership, and renew their international registration.

II. Method of Collection

Most of the items in this information collection can either be submitted electronically through Electronic Filing System-Web (EFS-Web) or mailed to the USPTO.

III. Data

OMB Number: 0651–0075.

Form Numbers: WIPO DM = WIPO Dessins et Modeles (design representations); PTOL = Patent Trademark Office Legal

- WIPO DM/1 (Application for International Registration—entitled Hague Agreement Concerning The International Registration of Industrial Design)
- PTOL–85 Part B (Hague): (Issue Fee to USPTO for an International Design Application)
- WIPO DM/1/I Annex: (Declaration on Inventorship for Purposes of Designation of the United States)
- WIPO DM/1/I Annex: (Substitute Statement in Lieu of a Declaration of Inventorship for the Purpose of Designating the United States)
- WIPO DM/1/III Annex: (Information On Eligibility For Protection)
- WIPO DM/1/IV Annex: (Reduction of United States Individual Designation Fee)
- WIPO DM/1/V Annex: (Supporting Document(s) Concerning Priority Claim To The Korean Intellectual Property Office (KIPO))
- PTO–1595: (Assignment Cover Sheet)

Type of Review: Revision of a currently approved information collection.

Affected Public: Private sector; individuals and households.

Estimated Number of Respondents: 1,406 respondents per year.

Estimated Number of Responses: 1,706 responses per year.

Estimated Time per Response: The USPTO estimates that it will take the public between 15 minutes (0.25 hours) and 6 hours to complete a response, depending upon the complexity of the situation. This includes the time to gather the necessary information, prepare the appropriate documents, and submit the completed request to the USPTO.

Estimated Total Response Burden Hours: 2,301 hours.

Estimated Total Annual Respondent (Hourly) Cost Burden: $1,279,400.

TABLE 1—TOTAL ESTIMATED HOURLY BURDEN FOR PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (a)	Estimated time for response (hours) (b)	Estimated annual burden hours (a) × (b) = (c)	Rate [1] ($/hour) (d)	Estimated annual burden (c) × (d) = (e)
1	Application for International Registration (WIPO DM/1).	151	151	6	906	$400	$362,400
2	Claim and Reproductions (Drawings)	Same as line 1	151	4	604	400	241,600
3	Transmittal Letter	Same as line 1	5	2	10	400	4,000
4	Appointment of a Representative (WIPO) (WIPO DM/7) filed indirectly through the USPTO	Same as line 1	62	0.25 (15 minutes)	16	400	6,400
5	Petition to Excuse a Failure to Comply with a Time Limit.	Same as line 1	1	4	4	400	1,600
6	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16.	Same as line 1	1	4	4	400	1,600
7	Petition to Review a Filing Date	Same as line 1	2	4	8	400	3,200
8	Fee Authorization	Same as line 1	10	.25 (15 minutes)	3	400	1,200
9	Petitions to the Commissioner	Same as line 1	4	4	16	400	6,400
10	Declaration on Inventorship for Purposes of Designation of the United States (WIPO DM/1/I Annex) filed indirectly through the USPTO.	Same as line 1	30	0.50 (30 minutes)	15	400	6,000
11	Substitute Statement in Lieu of a Declaration of Inventorship for the Purposes of Designating the United States (WIPO DM/1/I Annex) filed indirectly through the USPTO.	Same as line 1	2	0.50 (30 minutes)	1	400	400
12	Information On Eligibility For Protection (WIPO DM/1/III Annex) filed indirectly through the USPTO.	Same as line 1	3	1	3	400	1,200
13	Supporting Document(s) Concerning Priority Claim To The Korean Intellectual Property Office (KIPO) (WIPO DM/1/V (Annex) filed indirectly through the USPTO.	Same as line 1	5	.5 (30 minutes)	3	400	1,200
14	Issue Fee to USPTO for an International Design Application.	1,219	1,219	.5 (30 minutes)	610	400	244,000
Totals		1,370	1,646		2,203		881,200

[1] 2019 Report of the Economic Survey from the Law Practice Management Committee of the American Intellectual Property Law Association (AIPLA). *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey*. The hourly rate of $400.

TABLE 2—TOTAL ESTIMATED HOURLY BURDEN FOR INDIVIDUAL AND HOUSEHOLD RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (a)	Estimated time for response (hours) (b)	Estimated annual burden hours (a) × (b) = (c)	Rate [2] ($/hour) (d)	Estimated annual respondent cost burden (c) × (d) = (e)
1	Application for International Registration (Micro-Entity).	6	6	6	36	$400	$14,400
2	Claim and Reproductions (Drawings).	Same as line 1	6	4	24	400	9,600
3	Transmittal Letter	Same as line 1	1	2	2	400	800
4	Appointment of a Representative (WIPO DM/7) filed indirectly through the USPTO.	Same as line 1	2	0.25 (15 minutes)	1	400	400
5	Petition to Excuse a Failure to Comply with a Time Limit.	Same as line 1	1	4	4	400	1,600
6	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16.	Same as line 1	1	4	4	400	1,600
7	Petition to Review a Filing Date	Same as line 1	1	4	4	400	1,600
8	Fee Authorization	Same as line 1	1	0.25 (15 minutes)	1	400	400
9	Petitions to the Commissioner	Same as line 1	1	0.25 (15 minutes)	1	400	400
11	Declaration on Inventorship for Purposes of Designation of the United States (WIPO DM/1/I Annex) filed indirectly through the USPTO.	Same as line 1	3	0.50 (30 minutes)	2	400	800
12	Substitute Statement in Lieu of a Declaration of Inventorship for the Purposes of Designating the United States (WIPO DM/1/I Annex) filed indirectly through the USPTO.	Same as line 1	1	0.50 (30 minutes)	1	400	400
14	Issue Fee to UPSTO for an International Design Application.	30	30	0.50 (30 minutes)	15	400	6,000
15	Reduction of United States Individual Designation Fee (WIPO DM/1/IV (Annex) filed indirectly through the USPTO.	Same as line 1	6	0.50 (30 minutes)	3	400	1,200
Totals		36	60		98		39,200

Estimated Total Annual (Non-hour) Respondent Cost Burden: $3,389,280.

There are no maintenance, operation, capital start-up, or recordkeeping costs associated with this information collection. However, this information collection does have annual (non-hour) costs in the form of filing fees, drawing costs, and postage fees.

The total estimated filing fee costs for this information collection is $3,376,872, detailed in Table 3 below.

TABLE 3—FILING FEES

Item No.	Item	Estimated annual response (a)	Filing fee Amount (b)	Total filing fee cost (a) × (b) = (c)
1	Application for International Registration (electronic)—Average Fee per registration to WIPO (USPTO collects and transmits it to WIPO).	157	$2,131	$334,567
1	Application for International Registration (electronic)—Designation Fee (first part) for the U.S. (collecting for WIPO) (regular entity).	10	960	9,600
1	Application for International Registration (electronic)—Designation Fee (first part) for the U.S. (collecting for WIPO) (small entity).	11	480	5,280
1	Application for International Registration (electronic)—Designation Fee (first part) for the U.S. (collecting for WIPO) (micro entity).	6	240	1,440
1	Application for International Registration submitted to WIPO—Designation Fee (first part) for the U.S. (Transmitting to the USPTO by WIPO) (regular entity).	1,651	960	1,584,960
1	Application for International Registration submitted to WIPO—Designation Fee (first part) for the U.S. (Transmitting to the USPTO by WIPO) (small entity).	527	480	252,960
1	Application for International Registration submitted to WIPO—Designation Fee (first part) for the U.S. (Transmitting to the USPTO by WIPO) (micro entity).	138	240	33,120
1	Application for International Registration (electronic)—Transmittal Fee (set by and collected by USPTO) (regular entity).	89	120	10,680
1	Application for International Registration (electronic)—Transmittal Fee (set by and collected by USPTO) (small entity).	62	60	3,720
1	Application for International Registration (electronic)—Transmittal Fee (set by and collected by USPTO) (micro entity).	6	30	180

[2] 2019 Report of the Economic Survey from the Law Practice Management Committee of the American Intellectual Property Law Association (AIPLA). *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey* The hourly rate of $400.

TABLE 3—FILING FEES—Continued

Item No.	Item	Estimated annual response (a)	Filing fee Amount (b)	Total filing fee cost (a) × (b) = (c)
5	Petition to Excuse a Failure to Comply with a Time Limit (regular entity)	1	2,000	2,000
5	Petition to Excuse a Failure to Comply with a Time Limit (small entity)	1	1,000	1,000
5	Petition to Excuse a Failure to Comply with a Time Limit (micro entity)	1	500	500
6	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16 (regular entity)	1	180	180
6	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16 (small entity)	1	90	90
6	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16 (micro entity)	1	45	45
7	Petition to Review a Filing Date (regular entity)	1	400	400
7	Petition to Review a Filing Date (small entity)	1	200	200
7	Petition to Review a Filing Date (micro entity)	1	100	100
9	Petitions to Commissioner (regular entity)	3	400	1,200
9	Petitions to Commissioner (small entity)	1	200	200
9	Petitions to Commissioner (micro entity)	1	100	100
14	Issue Fee to UPSTO for an International Design Application (regular entity)	972	700	680,400
14	Issue Fee to UPSTO for an International Design Application (small entity)	247	350	86,450
14	Issue Fee to UPSTO for an International Design Application (micro entity)	30	175	5,250
14	Application for International Registration submitted to WIPO—Issue Fee (Second part) for the U.S. (Transmitting to the USPTO by WIPO) (regular entity).	420	700	294,000
14	Application for International Registration submitted to WIPO—Issue Fee (Second part) for the U.S. (Transmitting to the USPTO by WIPO) (small entity).	155	350	54,250
14	Application for International Registration submitted to WIPO—Issue Fee (Second part) for the U.S. (Transmitting to the USPTO by WIPO) (micro-entity).	80	175	14,000
Total				3,376,872

The USPTO estimates that around 20% (31) of the respondents that file international design applications through the USPTO as an office of indirect filing designate the United States for design protection. The costs for preparing the drawings associated with these applications are estimated to be $400 per application. Overall the costs associated with submitting these drawing are estimated to be $12,400.

Although the USPTO prefers that the items in this information collection be submitted electronically, the items may be submitted by mail through the United States Postal Service (USPS). The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail 2-day flat rate legal envelope, will be $8.05. The USPTO estimates that 1 paper submission will be mailed annually.

The USPTO estimates that the total annual (non-hour) respondent cost burden for this information collection in the forms of filling fees, drawing costs, and postage costs is estimated to be approximately $3,389,280 per year ($3,376,872 in filling fees, $12,400 in drawing costs, and $8 in postage costs).

Respondents's Obligation: Required to obtain or retain benefits.

IV. Request for Comments

The USPTO is soliciting public comments to:

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

(b) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personal identifying information in a comment, be aware that the entire comment—including personal identifying information—may be made publicly available at any time. While you may ask in your comment to withhold personal identifying information from public view, USPTO cannot guarantee that it will be able to do so.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2020–21553 Filed 9–28–20; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Initial Patent Applications

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), in accordance with the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0032 (Initial Patent Applications). The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before November 30, 2020.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email: InformationCollection@uspto.gov.* Include ''0651–0032 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the attention of Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–7728; or by email to *raul.tamayo@uspto.gov.* Additional information about this information collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The USPTO is required by Title 35 of the United States Code, including 35 U.S.C. 131, to examine applications for patents. The USPTO administers the patent statutes through various rules in Chapter 37 of the Code of Federal Regulations, including 37 CFR 1.16 through 1.84. Each patent applicant must provide sufficient information to allow the USPTO to properly examine the application to determine whether it meets the criteria set forth in the patent statutes and regulations for issuance as a patent. For example, the patent statutes and regulations require that an application for patent include the following information:

(1) A specification containing a description of the invention and at least one claim defining the property right sought by the applicant;

(2) A drawing(s) or photograph(s), where necessary, for an understanding of the invention;

(3) An oath or declaration signed by the applicant; and

(4) A filing fee.

The following types of patent applications are covered under the present information collection:

(1) New original utility, plant, design, and provisional applications;

(2) Continuation/divisional applications of international applications;

(3) Continued prosecution applications (design); and

(4) Continuation, divisional, and continuation-in-part applications of utility, plant, and design applications.

In addition, this information collection covers petitions to accept an unintentionally delayed priority or benefit claim, petitions under 37 CFR 1.47 (pre-Leahy-Smith America Invents Act (AIA)) to accept a filing by other than all of the inventors or a person not the inventor, petitions under 37 CFR 1.6(g) to accord an application under 37 CFR 1.495(b) a receipt date, and papers filed under 37 CFR 1.41(c), 1.41(a)(2) (pre-AIA), 1.48(d), 1.53(c)(2), and 1.53(c)(2) (pre-Patent Law Treaty (PLT) (AIA)) (the particular items covered under this information collection are identified in more detail at Table 1 below).

Most applications for a patent, including new utility, design, and provisional applications, can be submitted through the USPTO patent electronic filing systems (EFS-Web or Patent Center). EFS-Web and Patent Center are the USPTO's systems for electronic filing of patent correspondence and are accessible via the internet on the USPTO website. The Legal Framework for Patent Electronic System is available at *https://www.uspto.gov/patents-application-process/filing-online/legal-framework-efs-web.*

The forms in this information collection include: (1) Versions of the inventor's oath and declaration forms that were created to comply with the changes resulting from the AIA, *e.g.,* forms AIA/01, AIA/02, etc., (2) pre-AIA versions of the oath and declaration forms, *e.g.,* forms SB/01, SB/02, etc., and (3) foreign language translations of the oath and declaration forms, *e.g.,* forms AIA/01CN, SB/02CN, etc. Items in this information collection that do not have forms associated with them include the petitions and the papers filed under 37 CFR 1.41(c), 1.41(a)(2) (pre-AIA), 1.48(d), 1.53(c)(2), and 1.53(c)(2) (pre-PLT (AIA)).

II. Method of Collection

As set forth in the Legal Framework for Patent Electronic System, available at *https://www.uspto.gov/patents-application-process/filing-online/legal-framework-efs-web,* most of the items in this information collection can be submitted through EFS-Web. The USPTO also will accept submissions by mail, facsimile (except that in accordance with 37 CFR 1.6(d), the items covered under this information collection that may be submitted by facsimile are limited to the petitions and the papers filed under 37 CFR 1.41(c), 1.41(a)(2) (pre-AIA), 1.48(d), 1.53(c)(2), and 1.53(c)(2) (pre-PLT (AIA))), or hand delivery to the USPTO.

III. Data

OMB Number: 0651–0032.

Form Number(s): (AIA= American Invents; SB = Specimen Book).

- *PTO/SB/06 (Patent Application Fee Determination Record (Substitute for Form PTO–875)*
- *PTO/SB/07 (Multiple Dependent Claim Fee Calculation Sheet (Substitute for Form PTO–1360; For Use with Form PTO/SB/06)*
- *PTO/SB/17 (Fee Transmittal Form)*
- *PTO/AIA/15 (Utility Patent Application Transmittal)*
- *PTO/AIA/18 (Design Patent Application Transmittal)*
- *PTO/AIA/19 (Plant Patent Application Transmittal)*
- *PTO/SB/01 (Declaration for Utility or Design Patent Application (37 CFR 1.63))*
- *PTO/SB/AIA/01 (Declaration (37 CFR 1.63) for Utility or Design Patent Application using an Application Data Sheet (37 CFR 1.76))*
- *PTO/AIA/01CN (Chinese Language Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76))*
- *PTO/AIA/01DE (German Language Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76))*
- *PTO/AIA/01ES (Spanish Language Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76))*
- *PTO/AIA/01FR (French Language Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76))*
- *PTO/AIA/01IT (Italian Language Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76))*
- *PTO/AIA/01JP (Japanese Language Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76))*
- *PTO/AIA/01KR (Korean Language Declaration (37 CFR 1.63) for Utility or Design Application Using An Application Data Sheet (37 CFR 1.76))*
- *PTOAIA/01NL (Dutch Language Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76))*
- *PTO/AIA/01RU (Russian Language Declaration (37 CFR 1.63) for Utility or Design Application Using An Application Data Sheet (37 CFR 1.76))*
- *PTO/AIA/01SE (Swedish Language Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76))*

- *PTO/SB/AIA08 (Declaration for Utility or Design Patent Application (37 CFR 1.63))*
- *PTO/SB/AIA10 (Declaration (Supplemental Sheet for PTO/SB/AIA08, Declaration (Additional Inventors) and Supplemental Priority Data Sheet)*
- *PTO/SB/02 (Declaration (Supplemental Sheet for PTO/SB/AIA08 Declaration (Additional Inventors) and Supplemental Priority Data Sheet)*
- *PTO/SB/02A (Declaration—Additional Inventors—Supplemental Sheet)*
- *PTO/SB/AIA02 (Substitute Statement in Lieu of an Oath or Declaration for Utility or Design Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/AIA11 (Substitute Statement Supplemental Sheet (supplemental sheet for PTO/SB/AIA02))*
- *PTO/SB/02B (Declaration—Supplemental Priority Data Sheet)*
- *PTO/SB/02CN (Declaration (Additional Inventors) and Supplemental Priority Data Sheets [2 pages] (Chinese Language Declaration for Additional Inventors)*
- *PTO/AIA/02CN (Chinese (Simplified) Language Substitute Statement in Lieu of an Oath or Declaration for Utility or Design Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/02DE (Declaration (Additional Inventors) and Supplemental Priority Data Sheets [2 pages] (German Language Declaration for Additional Inventors))*
- *PTO/AIA/02DE (German Language Substitute Statement in Lieu of an Oath or Declaration for Utility or Design Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/02ES (Declaration (Additional Inventors) and Supplemental Priority Data Sheet [2 pages] (Spanish Language Declaration for Additional Inventors))*
- *PTO/AIA/02ES (Spanish Language Substitute Statement in Lieu of an Oath or Declaration for Utility or Design Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/02FR (Declaration (Additional Inventors) and Supplemental Priority Data Sheet [2 pages] (French Language Declaration for Additional Inventors))*
- *PTO/AIA/02FR (French Language Substitute Statement in Lieu of an Oath or Declaration for Utility or Design Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/02IT (Declaration (Additional Inventors) and Supplemental Priority Data Sheet [2 pages] (Italian Language Declaration for Additional Inventors))*
- *PTO/AIA/02IT (Italian Language Substitute Statement in Lieu of an Oath or Declaration for Utility or Design Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/02JP (Japanese Language Substitute Statement in Lieu of an Oath or Declaration for Utility or Design Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/02KR (Declaration (Additional Inventors) and Supplemental Priority Data Sheet [2 pages] (Korean Language Declaration for Additional Inventors))*
- *PTO/AIA/02KR (Korean Language Substitute Statement in Lieu of an Oath or Declaration for Utility or Design Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/02NL (Declaration (Additional Inventors) and Supplemental Priority Data Sheet [2 pages] (Dutch Language Declaration for Additional Inventors))*
- *PTO/AIA/02NL (Dutch Language Substitute Statement in Lieu of an Oath or Declaration for Utility or Design Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/02RU (Declaration (Additional Inventors) and Supplemental Priority Data Sheet [2 pages] (Russian Language Declaration for Additional Inventors))*
- *PTO/AIA/02RU (Russian Language Substitute Statement in Lieu of an Oath or Declaration for Utility or Design Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/02SE (Declaration (Additional Inventors) and Supplemental Priority Data Sheet [2 pages] (Swedish Language Declaration for Additional Inventors))*
- *PTO/AIA/02SE (Swedish Language Substitute Statement in Lieu of an Oath or Declaration for Utility or Design Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/02LR (Declaration Supplemental Sheet for Legal Representatives (35 U.S.C. 117) on Behalf of a Deceased or Incapacitated Inventor)*
- *PTO/SB/03 (Plant Patent Application (35 U.S. C. 161) Declaration (37 CFR 1.63))*
- *PTO/SB/AIA03 (Declaration (37 CFR 1.63) for Plant Patent Application using an Application Data Sheet (37 CFR 1.76))*
- *PTO/SB/AIA09 (Plant Patent Application (35 U.S.C. 161) Declaration (37 CFR 1.162))*
- *PTO/SB/04 (Supplemental Declaration for Utility or Design Patent Application (37 CFR 1.67))*
- *PTO/SB/AIA04 (Substitute Statement in Lieu of an Oath or Declaration for Plant Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64))*
- *PTO/SB/AIA11 (Substitute Statement Supplemental Sheet (Supplemental Sheet for PTO/SB/AIA04))*
- *PTO/SB/AIA10 (Declaration (Supplemental Sheet for PTO/SB/AIA09))*
- *PTO/SB/101 through 110 (Declaration and Power of Attorney for Patent Application (in various foreign languages))*
- *PTO/SB/01A (Declaration (37 CFR 1.63) for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76))*
- *PTO/SB/03A (Declaration (37 CFR 1.63) for Plant Application Using an Application Data Sheet (37 CFR 1.76))*
- *PTO/SB/14 EFS-Web (Application Data Sheet Form)*
- *PTO/AIA/14 (Application Data Sheet 37 CFR 1.76)*
- *EFS-Web (Electronic New Utility Patent Application and Electronic New Design Application)*
- *PTO/SB/29 (For Design Applications Only: Continued Prosecution Application (CPA) Request Transmittal)*
- *PTO/SB/29A (For Design Applications Only: Receipt for Facsimile Transmitted CPA)*
- *PTO/SB/16 (Provisional Application for Patent Cover Sheet—Paper and Electronic Filing)*

Type of Review: Revision of a currently approved information collection.

Affected Public: Private sector; individuals or households.

Estimated Number of Respondents: 633,209 respondents per year.

Estimated Number of Responses: 633,209 responses per year.

Estimated Time per Response: The USPTO estimates that it takes the respondents between 45 minutes to 40 hours (.75 to 40 hours) to complete a response, depending on the complexity of the particular item. This includes the time to gather the necessary information, create the documents, and submit the completed item to the USPTO.

Estimated Total Annual Respondent Burden Hours: 15,598,813 hours.

Estimated Total Annual Respondent Hourly Cost Burden: $6,239,525,200.

TABLE 1—TOTAL HOURLY BURDEN FOR PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (year) (a)	Estimated time for response (hours) (b)	Estimated annual burden (hour/year) (a) × (b) = c	Rate [1] ($/hour) (d)	Estimated annual burden (c) × (d) = e
1	Original New Utility Applications	283,425	283,425	40	11,337,000	$400	$4,534,800,000
2	Original New Plant Applications	1,333	1,333	9	11,997	400	4,798,800
3	Original New Design Applications	38,425	38,425	7	268,975	400	107,590,000
4	Continuation/Divisional of an International Application.	10,055	10,055	4	40,220	400	16,088,000
5	Utility Continuation/Divisional Applications.	94,820	94,820	4	379,280	400	151,712,000
6	Plant Continuation/Divisional Application.	12	12	3	36	400	14,400
7	Design Continuation/Divisional Application.	5,238	5,238	1	5,238	400	2,095,200
8	Continued Prosecution Applications—Design (Request Transmittal and Receipt).	1,272	1,272	1	1,272	400	508,800
9	Utility Continuation-in-Part Applications.	10,831	10,831	20	216,620	400	86,648,000
10	Design Continuation-in-Part Applications.	1,078	1,078	3	3,234	400	1,293,600
11	Provisional Application for Patent Cover Sheet.	158,174	158,174	18	2,847,132	400	1,138,852,800
12	Petition to Accept Unintentionally Delay Priority/Benefit Claim.	1,978	1,978	1	1,978	400	791,200
13	Petition Under 37 CFR 1.47 (pre-AIA) to Accept a Filing by Other Than all the Inventors or a Person not the Inventor.	39	39	1	39	400	15,600
14	Papers filed under the following: 1.41(c) or 1.41(a)(2) (pre-AIA)—to supply the name or names of the inventor or inventors after the filing date without a cover sheet as prescribed by 37 CFR 1.51(c)(1) in a provisional application. 1.48(d)—for correction of inventorship in a provisional application.. 1.53 (c)(2) or 1.53(c)(2) (pre-PLT (AIA))—to convert a nonprovisional application filed under 1.53(b) to a provisional application filed under 1.53(c).	7,026	7,026	.75	5,270	400	2,108,000
Total		613,706	613,706		15,118,291		6,047,316,400

[1] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.* The USPTO uses the mean rate for attorneys in private firms which is $400 per hour.

TABLE 2—TOTAL HOURLY BURDEN FOR INDIVIDUALS AND HOUSEHOLDS RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (year) (a)	Estimated time for response (hours) (b)	Estimated annual burden (hour/year) (a) × (b) = c	Rate [2] ($/hour) (d)	Estimated annual burden (c) × (d) = e
1	Original New Utility Applications	9,009	9,009	40	360,360	$400	$144,144,000
2	Original New Plant Applications	42	42	9	378	400	151,200
3	Original New Design Applications	1,221	1,221	7	8,547	400	3,418,800
4	Continuation/Divisional of an International Application.	320	320	4	1,280	400	512,000
5	Utility Continuation/Divisional Applications	3,013	3,013	4	12,052	400	4,820,800
6	Design Continuation/Divisional Application	166	166	1	166	400	66,400
8	Continued Prosecution Applications—Design (Request Transmittal and Receipt).	40	40	1	40	400	16,000
9	Utility Continuation-in-Part Applications	344	344	20	6,880	400	2,752,000
10	Design Continuation-in-Part Applications	34	34	3	102	400	40,800
11	Provisional Application for Patent Cover Sheet.	5,027	5,027	18	90,486	400	36,194,400
12	Petition to Accept Unintentionally Delay Priority/Benefit Claim.	63	63	1	63	400	25,200
13	Petition Under 37 CFR 1.47 (pre-AIA) to Accept a Filing by Other Than all the Inventors or a Person not the Inventor.	1	1	1	1	400	400
14	Papers filed under the following:						

TABLE 2—TOTAL HOURLY BURDEN FOR INDIVIDUALS AND HOUSEHOLDS RESPONDENTS—Continued

Item No.	Item	Estimated annual respondents	Estimated annual responses (year) (a)	Estimated time for response (hours) (b)	Estimated annual burden (hour/year) (a) × (b) = c	Rate [2] ($/hour) (d)	Estimated annual burden (c) × (d) = e
	1.41(c) or 1.41(a)(2) (pre-AIA)—to supply the name or names of the inventor or inventors after the filing date without a cover sheet as prescribed by 37 CFR 1.51(c)(1) in a provisional application.	223	223	.75	167	400	66,800
	1.48(d)—for correction of inventorship in a provisional application. 1.53(c)(2) or 1.53(c)(2) (pre-PLT (AIA))—to convert a nonprovisional application filed under 1.53(b) to a provisional application filed under 1.53(c).						
Total		19,503	19,503		480,522		192,208,800

[2] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.* The USPTO uses the mean rate for attorneys in private firms which is $400 per hour.

Estimated Total Annual Non-Hour Respondent Cost Burden: $1,205,915,848. There are no maintenance, operation, capital start-up, or recordkeeping costs associated with this information collection. However, this information collection does have annual (non-hour) costs in the form of postage, drawing costs, and filing fees.

Although the USPTO prefers that the items in this information collection be submitted electronically, the items may be submitted by mail through the United States Postal Service (USPS). The USPTO estimates that the average cost for sending a patent application by Priority Mail Express® 1 day legal envelope will be $26.50 and that up to 14,440 applications may be mailed to the USPTO, resulting in $382,660 in postage costs.

The USPTO estimates that the petitions and other papers covered under this information collection, if submitted by mail, will be sent by first-class mail (2 Day Priority Express for a flat rate legal envelope) at an average postage rate of $8.05. The USPTO estimates that up to 301 petitions and other papers may be mailed per year, thus resulting in $2,423 in first-class mailing costs.

Patent applicants can submit drawings with the applications covered under this information collection. As a basis for estimating the drawing costs, the USPTO expects that all applicants will have their drawings prepared by patent illustration firms.

Estimates for the drawings can vary greatly, depending on the number of figures that need to be produced, the total number of pages for the drawings, and the complexity of the drawings. Because there are many variables involved, the USPTO is using the average of the cost ranges found for the application drawings to derive the estimated cost per sheet that is then used to calculate the total drawing costs.

The USPTO estimates that total drawing cost is $601,432,030. The break-down of costs for utility, design, plant, and provisional drawings is broken down in table 3 below.

TABLE 3—DRAWING COST TO RESPONDENTS

Item No.	Item	Estimated annual responses (a)	Estimated drawing costs amount ($) (b)	Drawing cost totals (a) × (b) = c
1	Utility Application Drawings	292,434	$1,150	$336,299,100
3	Design Applications Drawings	39,646	1,930	76,516,780
2	Plant Application Drawings (Photographs)	1,375	680	935,000
15	Provisional Application Drawings	163,201	1,150	187,681,150
Total Drawing Costs.		496,656		601,432,030

In this information collection, there is also an annual (non-hour) cost burden in the way of filing fees. The total estimated filing cost for this information collection is $604,098,735 and is detailed in table 4 below.

TABLE 4—TOTAL NON-HOUR RESPONDENT COST

Item No.	Item	Estimated annual responses (a)	Amount (b)	Totals (a) × (b) = c
1, 4	Basic Filing fee—Utility (Paper Filing—Also Requires Non-Electronic Filing Fee Under 1.16(t)) (large entity).	233,866	$320	$74,837,120
1, 4	Basic Filing fee—Utility (Paper Filing—Also Requires Non-Electronic Filing Fee Under 1.16(t)) (small entity).	749	160	119,840
1, 4	Basic Filing fee—Utility (Paper Filing—Also Requires Non-Electronic Filing Fee Under 1.16(t)) (micro entity).	15,940	80	1,275,200
1, 4	Utility Application Size Fee—for Each Additional 50 Sheets That Exceeds 100 Sheets (large entity).	7,242	420	3,041,640
1, 4	Utility Application Size Fee—for Each Additional 50 Sheets That Exceeds 100 Sheets (small entity).	3,885	210	815,850
1, 4	Utility Application Size Fee—for Each Additional 50 Sheets That Exceeds 100 Sheets (micro entity).	108	105	11,340
1, 4	Utility Search Fee (large entity)	233,861	700	163,702,700
1, 4	Utility Search Fee (small entity)	79,942	$350	$27,979,700
1, 4	Utility Search Fee (micro entity)	15,718	175	2,750,650
1, 4	Utility Examination Fee (large entity)	233,362	800	186,689,600
1, 4	Utility Examination Fee (small entity)	79,842	400	31,936,800
1, 4	Utility Examination Fee (micro entity)	15,696	200	3,139,200
1,2 4–6, and 9	Each Independent Claim in Excess of Three (large entity)	31,900	480	15,312,000
1,2 4–6, and 9	Each Independent Claim in Excess of Three (small entity)	11,200	240	2,688,000
1,2 4–6, and 9	Each Independent Claim in Excess of Three (micro entity)	1,100	120	132,000
1,2 4–6, and 9	Each Claim in Excess of 20 (large entity)	57,300	100	5,730,000
1,2 4–6, and 9	Each Claim in Excess of 20 (small entity)	25,800	50	1,290,000
1,2 4–6, and 9	Each Claim in Excess of 20 (micro entity)	1700	25	42,500
1,2 4–6, and 9	Multiple Dependent Claim (large entity)	1144	860	983,840
1,2 4–6, and 9	Multiple Dependent Claim (small entity)	750	430	322,500
1,2 4–6, and 9	Multiple Dependent Claim (micro entity)	146	215	31,390
2, 5	Plant Examination Fee (micro entity)	10	165	1,650
3, 6	Basic Filing Fee—Design (large entity)	18,613	220	4,094,860
3, 6	Basic Filing Fee—Design (small entity)	17,665	110	1,943,150
3, 6	Basic Filing Fee—Design (micro entity)	5,634	55	309,870
3, 6	Basic Filing Fee—Design (CPA) (large entity)	534	220	117,480
3, 6	Basic Filing Fee—Design (CPA) (small entity)	455	110	50,050
3, 6	Basic Filing Fee—Design (CPA) (micro entity)	153	55	8,415
3, 6	Design Application Size Fee—for Each Additional 50 Sheets That Exceeds 100 Sheets (large entity).	70	420	29,400
3, 6	Design Application Size Fee—for Each Additional 50 Sheets That Exceeds 100 Sheets (small entity).	38	210	7,980
3, 6	Design Application Size Fee—for Each Additional 50 Sheets That Exceeds 100 Sheets (micro entity).	4	105	420
3, 6	Design Search Fee (large entity)	19,107	160	3,057,120
3, 6	Design Search Fee (small entity)	17,962	80	1,436,960
3, 6	Design Search Fee (micro entity)	5,607	40	224,280
3, 6	Design Examination Fee (large entity)	19,082	640	12,212,480
3, 6	Design Examination Fee (small entity)	17,922	320	5,735,040
3, 6	Design Examination Fee (micro entity)	5,596	160	895,360
15	Provisional Application Size Fee—for Each Additional 50 Sheets That Exceeds 100 Sheets (large entity).	2,621	420	1,100,820
15	Provisional Application Size Fee—for Each Additional 50 Sheets That Exceeds 100 Sheets (small entity).	3,264	210	685,440
15	Provisional Application Size Fee—for Each Additional 50 Sheets That Exceeds 100 Sheets (micro entity).	107	105	11,235
15	Provisional Application Filing Fee (large entity)	63,168	300	18,950,400
15	Provisional Application Filing Fee (small entity)	71,968	150	10,795,200
15	Provisional Application Filing Fee (micro entity)	30,253	75	2,268,975
16	Surcharge—Late Filing Fee, Search Fee, Examination Fee, Inventor's Oath or Declaration, or Application Filed Without at least One Claim or by Reference (large entity).	80,603	160	12,896,480
16	Surcharge—Late Filing Fee, Search Fee, Examination Fee, Inventor's Oath or Declaration, or Application Filed Without at least One Claim or by Reference (small entity).	36,442	80	2,915,360
16	Surcharge—Late Filing Fee, Search Fee, Examination Fee, Inventor's Oath or Declaration, or Application Filed Without at least One Claim or by Reference (micro entity).	4,403	40	176,120
16	Surcharge—Late Provisional Filing Fee or Cover Sheet (large entity)	1,798	60	107,880
16	Surcharge—Late Provisional Filing Fee or Cover Sheet (small entity)	2,849	30	85,470
16	Surcharge—Late Provisional Filing Fee or Cover Sheet (micro entity)	3,308	15	49,620
17	Petition Under 37 CFR 1.47 (pre-AIA) to Accept a Filing by Other Than all the Inventors or a Person not the Inventor (micro entity).	1	50	50
17	Electronic Petition Under 37 CFR 1.47 (pre-AIA) to Accept a Filing by Other Than the Inventors or a Person not the Inventor (large entity).	37	200	7,400
17	Electronic Petition Under 37 CFR 1.47 (pre-AIA) to Accept a Filing by Other Than the Inventors or a Person not the Inventor (small entity).	1	100	100
17	Electronic Petition Under 37 CFR 1.47 (pre-AIA) to Accept a Filing by Other Than the Inventors or a Person not the Inventor (micro entity).	1	50	50
Total Filing Fee				604,098,735

Respondent's Obligation: Required to obtain or retain benefits.

IV. Request for Comments

The USPTO is soliciting public comments to:

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

(b) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personal identifying information in a comment, be aware that the entire comment— including personal identifying information—may be made publicly available at any time. While you may ask in your comment to withhold personal identifying information from public view, USPTO cannot guarantee that it will be able to do so.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2020–21519 Filed 9–28–20; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Trademark Submissions Regarding Correspondence and Regarding Attorney Representation

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of an information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), in accordance with the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0056 (Trademark Submissions Regarding Correspondence and Regarding Attorney Representation). The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before November 30, 2020.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email: InformationCollection@uspto.gov.* Include ''0651–0056 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Catherine Cain, Attorney Advisor, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–8946; or by email to *catherine.cain@uspto.gov* with ''0651–0056 comment'' in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States Patent and Trademark Office (USPTO) administers the Trademark Act, 15 U.S.C. 1051 *et seq.,* which provides for the Federal registration of trademarks, service marks, collective trademarks and service marks, collective membership marks, and certification marks. Individuals and businesses that use or intend to use such marks in commerce may file an application to register their marks with the USPTO.

Such individuals and business may also submit various communications to the USPTO regarding their pending applications or registered trademarks, including providing additional information needed to process a pending application, filing amendments to the applications, or filing the papers necessary to keep a trademark in force. In the majority of circumstances, individuals and business retain attorneys to handle these matters. As such, these parties may also submit communications to the USPTO regarding the appointment of attorneys to represent applicants or registrants in the application and post-registration processes or, in the case of applicants or registrants who are not domiciled in the United States, the appointment of domestic representatives on whom may be served notices of process in proceedings affecting the mark, the revocation of an attorney's or domestic representative's appointment, and requests for permission to withdraw from representation.

The regulations implementing the Act are set forth in 37 CFR part 2. Regulations regarding representation of others before the USPTO are also set forth in 37 CFR part 11. In addition to governing the registration of trademarks, the Act and regulations govern the appointment and revocation of attorneys and domestic representatives and provide the specifics for filing requests for permission to withdraw as the attorney of record. The information in this information collection is available to the public.

II. Method of Collection

Items in this information collection must be submitted via online electronic submissions. In limited circumstances, applicants may be permitted to submit the information in paper form by mail, fax, or hand delivery.

III. Data

OMB Control Number: 0651–0056.

Forms:

- PTO Form 2300: (TEAS Change Address or Representation Form)
- PTO Form 2201: (TEAS Request for Withdrawal as Attorney of Record/ Update of USPTO's Database After Power of Attorney Ends)

Type of Review: Revision of a currently approved information collection.

Affected Public: Businesses or other for-profits, not-for-profit institutions; individuals or households.

Estimated Number of Respondents: 204,323 respondents per year.

Estimated Number of Responses: 204,323 responses per year.

Estimated Time per Response: The USPTO estimates that it will take the public between 12 minutes (0.2 hours)

and 1 hour to complete a response, depending upon the complexity of the situation. This includes the time to gather the necessary information, prepare the appropriate documents, and submit the completed request to the USPTO.

Estimated Time Annual Burden Hours: 50,437 hours.

Estimated Total Annual Respondent (Hourly) Cost Burden: $20,174,800.

TABLE 1—TOTAL ESTIMATED HOURLY BURDEN FOR PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses	Estimated time for response (hours)	Estimated annual burden hours	Rate [1] ($/hour)	Estimated annual cost burden
	(a)	(b)	(a) × (b) = (c)	(d)	(c) × (d) = (e)		
1	Revocation, Appointment, and/or Change of Address of Attorney/Domestic Representative.	162,368	162,368	0.25	40,592	$400	$16,236,800
2	Request for Withdrawal as Attorney of Record/Update of USPTO's Database After Power of Attorney Ends.	12,389	12,389	0.20	2,478	400	991,200
3	Replacement of Attorney of Record with Another Already-Appointed Attorney.	88	88	1	88	400	35,200
4	Request to Withdraw as Domestic Representative.	873	873	0.25	218	400	87,200
Total		175,718	175,718		43,376		17,350,400

[1] 2019 Report of the Economic Survey from the Law Practice Management Committee of the American Intellectual Property Law Association (AIPLA). *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey* The hourly rate of $400.

TABLE 2—TOTAL ESTIMATED HOURLY BURDEN FOR INDIVIDUAL AND HOUSEHOLD RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses	Estimated time for response (hours)	Estimated annual burden hours	Rate [2] ($/hour)	Estimated annual cost burden
	(a)	(b)	(a) × (b) = (c)	(d)	(c) × (d) = (e)		
1	Revocation, Appointment, and/or Change of Address of Attorney/Domestic Representative.	26,432	26,432	0.25	6,608	$400	$2,643,200
2	Request for Withdrawal as Attorney of Record/Update of USPTO's Database After Power of Attorney Ends.	2,017	2,017	0.20	403	400	161,200
3	Replacement of Attorney of Record with Another Already-Appointed Attorney.	14	14	1	14	400	5,600
4	Request to Withdraw as Domestic Representative.	142	142	0.25	36	400	14,400
Total		28,605	28,605		7,061		2,824,400

[2] 2019 Report of the Economic Survey from the Law Practice Management Committee of the American Intellectual Property Law Association (AIPLA). *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey* The hourly rate of $400.

Estimated Total Annual Non-Hour Respondent Cost Burden: $1,369.

There are no filing fees or capital start-up, maintenance, operation, or recordkeeping costs associated with this information collection. However, this information collection does have postage costs associated with applicants submitting permitted items by mail. The USPTO estimates that the average first-class postage cost for a mailed submission will be $8.05. The USPTO estimates that 170 permitted paper submissions will be mailed for a total non-hour respondent cost burden of $1,369.

Respondent's Obligation: Required to obtain or retain benefits.

IV. Request for Comments

The USPTO is soliciting public comments to:

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

(b) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personal identifying information in a comment, be aware that the entire comment—including personal identifying information—may be made publicly available at any time. While you may ask in your comment to withhold personal identifying information from public view, USPTO cannot guarantee that it will be able to do so.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2020–21555 Filed 9–28–20; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Patent Processing

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), in accordance with the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0031 (Patent Processing). The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before November 30, 2020.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email: InformationCollection@uspto.gov.* Include ''0651–0031 comment'' in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–7728; or by email to *raul.tamayo@uspto.gov* with ''0651–0031 comment'' in the subject line. Additional information about this information collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States Patent and Trademark Office (USPTO) is required by 35 U.S.C. 131 to examine an application for patent and, when appropriate, issue a patent. The USPTO is also required to publish patent applications, with certain exceptions, promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under Title 35, United States Code (''eighteen-month publication''). This information collection covers certain situations that may arise which require that additional information be supplied in order for the USPTO to further process the patent or application.

The information in this collection is used by the USPTO to continue the processing of the patent or application to ensure that applicants are complying with the patent regulations and to aid in the prosecution of the application. In addition, this renewal proposes to remove three items related to patent appeals and associate all submissions of those items to an existing information collection (0651–0063, Patent Trial and Appeal Board Appeals). These three items are: Notice of Appeal, Amendment to Cancel Claims During an Appeal, and Request for Oral Hearing.

II. Method of Collection

Items in this information collection may be submitted via online electronic submissions. In limited circumstances, applicants may be permitted to submit the information in paper form by mail, fax, or hand delivery.

III. Data

OMB Number: 0651–0031.

Form Number(s): (AIA = American Invents; SB = Specimen Book; PTOL = Patent and Trademark Office Legal)

- PTO/SB/08a/08b (Information Disclosure Statements)
- PTO/SB/21 (Transmittal Form)
- PTO/SB/22 and PTO/AIA/22 (Petitions for Extension of Time under 37 CFR 1.136(a))
- PTO/SB/24 and PTO/AIA/24 (Express Abandonment under 37 CFR 1.138)
- PTO/SB/25/26/43/63 (Statutory Disclaimers)
- PTO/SB/27 (Request for Expedited Examination of a Design Application)
- PTO/SB/61/64 (Petition for Revival of an Application for Patent Abandoned Unintentionally)
- PTO/SB/64a (Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing)
- PTO/SB/67/68 (Requests to Access, Inspect, and Copy)
- PTO/SB/91 (Deposit Account Order Form)
- PTO/SB/92 (Certificates of Mailing or Transmission)
- PTO/SB/96 and PTO/AIA/96 (Statement under 37 CFR 3.73(b))
- PTO/SB/35 (Non-Publication Request)
- PTO/SB/36 (Rescission of Previous Non-Publication Request (35 U.S.C. 122(b)(2)(B)(ii) and, if applicable, Notice of Foreign Filing (35 U.S.C. 122(b)(2)(B)(iii))
- PTO–2053–A/B, PTO–2054–A/B, and PTO–2055–A/B (Copy of the Applicant or Patentee's Record of the Application (including copies of the correspondence, list of the correspondence, and statements verifying whether the record is complete or not))
- PTO/SB/30 (Request for Continued Examination (RCE) Transmittal)
- PTO/SB/37 (Request for Suspension of Action or Deferral of Examination under 37 CFR 1.103(b), (c), or (d))
- PTOL/413A (Applicant-Initiated Interview Request Form)
- PTO/SB/17i (Processing Fee under 37 CFR 1.17(i) Transmittal)
- PTO/SB/38 (Request to Retrieve Electronic Priority Application(s) under 37 CFR 1.55(d))
- PTO/SB/39 (Authorization or Rescission of Authorization to Permit Access to Application-as-filed by Participating Offices under 37 CFR 1.14(h))
- PTO/SB/24B and PTO/AIA/24B (Petition for Express Abandonment to Obtain a Refund)
- PTO/SB/33 and PTO/AIA/33 (Pre-Appeal Brief Request for Review)
- PTOL–413C (Request for First-Action Interview (Pilot Program))
- PTO/SB/130 (Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1))

Type of Review: Revision of a currently approved information collection.

Affected Public: Private sector; individuals or households.

Estimated Number of Respondents: 3,669,397 respondents per year.

Estimated Number of Responses: 3,669,397 responses per year.

Estimated Time per Response: The USPTO estimates that it will take respondents between 2 minutes (.03 hours) and 8 hours to submit an item in this information collection depending on the instrument used, including the time to gather the necessary information, prepare the appropriate form or petition, and submit the completed request to the USPTO.

Estimated Total Annual Respondent Burden Hours: 3,187,341 hours.

Estimated Total Annual Respondent (Hourly) Cost Burden: $842,416,575.

TABLE 1—TOTAL HOURLY BURDEN FOR PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (year) (a)	Estimated time for response (hours) (b)	Estimated annual burden (hour/year) (a) × (b) = c	Rate [1] ($/hour) (d)	Estimated annual burden (c) × (d) = e
1	Information Disclosure Statements that require the fee set forth in 37 CFR 1.17(p).	624,824	624,824	2	1,249,648	$400	$499,859,200
2	Transmittal Form	663,023	663,023	2	1,326,046	145	192,276,670
3	Petition for Extension of Time under 37 CFR 1.136(a).	252,184	252,184	.3 (18 minutes)	75,655	145	10,969,975
4	Express Abandonment under 37 CFR 1.138.	1,838	1,838	.25 (15 minutes)	460	145	66,700
5	Statutory Disclaimers (including terminal disclaimers).	57,891	57,891	.25 (15 minutes)	14,473	400	5,789,200
6	Request for Expedited Examination of a Design Application.	1,034	1,034	.25 (15 minutes)	259	400	103,600
7	Petition for Revival of an Application for Patent Abandoned Unintentionally.	7,666	7,666	1	7,666	400	3,066,400
8	Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing.	140	140	1	140	400	56,000
9	Requests to Access, Inspect and Copy	824,500	824,500	.25 (15 minutes)	206,125	145	29,888,125
10	Deposit Account Order Form	64,460	64,460	.25 (15 minutes)	16,115	145	2,336,675
11	Certificates of Mailing or Transmission	582,000	582,000	.03 (2 minutes)	17,460	145	2,531,700
12	Statement Under 37 CFR 3.73(c)	172,469	172,469	.25 (15 minutes)	43,117	400	17,246,900
13	Non-publication Request	21,340	21,340	.25 (15 minutes)	5,335	400	2,134,000
14	Rescission of Previous Non-publication Request (35 U.S.C. § 122(b)(2)(B)(ii) and, if applicable, Notice of Foreign Filing (35 U.S.C. § 122(b)(2)(B)(iii).	2,134	2,134	.25 (15 minutes)	534	400	213,600
15	Electronic Filing System (EFS) Copy of Application for Publication.	1	1	2.5	3	145	435
16	Copy of File Content Showing Redactions.	1	1	4	4	400	1,600
17	Copy of the Applicant or Patentee's Record of the Application (including copies of the correspondence, list of the correspondence, and statements verifying whether the record is complete or not).	6	6	2	12	145	1,740
18	Request for Continued Examination (RCE) Transmittal.	154,766	154,766	.3 (18 minutes)	46,430	400	18,572,000
19	Request for Suspension of Action or Deferral of Examination Under 37 CFR 1.103(b), (c), or (d).	832	832	.2 (12 minutes)	166	400	66,400
20	Request for Voluntary Publication or Republication (includes publication fee for republication).	134	134	.2 (12 minutes)	27	145	3,915
21	Applicant Initiated Interview Request Form.	30,557	30,557	.4 (24 minutes)	12,223	400	4,889,200
22	Processing Fee Under 37 CFR 1.17(i) Transmittal.	119	119	.08 (5 minutes)	10	400	4,000
23	Request to Retrieve Electronic Priority Application (s) Under 37 CFR 1.55(h).	5,858	5,858	.25 (15 minutes)	1,465	400	585,600
24	Authorization or Rescission of Authorization to Permit Access to Application-as-filed by Participating Offices Under 37 CFR 1.14(h).	7,747	7,747	.25 (15 minutes)	1,937	400	774,800
25	Petition for Express Abandonment to Obtain a Refund.	1,827	1,827	.2 (12 minutes)	365	400	146,000
26	Pre-Appeal Brief Request for Review	7,760	7,760	5	38,800	400	15,520,000
27	Request for Corrected Filing Receipt	42,089	42,089	.08 (5 minutes)	3,367	145	488,215
28	Request for First Action Interview (Pilot Program) (Electronic only).	2,026	2,026	2.5	5,065	400	2,026,000
29	Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1) (EFS-Web only).	1,471	1,471	2	2,942	400	1,176,800
30	Filing a submission after final rejection (see 37 CFR 1.129(a)).	93	93	8	744	400	297,600
31	Correction of inventorship after first office action on the merits.	2,910	2,910	.75 (45 minutes)	2,183	400	873,200
32	Request for correction in a patent application relating to inventorship or an inventor name, or order of names, other than in a reissue application (37 CFR 1.48).	14,216	14,216	.75 (45 minutes)	10,662	400	4,264,800

TABLE 1—TOTAL HOURLY BURDEN FOR PRIVATE SECTOR RESPONDENTS—Continued

Item No.	Item	Estimated annual respondents	Estimated annual responses (year) (a)	Estimated time for response (hours) (b)	Estimated annual burden (hour/year) (a) × (b) = c	Rate [1] ($/hour) (d)	Estimated annual burden (c) × (d) = e
33	Request to correct or update the name of the applicant under 37 CFR 1.46(c)(1), or change the applicant under 37 CFR 1.46(c)(2).	11,398	11,398	.2 (12 minutes)	2,280	400	912,000
Total		3,559,314	3,559,314		3,091,718		817,143,050

[1] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.* The USPTO uses the mean rate for attorneys in private firms which is $400 per hour. The hourly rate for paraprofessional/paralegals is estimated at $145 from data published in the 2018 Utilization and Compensation Survey by the National Association of Legal Assistants (NALA).

TABLE 2—TOTAL HOURLY BURDEN FOR INDIVIDUALS AND HOUSEHOLDS RESPONDENTS

Item No.	Item	Estimated annual respondents	Estimated annual responses (year) (a)	Estimated time for response (hours) (b)	Estimated annual burden (hour/year) (a) × (b) = c	Rate [2] ($/hour) (d)	Estimated annual burden (c) × (d) = e
1	Information Disclosure Statements that require the fee set forth in 37 CFR 1.17(p).	19,324	19,324	2	38,648	$400	$15,459,200
2	Transmittal Form	20,506	20,506	2	41,012	145	5,946,740
3	Petition for Extension of Time under 37 CFR 1.136(a).	7,800	7,800	.3 (18 minutes)	2,340	145	339,300
4	Express Abandonment under 37 CFR 1.138.	57	57	.25 (15 minutes)	14	145	2,030
5	Statutory Disclaimers (including terminal disclaimers).	1,790	1,790	.25 (15 minutes)	448	400	179,200
6	Request for Expedited Examination of a Design Application.	32	32	.25 (15 minutes)	8	400	3,200
7	Petition for Revival of an Application for Patent Abandoned Unintentionally.	237	237	1	237	400	94,800
8	Petition for Revival of an Application for Patent Abandoned for Failure to Notify the Office of a Foreign or International Filing.	4	4	1	4	400	1,600
9	Requests to Access, Inspect and Copy	25,500	25,500	.25 (15 minutes)	6,375	145	924,375
10	Deposit Account Order Form	1,994	1,994	.25 (15 minutes)	499	145	72,355
11	Certificates of Mailing or Transmission	18,000	18,000	.03 (2 minutes)	540	145	78,300
12	Statement Under 37 CFR 3.73(c)	5,334	5,334	.25 (15 minutes)	1,334	400	533,600
13	Non-publication Request	660	660	.25 (15 minutes)	165	400	66,000
14	Rescission of Previous Non-publication Request (35 U.S.C. § 122(b)(2)(B)(ii) and, if applicable, Notice of Foreign Filing (35 U.S.C. § 122(b)(2)(B)(iii).	66	66	.25 (15 minutes)	17	400	6,800
18	Request for Continued Examination (RCE) Transmittal.	4,787	4,787	.3 (18 minutes)	1,436	400	574,400
19	Request for Suspension of Action or Deferral of Examination Under 37 CFR 1.103(b), (c), or (d).	26	26	.2 (12 minutes)	5	400	2,000
20	Request for Voluntary Publication or Republication (includes publication fee for republication).	4	4	.2 (12 minutes)	1	145	145
21	Applicant Initiated Interview Request Form.	945	945	.4 (24 minutes)	378	400	151,200
22	Processing Fee Under 37 CFR 1.17(i) Transmittal.	4	4	.08 (5 minutes)	1	400	400
23	Request to Retrieve Electronic Priority Application (s) Under 37 CFR 1.55(h).	181	181	.25 (15 minutes)	45	400	18,000
24	Authorization or Rescission of Authorization to Permit Access to Application-as-filed by Participating Offices Under 37 CFR 1.14(h).	240	240	.25 (15 minutes)	60	400	24,000
25	Petition for Express Abandonment to Obtain a Refund.	56	56	.2 (12 minutes)	11	400	4,400
26	Pre-Appeal Brief Request for Review	240	240	5	1,200	400	480,000
27	Request for Corrected Filing Receipt	1,302	1,302	.08 (5 minutes)	104	145	15,080
28	Request for First Action Interview (Pilot Program) (Electronic only).	63	63	2.5	158	400	63,200
29	Petition to Make Special Based on Age for Advancement of Examination under 37 CFR 1.102(c)(1) (EFS-Web only).	45	45	2	90	400	36,000

TABLE 2—TOTAL HOURLY BURDEN FOR INDIVIDUALS AND HOUSEHOLDS RESPONDENTS—Continued

Item No.	Item	Estimated annual respondents	Estimated annual responses (year) (a)	Estimated time for response (hours) (b)	Estimated annual burden (hour/year) (a) × (b) = c	Rate [2] ($/hour) (d)	Estimated annual burden (c) × (d) = e
30	Filing a submission after final rejection (see 37 CFR 1.129(a)).	3	3	8	24	400	9,600
31	Correction of inventorship after first office action on the merits.	90	90	.75 (45 minutes)	68	400	27,200
32	Request for correction in a patent application relating to inventorship or an inventor name, or order of names, other than in a reissue application (37 CFR 1.48).	440	440	.75 (45 minutes)	330	400	132,000
33	Request to correct or update the name of the applicant under 37 CFR 1.46(c)(1), or change the applicant under 37 CFR 1.46(c)(2).	353	353	.2 (12 minutes)	71	400	28,400
Total		110,083	110,083		95,623		25,273,525

[2] 2019 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); *https://www.aipla.org/detail/journal-issue/2019-report-of-the-economic-survey.* The USPTO uses the mean rate for attorneys in private firms which is $400 per hour. The hourly rate for paraprofessional/paralegals is estimated at $145 from data published in the 2018 Utilization and Compensation Survey by the National Association of Legal Assistants (NALA).

Estimated Total Annual Non-Hour Respondent Cost Burden: $408,845,999.

There are no recordkeeping, maintenance, or capital start-up costs associated with this information collection. However, this information collection has annual non-hour costs in the form of filing fees, as estimated in Table 3, and postage costs. The public may submit the paper forms and petitions in this information collection to the USPTO by mail through the United States Postal Service. If the submission is sent by first-class mail, the public may also include a signed certification of the date of mailing in order to receive credit for timely filing. The USPTO estimates that approximately 166,111 submissions per year may be mailed. The USPTO estimates that the average submission will be mailed in a legal flat-rate Priority Mail envelope at a cost of $8.05; resulting in a total postage cost of $1,377,194.

TABLE 3—FILING FEES

Item No.	Item	Estimated annual responses (a)	Estimated cost (b)	Estimated non-hour cost burden (a) × (b)
1	Information Disclosure Statements (IDS) that require the fee set forth in 37 CFR 1.17(p) (large entity).	$108,938	$260	$28,323,880
1	IDS that require the fee set forth in 37 CFR 1.17(p) (small entity)	27,198	130	3,535,740
1	IDS that require the fee set forth in 37 CFR 1.17(p) (micro entity)	770	65	50,050
3	One-month Extension of Time under 37 CFR 1.136(a) (large entity)	84,428	220	18,574,160
3	One-month Extension of Time under 37 CFR 1.136(a) (small entity)	34,564	110	3,802,040
3	One-month Extension of Time under 37 CFR 1.136(a) (micro entity)	4,035	55	221,925
3	Two-month Extension of Time under 37 CFR 1.136(a) (large entity)	36,165	640	23,145,600
3	Two-month Extension of Time under 37 CFR 1.136(a) (small entity)	19,728	320	6,312,960
3	Two-month Extension of Time under 37 CFR 1.136(a) (micro entity)	2,346	160	375,360
3	Three-month Extension of Time under 37 CFR 1.136(a) (large entity)	30,668	1480	45,388,640
3	Three-month Extension of Time under 37 CFR 1.136(a) (small entity)	30,442	740	22,527,080
3	Three-month Extension of Time under 37 CFR 1.136(a) (micro entity)	3,227	370	1,193,990
3	Four-month Extension of Time under 37 CFR 1.136(a) (large entity)	1,860	2320	4,315,200
3	Four-month Extension of Time under 37 CFR 1.136(a) (small entity)	2,366	1160	2,744,560
3	Four-month Extension of Time under 37 CFR 1.136(a) (micro entity)	294	580	170,520
3	Five-month Extension of Time under 37 CFR 1.136(a) (large entity)	2,038	3160	6,440,080
3	Five-month Extension of Time under 37 CFR 1.136(a) (small entity)	2,257	1580	3,566,060
3	Five-month Extension of Time under 37 CFR 1.136(a) (micro entity)	182	790	143,780
5	Statutory Disclaimer (including terminal disclaimer) (large entity)	44,625	170	7,586,250
5	Statutory Disclaimer (including terminal disclaimer) (small entity)	14,365	170	2,442,050
5	Statutory Disclaimer (including terminal disclaimer) (micro entity)	691	170	117,470
6	Request for Expedited Examination of a Design Application (large entity)	381	1600	609,600
6	Request for Expedited Examination of a Design Application (small entity)	468	800	374,400
6	Request for Expedited Examination of a Design Application (micro entity)	218	400	87,200
8	Petition for Revival of an Application for Patent Abandoned Unintentionally (large entity).	3,006	2100	6,312,600
8	Petition for Revival of an Application for Patent Abandoned Unintentionally (small entity).	3,730	1050	3,916,500

TABLE 3—FILING FEES—Continued

Item No.	Item	Estimated annual responses (a)	Estimated cost (b)	Estimated non-hour cost burden (a) × (b)
8	Petition for Revival of an Application for Patent Abandoned Unintentionally (micro entity).	1,167	525	612,675
9	Petition for revival of an application for patent abandoned for failure to notify the office of a foreign or international filing (large entity).	108	2100	226,800
9	Petition for revival of an application for patent abandoned for failure to notify the office of a foreign or international filing (small entity).	22	1050	23,100
9	Petition for revival of an application for patent abandoned for failure to notify the office of a foreign or international filing (micro entity).	14	525	7,350
17	Copy of File Content Showing Redactions	1	140	140
19	Request for Continued Examination (RCE) Transmittal (First Request) (large entity).	74,458	1360	101,262,880
19	Request for Continued Examination (RCE) Transmittal (First Request) (small entity).	26,592	680	18,082,560
19	Request for Continued Examination (RCE) Transmittal (First Request) (micro entity).	5,318	340	1,808,120
19	Request for Continued Examination (RCE) Transmittal (Second and Subsequent Requests) (large entity).	37,076	2000	74,152,000
19	Request for Continued Examination (RCE) Transmittal (Second and Subsequent Requests) (small entity).	13,241	1000	13,241,000
19	Request for Continued Examination (RCE) Transmittal (Second and Subsequent Requests) (micro entity).	2,648	500	1,324,000
21	Request for Suspension of Action or Deferral of Examination Under 37 CFR 1.103(b), (c), or (d) (large entity).	601	220	132,220
21	Request for Suspension of Action or Deferral of Examination Under 37 CFR 1.103(b), (c), or (d) (small entity).	215	110	23,650
21	Request for Suspension of Action or Deferral of Examination Under 37 CFR 1.103(b), (c), or (d) (micro entity).	42	55	2,310
22	Request for Voluntary Publication or Republication (includes publication fee for republication).	138	140	19,320
24	Processing Fee Under 37 CFR 1.17(i) Transmittal	123	140	17,220
32	Filing a submission after final rejection (see 37 CFR 1.129(a)) (large entity)	46	880	40,480
32	Filing a submission after final rejection (see 37 CFR 1.129(a)) (small entity)	44	440	19,360
32	Filing a submission after final rejection (see 37 CFR 1.129(a)) (micro entity)	5	220	1,100
33	Correction of inventorship after first office action on the merits (large entity)	1156	640	739,840
33	Correction of inventorship after first office action on the merits (small entity)	793	320	253,760
33	Correction of inventorship after first office action on the merits (micro entity)	62	160	9,920
34	Request for correction in a patent application relating to inventorship or an inventor name, or order of names, other than in a reissue application (37 CFR 1.48) (large entity).	10,259	260	2,667,340
34	Request for correction in a patent application relating to inventorship or an inventor name, or order of names, other than in a reissue application (37 CFR 1.48) (small entity).	3,664	130	476,320
34	Request for correction in a patent application relating to inventorship or an inventor name, or order of names, other than in a reissue application (37 CFR 1.48) (micro entity).	733	65	47,645
Total				407,468,805

Respondent's Obligation: Required to obtain or retain benefits.

IV. Request for Comments

The USPTO is soliciting public comments to:

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

(b) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personal identifying information in a comment, be aware that the entire comment— including personal identifying information—may be made publicly available at any time. While you may ask in your comment to withhold personal identifying information from public view, USPTO

cannot guarantee that it will be able to do so.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2020–21517 Filed 9–28–20; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Responses to Office Action and Voluntary Amendment Forms

The United States Patent and Trademark Office (USPTO) will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The USPTO invites comment on this information collection renewal, which helps the USPTO assess the impact of its information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on July 29, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: United States Patent and Trademark Office, Department of Commerce.

Title: Responses to Office Action and Voluntary Amendment Forms.

OMB Control Number: 0651–0050.

Form Number(s):

- PTO–1957 (Response to Office Action)
- PTO–1960 (Request for Reconsideration After Final Office Action)
- PTO–1966 (Voluntary Amendment Not in Response to USPTO Office Action/Letter)
- PTO–1771 (Post-Approval/Publication/Post-Notice of Allowance (NOA) Amendment)
- PTO–1771 (Petition to Amend Basis Post-Publication)
- PTO–1822 (Response to Suspension Inquiry or Letter of Suspension)

Type of Review: Extension and revision of a currently approved information collection.

Number of Respondents: 393,657 respondents.

Average Hours per Response: The USPTO estimates 393,665 responses and that it will take the public between 15 minutes to 40 minutes to complete this information collection, depending on the complexity of the submission. This includes the time to gather the necessary information, prepare the appropriate documents, and submit the completed items to the USPTO.

Estimated Total Annual Respondent Burden Hours: 253,058 hours.

Estimated Total Annual Non-Hour Cost Burden: $101,223,200.

Needs and Uses: This collection of information is required by the Trademark Act (Act), 15 U.S.C. 1051 *et seq.,* which provides for the Federal registration of trademarks, service marks, collective trademark and service marks, collective membership marks, and certification marks. Individuals and businesses that use such marks, or intend to use such marks, in interstate commerce may file an application to register their marks with the United States Patent and Trademark Office (USPTO). The USPTO also administers the Trademark Act through Title 37 of the Code of Federal Regulations. These regulations allow the USPTO to request and receive information required to process applications and allows applicants to submit certain amendments to their applications. This information collection includes information that was not submitted with the initial application and is needed by the USPTO to review applications for trademark registration.

In some cases, the USPTO issues Office Actions to applicants who have applied to register a mark, requesting information that was not provided with the initial submission, but is required before the issuance of a registration. Also, the USPTO may determine that a mark is not entitled to registration, pursuant to one or more provisions of the Trademark Act. In such cases, the USPTO will issue an Office Action advising the applicant of the refusal to register the mark. Applicants reply to these Office Actions by providing the required information and/or by putting forth legal arguments as to why the refusal of registration should be withdrawn.

Applicants may also supplement their applications and provide further information by filing a Voluntary Amendment Not in Response to USPTO Office Action/Letter, a Request for Reconsideration after Final Office Action, a Post-Approval/Publication/Post-Notice of Allowance (NOA) Amendment, a Petition to Amend Basis Post-Publication, or a Response to Suspension Inquiry or Letter of Suspension. In rare instances, an applicant may also submit a Substitute Trademark/Servicemark, Substitute Certification Mark, Substitute Collective Membership Mark, or Substitute Collective Trademark/Servicemark application.

Affected Public: Private Sector; individuals and households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce, USPTO information collections currently under review by OMB.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 0651–0050.

Further information can be obtained by:

- *Email: InformationCollection@uspto.gov.* Include ''0651–0050 information request'' in the subject line of the message.
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2020–21483 Filed 9–28–20; 8:45 am]

BILLING CODE 3510–16–P

COMMODITY FUTURES TRADING COMMISSION

Request for Nominations for a Subcommittee Under the Agricultural Advisory Committee

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (CFTC or Commission) is requesting nominations for membership on the Subcommittee to Evaluate Commission Policy with Respect to Implementation of Amendments to Enumerated Agricultural Futures Contracts with Open Interest (Subcommittee) under the Agricultural Advisory Committee

(AAC). The AAC is a discretionary advisory committee established by the Commission in accordance with the Federal Advisory Committee Act.

DATES: The deadline for the submission of nominations is October 29, 2020.

ADDRESSES: Nominations should be emailed to *AAC@cftc.gov* or sent by post to Summer Mersinger, AAC Designated Federal Officer, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. Please use the title ''AAC Subcommittee'' for any nominations you submit.

FOR FURTHER INFORMATION CONTACT: Summer Mersinger, AAC Designated Federal Officer at (202) 418–6074 or email: *AAC@cftc.gov.*

SUPPLEMENTARY INFORMATION: The Subcommittee was established to provide a report to the AAC that will make recommendations to the Commission on policy related to its evaluation of implementation plans for amendments to agricultural futures contracts with open interest. Within this charge, the Subcommittee may consider, but is not limited to, the following issues and topics:

- The Commodity Exchange Act, regulations, and guidance pertaining to Designated Contract Market (DCM) requests for Commission approval of amendments to enumerated agricultural futures contracts with open interest;
- Recent history of Commission-approved amendments to futures contracts, including the term or condition amended, ability of that term or condition to impact the economic value of futures positions, rationale provided by the DCM, date announced, and date implemented;
- Terms and conditions that could impact the economic value of futures positions, what the Commission should consider in terms of evaluating the implementation plans for those amendments, and whether there could be best practices developed for implementation of any amendments to those terms or conditions; and
- Appropriate methods to make market participants and the public aware of the potential for an enumerated agricultural futures contract with open interest to be amended.

The Subcommittee will provide its report directly to the AAC and will not provide reports and/or recommendations directly to the Commission. The Subcommittee has no authority to make decisions on behalf of the AAC, and no determination of fact or policy will be made by the Subcommittee on behalf of the Commission.

Subcommittee members will generally serve as representatives and provide advice reflecting the views of stakeholder organizations and entities throughout the derivatives and financial markets. The Subcommittee may also include regular government employees when doing so furthers its purpose. It is anticipated that the Subcommittee will hold at least three in-person or telephonic meetings. Subcommittee members serve at the pleasure of the Commission. Subcommittee members do not receive compensation or honoraria for their services, and they are not reimbursed for travel and per diem expenses.

The Subcommittee members will include individuals who are members of the AAC and/or other individuals. For these other individuals who are not serving on the AAC currently, the Commission seeks nominations of individuals from a wide range of perspectives, including from industry, academia, the government, and public interest. To advise the AAC effectively, Subcommittee members must have a high level of expertise and experience with: Hedging practices in the agricultural sector and/or trading in agricultural futures contracts, including a familiarity with the terms and conditions of agricultural futures contracts; the Commodity Exchange Act, Commission regulations, and guidance thereunder. To the extent practicable, the Commission will strive to select members reflecting wide ethnic, racial, gender, and age representation.

The Commission invites the submission of nominations for Subcommittee membership. Each nomination submission should include the proposed member's name, title, organization affiliation and address, email address and telephone number, as well as information that supports the individual's qualifications to serve on the Subcommittee. The submission should also include the name, email address, and telephone number of the person nominating the proposed Subcommittee member. Self-nominations are acceptable.

Submission of a nomination is not a guarantee of selection as a member of the Subcommittee. As noted in the AAC's Membership Balance Plan, the Commission seeks to ensure that the membership of a subcommittee is balanced relative to the particular issues addressed by the subcommittee in question. The AAC Sponsor, with the assistance of the AAC Designated Federal Officer (DFO), identifies candidates for Subcommittee membership. Following the identification, the candidates who are not already serving on the AAC are submitted by the DFO to appropriate CFTC Staff for review and then to the Commission for approval.

(Authority: 5 U.S.C. App. II)

Dated: September 23, 2020.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–21396 Filed 9–28–20; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Privacy Act of 1974; System of Records

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of a New System of Records.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is establishing CFTC–54, Ensuring Workplace Health and Safety in Response to a Public Health Emergency, a system of records under the Privacy Act of 1974. This system of records maintains information collected in response to a public health emergency, such as a pandemic or epidemic, from CFTC staff (including political appointees, employees, detailees, contractors, consultants, interns, and volunteers) and visitors to CFTC facilities that is necessary to ensure a safe and healthy work environment.

DATES: In accordance with 5 U.S.C. 552(e)(4) and (11), this System of Records will go in to effect without further notice on September 29, 2020 unless otherwise revised pursuant to comments received. New routine uses will go in to effect on October 29, 2020. Comments must be received on or before October 29, 2020.

ADDRESSES: You may submit comments identified as pertaining to ''Ensuring Workplace Health and Safety in Response to a Public Health Emergency'' by any of the following methods:

- *CFTC Website: https://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 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 *https://www.cftc.gov.* You should submit only information that you wish to make available publicly.

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse, or remove any or all of a submission from *https://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 notice will be retained in the comment file and will be considered as required under all applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT: Charlie Cutshall, Chief Privacy Officer, *privacy@cftc.gov,* 202–418–5833, Office of the Executive Director, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. CFTC–54, Ensuring Workplace Health and Safety in Response to a Public Health Emergency

The Commodity Futures Trading Commission is establishing CFTC–54, Ensuring Workplace Health and Safety in Response to a Public Health Emergency, a system of records under the Privacy Act of 1974. The CFTC is committed to providing all CFTC staff with a safe and healthy work environment and to that end it may develop and institute additional safety measures in response to a public health emergency. These measures may include instituting activities such as requiring CFTC staff and visitors to provide information before being allowed access to a CFTC facility, medical screening, and contact tracing. Contact tracing conducted by CFTC staff will involve collecting information about CFTC staff and visitors who are exhibiting symptoms or who have tested positive for an infectious disease in order to identify and notify other CFTC staff and visitors with whom they may have come into contact and who may have been exposed.

Information will be collected and maintained in accordance with the Americans with Disabilities Act of 1990 and regulations and guidance published by the U.S. Occupational Safety and Health Administration, the U.S. Equal Employment Opportunity Commission, and the U.S. Centers for Disease Control and Prevention.

II. The Privacy Act

Under the Privacy Act of 1974, 5 U.S.C. 552a, a ''system of records'' is defined as any group of records under the control of a Federal government agency from which information about individuals is retrieved by name or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act establishes the means by which government agencies must collect, maintain, and use information about an individual in a government system of records.

Each government agency is required to publish a notice in the **Federal Register** in which the agency identifies and describes each system of records it maintains, the reasons why the agency uses the information therein, the routine uses for which the agency will disclose such information outside the agency, and how individuals may exercise their rights under the Privacy Act.

In accordance with 5 U.S.C. 552a(r), CFTC has provided a report of this modified system of records to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

Ensuring Workplace Health and Safety in Response to a Public Health Emergency; CFTC–54.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

This system is maintained by the Security and Emergency Management Unit (SEMU) in the Commission's principal office at Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. Records may also be located at the regional offices in Chicago at 525 West Monroe Street, Suite 1100, Chicago, IL 60661; in Kansas City at Two Emanuel Cleaver II Blvd., Suite 300, Kansas City, MO 64112; and, New York at 140 Broadway, 19th Floor, New York, NY 10005.

SYSTEM MANAGER(S):

The system manager is the SEMU Officer located in the Commission's principal office at Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581, and available at *security@cftc.gov.* Additional records may be located and managed by Logistics and Operations staff in the regional offices in Chicago at 525 West Monroe Street, Suite 1100, Chicago, IL 60661; in Kansas City at Two Emanuel Cleaver II Blvd., Suite 300, Kansas City, MO 64112; and, in New York at 140 Broadway, 19th Floor, New York, NY 10005.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority to collect this information derives from General Duty Clause, Section 5(a)(1) of the Occupational Safety and Health (OSH) Act of 1970 (29 U.S.C. 654), Executive Order 12196, *Occupational safety and health programs for Federal employees* (Feb. 26, 1980), OMB Memorandum M–20–23 *Aligning Federal Agency Operations with the National Guidelines for Opening Up America Again* (Apr. 20, 2020), and the National Defense Authorization Act For Fiscal Year 2017 (5 U.S.C. 6329c(b)). Information will be collected and maintained in accordance with the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*)

PURPOSE(S) OF THE SYSTEM:

The information in the system is collected to assist the CFTC with maintaining a safe and healthy workplace and to protect CFTC staff working on-site from risks associated with a public health emergency (as defined by the U.S. Department of Health and Human Services and declared by its Secretary), such as a pandemic or epidemic. To that end, the CFTC may develop and institute additional safety measures in response to a public health emergency. These measures may include instituting activities such as requiring CFTC staff and visitors to provide information before being allowed access to a CFTC facility, medical screening, and contact tracing. Contact tracing conducted by CFTC staff will involve collecting information about CFTC staff and visitors who are exhibiting symptoms or who have tested positive for an infectious disease in order to identify and notify other CFTC staff and visitors with whom they may have come into contact and who may have been exposed.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system include CFTC staff (*e.g.,* political appointees, employees, detailees, contractors, consultants, interns, and volunteers) and visitors to a CFTC facility during a public health emergency, such as a pandemic or epidemic.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system maintains information collected about CFTC staff and visitors accessing CFTC facilities during a public health emergency, including a pandemic or epidemic. It maintains biographical information collected about CFTC staff and visitors that includes, but is not limited to, their

name, contact information, whether they are in a high-risk category or provide dependent care for individuals in a high-risk category, and recent travel. It maintains health information collected about CFTC staff and visitors to a CFTC facility, that includes, but is not limited to, temperature checks, expected or confirmed test results, dates, symptoms, potential or actual exposure to a pathogen, immunizations and vaccination information, or other medical history related to the treatment of a pathogen or communicable disease. It maintains information collected about CFTC staff and visitors to a CFTC facility necessary to conduct contact tracing that includes, but is not limited to, the dates when they visited the facility, the locations that they visited within the facility (*e.g.,* office and cubicle number), the duration of time spent in the facility, whether they may have potentially come into contact with a contagious person while visiting the facility, travel dates and locations, and a preferred contact number. It maintains information about emergency contacts for CFTC staff that includes, but is not limited to, the emergency contact's name, phone number, and email address.

RECORD SOURCE CATEGORIES:

The information in this system is collected in part directly from the individual or from the individual's emergency contact. Information is also collected from security systems monitoring access to CFTC facilities, such as video surveillance and turnstiles, human resources systems, emergency notification systems, and federal, state, and local agencies assisting with the response to a public health emergency. Information may also be collected from property management companies responsible for managing office buildings that house CFTC facilities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records and information in these records may be disclosed:

(a) To a Federal, State, or local agency to the extent necessary to comply with laws governing reporting of infectious disease;

(b) To the CFTC staff member's emergency contact for purposes of locating a staff member during a public health emergency or to communicate that the CFTC staff member may have potentially been exposed to a virus as the result of a pandemic or epidemic while visiting a CFTC facility;

(c) To another Federal agency, to a court, or a party in litigation before a court or in an administrative proceeding being conducted by a Federal agency when the Commission is a party to the judicial or administrative proceeding where the information is relevant and necessary to the proceeding;

(d) To contractors, performing or working on a contract for the Commission when necessary to accomplish an agency function;

(e) To the Department of Justice or in a proceeding before a court, adjudicative body, or other administrative body which the Commission is authorized to appear, when:

(1) The Commission; or

(2) Any employee of the Commission in his or her official capacity; or

(3) Any employee of the Commission in his or her official capacity where the Department of Justice or the Commission has agreed to represent the employee; or

(4) The United States, when the Commission determines that litigation is likely to affect the agency or any of its components;

Is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or the Commission is deemed by the agency to be relevant and necessary to the litigation.

(f) To appropriate agencies, entities, and persons when (1) the Commission suspects or has confirmed that there has been a breach of the system of records, (2) the Commission has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm; or

(g) To another Federal agency or Federal entity, when the Commission determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) 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.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system of records are stored electronically or on paper in secure facilities. Electronic records are stored on the Commission's secure network.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information covered by this system of records notice may be retrieved by the name of the individual.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records of emergency contacts for CFTC staff will be maintained in accordance with General Records Schedule 5.3, Item 020: Employee Emergency Contact Information, which requires that the records be destroyed when superseded or obsolete, or upon separation or transfer of employee. CFTC will work with the National Archives and Records Administration (NARA) to draft and secure approval of a records disposition schedule to cover the remainder of the records described in this SORN. Until this records disposition schedule is approved by NARA, CFTC will maintain, and not destroy, these records.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical, and physical security measures. Administrative safeguards include applying a coversheet to sensitive information. Technical security safeguards within CFTC include restrictions on computer access to authorized individuals who have a legitimate need to know the information; required use of strong passwords that are frequently changed; multi-factor authentication for remote access and access to many CFTC network components; use of encryption for certain data types and transfers; firewalls and intrusion detection applications; and regular review of security procedures and best practices to enhance security. Physical safeguards include restrictions on building access to authorized individuals, 24-hour security guard service, and maintenance of records in lockable offices and filing cabinets.

RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records should address written inquiries to the Office of General

Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.3 for full details on what to include in a Privacy Act access request.

CONTESTING RECORD PROCEDURES:

Individuals contesting the content of records about themselves contained in this system of records should address written inquiries to the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.8 for full details on what to include in a Privacy Act amendment request.

NOTIFICATION PROCEDURES:

Individuals seeking notification of any records about themselves contained in this system of records should address written inquiries to the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.3 for full details on what to include in a Privacy Act notification request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Issued in Washington, DC, on September 23, 2020, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–21423 Filed 9–28–20; 8:45 am]

BILLING CODE 6351–01–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Sunshine Act Meetings

TIME AND DATE: 3:00 p.m., September 28, 2020.

PLACE: This meeting was held via teleconference.

STATUS: Closed. During the closed meeting, the Board Members discussed issues dealing with potential Recommendations to the Secretary of Energy. The Board invoked the Exemption to close a meeting described in 5 U.S.C. 552b(c)(3) and 10 CFR 1704.4(c). The Board determined that it was necessary to close the meeting since conducting an open meeting was likely to disclose matters that are specifically exempted from disclosure by statute. In this case, the deliberations pertained to potential Board Recommendations which, under 42 U.S.C. 2286d(b) and (h)(3), may not be made publicly available until after they have been received by the Secretary of Energy or the President, respectively.

MATTERS TO BE CONSIDERED: The meeting proceeded in accordance with the closed meeting agenda that is posted on the Board's public website at *www.dnfsb.gov.* Technical staff may have presented information to the Board. The Board Members were expected to conduct deliberations regarding potential Recommendations to the Secretary of Energy.

CONTACT PERSON FOR MORE INFORMATION: Tara Tadlock, Director of Board Operations, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW, Suite 700, Washington, DC 20004–2901, (800) 788–4016. This is a toll-free number.

Dated: September 25, 2020.

Joyce L. Connery,

Acting Chairman.

[FR Doc. 2020–21651 Filed 9–25–20; 4:15 pm]

BILLING CODE 3670–01–P

DEPARTMENT OF EDUCATION

National Assessment Governing Board

National Assessment Governing Board Meeting; Correction

AGENCY: National Assessment Governing Board, Department of Education.

ACTION: Notice; correction.

SUMMARY: The National Assessment Governing Board (Governing Board) published a document in the **Federal Register** on September 23, 2020, announcing the schedule and proposed agenda of a September 29, 2020 virtual meeting of the Governing Board. The September 29, 2020 meeting agenda is being revised.

FOR FURTHER INFORMATION CONTACT: Munira Mwalimu at (202) 357–6906.

Access to Records of the Meeting: Pursuant to FACA requirements, the public may also inspect the agenda and meeting materials at *www.nagb.gov* no later than Monday, September 28, 2020 by 10:00 a.m. ET. The official minutes of the open session of the meeting will be available for public inspection no later than 30 calendar days following the meeting.

Reasonable Accommodations: The meeting site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice no later than noon on Friday, September 25, 2020. Although we will attempt to meet a request received after that date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the Adobe website. You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of September 23, 2020, in FR Doc. 2020–20267, on pages 60139–60140 (2 pages), correct the following:

1. The meeting times have changed; the meeting will now begin at 4:30 p.m. and adjourn at 7:00 p.m. ET instead of the announced time of 3:00 p.m. to 5:15 p.m. (ET).

2. The closed sessions of the meeting will now begin at 4:30 p.m. and adjourn at 6:15 p.m. instead of the posted times of 3:45 p.m. to 5:15 p.m. (ET).

3. The closed session topics are unchanged. The first closed session on the 2019 Nation's Report Card in Reading and Mathematics Grade 12 will begin at 4:30 p.m. and end at 5:15 p.m. The second closed session on Policy and Operational Updates for NAEP 2021 will begin at 5:15 p.m. and adjourn at 6:15 p.m.

4. Following a 15-minute break, the Governing Board will meet in open session at 6:30 p.m. to discuss and take action on the Strategic Vision.

5. The September 29, 2020 session of the Governing Board meeting will adjourn at 7:00 p.m.

Authority: Pub. L. 107–279, Title III—National Assessment of Educational Progress § 301.

Lesley A. Muldoon,

Executive Director, National Assessment Governing Board (NAGB), U. S. Department of Education.

[FR Doc. 2020–21515 Filed 9–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0118]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Talent Search (TS) Annual Performance Report

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before October 29, 2020.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Antoinette Edwards, 202–453–7121.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Talent Search (TS) Annual Performance Report.

OMB Control Number: 1840–0826.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: State, Local, or Tribal Governments, and Private Sector.

Total Estimated Number of Annual Responses: 473.

Total Estimated Number of Annual Burden Hours: 8,514.

Abstract: Talent Search grantees must submit the report annually. The report provides the Department of Education with information needed to evaluate a grantee's performance and compliance with program requirements and to award prior experience points in accordance with the program regulations. The data collection is also aggregated to provide national information on project participants and program outcomes.

Dated: September 24, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–21433 Filed 9–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0119]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Teacher Education Assistance for College and Higher Education Grant Eligibility Regulations

AGENCY: Office of Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before October 29, 2020.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Teacher Education Assistance for College and Higher Education Grant Eligibility Regulations.

OMB Control Number: 1845–0084.

Type of Review: A revision of a currently approved collection.

Respondents/Affected Public: Private Sector, Individuals, and State, Local, or Tribal Government.

Total Estimated Number of Annual Responses: 233,844.

Total Estimated Number of Annual Burden Hours: 37,175.

Abstract: The TEACH Grant Program was included for review in the Negotiated Rulemaking which took place in early 2019. Section 686.32 of the TEACH Grant regulations is being updated via this information collection. The final regulations in section 686.32 revise the information that is provided to TEACH Grant recipients during initial, subsequent, and exit counseling. The final regulations also add a new conversion counseling requirement for grant recipients whose TEACH Grants are converted to Direct Unsubsidized Loans. This conversion counseling material will be provided directly to the recipient from the Department based on the last address provided by the recipient. This is a request for a revision of the existing burden hours in OMB Control Number 1845–0084 which provides for TEACH Grant counseling.

Dated: September 24, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–21439 Filed 9–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0157]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Package for Grants Under the Predominantly Black Institutions Program (PBI)

AGENCY: Office of Postsecondary Education, Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a reinstatement without change of a previously approved collection.

DATES: Interested persons are invited to submit comments on or before October 29, 2020.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kelley Harris, 202–453–7346.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application Package for Grants under the Predominantly Black Institutions Program (PBI).

OMB Control Number: 1840–0797.

Type of Review: Reinstatement without change of a previously approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 130.

Total Estimated Number of Annual Burden Hours: 4,550.

Abstract: The Predominantly Black Institutions (PBI) Program is authorized under Title III, Part F of the Higher Education Act of 1965, as amended (HEA). The PBI Program makes grant awards to eligible colleges and universities to support the strengthening of PBIs to carry out programs in the following areas: Science, technology, engineering, or mathematics; health education; internationalization or globalization; teacher preparation; or improving the educational outcomes of African American males. Grants support the establishment or strengthening of such programs that are designed to increase the institutions capacity to prepare students for instruction in the above noted fields. Grants are awarded competitively. This information collection is necessary to comply with Title III, Part F of the HEA. This collection is being submitted under the Streamlined Clearance Process for Discretionary Grant Information Collections (1894–0001). Therefore, the 30-day public comment period notice will be the only public comment notice published for this information collection request.

Dated: September 24, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–21430 Filed 9–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[FE Docket Nos. 10–161–LNG, 11–161–LNG, 16–108–LNG]

Freeport LNG Expansion, L.P.; FLNG Liquefaction, LLC; FLNG Liquefaction 2, LLC; and FLNG Liquefaction 3, LLC; Application To Amend Export Term Through December 31, 2050, for Existing Non-Free Trade Agreement Authorizations

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice (Notice) of receipt of an application (Application), filed on September 9, 2020, by Freeport LNG Expansion, L.P.; FLNG Liquefaction, LLC; FLNG Liquefaction 2, LLC; and FLNG Liquefaction 3, LLC (collectively, FLEX). FLEX seeks to amend the export term set forth in its current authorizations to export liquefied natural gas (LNG) to non-free trade agreement countries, DOE/FE Order Nos. 3282–C, 3357–B, and 3957, to a term ending on December 31, 2050. FLEX filed the Application under the Natural Gas Act (NGA) and DOE's policy statement entitled, ''Extending Natural Gas Export Authorizations to Non-Free Trade Agreement Countries Through the Year 2050'' (Policy Statement). Protests, motions to intervene, notices of intervention, and

written comments on the requested term extension are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed using procedures detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, October 14, 2020.

ADDRESSES:

Electronic Filing by email: fergas@hq.doe.gov.

Regular Mail: U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, P.O. Box 44375, Washington, DC 20026–4375.

Hand Delivery or Private Delivery Services (*e.g.,* FedEx, UPS, etc.): U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Benjamin Nussdorf or Amy Sweeney, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–7893; (202) 586–2627, *benjamin.nussdorf@hq.doe.gov* or *amy.sweeney@hq.doe.gov*

Cassandra Bernstein or Edward Toyozaki,U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, Room 6D–033, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9793; (202) 586–0126, *cassandra.bernstein@hq.doe.gov* or *edward.toyozaki@hq.doe.gov*

SUPPLEMENTARY INFORMATION: FLEX is currently authorized by DOE/FE to export domestically produced LNG in a total volume equivalent to 782 billion cubic feet per year (Bcf/yr) of natural gas, pursuant to NGA section 3(a), 15 U.S.C. 717b(a), under the following orders:

(i) 511 Bcf/yr under Order No. 3282–C (FE Docket No. 10–161–LNG); [1]

(ii) 146 Bcf/yr under Order No. 3357–B (FE Docket No. 11–161–LNG); [2] and

(iii) 125 Bcf/yr under Order No. 3957 (FE Docket No. 16–108–LNG).[3]

Under each order, FLEX is authorized to export the LNG by vessel from the Freeport LNG Terminal, located on Quintana Island near Freeport, Texas, to any country with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries) for a 20-year term. In the Application,[4] FLEX asks DOE to extend its export term in each of these three orders to a term ending on December 31, 2050, as provided in the Policy Statement.[5] Additional details can be found in the Application, posted on the DOE/FE website at: *https://www.energy.gov/sites/prod/files/2020/09/f78/Freeport%20DOE%20Extension%20Application.pdf.*

DOE/FE Evaluation

In the Policy Statement, DOE adopted a term through December 31, 2050 (inclusive of any make-up period), as the standard export term for long-term non-FTA authorizations.[6] As the basis for its decision, DOE considered its obligations under NGA section 3(a), the public comments supporting and opposing the proposed Policy Statement, and a wide range of information bearing on the public interest.[7] DOE explained that, upon receipt of an application under the Policy Statement, it would conduct a public interest analysis of the application under NGA section 3(a). DOE further stated that ''the public interest analysis will be limited to the application for the term extension—meaning an intervenor or protestor may challenge the requested extension but not the existing non-FTA order.'' [8]

Accordingly, in reviewing FLEX's Application, DOE/FE will consider any issues required by law or policy under NGA section 3(a), as informed by the Policy Statement. To the extent appropriate, DOE will consider the study entitled, *Macroeconomic Outcomes of Market Determined Levels of U.S. LNG Exports* (2018 LNG Export Study),[9] DOE's response to public comments received on that Study,[10] and the following environmental documents:

- *Addendum to Environmental Review Documents Concerning Exports of Natural Gas From the United States,* 79 FR 48132 (Aug. 15, 2014); [11]
- *Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States,* 79 FR 32260 (June 4, 2014); [12] and
- *Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States: 2019 Update,* 84 FR 49278 (Sept. 19, 2019), and DOE/FE's response to public comments received on that study.[13]

Parties that may oppose the Application should address these issues and documents in their comments and/or protests, as well as other issues deemed relevant to the Application.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its environmental responsibilities.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a

[1] *Freeport LNG Expansion, L.P., et al.,* DOE/FE Order No. 3282–C, FE Docket No. 10–161–LNG, Final Opinion and Order Granting Long-Term Multi-Contract Authorization to Export Liquefied Natural Gas by Vessel from the Freeport LNG Terminal on Quintana Island, Texas, to Non-Free Trade Agreement Nations (Nov. 14, 2014).

[2] *Freeport LNG Expansion, L.P., et al.,* DOE/FE Order No. 3357–B, FE Docket No. 11–161–LNG, Final Opinion and Order Granting Long-Term Multi-Contract Authorization to Export Liquefied Natural Gas by Vessel from the Freeport LNG Terminal on Quintana Island, Texas, to Non-Free Trade Agreement Nations (Nov. 14, 2014).

[3] *Freeport LNG Expansion, L.P., et al.,* DOE/FE Order No. 3957, FE Docket No. 16–108–LNG, Opinion and Order Granting Long-Term, Multi-Contract Authorization to Export Liquefied Natural Gas by Vessel from the Freeport LNG Terminal on Quintana Island, Texas, to Non-Free Trade Agreement Nations (Dec. 19, 2016).

[4] Freeport LNG Expansion, L.P., *et al.,* Application to Amend Export Term for Existing Long-Term Authorizations Through December 31, 2050, FE Docket Nos. 10–160–LNG, *et al.* (Sept. 9, 2020). FLEX's requests regarding its FTA authorizations are not subject to this Notice. *See* 15 U.S.C. 717b(c).

[5] U.S. Dep't of Energy, Extending Natural Gas Export Authorizations to Non-Free Trade Agreement Countries Through the Year 2050; Notice of Final Policy Statement and Response to Comments, 85 FR 52237 (Aug. 25, 2020) [hereinafter Policy Statement].

[6] *See id.,* 85 FR 52247.

[7] *See id.,* 85 FR 52247.

[8] *Id.,* 85 FR 52247.

[9] *See* NERA Economic Consulting, Macroeconomic Outcomes of Market Determined Levels of U.S. LNG Exports (June 7, 2018), *available at: https://www.energy.gov/sites/prod/files/2018/06/f52/Macroeconomic%20LNG%20Export%20Study%202018.pdf.*

[10] U.S. Dep't of Energy, Study on Macroeconomic Outcomes of LNG Exports: Response to Comments Received on Study; Notice of Response to Comments, 83 FR 67251 (Dec. 28, 2018).

[11] The Addendum and related documents are available at: *http://energy.gov/fe/draft-addendum-environmental-review-documents-concerning-exports-natural-gas-united-states.*

[12] The 2014 Life Cycle Greenhouse Gas Report is available at: *http://energy.gov/fe/life-cycle-greenhouse-gas-perspective-exporting-liquefied-natural-gas-united-states.*

[13] U.S. Dep't of Energy, Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States: 2019 Update—Response to Comments, 85 FR 72 (Jan. 2, 2020). The 2019 Update and related documents are available at: *https://fossil.energy.gov/app/docketindex/docket/index/21.*

motion to intervene or notice of intervention, as applicable, addressing the Application. Interested parties will be provided 15 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, or notices of intervention. The public previously was given an opportunity to intervene in, protest, and comment on FLEX's long-term non-FTA applications. Therefore, DOE will not consider comments or protests that do not bear directly on the requested term extension.

Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention. The filing of comments or a protest with respect to the Application will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590.

Filings may be submitted using one of the following methods: (1) Emailing the filing to *fergas@hq.doe.gov,* with FE Docket Nos. 10–161–LNG, 11–161–LNG, and 16–108–LNG in the title line; (2) mailing an original and three paper copies of the filing to the Office of Regulation, Analysis, and Engagement at the address listed in **ADDRESSES**; or (3) hand delivering an original and three paper copies of the filing to the Office of Regulation, Analysis, and Engagement at the address listed in **ADDRESSES**. All filings must include a reference to FE Docket Nos. 10–161–LNG, 11–161–LNG, and 16–108–LNG. PLEASE NOTE: If submitting a filing via email, please include all related documents and attachments (*e.g.,* exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner. Any hardcopy filing submitted greater in length than 50 pages must also include, at the time of the filing, a digital copy on disk of the entire submission.

A decisional record on the Application will be developed through responses to this Notice by parties, including the parties' written comments and replies thereto. If no party requests additional procedures, a final Opinion and Order may be issued based on the official record, including the Application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

The Application is available for inspection and copying in the Office of Regulation, Analysis, and Engagement docket room, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The Application and any filed protests, motions to intervene or notice of interventions, and comments will also be available electronically by going to the following DOE/FE Web address: *http://www.fe.doe.gov/programs/gasregulation/index.html.*

Signed in Washington, DC, on September 24, 2020.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Fossil Energy.

[FR Doc. 2020–21511 Filed 9–28–20; 8:45 am]

BILLING CODE 6450–01–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: EG20–248–000.
Applicants: Concho Bluff LLC.
Description: Concho Bluff LLC Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 9/22/20.
Accession Number: 20200922–5091.
Comments Due: 5 p.m. ET 10/13/20.

Docket Numbers: EG20–249–000.
Applicants: Hill Top Energy Center LLC.
Description: Self-Certification of EWG Status of Hill Top Energy Center LLC.
Filed Date: 9/23/20.
Accession Number: 20200923–5029.
Comments Due: 5 p.m. ET 10/14/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14–2080–004.
Applicants: Louisiana Generating LLC.
Description: Compliance filing: Reactive Service Rate Schedule Settlement Compliance Filing to be effective 12/18/2018.
Filed Date: 9/23/20.
Accession Number: 20200923–5073.
Comments Due: 5 p.m. ET 10/14/20.

Docket Numbers: ER15–502–005.
Applicants: Bayou Cove Peaking Power, LLC.
Description: Compliance filing: Reactive Service Rate Schedule Settlement Compliance Filing to be effective 12/18/2018.
Filed Date: 9/23/20.
Accession Number: 20200923–5071.
Comments Due: 5 p.m. ET 10/14/20.

Docket Numbers: ER15–1136–005.
Applicants: Big Cajun I Peaking Power LLC.
Description: Compliance filing: Reactive Service Rate Schedule Settlement Compliance Filing to be effective 12/18/2018.
Filed Date: 9/23/20.
Accession Number: 20200923–5072.
Comments Due: 5 p.m. ET 10/14/20.

Docket Numbers: ER17–1394–002; ER19–2728–001; ER19–2729–001.
Applicants: 83WI 8me, LLC, Lily Solar LLC, Lily Solar Lessee, LLC.
Description: Notice of Non-Material Change in Status and PRO FORMA Market-Based Rate Tariff Revisions of the X-Elio Public Utilities.
Filed Date: 9/22/20.
Accession Number: 20200922–5135.
Comments Due: 5 p.m. ET 10/13/20.

Docket Numbers: ER20–588–002.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Compliance filing: 2020–09–23_Compliance Filing for Storage As Transmission Only Asset (SATOA) to be effective 8/11/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5099.
Comments Due: 5 p.m. ET 10/14/20.

Docket Numbers: ER20–1939–000.
Applicants: Calpine Northeast Development, LLC.
Description: Supplement to May 29, 2020 Calpine Northeast Development, LLC tariff filing, et al.
Filed Date: 9/22/20.
Accession Number: 20200922–5139.
Comments Due: 5 p.m. ET 10/2/20.

Docket Numbers: ER20–2186–001.
Applicants: Fern Solar LLC.
Description: Compliance filing: Compliance to 2 to be effective 12/31/9998.
Filed Date: 9/22/20.
Accession Number: 20200922–5114.
Comments Due: 5 p.m. ET 10/13/20.

Docket Numbers: ER20–2550–001.
Applicants: Entergy Mississippi, LLC.
Description: Tariff Amendment: EML Choctaw Reactive Extension to be effective 12/31/9998.
Filed Date: 9/23/20.
Accession Number: 20200923–5067.
Comments Due: 5 p.m. ET 10/14/20.

Docket Numbers: ER20–2830–000.

Applicants: PPM Roaring Brook, LLC.
Description: Supplement to September 4, 2020 AB Lessee, LLC tariff filing.
Filed Date: 9/22/20.
Accession Number: 20200922–5136.
Comments Due: 5 p.m. ET 10/13/20.
Docket Numbers: ER20–2950–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of ICSA, SA No. 4241; Queue No. AA1–067 to be effective 6/27/2017.
Filed Date: 9/22/20.
Accession Number: 20200922–5084.
Comments Due: 5 p.m. ET 10/13/20.
Docket Numbers: ER20–2951–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of ICSA, SA No. 4067; Queue No. Z2–088 to be effective 3/29/2017.
Filed Date: 9/22/20.
Accession Number: 20200922–5117.
Comments Due: 5 p.m. ET 10/13/20.
Docket Numbers: ER20–2952–000.
Applicants: PPL Electric Utilities Corporation, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: PPL submits Interconnection Agreement, SA No. 5766 with Amtrak to be effective 9/23/2020.
Filed Date: 9/22/20.
Accession Number: 20200922–5121.
Comments Due: 5 p.m. ET 10/13/20.
Docket Numbers: ER20–2953–000.
Applicants: Lone Tree Wind, LLC.
Description: Baseline eTariff Filing: Reactive Power Compensation Filing to be effective 11/22/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5000.
Comments Due: 5 p.m. ET 10/14/20.
Docket Numbers: ER20–2954–000.
Applicants: Midcontinent Independent System Operator, Inc., American Transmission Company LLC.
Description: § 205(d) Rate Filing: 2020–09–23_SA 3562 ATC–ITC–Dairyland TCEA to be effective 8/28/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5022.
Comments Due: 5 p.m. ET 10/14/20.
Docket Numbers: ER20–2955–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Tariff Clean-Up Filing 3Q2020 to be effective 12/1/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5026.
Comments Due: 5 p.m. ET 10/14/20.
Docket Numbers: ER20–2956–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: PJM submits Revisions to OATT re: Credit Reform Clean-Up to be effective 11/23/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5030.
Comments Due: 5 p.m. ET 10/14/20.
Docket Numbers: ER20–2957–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: First Revised ISA, Service Agreement No. 5067; Queue No. AF2–436 to be effective 8/24/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5068.
Comments Due: 5 p.m. ET 10/14/20.
Docket Numbers: ER20–2958–000.
Applicants: Gulf Power Company.
Description: § 205(d) Rate Filing: Filing of PowerSouth Interconnection Agreement and Notice of Termination to be effective 8/12/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5074.
Comments Due: 5 p.m. ET 10/14/20.
Docket Numbers: ER20–2959–000.
Applicants: Antelope Big Sky Ranch LLC.
Description: § 205(d) Rate Filing: Shared Facilities Agreement to be effective 9/24/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5084.
Comments Due: 5 p.m. ET 10/14/20.
Docket Numbers: ER20–2960–000.
Applicants: Antelope DSR 1, LLC.
Description: § 205(d) Rate Filing: Shared Facilities Agreement to be effective 9/24/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5100.
Comments Due: 5 p.m. ET 10/14/20.
Docket Numbers: ER20–2961–000.
Applicants: Antelope DSR 2, LLC.
Description: § 205(d) Rate Filing: Shared Facilities Agreement to be effective 9/24/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5103.
Comments Due: 5 p.m. ET 10/14/20.
Docket Numbers: ER20–2962–000.
Applicants: Antelope DSR 3, LLC.
Description: § 205(d) Rate Filing: Shared Facilities Agreement to be effective 9/24/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5107.
Comments Due: 5 p.m. ET 10/14/20.
Docket Numbers: ER20–2963–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of Upgrade CSA, SA No. 5357; Queue No. NQ–J468 to be effective 8/26/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5108.
Comments Due: 5 p.m. ET 10/14/20.
Docket Numbers: ER20–2964–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original ISA, SA No. 5772; Queue No. AC1–113/AC2–115 to be effective 8/24/2020.
Filed Date: 9/23/20.
Accession Number: 20200923–5113.
Comments Due: 5 p.m. ET 10/14/20.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF20–1421–000.
Applicants: Patmar Land Co, LLC.
Description: Form 556 of Patmar Land Co, LLC.
Filed Date: 9/22/20.
Accession Number: 20200922–5148.
Comments Due: None-Applicable.

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: September 23, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–21460 Filed 9–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP20–988–000.
Applicants: Texas Eastern Transmission, LP.
Description: Report Filing: EPC Refund Report Informational Filing.

Filed Date: 9/21/20.
Accession Number: 20200921–5033.
Comments Due: 5 p.m. ET 10/5/20.
Docket Numbers: RP20–1205–000.
Applicants: Southeast Supply Header, LLC.
Description: § 4(d) Rate Filing: Cleanup Filing—Removal of Terminated Contracts to be effective 10/22/2020.
Filed Date: 9/22/20.
Accession Number: 20200922–5041.
Comments Due: 5 p.m. ET 10/5/20.
Docket Numbers: RP20–608–001.
Applicants: ANR Pipeline Company.
Description: Compliance filing Penalty Updates Compliance Filing to be effective 9/1/2020.
Filed Date: 9/22/20.
Accession Number: 20200922–5025.
Comments Due: 5 p.m. ET 10/5/20.

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 date(s). 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: September 23, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–21457 Filed 9–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD20–8–000]

InPipe Energy; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On September 22, 2020, InPipe Energy filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA). The proposed Piedmont Temporary Regulator Pressure Recovery Project would have an installed capacity of 30 kilowatts (kW), and would be located along an existing municipal water pipeline in the city of Piedmont, Alameda County, California.

Applicant Contact: Gregg Semler, 222 NW 8th Ave, Portland, Oregon 97209, Phone No. (503) 341–0004, Email: *gregg@inpipeenergy.com.*

FERC Contact: Christopher Chaney, Phone No. (202) 502–6778, Email: *christopher.chaney@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) One 30-kW turbine-generator within a 13-foot by 5-foot by 5-foot fiberglass enclosure at the Piedmont Temporary Regulator; and (2) appurtenant facilities. The proposed project would have an estimated annual generation of approximately 125 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A)	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar man-made water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i)	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii)	The facility has an installed capacity that does not exceed 40 megawatts	Y
FPA 30(a)(3)(C)(iii)	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: The proposed Piedmont Temporary Regulator Pressure Recovery Project will not alter the primary purpose of the conduit, which is used to distribute potable water within the city of Piedmont's municipal water supply system. Therefore, based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 30 days from the issuance date of this notice. Deadline for filing motions to intervene is 30 days from the issuance date of this notice. Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY or MOTION TO INTERVENE, as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866)

[1] 18 CFR 385.2001–2005 (2020).

208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may send a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Locations of Notice of Intent: 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 website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (*i.e.,* CD20–8) in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. Copies of the notice of intent can be obtained directly from the applicant. 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, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: September 23, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–21459 Filed 9–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–524–000]

Bradford County Real Estate Partners LLC; Notice of Petition for Declaratory Order

Take notice that on September 18, 2020, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, Bradford County Real Estate Partners LLC (BCREP or Petitioner) filed a petition for declaratory order. The petition seeks a declaratory order from the Commission stating that BCREP's construction and operation of a natural gas liquefaction and truck and rail loading facility (Wyalusing Facility) in Wyalusing Township, Bradford County, Pennsylvania, would not be subject to the Commission's jurisdiction under section 3 or section 7 of the Natural Gas Act, 15 U.S.C. 717b and 717f (2018), as more fully explained in BCREP's petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of 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 October 23, 2020.

Dated: September 23, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–21458 Filed 9–28–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2020–0259; FRL–10015–37–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Anaerobic Digestion Facilities Processing Wasted Food To Support EPA's Sustainable Materials Management Program and Sustainable Management of Food Efforts (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Anaerobic Digestion Facilities Processing Wasted Food to Support EPA's Sustainable Materials Management Program and Sustainable Management of Food Efforts (EPA ICR Number 2533.04, OMB Control Number 2050–0217) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed renewal of a previous ICR, which is currently approved through September 30, 2020. Public comments were previously requested via the **Federal Register** on June 5, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 29, 2020.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–OLEM–2020–0259, online using *www.regulations.gov* (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information

provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Chris Carusiello, U.S. Environmental Protection Agency, Mail Code 5306P, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 308–8757; fax number: (703) 308–0522; email address: *Carusiello.Chris@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: Sustainable Management of Food (SMF) is a systematic approach that seeks to reduce wasted food and its associated impacts over the entire lifecycle of food. The lifecycle of food includes use of natural resources, manufacturing, sales, and consumption and ends with decisions on recovery or final disposal. Diversion of food waste from landfills is a critical component of this effort. To effectively divert food waste from landfills, sufficient capacity to process the diverted materials is required, much of which is provided by anaerobic digestion facilities. Knowledge of organics recycling capacity is needed to facilitate food waste diversion.

EPA's food recovery hierarchy prioritizes potential actions to prevent and divert wasted food. According to the hierarchy, processing wasted food via anaerobic digestion is a more desirable option than landfilling or incineration because it creates more benefits for the environment, society, and the economy. Anaerobic digestion of food waste and other organic materials generates renewable energy, reduces methane emissions to the atmosphere, and provides opportunities to improve soil health through the production of soil amendments. The SMF work supports these efforts by educating state and local governments and communities about the benefits of wasted food diversion. The SMF work also builds partnerships with state agencies and other strategic partners interested in developing organics recycling capacity and provides tools to assist organizations in developing anaerobic digestion (AD) projects.

The nationwide collection of data about AD facilities processing food waste began in 2017 with a survey of all known AD facilities under the currently approved ICR. EPA published the first annual report of findings based on these data in July 2018, and second in September 2019. EPA is renewing this ICR in order to continue to monitor growth and evaluate trends in the capacity for processing of food waste and the amount of food waste being processed via AD in the United States.

Data will be collected using electronic surveys that will be distributed to respondents by email and will be available on EPA's AD website. Participation in this data collection effort is voluntary. Respondents are not required to reveal confidential business information.

Form Numbers: EPA Form 6700–03, EPA Form 6700–04, EPA Form 6700–05.

Respondents/affected entities: Project Developers, Project Owners or Plant Operators, and Livestock Farmers.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 254 (total).

Frequency of response: Annually.

Total estimated burden: 127 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $7,615 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the estimates: This renewal request contains no change in burden compared to the ICR currently approved by OMB.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2020–21525 Filed 9–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2019–0644; FRL–10010–16–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Application for New and Amended Pesticide Registration (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Application for New and Amended Pesticide Registration (EPA ICR Number 0277.20, OMB Control Number 2070–0060) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through September 30, 2020. Public comments were previously requested via the **Federal Register** on February 6, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 29, 2020.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–OPP–2019–0644, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public

Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Callie Koller, Field and External Affairs Division, Office of Pesticide Programs, 7650P, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 347–8248; email address: *koller.callie@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This information collection request (ICR) is designed to provide the EPA with the necessary information to evaluate an application for the registration of a pesticide product, as required under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA provides EPA with the authority to regulate the distribution, sale and use of pesticides in the United States to ensure that they will not pose unreasonable adverse effects to human health and the environment. Pesticides that meet this test receive a license or ''registration.''

Form Numbers: 8570–1, 8570–4, 8570–27, 8570–34, 8570–35, 8570–36, 8570–37.

Respondents/affected entities: Pesticide and other agricultural chemical manufacturing engaged in activities related to the registration of a pesticide product.

Respondent's obligation to respond: Responses to the collection of information are mandatory under FIFRA § 3 and FFDCA § 408 as amended by FQPA.

Estimated number of respondents: 1,808 (total).

Frequency of response: On occasion.

Total estimated burden: 1,562,517 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $120,563,052 (per year), which includes $0 annualized capital or operation & maintenance costs.

Changes in the estimates: The activities in this ICR increase net respondent burden by 37,624 hours annually over the levels in the currently approved collection. While burden per response levels remain unchanged, the number of responses expected in certain categories has shifted as a result of using an updated data set (Section 3 registration actions annually, on average, during the years 2015–2017) to predict future registration application levels. Additionally, in this iteration of the ICR, the Agency calculates the expected annual application burden of three proposed programs that are anticipated to come online in the next three years.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2020–21524 Filed 9–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL 10015–20–OW]

Notice of Public Meeting of the Environmental Financial Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The United States Environmental Protection Agency (EPA) announces a public meeting of the Environmental Financial Advisory Board (EFAB). The purpose of the meeting will be for the EFAB to provide advice on how the EPA can encourage private investment in Opportunity Zones, receive a briefing on the Agency's response to recent EFAB reports, receive updates on EPA activities relating to environmental finance, and consider possible future advisory topics.

DATES: The meeting will be held on October 14, 2020 from 11 a.m. to 3 p.m. (Eastern Time) and October 15, 2020 from 11 a.m. to 3 p.m. (Eastern Time).

ADDRESSES: The meeting will be conducted via webcast and telephone. Interested persons must register in advance at the weblink below to access the meeting in the *Registration for the Meeting* section of this document.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants information about the meeting may contact Ed Chu, the Designated Federal Officer, via telephone/voice mail at (913) 551–7333 or email to *chu.ed@epa.gov.* General information concerning the EFAB is available at *https://www.epa.gov/waterfinancecenter/efab.*

SUPPLEMENTARY INFORMATION:

Background: The EFAB is an EPA advisory committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, to provide advice and recommendations to EPA on innovative approaches to funding environmental programs, projects, and activities. Administrative support for the EFAB is provided by the Water Infrastructure and Resiliency Finance Center within EPA's Office of Water. Pursuant to FACA and EPA policy, notice is hereby given that the EFAB will hold a virtual public meeting for the following purposes:

(1) Engage in a consultation on how the EPA can encourage private investment in Opportunity Zones. Qualified Opportunity Zones are census tracts of low-income and distressed communities designated by state governors and certified by the Department of Treasury. These are areas where new investments, under certain conditions, may be eligible for preferential tax treatment.

(2) Receive a briefing from EPA's Office of Water on the Agency's response to recent EFAB reports on funding and financing of stormwater infrastructure, water system regionalization, and alternative service delivery options for public utility projects.

(3) Receive briefings from invited speakers from EPA and the Environmental Finance Center Network on environmental finance topics, including activities to respond to the COVID–19 pandemic.

(4) Discuss potential future EFAB projects.

Availability of Meeting Materials: Meeting materials (including meeting agenda and briefing materials) will be available on EPA's website at *https://www.epa.gov/waterfinancecenter/efab.*

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees provide independent advice to EPA. Members of the public can submit comments on matters being considered by the EFAB for consideration by members as they develop their advice and recommendations to EPA.

Registration for the Meeting: Register for the meeting at: *https://gcc01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.avcontact.com%2Fefab.*

html&%data=%02%7C01%7C Brubaker.Sonia%40epa.gov% 7C915e3e05629945a554dc08d85be5de 1d%7C88b378b367484867acf 976aacbeca6a7 %7C0%7C0%7C63736039 0137001741& sdata=xDb51i46ng2VZg 5GbVYjIUkprXQKpFnpdCa%2Bx sAFEEA%3D&reserved=0.

Oral Statements: In general, individuals or groups requesting an oral presentation at a virtual EFAB public meeting will be limited to three minutes. Persons interested in providing oral statements at the October 14 and 15, 2020 meetings should register and provide notification as noted in the registration confirmation by October 13, 2020 to be placed on the list of registered speakers.

Written Statements: Written statements for the October 14 and15, 2020 meetings should be received by October 7, 2020 so that the information can be made available to the EFAB for its consideration prior to the meeting. Written statements should be sent via email to *efab@epa.gov.* Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the EFAB website. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, or to request accommodations for a disability, please register for the meeting and list any special requirements or accommodations needed on the registration form at least 10 business days prior to the meeting to allow as much time as possible to process your request.

Dated: September 23, 2020.

Andrew D. Sawyers,

Director, Office of Wastewater Management, Office of Water.

[FR Doc. 2020–21432 Filed 9–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R08–OAR–2018–0349; FRL–10015–14–Region 8]

Clean Air Act Operating Permit Program; Notice of Issuance of Title V Federal Operating Permit to MPLX

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final action.

SUMMARY: This notice announces that the Environmental Protection Agency issued a final permit decision under Title V of the Clean Air Act (CAA) to MPLX for the operation of MPLX's Uintah County, Utah, Wonsits Valley Compressor Station.

DATES: EPA issued Title V Permit to Operate No. V–UO–000005–2018.00 to MPLX, effective September 16, 2020 under 40 CFR part 71. EPA issued the final permit decision as to the contested portions of this permit on September 16, 2020. Pursuant to section 307(b)(1) of the CAA, judicial review of EPA's final permit decision, to the extent it is available, may be sought by filing a petition for review in the United States Court of Appeals for the Tenth Circuit by November 30, 2020.

FOR FURTHER INFORMATION CONTACT: Colin Schwartz, Environmental Scientist, Air and Radiation Division (8ARD–PM), Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, Colorado 80202, telephone number: (303) 312–6043, email address: *schwartz.colin@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This **SUPPLEMENTARY INFORMATION** section is arranged as follows:

I. How can I get copies of this document and other related information?

Docket. EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2018–0349. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Region 8, Air and Radiation Division, 1595 Wynkoop Street, Denver, Colorado 80202. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID 19. We recommend that you telephone Colin Schwartz, Environmental Scientist, at (303) 312–6043 with any questions about reviewing the docket material. before visiting the Region 8 office.

II. Background

The 1990 amendments to the CAA established a comprehensive air quality permit program under the authority of Title V of the CAA. Title V requires certain facilities that emit large amounts of air pollution, or that meet other specified criteria, to obtain an operating permit, known as a Title V permit, after the source has begun to operate. This permit is an enforceable compilation of all enforceable terms, conditions, and limitations applicable to the source, and is designed to improve compliance by clarifying what facilities must do to control air pollution. EPA regulations implementing Title V are codified at 40 CFR part 71 for permits issued by EPA or its delegatees, and at 40 CFR part 70 for permits issued by states and local agencies pursuant to approved programs. A Title V permit is valid for no more than five years and may be renewed in five-year-increments.

MPLX, LP operates a facility in Uintah County, Utah, known as the Wonsits Valley Compressor Station. The owner of the facility is Andeavor Field Services, LLC. At the facility, natural gas is dehydrated and compressed before being routed offsite through a pipeline. The facility operates two control devices to control the emissions from the dehydration unit. In 2013, EPA issued an initial Title V permit for the Wonsits Valley facility pursuant to 40 CFR part 71. On May 13, 2020, EPA issued a renewed Title V permit to Andeavor and MPLX. See Title V Permit to Operate No. V–UO–000005–2018.00, Docket ID: EPA–R08–OAR–2018–0349. By its own terms, and consistent with 40 CFR 71.11(i)(2), most provisions of the renewal permit became effective on May 13, 2020. But on May 13, 2020, MPLX petitioned the EPA's Environmental Appeals Board (EAB) to review certain terms and conditions of the May 2020 Title V permit. Consequently, under 40 CFR 71.11(i)(2)(ii), the effective date of the contested terms and conditions of the permit was delayed.

III. Effect of This Action

On September 2, 2020, the EAB denied MPLX's petition for review. See *In re MPLX,* Permit No. V–UO–000005–2018.00, CAA Appeal No. 20–01 (EAB, Sep. 2, 2020) (Order Denying Review). Following the EAB's action, pursuant to 40 CFR 71.11(l)(5)(i), EPA issued a final permit decision as to the contested portions of the permit on September 16, 2020. All contested conditions of Title V Permit No. V–UO–000005–2018.00, as issued by EPA on May 13, 2020, were therefore final and effective as of September 16, 2020. Except as provided in the permit, the final Title V permit will expire on September 16, 2025.

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

Dated: September 23, 2020.

Debra Thomas,

Acting Regional Administrator, Region 8.

[FR Doc. 2020–21479 Filed 9–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2016–0654; FRL–10014–49–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Procedures for Requesting a Chemical Risk Evaluation Under TSCA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Procedures for Requesting a Chemical Risk Evaluation under TSCA (EPA ICR Number 2559.03, OMB Control Number 2070–0202) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through September 30, 2020. Public comments were previously requested via the **Federal Register** on January 28, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 29, 2020.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–OPPT–2016–0654, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Susanna Blair, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–4371; email address: *blair.susanna@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The information collection activities covered by this ICR renewal are those carried out by a chemical manufacturer in requesting a specific chemical risk evaluation under the Toxic Substance Control Act (TSCA) be conducted by EPA. EPA established the process for conducting risk evaluations under TSCA. Chemicals that will undergo this evaluation include chemicals the Agency has prioritized, as well as chemicals for which EPA has granted requests made by manufacturers to have the chemicals evaluated under EPA's risk evaluation process. EPA has established criteria and information chemical manufacturers must provide for EPA to consider a chemical substance for risk evaluation. This information is necessary in order for EPA to review information covered by chemical manufacturers and determine if the chemical substance is suitable for risk evaluation.

Form Numbers: None.

Respondents/affected entities: Persons that manufacture chemical substances and request a chemical be considered for risk evaluation by EPA.

Respondent's obligation to respond: Voluntary (15 U.S.C. 2605(b)(4)).

Estimated number of respondents: 5.

Frequency of response: On occasion.

Total estimated burden: 419 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $283,570 (per year), which includes $0 annualized capital or operation & maintenance costs.

Changes in the estimates: There is no change in hour or cost burden as compared with what is currently approved by OMB. There is an increase of $709 in the total estimated labor costs, which reflects the increase in wage rates since the initial ICR.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2020–21528 Filed 9–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2019–0563; FRL–10009–21–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Pesticide Registration Fees Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Pesticide Registration Fees Program (EPA ICR Number 2330.04, OMB Control Number 2070–0179) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through September 30, 2020. Public comments were previously requested via the **Federal Register** on December 3, 2019 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 29, 2020.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–OPP–2019–0563, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Carolyn Siu, Field and External Affairs Division, Office of Pesticide Programs, 7506P, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 347–0159; email address: *siu.carolyn@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This ICR covers the paperwork burden hours and costs associated with the information collection activities under the pesticide registration fee programs implemented through the Office of Pesticide Programs (OPP), Environmental Protection Agency (EPA). Pesticide registrants are required by statute to pay an annual registration maintenance fee for all products registered under Section 3 and Section 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In addition, the Pesticide Registration Improvement Act (PRIA) amended FIFRA in 2004 to create a registration service fee system for applications for specific pesticide registration, amended registration, and associated tolerance actions (Section 33). This ICR specifically covers the activities related to the collection of the annual registration maintenance fees, the registration service fees and the burden associated with the submission of requests for fees to be waived.

Form Numbers: 8570–30.

Respondents/affected entities: North American Industrial Classification System (NAICS) codes: 3250A1—Pesticide and other agricultural chemical manufacturing; 32518—Other Basic Inorganic Chemical Manufacturing; 32519—Other Basic Organic Chemical Manufacturing and 9641—Regulation of Agricultural Marketing and Commodities.

Respondent's obligation to respond: Mandatory under FIFRA sections 4(i)(5) and 33.

Estimated number of respondents: 1,523 (total).

Frequency of response: Annually and on occasion.

Total estimated burden: 8,540 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $687,301 (per year), which includes $3,600 annualized capital or operation & maintenance costs.

Changes in the estimates: There is an increase of 229 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This modest addition is associated with an increase in respondents for pesticide registration maintenance fees (from 1,471 to 1,523) and in refinements of the burden calculations. The total estimated annual respondent burden for service fee waivers has not changed.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2020–21529 Filed 9–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R07–SFUND–2020–0494; FRL–10015–18–Region 7]

Notice of Proposed Administrative Settlement Agreement and Covenant Not To Sue

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: Notice is hereby given by the U.S. Environmental Protection Agency (EPA), Region 7, of a proposed prospective purchaser agreement, embodied in an Administrative Settlement Agreement and Covenant Not to Sue, with the Herbert Hoover Boys and Girls Club of St. Louis, Inc. This agreement pertains to a portion of the Carter Carburetor Superfund Site located at approximately 2840 N Spring Ave. in the City of St. Louis, Missouri.

DATES: Comments must be received on or before October 29, 2020.

ADDRESSES: The proposed settlement agreement is available for public inspection at EPA Region 7's office. A copy of the proposed agreement may also be obtained from Catherine Chiccine, EPA Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219, telephone number (913) 551–7917. You may send comments, identified by Docket ID No. EPA–R07–SFUND–2020–0494, to *https://www.regulations.gov.* Follow the online instructions for submitting comments. You may also send comments, identified by 'Carter Careburetor Superfund Site Public Comment,' to Ms. Chiccine at the above address or electronically to *chiccine.catherine@epa.gov.*

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

FOR FURTHER INFORMATION CONTACT: Catherine Chiccine, Assistant Regional Counsel, Office of Regional Counsel, Environmental Protection Agency Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number (913) 551–7917; email address *chiccine.catherine@epa.gov.*

SUPPLEMENTARY INFORMATION:

Written Comments

Submit your comments, identified by Docket ID No. EPA–R07- SFUND–2020–0494 at *https://www.regulations.gov.* 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. If CBI exists, please contact Ms. Chiccine. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

Notice is hereby given by the U.S. Environmental Protection Agency, Region 7, of a proposed prospective

purchaser agreement, embodied in an Administrative Settlement Agreement and Covenant Not to Sue, with Herbert Hoover Boys and Girls Club of St. Louis, Inc. regarding property located at approximately 2840 N Spring Ave., more specifically bounded by North Spring Avenue, Dodier Street, North Grand Boulevard, and St. Louis Avenue in the City of St. Louis, Missouri. Herbert Hoover Boys and Girls Club of St. Louis, Inc. seeks to acquire the property for reuse and redevelopment. This project will result in a formerly contaminated property being restored to beneficial use by a community stakeholder.

The settlement includes a covenant by EPA not to sue or take administrative action against the Herbert Hoover Boys and Girls Club of St. Louis, Inc., pursuant to sections 106 and 107(a) of CERCLA. For thirty (30) days following the date of publication of this document, EPA will receive written comments relating to the settlement. EPA will consider all comments received and may modify or withdraw its consent to the settlement agreement if comments received disclose facts or considerations that indicate that the proposed settlement is inappropriate, improper, or inadequate. EPA's response to any comments received will be available for public inspection at EPA Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219.

Dated: September 23, 2020.

Mary Peterson,

Director, Superfund Division, EPA Region 7.

[FR Doc. 2020–21398 Filed 9–28–20; 8:45 am]

BILLING CODE 6560–50–P

EXPORT–IMPORT BANK

Intent to Conduct a Detailed Economic Impact Analysis

AGENCY: Export-Import Bank.

ACTION: Notice.

SUMMARY: Pursuant to the Charter of the Export-Import Bank of the United States, this notice is to inform the public that the Export-Import Bank of the United States has received an application for a $233.8 million comprehensive loan guarantee to support the export of approximately $351 million worth of hydrotreatment and steam methane reforming equipment to Paraguay. The U.S. exports will enable the Paraguayan company to produce up to 16,092 barrels per day of renewable diesel (also referred to as Hydrotreated Vegetable Oil or HVO) or up to 13,162 barrels per day of renewable jet fuel (also referred to as Synthesized Paraffinic Kerosene or SPK). New production will be sold in the United States and in Western Europe.

DATES: Comments are due 14 days from publication in the **Federal Register**.

ADDRESSES: Interested parties may submit comments on this transaction electronically on *www.regulations.gov,* or by email to *economic.impact@exim.gov.*

Scott Condren,

Policy Analysis Division.

[FR Doc. 2020–21472 Filed 9–28–20; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

FDIC Advisory Committee of State Regulators; Notice of Meeting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of open meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Advisory Committee of State Regulators. The Advisory Committee will provide advice and recommendations on a broad range of policy issues regarding the regulation of state-chartered financial institutions throughout the United States, including its territories. The meeting is open to the public. Out of an abundance of caution related to current and potential coronavirus developments, the public's means to observe this meeting of the Advisory Committee of State Regulators will be via a Webcast live on the internet. In addition, the meeting will be recorded and subsequently made available on-demand approximately two weeks after the event. To view the live event, visit *http://fdic.windrosemedia.com.* To view the recording, visit *http://fdic.windrosemedia.com/index.php?category=Advisory+Committee+State+Regulators.* If you require a reasonable accommodation to participate, please contact *DisabilityProgram@fdic.gov* or call 703–562–2096 to make necessary arrangements.

DATES: Wednesday, October 14, 2020, from 1:00 p.m. to 5:15 p.m.

FOR FURTHER INFORMATION CONTACT: Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Committee Management Officer of the FDIC, at (202) 898–7043.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will include a discussion of a variety of current and emerging issues that have potential implications regarding the regulation and supervision of state-chartered financial institutions. The agenda is subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: This meeting of the Advisory Committee of State Regulators will be Webcast live via the internet *http://fdic.windrosemedia.com.* For optimal viewing, a high-speed internet connection is recommended.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on September 24, 2020.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2020–21490 Filed 9–28–20; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS20–12]

Appraisal Subcommittee; Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of Special Meeting.

Description: In accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for a Special Meeting:

Location: Due to the COVID–19 Pandemic, the meeting will be open to the public via live webcast only. Visit the agency's homepage (*www.asc.gov*) and access the provided registration link in the What's New box. You MUST register in advance to attend this Meeting.

Date: October 5, 2020.

Time: 1:30 p.m. ET.

Status: Open.

Action and Discussion Items

Notice of Funding Availability (NOFA) Summary for the Appraisal Foundation Grant.

How to Attend and Observe an ASC meeting: Due to the COVID–19 Pandemic, the meeting will be open to the public via live webcast only. Visit the agency's homepage (*www.asc.gov*) and access the provided registration link in the What's New box. The meeting

space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC meetings.

James R. Park,

Executive Director.

[FR Doc. 2020–21518 Filed 9–28–20; 8:45 am]

BILLING CODE 6700–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than October 29, 2020.

A. Federal Reserve Bank of Cleveland (Mary S. Johnson, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566. Comments can also be sent electronically to *Comments.applications@clev.frb.org:*

1. *Northwest Bancshares, Inc., Warren, Pennsylvania;* to become a bank holding company upon the revocation of qualified thrift lender status by its subsidiary, Northwest Bank, Warren, Pennsylvania.

Board of Governors of the Federal Reserve System, September 24, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–21512 Filed 9–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Collection of Certain Data Regarding Passengers and Crew Arriving From Foreign Countries by Airlines; Rescission of Agency Order

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the rescission of an Agency Order that was published in the **Federal Register** on February 24, 2020.

DATES: The Agency Order titled *Collection of Certain Data Regarding Passengers and Crew Arriving from Foreign Countries by Airlines* issued on February 18, 2020 is rescinded effective September 29, 2020.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329. Email: *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION: On February 24, 2020, the Centers for Disease Control and Prevention (CDC) published a notice titled ''*Collection of Certain Data Regarding Passengers and Crew Arriving from Foreign Countries by Airlines*'' (85 FR 10439) announcing the issuance of an Agency Order on February 18, 2020 to airlines requiring them to collect and provide contact information to CDC about any passenger who had departed from, or was otherwise present within, the People's Republic of China (excluding the special administrative regions of Hong Kong and Macau) within 14 days of the person's entry or attempted entry into the United States via that airline's carriage.

CDC has determined that this information is no longer required to be collected and provided to the Agency by the subject airlines in the manner stipulated in the Order. Accordingly, that Order is hereby rescinded as of September 29, 2020.

Dated: September 24, 2020.

Robert R. Redfield,

Director, Centers for Disease Control and Prevention.

[FR Doc. 2020–21572 Filed 9–25–20; 10:00 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; National Survey of Early Care and Education COVID–19 Follow-Up (OMB #0970–0391)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a two-wave data collection as part of the National Survey of Early Care and Education (NSECE) (OMB #0970–0391), which will be conducted October 2020 through June 2021. The objective of the NSECE COVID–19 Follow-up is to document the nation's current supply of early care and education (ECE) services that is home-based providers, center-based providers, and the center-based provider workforce. In the context of the COVID–19 pandemic, the NSECE COVID–19 Follow-up will deepen our understanding of the state of ECE supply and the ECE workforce following the initial period of crisis, including changes in supply or departures from and re-entries to the workforce.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting

''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The NSECE COVID–19 Follow-up will collect information from center-based ECE providers of care to children birth through age 5 (not yet in kindergarten), home-based ECE providers that serve children under age 13, as well as the ECE workforce providing these services. The proposed collection will consist of the following three coordinated nationally representative surveys:

1. A two-wave survey of individuals who provided paid care for children under the age of 13 in a residential setting, as of 2019, and who participated in the 2019 NSECE (Home-based Provider Interview);

2. a two-wave survey of providers of care to children ages 0 through 5 years of age (not yet in kindergarten) in a non-residential setting (Center-based Provider Interview), as of 2019, and who participated in the 2019 NSECE; and

3. a two-wave survey conducted with individuals employed in center-based child care programs working directly with children in classrooms (Center-based Classroom Staff [Workforce] Interview), as of 2019, and who participated in the 2019 NSECE.

The NSECE COVID–19 Follow-up will provide urgently needed information about the supply of child care and early education available to families across all income levels, including providers serving low-income families of various racial, ethnic, language, and cultural backgrounds, in diverse geographic areas. The study will also dramatically extend the available resources for understanding the national impact of the COVID–19 pandemic on the country's ECE supply and workforce, including geographic variation therein. Accurate data on the availability and characteristics of ECE programs are essential to assess the current and changing landscape of child care and early education programs and understand the ability of the nation's supply and workforce to meet the needs of parents of young children in the post-pandemic economy, and will provide insights to advance policy and initiatives in the ECE field.

Respondents: Home-based providers, as of 2019, serving children under 13 years of age (listed and unlisted paid)—regardless of their status serving children in 2020–2021; center-based child care providers, as of 2019, serving children ages 0 through 5 years of age (not yet in kindergarten)—regardless of their status serving children in 2020–2021; and classroom-assigned instructional staff members working with children ages 0 through 5 years of age (not yet in kindergarten) in center-based child care providers, as of 2019, regardless of their employment status in 2020–2021.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Home-based Provider Interview, Waves 1 and 2	3,375	1.5	.33	1,671
Center-based Provider Interview, Waves 1 and 2	5,850	1.5	.33	2,896
Center-based Classroom Staff (Workforce) Interview, Waves 1 and 2	3,533	1.5	.33	1,749

Estimated Total Annual Burden Hours: 6,316.

Authority: Child Care and Development Block Grant Act (42 U.S.C. 9858 et. seq.).

John M. Sweet Jr,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–21509 Filed 9–28–20; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0987]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, 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 on generic clearance for the collection of qualitative data on tobacco products and communications.

DATES: Submit either electronic or written comments on the collection of information by November 30, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 30, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 30, 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.

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–2014–N–0987 for ''Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications.'' 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications

OMB Control Number 0910–0796—Extension

Under section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA is authorized to conduct educational and public information programs.

In conducting studies relating to the regulation and communications related to tobacco products, FDA will need to employ formative qualitative research including focus groups, usability testing, and/or in-depth interviews (IDIs) to assess knowledge and perceptions about tobacco-related topics with specific target audiences. The information collected will serve three major purposes. First, formative research will provide critical knowledge about target audiences. FDA must first understand people's knowledge and perceptions about tobacco related topics prior to developing survey/research questions as well as stimuli for experimental studies. Second, by collecting communications usability information, FDA will be able to serve and respond to the ever-changing demands of consumers of tobacco products. Additionally, we will be able to determine the best way to present messages. Third, initial testing will allow FDA to assess consumer understanding of survey/research questions and study stimuli. Focus groups and/or IDIs with a sample of the target audience will allow FDA to refine the survey/research questions and study stimuli while they are still in the developmental stage. FDA will collect, and interpret information gathered through this generic clearance in order to: (1) Better understand characteristics of the target audience—its perceptions, knowledge, attitudes, beliefs, and behaviors—and use these in the development of appropriate survey/research questions, study stimuli, or communications; (2) more efficiently and effectively design survey/research questions and study stimuli; and (3) more efficiently and effectively design experimental studies.

FDA is requesting approval of an extension of this generic clearance for collecting information using qualitative methods (*i.e.,* individual interviews, small group discussions, and focus groups) for studies involving all tobacco products regulated by FDA. This information will be used as a first step to explore concepts of interest and assist in the development of quantitative study proposals, complementing other important research efforts in the Agency. This information may also be used to help identify and develop communication messages, which may be used in education campaigns. Focus groups play an important role in gathering information because they allow for an in-depth understanding of individuals' attitudes, beliefs, motivations, and feelings. Focus group

research serves the narrowly defined need for direct and informal public opinion on a specific topic.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
In-Person Individual In-depth Interviews.	1,092	1	1,092	1	1,092
In-depth Interview (IDI) Screener	1,800	1	1,800	0.083 (5 minutes)	150
Focus Group Screener	19,385	1	19,385	0.25 (15 minutes)	4,846
Focus Group Interviews	5,897	1	5,897	1.5	8,846
Total					14,934

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents to be included in each new pretest may vary, depending on the nature of the material or message being tested and the target audience. Table 1 provides examples of the types of studies that may be administered and estimated burden levels during the 3-year period. Time to read, view, or listen to the message being tested is built into the ''Hours per Response'' figures. Our estimated burden for the information collection reflects an overall increase of 5,641 hours and a corresponding increase of 16,585 responses. We attribute this adjustment to the number of study responses used during the current approval and now estimated for the next 3 years.

Dated: September 18, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21452 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4467]

Breast Implants—Certain Labeling Recommendations To Improve Patient Communication; Guidance for Industry and Food and Drug Administration Staff; 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 entitled ''Breast Implants—Certain Labeling Recommendations to Improve Patient Communication.'' This guidance contains recommendations concerning the content and format for certain labeling information for saline and silicone gel-filled breast implants. FDA is issuing this guidance to help ensure that a patient receives and understands the benefits and risks of breast implants. These labeling recommendations are intended to enhance, but not replace, the physician-patient discussion of the benefits and risks of breast implants that uniquely pertain to individual patients.

DATES: The announcement of the guidance is published in the **Federal Register** on September 29, 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–2019–D–4467 for ''Breast Implants—Certain Labeling Recommendations to Improve Patient Communication.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly

available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Breast Implants—Certain Labeling Recommendations to Improve Patient Communication'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Joseph Nielsen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4608, Silver Spring, MD 20993–0002, 301–796–6244.

SUPPLEMENTARY INFORMATION:

I. Background

Over the past few years, FDA has received new information pertaining to risks associated with breast implants, including breast implant-associated anaplastic large cell lymphoma (BIA–ALCL) and systemic symptoms commonly referred to as breast implant illness (BII) that some patients attribute to their implants. FDA has taken a number of steps to better understand and address risks associated with breast implants, including convening the General and Plastic Surgery Devices Advisory Panel on March 25 to 26, 2019, to discuss the long-term benefits and risks of breast implants indicated for breast augmentation and reconstruction. FDA learned from presentations at the March 2019 Panel meeting and through comments submitted to the associated public docket that some patients may not be receiving or understanding important information regarding the benefits and risks of breast implants in a format that allows them to make a well-informed decision about whether to have a breast implantation.

For these reasons, FDA is now providing recommendations concerning the content and format of certain labeling information for these devices. Specifically, FDA is recommending that manufacturers incorporate a boxed warning and a patient decision checklist into the labeling for these devices to better ensure certain information is received and understood by patients. This guidance also recommends updated and additional labeling information, including updates to the silicone gel-filled breast implant rupture screening recommendations, inclusion of an easy-to-find description of materials, and provision of patient device cards that were recommended at the March 2019 Panel meeting. The recommendations in this guidance document supplement the recommendations in FDA's guidance entitled ''Saline, Silicone Gel, and Alternative Breast Implants.'' [1]

A notice of availability of the draft guidance appeared in the **Federal Register** of October 24, 2019 (84 FR 57028). FDA considered comments received and revised the guidance as appropriate in response to the comments, including revisions to clarify the labeling recommendations regarding the relationship between breast implants and systemic symptoms and certain other risks, to refine the recommendations regarding information on the patient device card to improve clarity and readability, and to provide reference to and information regarding ongoing patient registries in the patient decision checklist.

This 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 ''Breast Implants—Certain Labeling Recommendations to Improve Patient Communication.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Breast Implants—Certain Labeling Recommendations to Improve Patient Communication'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 19021 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
814, subparts A through E	Premarket approval	0910–0231
812	Investigational Device Exemption	0910–0078
801	Medical Device Labeling Regulations	0910–0485

[1] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/saline-silicone-gel-and-alternative-breast-implants.*

21 CFR part; guidance; or FDA form	Topic	OMB control No.
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910–0755
830	Unique Device Identification System	0910–0720
820	Quality System Regulation	0910–0073

Dated: September 24, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21453 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1787]

Advisory Committee; Blood Products Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Blood Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Blood Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 13, 2022, expiration date.

DATES: Authority for the Blood Products Advisory Committee will expire on May 13, 2022, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Christina Vert, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993–0002, 240–402–8054 *Christina.Vert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Blood Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Blood Products Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee shall consist of a core of 17 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm121602.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/advisory-committees.*

Dated: September 18, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21454 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3091]

Advisory Committee; Cardiovascular and Renal Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Cardiovascular and Renal Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Cardiovascular and Renal Drugs Advisory Committee for an additional 2 years beyond the charter

expiration date. The new charter will be in effect until August 27, 2022.

DATES: Authority for the Cardiovascular and Renal Drugs Advisory Committee will expire on August 27, 2022, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Joyce Yu, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2438, Silver Spring, MD 20993–0002, 301–796–9001, email: *CRDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under 41 CFR 102–3, FDA is announcing the renewal of the Cardiovascular and Renal Drugs Advisory Committee (Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

Under its Charter, the Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests. There may also be alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/cardiovascular-and-renal-drugs-advisory-committee/cardiovascular-and-renal-drugs-advisory-committee-charter* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the Committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: September 18, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21465 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1227]

Roerig Division of Pfizer Inc., et al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on July 21, 2020. The document announced the withdrawal of approval of 10 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of August 20, 2020. The document indicated that FDA was withdrawing approval of the following two ANDAs after receiving a withdrawal request from Kadmon Pharmaceuticals, LLC., 119 Commonwealth Dr., Warrendale, PA 15086: ANDA 076203, Ribavirin Capsules, 200 milligrams (mg) and ANDA 077456, Ribavirin Tablets, 200 mg, 400 mg, and 600 mg. Before FDA withdrew the approval of these ANDAs, Kadmon Pharmaceuticals, LLC. informed FDA that it did not want the approval of the ANDAs withdrawn. Because Kadmon Pharmaceuticals, LLC., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 076203 and 077456 are still in effect.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of Tuesday, July 21, 2020 (85 FR 44096), appearing on page 44096 in FR Doc. 2020–15727, the following correction is made:

On page 44096, in the table, the entries for ANDAs 076203 and 077456 are removed.

Dated: September 21, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21456 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1445]

Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.'' This guidance describes studies and information that FDA recommends be used when submitting premarket notifications (510(k)s) for blood glucose monitoring systems (BGMSs) that are for prescription point-of-care use.

DATES: The announcement of the guidance is published in the **Federal Register** on September 29, 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–2013–D–1445 for ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Leslie Landree, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3566, Silver Spring, MD 20993–0002, 301–796–6147.

SUPPLEMENTARY INFORMATION:

I. Background

On October 11, 2016 (81 FR 70122), FDA published a final guidance entitled ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.'' That guidance document described studies and information that FDA recommends be used when submitting 510(k)s for BGMSs that are for prescription point-of-care use.

On November 30, 2018, FDA published a notice of availability in the **Federal Register** (83 FR 61648) of a draft guidance that proposed revisions to the guidance. FDA proposed modifications based on feedback received from stakeholders and to better align with the evolving understanding and development of these types of devices.

FDA considered comments received on the draft guidance and made revisions as appropriate in response to the comments, including a minor edit encouraging manufacturers to consider design features that will aid in user accessibility and a technical edit in hemoglobin testing concentration. This revised guidance replaces the existing final guidance of the same title issued on October 11, 2016.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1755 and title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for this guidance. The collections of information in the following FDA guidances and regulations have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-Submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices—Guidance for Industry and Food and Drug Administration Staff.	CLIA Waiver Applications	0910–0598
Administrative Procedures for CLIA Categorization—Guidance for Industry and Food and Drug Administration Staff.	Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization (42 CFR 493.17).	0910–0607

Dated: September 23, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21463 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1548]

Failure To Respond to an Abbreviated New Drug Application Complete Response Letter Within the Regulatory Timeframe; Draft 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 draft guidance for industry entitled ''Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe.'' This guidance is intended to assist applicants in responding to complete response letters (CRLs) to abbreviated new drug applications (ANDAs) submitted to FDA under the Federal Food, Drug, and Cosmetic Act. This guidance provides information and recommendations regarding potential courses of action for an ANDA applicant after issuance of a CRL as well as the actions that FDA may take if the applicant fails to respond to a CRL. In addition, this guidance recommends information an applicant may submit in its request for an extension to respond to a CRL as well as a non-exhaustive list of factors that FDA will consider in determining whether such a request is reasonable.

DATES: Submit either electronic or written comments on the draft guidance by November 30, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–1548 for ''Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe.'' 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 draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lisa Bercu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–6902, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe.'' This guidance provides information and recommendations regarding the potential courses of action for an ANDA applicant after issuance of a CRL as well as the actions that FDA may take if the applicant fails to respond to the CRL. This guidance also identifies information that an applicant may submit in its request for an extension to respond to a CRL as well as a non-exhaustive list of factors that FDA will consider in determining whether such a request is reasonable.

As defined in 21 CFR 314.3(b), a CRL is a written communication to an applicant from FDA usually describing all of the deficiencies that the Agency has identified in an NDA or ANDA that must be satisfactorily addressed before it can be approved. After receiving a CRL, an applicant must, under § 314.110(b) (21 CFR 314.110(b)): (1) Resubmit the ANDA (*i.e.,* submit all materials needed to fully address all deficiencies identified in the CRL), (2) withdraw the application, or (3) request the opportunity for a hearing. If an applicant fails to take one of these three actions within 1 year after issuance of a CRL, FDA may consider this failure to be a request to withdraw the ANDA unless the applicant has requested an extension of time in which to address all deficiencies identified in the CRL.

Historically, FDA, in its discretion, has liberally granted requests for multiple extensions to respond to an individual CRL. However, FDA has seen a steady increase of applications pending with industry for more than a year. Lengthy response times because of multiple extensions, which can result in a submission addressing deficiencies years after the initial assessment of the ANDA and issuance of the CRL, are disruptive to the assessment process and can create additional assessment cycles. Over time, information submitted in the original ANDA can become obsolete because of changes such as new or revised United States Pharmacopeia requirements, reference listed drug labeling changes, or other events such as a facility evaluation becoming outdated. In addition, over time, there may have been changes in FDA assessors, and it may take time for them to familiarize themselves with the original submission. For these reasons, assessing an amendment submitted years after the initial ANDA assessment and issuance of the CRL diverts the Agency's limited resources from the review of other applications.

FDA is issuing this guidance as part of the ''Drug Competition Action Plan,'' which aims to increase competition in the market for prescription drugs, facilitate entry of high-quality and affordable generic drugs, and improve the public health. FDA intends for this guidance to promote efforts to address deficiencies more quickly, make the process for submitting and reviewing extension requests more efficient and predictable, and allow the Agency to focus its resources on ANDA assessment.

In addition to general comments on this guidance, FDA is interested in responses to the following questions:

1. Are there any categories of deficiencies in which a year would not be expected to be a sufficient amount of time to respond to a CRL?

2. Why may it take an applicant more than 1 year to respond to a CRL?

a. Does the patent landscape impact the timing of an applicant's response to a CRL?

b. Are there disincentives (*e.g.,* business reasons) to responding to a CRL within 1 year?

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe.'' 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 draft guidance for industry entitled, ''Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe,'' describes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). In particular, the draft guidance refers to collection of information under § 314.110, Complete Response Letter to the Applicant, after FDA review of an ANDA and issuance of a CRL identifying deficiencies in the application to the ANDA applicant.

Any burden of communications, as outlined in 21 CFR 314.102 and 314.110, incurred during the review of new drug applications, ANDAs, and drug master files, is already accounted for as part of the FDA review process and attributable to other specific references in 21 CFR 314, within the OMB approved collection 0910–0001.

The draft guidance also refers to previously approved collections of information found in FDA regulations and approved under OMB control numbers 0910–0001 and 0910–0191. When finalized, the guidance will be included in 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances* or *https://www.regulations.gov.*

Dated: September 18, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21469 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1824]

Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment.'' Sponsors may encounter challenges in identifying methods to assess the numerous and heterogeneous Coronavirus Disease 2019 (COVID–19)-related symptoms across subjects when designing clinical trials of drugs to treat or prevent COVID–19 in adult and adolescent outpatient subjects. To assist sponsors, this guidance describes an example with a set of common COVID–19-related symptoms as well as an approach to their measurement for use in clinical trials. Given the public health emergency presented by COVID–19, this guidance document is being implemented without prior public comment because FDA has determined that prior public participation is not feasible or appropriate, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on September 29, 2020. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–1824 for ''Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment.'' 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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Elektra Papadopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6445, Silver Spring, MD 20993–0002, 301–796–0967; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903

New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment.'' Sponsors may encounter challenges in identifying methods to assess the numerous and heterogeneous COVID–19-related symptoms across subjects when designing clinical trials of drugs to treat or prevent COVID–19 in adult and adolescent outpatient subjects. In many instances, daily assessment of all COVID–19-related symptoms may not be feasible.

To assist sponsors, the guidance describes an example with a set of common COVID–19-related symptoms derived from information provided by the Centers for Disease Control and Prevention as of August 28, 2020, as well as an approach to their measurement for use in clinical trials.

The guidance also includes considerations and recommendations for handling data and for standardizing other COVID–19-related clinical trial assessments for trial subjects.

In light of the public health emergency related to COVID–19 declared by the Secretary of the Department of Health and Human Services (HHS), FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment (see section 701(h)(1)(C)(i) of the FD&C Act (21 U.S.C. 371(h)(1)(C)(i)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices. FDA will review comments, and the guidance will be updated accordingly.

This guidance is intended to remain in effect for the duration of the public health emergency related to COVID–19 declared by HHS, including any renewals made by the Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). However, the recommendations and processes described in the guidance are expected to assist the Agency more broadly in its efforts to provide sponsors with considerations for the assessment of COVID–19-related symptoms in outpatient adult and adolescent subjects in clinical trials evaluating drugs to treat or prevent COVID–19 beyond the termination of the COVID–19 public health emergency and reflect the Agency's current thinking on this issue. Therefore, within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance with any appropriate changes based on comments received on this guidance and the Agency's experience with implementation.

This 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 ''Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. 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 for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR parts 312 and 320 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: September 18, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21455 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1790]

M7 Assessment and Control of Deoxyribonucleic Acid Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk—Questions and Answers; International Council for Harmonisation; Draft 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 draft guidance for industry entitled ''M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk—Questions and Answers.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The draft guidance provides a practical approach that is applicable to the identification, categorization, qualification, and control of mutagenic impurities to limit potential carcinogenic risk. Since the ICH M7 Guideline was finalized, the worldwide experience with implementation of the recommendations for DNA reactive (mutagenic) impurities has given rise to requests for clarification relating to the assessment and control of DNA reactive (mutagenic) impurities. To facilitate the implementation of the ICH M7 Guideline, the ICH M7 Implementation Working Group has developed a series of questions and answers (Q&As). The scope of this draft Q&A guidance follows that of the ICH M7 Guideline. The draft Q&A guidance is intended to clarify, promote the convergence of, and improve the harmonization of the considerations for assessment and control of DNA reactive (mutagenic) impurities and of the information that should be provided when developing

drugs, completing marketing authorization applications, and using drug master files.

DATES: Submit either electronic or written comments on the draft guidance by December 28, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1790 for ''M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk—Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Aisar Atrakchi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4118, Silver Spring, MD 20993–0002, 301–796–1036; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk—Questions and Answers.'' The draft guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally,

the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (*https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In June 2020, the ICH Assembly endorsed the draft guideline entitled ''M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk—Questions and Answers'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft Q&A guidance is intended to clarify, promote the convergence of, and improve the harmonization of the considerations for assessment and control of DNA reactive (mutagenic) impurities and of the information that should be provided when developing drugs, completing marketing authorization applications, and using drug master files. This is important because since the ICH M7 Guideline was finalized, the worldwide experience with implementation of the recommendations for DNA reactive (mutagenic) impurities has given rise to requests for clarification relating to the assessment and control of DNA reactive (mutagenic) impurities. To facilitate the implementation of the ICH M7 Guideline, the ICH M7 Implementation Working Group has developed a series of Q&As. The scope of this draft Q&A guidance follows that of the ICH M7 Guideline.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk—Questions and Answers.'' 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

FDA tentatively concludes that this draft 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 draft 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 601 has been approved under OMB control number 0910–0338. The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, and the collection of information under 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: September 22, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21461 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1446]

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of the final guidance entitled ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.'' This guidance described studies and information that FDA recommends be used when submitting premarket notifications (510(k)s) for self-monitoring blood glucose test systems (SMBGs), which are for over-the-counter (OTC) home use by lay users. This guidance is not meant to address blood glucose monitoring test systems (BGMS) that are intended for prescription point-of-care use in professional healthcare settings (*e.g.,* hospitals, physician offices, long-term care facilities).

DATES: The announcement of the guidance is published in the **Federal Register** on September 29, 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–2013–D–1446 for ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Leslie Landree, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3566, Silver Spring, MD 20993–0002, 301–796–6147.

SUPPLEMENTARY INFORMATION:

I. Background

On October 11, 2016 (81 FR 70120), FDA published a final guidance entitled, ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.'' This guidance described studies and information that FDA recommends be used when submitting premarket notifications (510(k)s) for SMBGs, which are for home use by lay users.

On November 30, 2018, FDA published a notice of availability in the **Federal Register** (83 FR 61640) of a draft guidance that proposed revisions to the guidance. FDA proposed modifications based on feedback received from stakeholders and to better align with the evolving understanding and development of these types of devices.

FDA considered comments received on the draft guidance and we made revisions as appropriate in response to the comments, including a minor edit encouraging manufacturers to consider design features that will aid in user accessibility and a technical edit in hemoglobin testing concentration. This guidance replaces the existing final guidance of the same title issued on October 11, 2016.

This guidance is not meant to address BGMS that are intended for prescription point-of-care use in professional healthcare settings (*e.g.,* hospitals, physician offices, long-term care facilities). FDA addresses those device types in another guidance entitled, ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.'' [1]

This 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 ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1756 and title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for this guidance. The collections of information in the following FDA guidance and regulations

[1] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/self-monitoring-blood-glucose-test-systems-over-counter-use-0.*

have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-Submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

Dated: September 23, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21462 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0410]

Peripheral and Central Nervous System Drugs 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) announces a forthcoming public advisory committee meeting of the Peripheral and Central Nervous System Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will take place virtually on November 6, 2020, from 10 a.m. Eastern Time to 4 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 about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018 N–0410. The docket will close on November 5, 2020. Submit either electronic or written comments on this public meeting by November 5, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 5, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 5, 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 October 23, 2020, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications 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–2018–N–0410 for ''Peripheral and Central Nervous System Drugs Advisory Committee; 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. Please call 240–402–7500 ahead of the meeting time to verify access.

- 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: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PCNS@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 FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On November 6, 2020, the committee will discuss biologics license application (BLA) 761178, for aducanumab solution for intravenous infusion, submitted by Biogen Inc., for the treatment of Alzheimer's disease.

FDA intends to make the meeting's background material and pre-recorded presentations available to the public no later than 2 business days before the meeting. The pre-recorded presentations will be viewed by the committee prior to the meeting and will not be replayed on meeting day. If FDA is unable to post the background material and/or pre-recorded presentations on its website prior to the meeting, the background material and/or pre-recorded presentations will be made publicly available on FDA's website at the time of the advisory committee meeting. The meeting will include brief summaries of the pre-recorded presentations. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

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 October 23, 2020, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 October 15, 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 October 16, 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 LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* 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: September 22, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21448 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4726]

Abbreviated New Drug Application Submissions—Amendments and Requests for Final Approval To Tentatively Approved Abbreviated New Drug Applications; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs.'' This guidance is intended to assist applicants in preparing and submitting amendments to tentatively approved abbreviated new drug applications (ANDAs), including requests for final approval. This guidance provides recommendations on the timing and content of amendments to tentatively approved ANDAs to facilitate submission in a timely fashion to enable final approval on the earliest date on which the ANDA may lawfully be approved based on patent and/or exclusivity protections (earliest lawful approval date). This guidance finalizes the draft guidance of the same title issued on February 1, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on September 29, 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–2018–D–4726 for ''ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7930, *elizabeth.giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs.'' This guidance is intended to assist applicants in preparing and submitting amendments to tentatively approved ANDAs, including requests for final approval. This guidance provides recommendations on the timing and content of amendments to tentatively approved ANDAs to facilitate submission in a timely fashion to enable final approval on the earliest date on which the ANDA may lawfully be approved based on patent and/or exclusivity protections (earliest lawful approval date).

If an ANDA meets the substantive requirements for approval but cannot be finally approved by FDA because of unexpired patents or exclusivities, FDA will tentatively approve the ANDA. Under section 505 of the Federal Food, Drug, and Cosmetic Act) (21 U.S.C. 355), a drug product that is the subject of a tentatively approved ANDA is not an approved drug and does not have an effective approval until FDA issues an approval after any necessary additional review of the application.

An ANDA applicant may submit amendments to a tentatively approved application that propose changes to the application, request final approval, or propose changes and request final approval. As described in the guidance, an amendment proposing changes to the application may delay FDA's final approval of the ANDA, depending on the timing of submission of the amendment and the nature of the changes proposed and any related deficiencies identified upon review. The guidance is intended to assist applicants in preparing an amendment for submission in a timely fashion to enable final approval on the earliest lawful approval date. In particular, applicants that wish to request final approval should determine whether changes are necessary before requesting this final approval, review any changes that have been made to their application since the tentative approval was granted, and consider the possible review goal dates that may be assigned to the request for final approval to request final approval in a timely fashion.

In the **Federal Register** of February 1, 2019 (84 FR 1164), FDA announced the availability of the draft guidance of the same title dated January 2019. The draft guidance was posted on FDA's website on January 16, 2019, during the lapse in appropriations to provide advance notice of the document to the public. The comment period opened upon publication in the **Federal Register**. FDA received five comments on the draft guidance and those comments were considered as the guidance was finalized. The final guidance contains minor clarifications to the draft guidance. The guidance announced in

this notice finalizes the draft guidance dated January 2019.

This 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 ''ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: September 22, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21470 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice To Announce Supplemental Award To Support Training and Technical Assistance To Address Clinical Workforce Development

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Announcing supplemental award to support training and technical assistance to address clinical workforce development.

SUMMARY: HRSA provided supplemental funding to Community Health Center, Inc. (CHCI), a currently-funded National Training and Technical Assistance Partner (NTTAP) award recipient. CHCI will expand training and technical assistance (T/TA) to health centers and HRSA-funded State and Regional Primary Care Associations (PCAs) to support implementation of a tool developed for health centers to assess and improve their readiness to engage in health professional training programs and address national health care workforce shortages.

FOR FURTHER INFORMATION CONTACT: Tracey Orloff, Director, HRSA, Strategic Partnerships Division, Office of Quality Improvement, at *TOrloff@hrsa.gov* or (301) 443–3197.

SUPPLEMENTARY INFORMATION:

Recipient of the Award: Community Health Center, Inc.

Amount of Non-Competitive Award: $320,000.

Period of Supplemental Funding: August 2020 to June 2022.

CFDA Number: 93.129.

Authority: Section 330(l) of the Public Health Service Act, 42 U.S.C. 254b(l).

Justification: The National Center for Health Workforce Analysis estimates a shortage of over 23,000 primary care physician positions by 2025. Residency programs are needed for health centers to address health care workforce shortages that limit their ability to deliver comprehensive, culturally competent, high quality primary health care services.

CHCI created the Readiness to Train Assessment Tool (RTAT™) for health centers to assess their own readiness to engage in health professional training programs and use the results to manage their workforce shortages. Supplemental funding is necessary to ensure timely implementation of the RTAT™ in order to complete the data collection, analysis, and results dissemination needed for health centers to address critical workforce shortages. As the organization that developed the RTAT™, and the only NTTAP currently funded to provide enhanced T/TA on clinical workforce development to health centers, CHCI has the necessary expertise, organizational systems, and structure in place to immediately expand T/TA efforts in this area.

Thomas J. Engels,

Administrator.

[FR Doc. 2020–21514 Filed 9–28–20; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Centers for Disease Control and Prevention (CDC)/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) has scheduled a public meeting.

DATES: November 5, 2020, 2:00 p.m.–5:15 p.m. Eastern Time (ET) and November 6, 2020, 2:00 p.m.–5:15 p.m. ET. The deadline for online registration is 12:00 p.m. ET on November 2, 2020.

ADDRESSES: This meeting will be held virtually. Please visit the meeting information page to register: *https://chacfall2020.org.*

FOR FURTHER INFORMATION CONTACT: Theresa Jumento, Senior Public Health Advisor, HIV/AIDS Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–5807; or *CHACAdvisoryComm@hrsa.gov.*

SUPPLEMENTARY INFORMATION: CHAC was established under section 222 of the Public Health Service Act, [42 U.S.C. 217a], as amended.

The purpose of CHAC is to advise the Secretary, HHS; the Director, CDC; and the Administrator, HRSA regarding objectives, strategies, policies, and priorities for HIV, viral hepatitis, and other STDs; prevention and treatment efforts including surveillance of HIV infection, viral hepatitis, and other STDs, and related behaviors; epidemiologic, behavioral, health services, and laboratory research on HIV, viral hepatitis, and other STDs; identification of policy issues related to HIV/viral hepatitis/STD professional eduction, patient healthcare delivery, and prevention services; agency policies about prevention of HIV, viral hepatitis and other STDs; treatment, healthcare delivery, and research and training; strategic issues influencing the ability of CDC and HRSA to fulfill their missions of providing prevention and treatment services; programmatic efforts to prevent and treat HIV, viral hepatitis, and other STDs; and support to the agencies in their developoment of responses to emerging health needs related to HIV, viral hepatitis, and other STDs.

During the November 5–6, 2020, meeting, CHAC will discuss community engagement activities related to the President's initiative on ''Ending the HIV Epidemic: A Plan for America'' and the COVID–19 pandemic. CHAC will also discuss the needs and challenges of HIV prevention and care for women. Agenda items are subject to change as priorities dictate. Refer to the CHAC meeting information page for any updated information concerning the meeting.

While this meeting is open to the public, advance registration is required. Members of the public will have the opportunity to provide comments. Requests to offer oral comments will be accepted in the order they are received and may be limited as time allows.

Public participants may also submit written statements as further described below. To submit written comments or to request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on October 28, 2020.

Information about CHAC can be found on the CHAC website at *https://www.cdc.gov/maso/facm/facmCHACHSPT.html.* Visit the meeting information page for additional details *https://chacfall2020.org.* Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Theresa Jumento at the email address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–20943 Filed 9–28–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 on Drug Abuse Special Emphasis Panel; NIDA SEP for Career Development (K99/R00 and K12 applications).

Date: November 4, 2020.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sindhu Kizhakke Madathil, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, 3 WFN 9th Floor, MSC 6021, Bethesda, MD 20892, (301) 827–5702, *sindhu.kizhakkemadathil@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: September 23, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–21497 Filed 9–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the President's Cancer Panel.

The meetings will be held as virtual meetings and are open to the public. Individuals who plan to view the virtual meetings and need special assistance or other reasonable accommodations to view the meetings should notify the Contact Person listed below in advance of the meetings. The meetings can be accessed by clicking on the following link: *https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel.*

Name of Committee: President's Cancer Panel.

Date: November 2, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID–19 and Beyond (Day 1—Colorectal Cancer).

Place: National Cancer Institute, 31 Center Drive, Building 31, Room 11A48, Rockville, MD 20850, (Virtual Meeting).

Access to Meeting: https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel.

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48 MSC 2590, Bethesda, MD 20892, 240–781–3327, *johnsonr@mail.nih.gov.*

Name of Committee: President's Cancer Panel.

Date: November 4, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID–19 and Beyond (Day 2—Colorectal Cancer).

Place: National Cancer Institute, 31 Center Drive, Building 31, Room 11A48, Rockville, MD 20850 (Virtual Meeting).

Access to Meeting: https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel.

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48 MSC 2590, Bethesda, MD 20892, 240–781–3327, *johnsonr@mail.nih.gov.*

Name of Committee: President's Cancer Panel.

Date: November 9, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID–19 and Beyond (Day 1—Cervical Cancer).

Place: National Cancer Institute, 31 Center Drive, Building 31, Room 11A48, Rockville, MD 20850, (Virtual Meeting).

Access to Meeting: https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel.

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48 MSC 2590, Bethesda, MD 20892, 240–781–3327, *johnsonr@mail.nih.gov.*

Name of Committee: President's Cancer Panel.

Date: November 10, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID–19 and Beyond (Day 2—Cervical Cancer).

Place: National Cancer Institute, 31 Center Drive, Building 31, Room 11A48, Rockville, MD, 20850 (Virtual Meeting).

Access to Meeting: https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel.

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48 MSC 2590 Bethesda, MD 20892, 240–781–3327, *johnsonr@mail.nih.gov.*

Name of Committee: President's Cancer Panel.

Date: November 16, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID–19 and Beyond (Day 1—Breast Cancer).

Place: National Cancer Institute, 31 Center Drive, Building 31, Room 11A48, Rockville, MD 20850, (Virtual Meeting).

Access to Meeting: https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel.

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48, MSC 2590, Bethesda, MD 20892, 240–781–3327, *johnsonr@mail.nih.gov.*

Name of Committee: President's Cancer Panel.

Date: November 18, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID–19 and Beyond (Day 2—Breast Cancer).

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48 MSC 2590, Bethesda, MD 20892, 240–781–3327, *johnsonr@mail.nih.gov.*

Place: National Cancer Institute, 31 Center Drive, Building 31, Room 11A48, Rockville, MD 20850 (Virtual Meeting).

Access to Meeting: https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel.

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48 MSC 2590, Bethesda, MD 20892, 240–781–3327 *johnsonr@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/pcp/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 23, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–21401 Filed 9–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Individual Fellowship (F30, F31, F32) Review Panel.

Date: October 28, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700 B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting)

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2109, Bethesda, MD 20892, (301) 443–8599, *espinozala@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: September 24, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–21496 Filed 9–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 of Environmental Health Sciences Special Emphasis Panel; Environmental Health Sciences Core Centers Review Meeting II.

Date: October 21–23, 2020.

Time: 2:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Varsha Shukla, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, (984) 287–3288, *Varsha.shukla@nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Career Development in K Applications.

Date: October 26, 2020.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Laura A. Thomas, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, (984) 287–3328, *laura.thomas@nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Emerging Research Opportunities in Environmental Health Sciences-Population-based Studies.

Date: October 27, 2020.

Time: 10:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, (984) 287–3340, *worth@niehs.nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Career Development in K Applications II.

Date: October 28, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Laura A. Thomas, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, 984–287–3328, *laura.thomas@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to

Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: September 23, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–21498 Filed 9–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biostatistical Methods and Research Design.

Date: October 21, 2020.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 257–2638, *steeleln@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR–20–125: Native American Research Centers for Health (NARCH).

Date: October 27–29, 2020.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gabriel B Fosu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health 6701 Rockledge Drive, Room 3108, MSC 7808, Bethesda, MD 20892, (301) 435–3562, *fosug@csr.nih.gov*.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group Therapeutic Approaches to Genetic Diseases Study Section.

Date: October 28–29, 2020.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Methode Bacanamwo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200, Bethesda, MD 20892, 301–827–7088, *methode.bacanamwo@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: High Throughput Screening.

Date: October 28, 2020.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David Filpula, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6181, MSC 7892, Bethesda, MD 20892, 301–435–2902, *filpuladr@mail.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Aging Systems and Geriatrics Study Section.

Date: October 28–29, 2020.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Inese Z Beitins, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7892, Bethesda, MD 20892, 301–435–1034, *beitinsi@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR Panel: Alzheimer's Disease.

Date: October 28, 2020.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Boris P Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov*.

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Electrical Signaling, Ion Transport, and Arrhythmias Study Section.

Date: October 28, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4136, Bethesda, MD 20892, 301–435–0904, *sara.ahlgren@nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group Neurodifferentiation, Plasticity, Regeneration and Rhythmicity Study Section.

Date: October 28–29, 2020.

Time: 11:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joanne T Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435–1178, *fujiij@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 24, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–21495 Filed 9–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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: Environmental Health Sciences Review Committee Environmental Health Sciences Core Centers (EHSCC) Review Meeting.

Date: October 19–21, 2020.

Time: 9:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530

Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Linda K. Bass, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (984) 287–3236, *bass@niehs.nih.gov*.

Name of Committee: Environmental Health Sciences Review Committee Environmental Health Training Grant Review Meeting.

Date: November 19, 2020.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Linda K. Bass, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (984) 287–3236, *bass@niehs.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: September 23, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–21499 Filed 9–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meetings

Pursuant to section 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 materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel; UG4 and U24 SEP.

Date: December 3, 2020.

Time: 9:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Video Assisted Meeting.

Contact Person: Zoe E. Huang, MD, Chief Scientific Review Officer, Scientific Review Office, Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968, 301–594–4937, *huangz@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: September 24, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–21500 Filed 9–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0044]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Application for Action on an Approved Application or Petition

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until November 30, 2020.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0044 in the body of the letter, the agency name and Docket ID USCIS–2007–0012. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2007–0012. USCIS is limiting communications for this Notice as a result of USCIS' COVID–19 response actions.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2007–0012 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines 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 *https://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

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

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Action on an Approved Application or Petition.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–824; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. This information collection is used to request a duplicate approval notice, as well as to notify and to verify the U.S. Consulate that a petition has been approved or that a person has been adjusted to permanent resident status.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–824 is 10,571 and the estimated hour burden per response is 0.42 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 4,440 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $1,361,016.

Dated: September 22, 2020.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2020–21480 Filed 9–28–20; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0014]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Declaration of Financial Support

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until November 30, 2020.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0014 in the body of the letter, the agency name and Docket ID USCIS–2006–0072. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2006–0072. USCIS is limiting communications for this Notice as a result of USCIS' COVID–19 response actions.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2006–0072 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines 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 *https://www.regulations.gov.*

USCIS is changing the title of this information collection from ''Affidavit of Support'' to ''Declaration of Financial Support'' to avoid potential association with Form I–864, Affidavit of Support Under Section 213A of the INA (OMB control Number 1615–0075).

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

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

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Declaration of Financial Support.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–134; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. U.S. Citizenship and Immigration Services (USCIS) and consular officers of the Department of State (DOS) use Form I–134 to determine whether, at the time of the beneficiary's application, petition, or request for certain immigration benefits, an alien has sufficient financial support to pay for expenses for the duration of their temporary stay in the United States.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–134 is 2,500 and the estimated hour burden per response is 2 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 5,000 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $10,625.

Dated: September 22, 2020.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2020–21443 Filed 9–28–20; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0120]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Application for Free Training for Civics and Citizenship Teachers of Adults and Civics and Citizenship Toolkit

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until October 29, 2020.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2011–0001. All submissions received must include the OMB Control Number 1615–0120 in the body of the letter, the agency name and Docket ID USCIS–2011–0001.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (202) 272–8377 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on June 18, 2020, at 85 FR 36875, allowing for a 60-day public comment period. USCIS did receive 1 comment in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2011–0001 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines 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.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

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

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Free Training for Civics and Citizenship of Adults; Civics and Citizenship Toolkit.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G–1190, G–1515; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. This information is necessary to register for civics and citizenship of adults training and to obtain a civics and citizenship toolkit.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection Form G–1190 is 2,500 and the estimated hour burden per response is 0.083 hours. The estimated total number of respondents for the information collection Form G–1515 is 1,200 and the estimated hour burden per response is responses is 0.166 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 407 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $0. The registration occurs electronically which eliminates any cost for postage, and no other costs are incurred by the respondent.

Dated: September 22, 2020.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2020–21475 Filed 9–28–20; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0023]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Application To Register Permanent Residence or Adjustment of Status

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until October 29, 2020.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2009–0020. All submissions received must include the OMB Control Number 1615–0023 in the body of the letter, the agency name and Docket ID USCIS–2009–0020.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (202) 272–8377 (This is not a toll-free number; comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on June 25, 2020, at 85 FR 38151, allowing for a 60-day public comment period. USCIS did receive 7 comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2009–0020 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines 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.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

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

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application to Register Permanent Residence or Adjust Status.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–485, Supplement A, Supplement J, National Interest Waiver; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The information on Form I–485 will be used to request and determine eligibility for adjustment of permanent residence status. Supplement A is used to adjust status under section 245(i) of the Immigration and Nationality Act (Act).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–485 is 576,000 and the estimated hour burden per response is 8.28 hours. The estimated total number of respondents for the information collection Supplement A is 23,355 and the estimated hour burden per response is 1.4 hour. The estimated total number of respondents for the information collection Supplement J is 30,841 and the estimated hour burden per response is 1.07 hours. The estimated total number of respondents for the information collection National Interest Waiver is 8,000 who will respond an average of 2 times per year and the estimated hour burden per response is 1 hour. The estimated total number of respondents for the information collection Biometrics Processing is 570,932 and the estimated hour burden per response is 1.17 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 5,515,985 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $211,680,000.

Dated: September 22, 2020.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2020–21447 Filed 9–28–20; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2020–N129; FXES11140400000–201–FF04E00000]

Endangered Species; Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered species under the Endangered Species Act of 1973, as amended. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive written data or comments on the applications by October 29, 2020.

ADDRESSES:

Reviewing Documents: Documents and other information submitted with the applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act. Submit a request for a copy of such documents to Karen Marlowe (see **FOR FURTHER INFORMATION CONTACT**).

Submitting Comments: If you wish to comment, you may submit comments by one of the following methods:

- *U.S. mail:* U.S. Fish and Wildlife Service Regional Office, Ecological Services, 1875 Century Boulevard, Atlanta, GA 30345 (Attn: Karen Marlowe, Permit Coordinator).
- *Email: permitsR4ES@fws.gov.* Please include your name and return address in your email message. If you do not receive a confirmation from the U.S. Fish and Wildlife Service that we have received your email message, contact us directly at the telephone number listed in **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Karen Marlowe, Permit Coordinator, 404–679–7097 (telephone), *karen_marlowe@fws.gov* (email), or 404–679–7081 (fax). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We invite review and comment from local, State, and Federal agencies and the public on applications we have received for permits to conduct certain activities with endangered and threatened species under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17. With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activities. The ESA's definition of ''take'' includes hunting, shooting, harming, wounding, or killing, and also such activities as pursuing, harassing, trapping, capturing, or collecting.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

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.

Permit application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE 88789B–1	Sharon Davis, Evening Shade, AR.	Indiana bat (*Myotis sodalis*), gray bat (*Myotis grisescens*), northern long-eared bat (*Myotis septentrionalis*), Ozark big-eared bat (*Corynorhinus townsendii ingens*), and Virginia big-eared bat (*Corynorhinus townsendii virginianus*).	Alabama, Arkansas, Connecticut, Delaware, the District of Columbia, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.	Presence/absence surveys, population monitoring.	Enter hibernacula or maternity roost caves, salvage dead bats, capture with mist nets or harp traps, handle, identify, band, radio-tag, collect hair samples, swab, and wing-punch.	Amendment.
TE 06338C–2	David Foltz II, Weirton, WV.	Fish: Candy darter (*Etheostoma osburni*), diamond darter (*Crystallaria cincotta*), and Roanoke logperch (*Percina rex*); Mussels: Clubshell (*Pleurobema clava*), cracking pearlymussel (*Hemistena lata*), Cumberland combshell (*Epioblasma brevidens*), dromedary pearlymussel (*Dromus dromas*), fanshell (*Cyprogenia stegaria*), fat pocketbook (*Potamilus capax*), fluted kidneyshell (*Ptychobranchus subtentus*), Higgins eye pearlymussel (*Lampsilis higginsii*), James River spinymussel (*Pleurobema collina*), northern riffleshell (*Epioblasma torulosa rangiana*), orangefoot pimpleback (*Plethobasus cooperianus*), oyster mussel (*Epioblasma capsaeformis*), pink mucket (*Lampsilis abrupta*), purple cat's paw (*Epioblasma obliquata obliquata*), rabbitsfoot (*Quadrula cylindrica* spp. *cylindrica*), rayed bean (*Villosa fabalis*), ring pink (*Obovaria retusa*), rough pigtoe (*Pleurobema plenum*), sheepnose (*Plethobasus cyphyus*), snuffbox (*Epioblasma triquetra*), spectaclecase (*Cumberlandia monodonta*), tubercled blossom (*Epioblasma torulosa torulosa*), white cat's paw (*Epioblasma obliquata perobliqua*), and white wartyback (*Plethobasus cicatricosus*); Crayfish: Nashville crayfish (*Orconectes shoupi*).	Alabama, Arkansas, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Tennessee, Virginia, West Virginia, and Wisconsin.	Presence/absence surveys, population monitoring.	Fish: Electro-shock, seine, capture, handle, identify, and release; Mussels: Remove from the substrate for identification, identify, return, and salvage relic shells; Crayfish: Capture via seining, handle, identify, and release.	Amendment.

Permit application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE 64232B–1	Joshua Young, Lexington, KY.	Bats: Indiana bat (*Myotis sodalis*), gray bat (*Myotis grisescens*), northern long-eared bat (*Myotis septentrionalis*), and Virginia big-eared bat (*Corynorhinus townsendii virginianus*); Mussels: Clubshell (*Pleurobema clava*), cracking pearlymussel (*Hemistena lata*), Cumberland bean pearlymussel (*Villosa trabalis*), Cumberlandian combshell (*Epioblasma brevidans*), Cumberland elktoe (*Alasmidonta atropurpurea*), dromedary pearlymussel (*Dromus dromas*), fanshell (*Cyprogenia stegaria*), fat pocketbook (*Potamilus capax*), fluted kidneyshell (*Ptychobranchus subtentus*), little-wing pearlymussel (*Pegias fabula*), northern riffleshell (*Epioblasma torulosa rangiana*), orange-foot pimpleback pearlymussel (*Plethobasus cooperianus*), oyster mussel (*Epioblasma capsaeformis*), pink mucket pearlymussel (*Lampsilis abrupta*), purple cat's paw (*Epioblasma obliquata obliquata*), rabbitsfoot (*Quadrula cylindrica cylindrica*), rink ping (*Obovaria retusa*), rough pigtoe (*Pleurobema plenum*), scaleshell (*Leptodea leptodon*), sheepnose (*Plethobasus cyphyus),* slabside pearlymussel (*Pleuronaia dolabelloidies*), snuffbox (*Epioblasma triquetra*), spectaclecase mussel (*Cumberlandia monodonta*), tan riffleshell (*Epioblasma walkeri*), tubercled-blossom pearlymussel (*Epioblasma torulosa torulosa*), and white wartyback pearlymussel (*Plethobasus cicatricosus*).	Bats: Alabama, Arkansas, Georgia, Illinois, Indiana, Kentucky, Maryland, Mississippi, Missouri, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Virginia, and West Virginia; Mussels: Kentucky.	Presence/absence surveys, studies to document habitat use, and population monitoring.	Bats: Enter hibernacula and maternity roost caves, capture with mist nets or harp traps, handle, identify, band, and radio-tag; Mussels: capture, identify, tag, release, and collect relict shells.	Renewal.
TE 206741–2 ..	Metro Water Services, Nashville, TN.	Nashville crayfish (*Orconectes shoupi*).	Mill Creek Watershed, Davidson County, TN.	Presence/absence surveys, population monitoring.	Capture, handle, identify, measure, sex, and release.	Renewal/ Amendment.
TE 98596B–2	Sarah Veselka, Morgantown, WV.	Big Sandy crayfish (*Cambarus callainus*) and Guyandotte River crayfish (*Cambarus veteranus*).	Kentucky, Virginia, and West Virginia.	Presence/absence surveys.	Capture, handle, identify, measure, and release.	Amendment.
TE 82659D–0	Sarah Messer, Huntington, WV.	American burying beetle (*Nicrophorus americanus*).	Arkansas, Kansas, Massachusetts, Nebraska, Ohio, Oklahoma, Rhode Island, South Dakota, and Texas.	Presence/absence surveys.	Capture, handle, identify, and release.	New.
TE 83157D–0	Matthew Miller, Ashland, OR.	*Sarracenia oreophila* (green pitcher-plant), *S. rubra* ssp. *alabamensis* (Alabama canebrake pitcher-plant), and *S. r.* ssp. *jonesii* (Mountain sweet pitcher-plant).	Oregon	Interstate commerce	Sell artificially propagated plants in interstate commerce.	New.

Permit application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE 68616B–2	Carla Atkinson, University of Alabama, Tuscaloosa, AL.	Mussels: Alabama (=inflated) heelsplitter (*Potamilus inflatus*), Alabama lampmussel (*Lampsilis virescens*), Alabama moccasinshell (*Medionidus acutissimus*), Chipola slabshell (*Elliptio chipolaensis*), Coosa moccasinshell (*Medionidus parvulus*), cracking pearlymussel (*Hemistena lata*), Cumberlandian combshell (*Epioblasma brevidans*), dark pigtoe (*Pleurobema furvum*), fat threeridge (*Amblema neislerii*), fine-lined pocketbook (*Lampsilis altilis*), fine-rayed pigtoe (*Fusconaia cuneolus*), fluted kidneyshell (*Ptychobranchus subtentus*), Georgia pigtoe (*Pleurobema hanleyianum*), Gulf moccasinshell (*Medionidus penicillatus*), heavy pigtoe (*Pleurobema taitianum*), orange-nacre mucket (*Lampsilis perovalis*), oval pigtoe (*Pleurobema pyriforme*), ovate clubshell (*Pleurobema perovatum*), oyster mussel (*Epioblasma capsaeformis*), pale lilliput pearlymussel (*Toxolasma cylindrellus*), purple bankclimber (*Elliptoideus sloatianus*), rabbitsfoot (*Quadrula cylindrica cylindrica*), ring pink (*Obovaria retusa*), round ebonyshell (*Fusconaia rotulata*), shiny pigtoe (*Fusconaia cor*), shinyrayed pocketbook (*Lampsilis subangulata*), slabside pearlymussel (*Lexingtonia dolabelloides*), snuffbox mussel (*Epioblasma triquetra*), southern clubshell (*Pleurobema decisum*), southern combshell (*Epioblasma penita*), southern pigtoe (*Pleurobema georgianum*), and triangular kidneyshell (*Ptychobranchus greeni*); Gastropods: Tulotoma snail (*Tulotoma magnifica*).	Alabama, Georgia, and Tennessee.	Presence/absence surveys and excretion/respiration Studies.	Capture, handle, identify, hold temporarily in containers in stream, and release.	Renewal.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

John Tirpak,

Deputy Assistant Regional Director, Ecological Services.

[FR Doc. 2020–21394 Filed 9–28–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX20EE000101100]

Public Meeting of the National Geospatial Advisory Committee

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of public webinar meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the U.S. Geological Survey (USGS) is publishing this notice to announce that a Federal Advisory Committee meeting of the National Geospatial Advisory Committee (NGAC) will take place.

DATES: The webinar meeting will be held on Tuesday, October 27, 2020 from 1:00 p.m. to 5:00 p.m., and on Wednesday, October 28, 2020 from 1:00 p.m. to 5:00 p.m. (Eastern Daylight Time).

ADDRESSES: The meeting will be held via webinar and teleconference. Send your comments to Mr. James Sayer, Group Federal Officer by email to *gs-faca-mail@usgs.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. John Mahoney, Federal Geographic Data Committee, U.S. Geological Survey, 909 First Avenue, Suite 800, Seattle, WA 98104; by email at *jmahoney@usgs.gov;* or by telephone at (206) 220–4621.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix 2), the Government in the Sunshine Act of 1976 (5 U.S.C. 552B, as amended), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: The NGAC provides advice and recommendations related to management of Federal and national geospatial programs, the development of the National Spatial Data Infrastructure, and the implementation of the Geospatial Data Act of 2018 and Office of Management

and Budget Circular A–16. The NGAC reviews and comments on geospatial policy and management issues and provides a forum to convey views representative of non-federal stakeholders in the geospatial community. The NGAC meeting is one of the primary ways that the FGDC collaborates with its broad network of partners. Additional information about the NGAC meeting is available at: *www.fgdc.gov/ngac.*

Agenda Topics

—FGDC Update
—Geospatial Data Act Implementation
—National Spatial Data Infrastructure Strategic Plan
—Landsat Advisory Group
—NGAC Operations
—Public-Private Partnerships
—Public Comments

Meeting Accessibility/Special Accommodations: The webinar meeting is open to the public and will take place from 1:00 p.m. to 5:00 p.m. on October 27 and from 1:00 p.m. to 5:00 p.m. on October 28. Members of the public wishing to attend the meeting should contact Mr. John Mahoney by email at *jmahoney@usgs.gov* to register. Webinar/conference line instructions will be provided to registered attendees prior to the meeting. Individuals requiring special accommodations to access the public meeting should contact Mr. John Mahoney at the email stated above or by telephone at (206) 220–4621 at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Public Disclosure of Comments: There will be an opportunity for public comment during the meeting. Depending on the number of people who wish to speak and the time available, the time for individual comments may be limited. Written comments may also be sent to the Committee for consideration. To allow for full consideration of information by the Committee members, written comments must be provided to John Mahoney, Federal Geographic Data Committee, U.S. Geological Survey, 909 First Avenue, Seattle, WA 98104; by email at *jmahoney@usgs.gov;* or by telephone at (206) 220–4621, at least three (3) business days prior to the meeting. Any written comments received will be provided to the committee members before the meeting.

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 may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 5 U.S.C. Appendix 2)

Kenneth M. Shaffer,

Deputy Executive Director, Federal Geographic Data Committee.

[FR Doc. 2020–21412 Filed 9–28–20; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM954000.L14400000.BJ0000.BX0000]

Notice of Filing of Plats of Survey; New Mexico; Oklahoma

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of the following described land are scheduled to be officially filed 30 days after the date of this publication in the Bureau of Land Management (BLM), New Mexico Office, Santa Fe, New Mexico. The surveys announced in this notice are necessary for the management of lands administered by the agency indicated.

ADDRESSES: These plats will be available for inspection in the New Mexico Office, Bureau of Land Management, 301 Dinosaur Trail, Santa Fe, New Mexico 85004–4427. Protests of a survey should be sent to the New Mexico Director at the above address.

FOR FURTHER INFORMATION CONTACT: Michael J. Purtee, Chief Cadastral Surveyor; (505) 761–8903; *mpurtee@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:

New Mexico Principal Meridian, New Mexico

The plat, representing the corrective resurvey, dependent resurvey, and metes-and-bounds survey of a tract of land within Township 10 South, Range 14 East, accepted August 13, 2020, for Group 1204, New Mexico.

This plat was prepared at the request of the Bureau of Land Management, Roswell, NM Field Office.

Indian Meridian, Oklahoma

The plat, representing the dependent resurvey and survey of a tract of land in Township 16 North, Range 15 West, accepted July 8, 2020, for Group 241, Oklahoma.

This plat was prepared at the request of the Concho Agency, Southern Plains Region.

The supplemental plat, within Township 10 North, Range 27 East, section 4, accepted July 8, 2020, for Group 224, Oklahoma.

The supplemental plat, within Township 10 North, Range 27 East, section 5, accepted July 8, 2020, for Group 224, Oklahoma.

The supplemental plat, in two sheets, within Township 10 North, Range 27 East, section 19, accepted August 13, 2020, for Group 223, Oklahoma.

The supplemental plat, within Township 11 North, Range 27 East, section 33, accepted July 8, 2020, for Group 224, Oklahoma.

These supplemental plats were prepared at the request of the Arkansas Riverbed Authority.

A person or party who wishes to protest against any of these surveys must file a written notice of protest within 30 calendar days from the date of this publication with the New Mexico Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within 30 days after the protest is filed. Before including your address, or other personal information in your protest, please be aware that your entire protest, 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.

Authority: 43 U.S.C. Chap. 3.

Michael J. Purtee,

Chief Cadastral Surveyor of New Mexico; and Oklahoma.

[FR Doc. 2020–21538 Filed 9–28–20; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[20X.LLIDC00000. L16100000. XG0000. 241A00. 4500146430]

Notice of Mailing/Street Address Change for the BLM—Coeur d'Alene District Office, Field Office, and District Warehouse

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This notice announces changes to the mailing and street address for the Bureau of Land Management (BLM) Coeur d'Alene District Office, the Coeur d'Alene Field Office, and the BLM Coeur d'Alene District Warehouse.

DATES: The date for the changes will be on or about October 19, 2020.

FOR FURTHER INFORMATION CONTACT: Richard Alvarez, Lead Property Management Specialist, BLM Idaho State Office; 208–373–3916; *ralvarez@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 Mr. Alvarez during normal business hours. The FRS is available 24 hours a day, seven days a week, to leave a message or question with Mr. Alvarez. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The mailing and street address for the Bureau of Land Management (BLM) Coeur d'Alene District Office and Coeur d'Alene Field Office will be changed from 3815 Schreiber Way, Coeur d'Alene, Idaho 83815, to 3232 West Nursery Road, Coeur d'Alene, Idaho 83815.

The mailing and street address for the BLM Coeur d'Alene District Warehouse will be changed from 3815 Schreiber Way, Coeur d'Alene, Idaho 83815, to 3260 West Nursery Road, Coeur d'Alene, Idaho 83815.

Authority: Departmental Manual 382, Chapter 2.1.

John F. Ruhs,

BLM Idaho State Director.

[FR Doc. 2020–21503 Filed 9–28–20; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR04084000, XXXR4081X1, RN.20350010.REG0000]

Colorado River Basin Salinity Control Advisory Council Notice of Public Meeting

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of public meeting.

SUMMARY: The Bureau of Reclamation is publishing this notice to announce that a Federal Advisory Committee meeting of the Colorado River Basin Salinity Control Council (Council) will take place.

DATES: The Council will convene on Wednesday, October 28, 2020, at 1:00 p.m. Mountain Standard Time and adjourn at approximately 4:00 p.m. The Council will reconvene on Thursday, October 29, 2020, at 9:00 a.m. Mountain Standard Time and adjourn at 11:00 a.m. A public comment period will be held on both days.

ADDRESSES: Due to restrictions put in place to address the COVID 19 pandemic the meeting will be a virtual meeting. For information about accessing the meeting you must contact Mr. Kib Jacobson; see **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Kib Jacobson, telephone (801) 524–3753; email at *kjacobson@usbr.gov.*

SUPPLEMENTARY INFORMATION: The meeting of the Council is being held under the provisions of the Federal Advisory Committee Act of 1972. The Council was established by the Colorado River Basin Salinity Control Act of 1974 (Pub. L. 93–320) (Act) to receive reports and advise Federal agencies on implementing the Act.

Purpose of the Meeting: The purpose of the meeting is to discuss the accomplishments of Federal agencies and make recommendations on future activities to control salinity.

Agenda: Council members will be briefed on the status of salinity control activities and receive input for drafting the Council's annual report. The Bureau of Reclamation, Bureau of Land Management, U.S. Fish and Wildlife Service, and United States Geological Survey of the Department of the Interior; the Natural Resources Conservation Service of the Department of Agriculture; and the Environmental Protection Agency will each present a progress report and a schedule of activities on salinity control in the Colorado River Basin. The Council will discuss salinity control activities, the contents of the reports, and the Basin States Program created by Public Law 110–246, which amended the Act. A final agenda will be posted online at *https://www.usbr.gov/uc/progact/salinity/* at least one week prior to the meeting.

Meeting Accessibility: The meeting is open to the public. Individuals wanting access to the virtual meeting should contact Mr. Kib Jacobson (see **FOR FURTHER INFORMATION CONTACT**) no later than October 26, 2020, to receive instructions.

Public Comments: The Council chairman will provide time for oral comments from members of the public at the meeting. Individuals wanting to make an oral comment should contact Mr. Kib Jacobson (see **FOR FURTHER INFORMATION CONTACT**) to be placed on the public comment list. Members of the public may also file written statements with the Council before, during, or up to 30 days after the meeting either in person or by mail. To allow full consideration of information by Council members at this meeting, written comments must be provided to Mr. Kib Jacobson (see **FOR FURTHER INFORMATION CONTACT**) by October 23, 2020.

Public Disclosure of Personal Information: 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.

Authority: 5 U.S.C. Appendix 2.

Wayne Pullan,

Deputy Regional Director, Upper Colorado Basin—Interior Region 7, Bureau of Reclamation.

[FR Doc. 2020–21391 Filed 9–28–20; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1148]

Certain Integrated Circuits and Products Containing the Same; Commission Determination To Review in Part a Final Initial Determination Finding No Violation of Section 337 and, on Review, To Affirm the Finding of No Violation; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the final initial determination (''ID'') issued by the presiding administrative law judge (''ALJ'') on May 22, 2020, finding no violation of section 337 in the above-referenced investigation and, on review, to affirm the finding of no violation. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On March 15, 2019, the Commission instituted Inv. No. 337–TA–1148, *Certain Integrated Circuits and Products Containing the Same* under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by Tela Innovations, Inc. of Los Gatos, California (''Tela''). 84 FR 9558–59 (Mar. 15, 2019). The complaint alleges a violation of section 337 by reason of infringement of certain claims of U.S. Patent Nos. 7,943,966 (''the '966 patent''); 7,948,012 (''the '012 patent''); 10,141,334 (''the '334 patent''); 10,141,335 (''the '335 patent''); and 10,186,523 (''the '523 patent''). The complainant also alleges the existence of a domestic industry. The notice of investigation names as respondents Acer, Inc. of New Taipei City, Taiwan; Acer America Corporation of San Jose, California; AsusTek Computer Inc. of Taipai, Taiwan; Asus Computer International of Fremont, California; Intel Corporation of Santa Clara, California; Lenovo Group Ltd. of Beijing, China; Lenovo (United States) Inc. of Morrisville, North Carolina; Micro-Star International Co., Ltd. of New Taipei City, Taiwan; and MSI Computer Corp. of City of Industry, California (collectively, ''Respondents''). *Id.* at 9559. The Commission's Office of Unfair Import Investigations (''OUII'') is also named as a party in this investigation. *Id.*

The Commission has previously terminated the investigation as to the '966, '012 and '335 patents, and as to certain claims of the '334 and '523 patents. *See* Order No. 33 (Oct. 2, 2019), *unreviewed by* Notice (Oct. 22, 2019); Order No. 36 (Oct. 23, 2019), *unreviewed by* Notice (Nov. 15, 2019); and Order No. 44 (Jan. 6, 2020), *unreviewed by* Notice (Feb. 3, 2020).

On May 22, 2020, the ALJ issued his ''Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond'' (''ID/RD'') finding that there is no violation of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain integrated circuits and products containing the same, in connection with the asserted claims of the '334 and '523 patents, and that a domestic industry in the United States that practices or exploits the asserted patents does not exist.

The ID finds that Respondents directly infringe claims 1, 2, and 5 of the '334 patent, and that claims 1, 2, 5, and 15 of the '334 patent have been shown to be invalid. The ID also finds that Tela's licensee has not been shown to practice any claims of the '334 patent, and that the domestic industry requirement is not satisfied with respect to the '334 patent. The ID finds that there is no violation of section 337 with respect to the '334 patent.

The ID further finds that Respondents directly infringe claims 1–11, 14–20, 25, and 26 of the '523 patent, and that no claims of the '523 patent have been shown to be invalid. The ID also finds that Tela's licensee has not been shown to practice any claims of the '523 patent, and that the domestic industry requirement is not satisfied with respect to the '523 patent. The ID finds that there is no violation of Section 337 with respect to the '523 patent.

All the parties to the investigation filed petitions for review of various portions of the ID. On June 8, 2020, OUII filed a petition seeking review of the ID's determination not to analyze whether the asserted domestic industry claims are invalid and, contingently, seeking review of the ID's infringement findings. Also on June 8, 2020, Respondents filed a petition contingently seeking review of the ID's infringement and validity findings.

On June 11, 2020, Tela filed a petition seeking review of the ID's findings concerning the validity and the technical prong of the domestic industry requirement. Tela also seeks contingent review of the ID's infringement findings and the ID's finding that Intel's 45 nm process is prior art under 35 U.S.C. 102(g)(2). In addition, Tela seeks review of Order No. 30 (Sept. 4, 2019), which granted-in-part Tela's motion for leave to supplement its contention interrogatory responses.

On June 18, 2020, the parties filed responses to the various petitions.

Having examined the record in this investigation, including the final ID, the petitions for review, and the responses thereto, the Commission has determined to review the ID in part to correct a legal error in the ID's domestic industry findings. On review, the Commission has determined to strike the paragraph relating to the '334 patent on pages 101–102 of the ID and certain sentences relating to the '523 patent on page 168 of the ID. The Commission takes no position on the issue of whether the asserted domestic industry claims, *i.e.,* claims 29–30 of the '334 patent and claims 27–28 of the '523 patent, are invalid. *See Beloit Corp.* v. *Valmet Oy,* 742 F.2d 1421, 1423 (Fed. Cir. 1984).

The Commission has also determined to review the ID in part on the issue of whether Tela satisfied the economic prong of the domestic industry requirement, *see* ID at 185–188, and to take no position on this issue. *See Beloit,* 742 F.2d at 1423.

The Commission has determined not to review the remainder of the ID, including the ID's finding of no violation of section 337 in this investigation. The Commission has also determined not to review Order No. 30.

The investigation is terminated.

The Commission vote for this determination took place on September 23, 2020.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: September 23, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–21421 Filed 9–28–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–459 and 731–TA–1155 (Second Review)]

Commodity Matchbooks From India; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the countervailing and antidumping duty orders on commodity matchbooks from India would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: June 5, 2020.

FOR FURTHER INFORMATION CONTACT: Alejandro Orozco (202–205–3177), 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 reviews may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On June 5, 2020, the Commission determined that the domestic interested party group response to its notice of institution (85 FR 12334, March 2, 2020) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews 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, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings at 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.

Staff report.—A staff report containing information concerning the subject matter of the reviews will be placed in the nonpublic record on September 28, 2020, and made available to persons on the Administrative Protective Order service list for these reviews. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before October 5, 2020 and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by October 5, 2020. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 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.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the review (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.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Dated: September 23, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–21395 Filed 9–28–20; 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—Advanced Media Workflow Association, Inc.

Notice is hereby given that, on September 15, 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''), Advanced Media Workflow Association, Inc. 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, Skyline Communications, Izegem, BELGIUM; and Mike Coleman (individual member), Portland, OR, have been added as parties to this venture.

Also, Stordis GmbH, Stuttgart, GERMANY; and Tedial S.L., Campanillas, SPAIN, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research

[1] A record of the Commissioners' votes is available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the response to its notice of institution filed on behalf of domestic producer D.D. Bean & Sons Co. to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

project remains open, and Advanced Media Workflow Association, Inc. intends to file additional written notifications disclosing all changes in membership.

On March 28, 2000, Advanced Media Workflow Association, Inc. 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 June 29, 2000 (65 FR 40127).

The last notification was filed with the Department on June 25, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 16, 2020 (85 FR 43261).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2020–21489 Filed 9–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—MLCommons Association

Notice is hereby given that, on September 15, 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''), MLCommons Association filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to MLCommons Association and (2) the nature and objectives of MLCommons Association. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the members of MLCommons Association are the following companies: Advanced Micro Devices, Inc., Markham, CANADA; Alibaba(China) Co., Ltd., Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA; dividiti Limited, Cambridge, UNITED KINGDOM; Arm Limited & Its Subsidiaries, Austin, TX; Baidu USA LLC, Sunnyvale, CA; Cognitiviti Pty Ltd., West End, AUSTRALIA; Cerebras Systems, Los Altos, CA; Centaur Technology, Inc., Austin, TX; Cisco Systems, Inc., San Jose, CA; Cody Coleman(individual member), Stanford, CA; Real World Insights, LLC, San Francisco, CA; Dell Inc., Round Rock, TX; d-matrix Corp., Santa Clara, CA; Facebook, Menlo Park, CA; Polytechnique Montreal, Montreal, CANADA; Fujitsu Ltd, Kanagawa, JAPAN; FuriosaAI, Inc., Seoul, SOUTH KOREA; University of Toronto, Toronto, CANADA; Indiana University, Bloomington, IN; Gigabyte Technology Co., LTD., New Taipei, TAIWAN; Google LLC, Mountain View, CA; Grai Matter Labs, San Jose, CA; Graphcore Limited, Bristol, UNITED KINGDOM; Groq Inc., Mountain View, CA; Guangdong OPPO Mobile Telecommunications Corp., Ltd, DongGuan City, PEOPLE'S REPUBLIC OF CHINA; Hewlett Packard Enterprise, Grenoble, FRANCE; Horizon Robotics Inc., Cupertino, CA; Inspur, Beijing, PEOPLE'S REPUBLIC OF CHINA; Intel Corporation, Santa Clara, CA; MOBILINT, Inc., Seoul, SOUTH KOREA; KALRAY, Montbonnot, FRANCE; MediaTek, Hsinchu, TAIWAN; Microsoft, Redmond, WA; Myrtle.ai, Cambridge, UNITED KINGDOM; Nettrix Information Industry Co., Ltd., Beijing, PEOPLE'S REPUBLIC OF CHINA; NVIDIA Corporation, San Jose, CA; Qualcomm Technologies, Inc., San Diego, CA; Red Hat, Inc., Raleigh, NC; SambaNova Systems, Palo Alto, CA; Samsung Electronics Co., Ltd, Gyeonggi-do, SOUTH KOREA; Advantage Engineering, Austin, TX; Shanghai Enflame Technology Co., Ltd, Shanghai, PEOPLE'S REPUBLIC OF CHINA; Syntiant Corp., Irvine, CA; Tenstorrent Inc., Toronto, CANADA; Harvard University, Cambridge, MA; and Xilinx, San Jose, CA. The general areas of MLCommons Association's planned activity are to advance the scientific field of machine learning and increase the positive impact of machine learning and artificial intelligence on society, to engage in or sponsor collaborative research and development in connection with the measurement and validation of machine learning, to publish the results of the collaborative research and development projects of the Joint Venture and to provide other resources to the scientific community and the public at large with respect to machine learning, and to undertake those other activities which the Board of Directors may from time to time approve.

Membership in MLCommons Association remains open and MLCommons Association intends to file additional written notifications disclosing all changes in membership.

Suzanne Morris,

Chief, Premerger and Division Statistics Antitrust Division.

[FR Doc. 2020–21488 Filed 9–28–20; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF LABOR

Office of Disability Employment Policy

[Agency Docket Number: DOL–2020–0006]

RIN 1230–ZA00

Request for Information on Proposed Transfer of Ticket to Work Program From the Social Security Administration to the U.S. Department of Labor

AGENCY: Office of Disability Employment Policy, U.S. Department of Labor.

ACTION: Request for information.

SUMMARY: The Social Security Administration's (SSA) Ticket to Work and Self-Sufficiency Program (Ticket program) is intended to assist adult disability beneficiaries in becoming employed, yet relatively few disability beneficiaries have successfully participated in the program. In order to strengthen the Ticket program, the President's Budget for Fiscal Year 2021 includes a legislative proposal to improve program structure and coordination and transfer administration of the program to the Department of Labor (DOL), in order to better integrate the program into the public workforce system and better serve disability beneficiaries who want to work. This request for information (RFI) seeks public input regarding how the proposed changes to the Ticket program would impact disability beneficiaries who want to work and the systems that currently serve their employment and related needs, and to identify critical considerations for designing and implementing an improved program.

DATES: Comments must be received by November 13, 2020.

ADDRESSES: You may submit comments via the internet. Please visit the Federal eRulemaking portal at *http://www.regulations.gov.* Use the ''Search'' function to find docket number DOL–2020–0006. The system will issue a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

Caution: In your comments, you should be careful to include only the information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

FOR FURTHER INFORMATION CONTACT: Jennifer Sheehy, Deputy Assistant Secretary, Office of Disability Employment Policy, U.S. Department of Labor, 200 Constitution Avenue NW, S–1303, Washington, DC 20210, (202) 693–7880, or visit *https://www.dol.gov/dol/contact/contactphonecallcenter.htm* (TTY), for information about this notice.

SUPPLEMENTARY INFORMATION:

Purpose

In order to streamline and strengthen employment services for Social Security Disability Insurance (SSDI) beneficiaries and Supplemental Security Income (SSI) recipients seeking employment, the President's Budget for Fiscal Year 2021 includes a legislative proposal to transfer the Ticket program to DOL given its capacity to promote innovative workforce development and disability employment. Better integrating services for SSDI beneficiaries and SSI recipients into the core workforce system should result in a more effective and efficient system to support them in achieving and sustaining employment. A key challenge in transferring the program to DOL will be to reduce program complexity and overall administrative burden, rather than to simply recreate complexity or transfer the burden to other entities. Given the complexity of the current program and the significance of the proposed changes, public input is necessary to help ensure the success of the reformed program.

This RFI offers interested parties—including state and local governments, nonprofit and community-based organizations, philanthropic organizations, research experts, employers, health care providers, private disability insurance providers, vocational rehabilitation specialists, and members of the public—the opportunity to inform the development of a redesigned Ticket program aimed at increasing the employment and labor force participation of SSDI beneficiaries and SSI recipients.

Further Information

SSA's Ticket program is intended to assist adult disability beneficiaries in achieving and sustaining employment.[1] Under the Ticket program, SSA notifies beneficiaries of their eligibility to participate in the program, which allows them to obtain services from SSA-approved public or private providers, referred to as Employment Networks (EN), or from traditional state Vocational Rehabilitation (VR) agencies.

The Ticket program has helped thousands of disability beneficiaries return to work since it was established in 1999. Yet, despite the availability of the program, significant numbers of beneficiaries have not achieved levels of sustained employment that result in economic self-sufficiency and reduced reliance on disability benefits. Despite improvements over the years, the Ticket program faces fundamental challenges in attempting to meet its objectives. First, the program falls outside SSA's core mission of administering the Old Age, Survivors, and Disability Insurance (OASDI) and the SSI programs. Second, the program duplicates administrative structures and services where robust state and local workforce systems already exist. Finally, while the program is designed to promote beneficiary choice in accessing employment services and to incentivize providers by paying for successful individual outcomes, these features entail significant administrative burden for beneficiaries and service providers.

As designed, the Ticket program is largely separate from the broader workforce system. In contrast to when the program was created, the workforce system now provides similar services and is directed by the Workforce Innovation and Opportunity Act (WIOA) to prioritize services for recipients of public assistance and low-income individuals, including persons with disabilities, and to ensure accessibility for all persons. In addition, the milestone/outcome payment structure currently used in the Ticket program is complicated and delays reimbursement to service providers for many months, which may limit provider participation.

The rationale for transferring the Ticket program to DOL is to create a more integrated, effective, and efficient system for supporting disability beneficiaries in obtaining and sustaining employment. The ultimate goals of program redesign include the following:

- Increasing the number of disability beneficiaries who participate in the program, succeed in employment, and achieve economic mobility, while decreasing reliance on disability benefits and other forms of public assistance;
- Improving the experience of individual program participants;
- Reducing program fragmentation and duplication;
- Establishing national uniformity in essential program features while allowing opportunity for local innovation;
- Restructuring funding mechanisms and performance metrics to align with WIOA;
- Providing financial incentives to states in order to reward performance;
- Better integrating services for disability beneficiaries into the broader workforce system; and
- Leveraging DOL's expertise and capacity in promoting innovative workforce development and employment of persons with disabilities.

Although DOL and SSA have attempted to increase workforce system participation in the Ticket program, the workforce system historically has not served large numbers of SSA beneficiaries.[2] In order to drive changes on the scale necessary to improve economic mobility for disability beneficiaries, the President's Budget proposes to significantly reform the Ticket program through transferring administration of the program and redesigning key elements. Specifically, the proposal is to transfer the administration of the Ticket program to DOL's Employment and Training Administration (ETA). This would empower ETA's American Job Center (AJC) network to provide Ticket services in concert with other workforce programs. It would also simplify Ticket program rules, including the payment model used to pay ENs and other providers for services, in order to improve the structure and outcomes through a performance-based funding allocation. Program redesign would include aligning Ticket performance measures with WIOA core performance measures, improving the capacity of state public workforce systems to serve persons with disabilities, and changing the payment structure from individual vouchers to one in which states receive base administrative funding based on a formula and additional payments that reflect level of performance. State and

[1] The Ticket to Work and Work Incentives Improvement Act of 1999. Public Law 106–170, 101, 113 Stat. 1860, 1863–73 (codified as amended at 42 U.S.C. 1320b–19).

[2] After several years of sharing information on the Ticket program with the workforce system, the commitment to increase the number of workforce ENs resulted in multiple Training and Employment Notices (TENs), beginning in 2012 with TEN 14–12, *Receiving Ticket to Work Payment as an Employment Network,* which explained the Payment Agreement process. This was updated in 2014 as TEN 02–14, *Receiving Ticket to Work Payment as an Employment Network,* which explained a new process for public workforce entities to become ENs. In 2018, DOL published TEN 16–18, *New Administrative Processes for Public Workforce Employment Networks under the Social Security Administration's Ticket to Work Program,* to support DOL's goal of expanding the capacity of the American Job Center network to serve persons receiving disability benefits. The 2018 TEN notified the workforce system regarding the Ticket program's new administrative processes for public workforce ENs and alternative EN models.

local workforce entities would receive funding and technical assistance from ETA in order to better serve disability beneficiaries, with a portion of Ticket funding reserved for rewarding strong performance and program innovation. States and localities would be allowed greater flexibility in tailoring services to fit local circumstances. The redesigned program would retain key features of the current program, such as benefits counseling and suspension of SSA medical Continuing Disability Reviews (CDRs) while program participants pursue employment.[3]

In close coordination with SSA and ETA, DOL's Office of Disability Employment Policy (ODEP) will provide policy analysis and guidance to support the transfer and improvement of the program.

Request for Information

Through this RFI, we are soliciting feedback from interested and affected parties on the potential benefits and challenges in transferring the Ticket program to DOL and serving program participants through the public workforce systems, in order to enable them to increase employment and earnings and maximize self-sufficiency. We are also interested in evidence supporting or challenging the assumptions underlying this proposal. Responses to this RFI will inform decisions regarding the development, design, and implementation of the redesigned program. As such, responses supported by substantial evidence and careful reasoning will be afforded greatest weight. This RFI notice is for internal planning purposes only and should not be construed as a solicitation or as an obligation on the part of DOL or any participating federal agencies.

We ask respondents to address the following questions in the context of the preceding discussion in this document. Respondents do not need to address every question and should focus on those that relate to their expertise or perspective. To the extent possible, please clearly indicate the question(s) addressed in your response. We ask that each respondent include the name and street address of his or her institution or affiliation, if any, and the name, title, street address, email address, and telephone number of a contact person for his or her institution or affiliation, if any.

[3] Medical CDRs are periodic reviews of an individual's medical impairment(s) to determine continuing eligibility for SSI and/or SSDI.

Questions

Workforce System Capacity

1. How might state workforce systems use new Ticket program funding to increase capacity to effectively serve SSA disability beneficiaries, given that the number of SSA disability beneficiaries who will seek services in a particular locality is unknown?

2. How might state workforce systems integrate the provision of the Ticket program with other existing WIOA services? What opportunities and challenges will arise in doing so?

3. How could DOL's ETA help prepare state workforce systems for a potentially significant increase in SSA disability beneficiaries seeking services?

4. What ongoing federal support would be most helpful to state workforce systems as they administer the Ticket program?

5. How could state workforce systems provide quality remote services, when necessary, to serve SSA disability beneficiaries regionally or nationwide?

6. What are key considerations in transferring SSA's Work Incentives Planning and Assistance (WIPA) services to state workforce agencies?

Participant Experience and Outcomes

7. What specific program changes could improve experiences and outcomes for persons accessing the redesigned Ticket program services through the workforce system?

8. What is the capacity of the workforce system to effectively serve young adults or transition-age youth (*i.e.,* ages 14–18) under a redesigned Ticket program? What capacity and coordination issues would arise in serving transition-age youth?

Employment Networks and Vocational Rehabilitation

9. What lessons can be taken from current EN models (*e.g.,* community-based, nonprofit, workforce ENs) or collaborative AJC program models that can inform the new Ticket program?

10. How can VR entities partner with state workforce systems to support SSA disability beneficiaries in the redesigned Ticket program?

Funding Structure, Performance Metrics and Performance-Based Payments

11. What payment structures and which WIOA performance indicators (if any) would encourage state workforce systems to provide robust employment and training services to persons with disabilities, leading to job placement and ongoing support to ensure job retention?

12. Which of the WIOA performance indicators (if any) could serve as potential interim measures to trigger partial performance-based payments?

13. What are appropriate intervals (medium- and long-term) for performance-based payments?

14. How would workforce entities and DOL track and measure program success? Would workforce entities require access to new administrative data sources?

General

15. What challenges within the current Ticket program would potentially remain in a redesigned program administered by state workforce entities, and what could DOL do to address or mitigate them?

16. What strengths of the current Ticket program contribute to the success of individual Ticket holders, and how could these be preserved in the redesigned program?

17. Are there current or recent state examples of integrated systems that offer lessons for successful implementation of the redesigned Ticket program?

18. What are the implications of the current COVID–19 pandemic for redesigning the Ticket program at this time, such as employer demand, workforce system capacity, and remote services?

19. Are there additional considerations in transferring the Ticket program from SSA to DOL?

Signed at Washington, DC, this __th day of September, 2020.

Jennifer Sheehy,

Deputy Assistant Secretary for Disability Employment Policy.

[FR Doc. 2020–21533 Filed 9–28–20; 8:45 am]

BILLING CODE 4510–FK–P

LIBRARY OF CONGRESS

Copyright Office

[Docket No. 2020–9]

Sovereign Immunity Study: Notice and Request for Public Comment

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

ACTION: Notice of inquiry; extension of comment period.

SUMMARY: The U.S. Copyright Office is extending the deadline for the submission of reply comments and empirical research studies in response to the June 3 and June 24, 2020, notices regarding its state sovereign immunity policy study.

DATES: Written reply comments and empirical research studies in response

to the notices published June 3, 2020, at 85 FR 34252, and June 24, 2020, at 85 FR 37961, must be received no later than 11:59 p.m. Eastern Time on October 22, 2020.

ADDRESSES: For reasons of government efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are available on the Copyright Office website at *http://www.copyright.gov/docs/sovereignimmunitystudy.* If electronic submission of comments is not feasible due to lack of access to a computer and/or the internet, please contact the Office, using the contact information below, for special instructions.

FOR FURTHER INFORMATION CONTACT: Kevin Amer, Deputy General Counsel, *kamer@copyright.gov;* Mark T. Gray, Attorney-Advisor, *mgray@copyright.gov;* or Jalyce E. Mangum, Attorney-Advisor, *jmang@copyright.gov.* They can be reached by telephone at 202–707–3000.

SUPPLEMENTARY INFORMATION: On June 3, 2020, the U.S. Copyright Office issued a notice of inquiry (''NOI'') commencing a policy study on state sovereign immunity from copyright infringement suits.[1] Congress has requested that the Office ''research this issue to determine whether there is sufficient basis for federal legislation abrogating State sovereign immunity when States infringe copyrights.'' [2] To assist Congress in making that assessment, the Office solicited public comment on several issues concerning the degree to which copyright owners face infringement from state actors today, whether such infringement is based on intentional or reckless conduct, and what remedies, if any, are available to copyright owners under state law.

On June 24, 2020, the Office issued an additional notice providing for a second round of written comments to permit interested parties the opportunity to address any comments submitted in response to the NOI and to allow parties engaged in empirical research to complete and submit their findings.[3] To ensure that members of the public have sufficient time to comment, and to ensure that the Office has the benefit of a complete record, the Office is extending the deadline for the submission of additional comments and/or empirical research to 11:59 p.m. Eastern Time on October 22, 2020.

Dated: September 24, 2020.

Regan A. Smith,

General Counsel and Associate Register of Copyrights.

[FR Doc. 2020–21566 Filed 9–28–20; 8:45 am]

BILLING CODE 1410–30–P

[1] 85 FR 34252 (June 3, 2020).

[2] Letter from Sens. Thom Tillis & Patrick Leahy to Maria Strong, Acting Register of Copyrights, U.S. Copyright Office at 1 (Apr. 28, 2020), *https://www.copyright.gov/rulemaking/statesovereign-immunity/letter.pdf.*

[3] 85 FR 37961 (June 24, 2020); *see* 85 FR at 34255.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (20–078)]

NASA Astrophysics Advisory Committee; Meeting.

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Aeronautics and Space Administration (NASA) announces a meeting of the Astrophysics Advisory Committee. This Committee reports to the Director, Astrophysics Division, Science Mission Directorate, NASA Headquarters. 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.

DATES: Monday, October 19, 2020, 11:00 a.m.–5:00 p.m., Tuesday, October 20, 2020, 11:00 a.m.–5:00 p.m., and Wednesday, October 21, 2020, 11:00 a.m.–5:00 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 meeting will be available to the public by WebEx.

On Monday, October 19, the event address for attendees is: *https://nasaenterprise.webex.com/nasaenterprise/onstage/g.php?MTID=e8ac0c8ba6c20d6158a15014539ff4fe5,* the event number is 199 918 6105, and event password is ixXyezN@783.

On Tuesday, October 20, the event address for attendees is: *https://nasaenterprise.webex.com/nasaenterprise/onstage/g.php?MTID=e2402f4eea7472e33624d6ab4cfee14f5,* the event number is 199 163 7113, and the event password is TSpcp97Hd*5.

On Wednesday, October 21, the event address for attendees is: *https://nasaenterprise.webex.com/nasaenterprise/onstage/g.php?MTID=eb739cd4ce1f20ff24be91839cbc1d217,* the event number is 199 599 3836, and the event password is bKsf3Unn$57.

The agenda for the meeting includes the following topics:

—Astrophysics Division Update

—Updates on Specific Astrophysics Missions

—Reports from the Program Analysis Groups

—Reports from Specific Research and Analysis Programs

The agenda will be posted on the Astrophysics Advisory Committee web page: *https://science.nasa.gov/researchers/nac/science-advisory-committees/apac.*

The public may submit and upvote comments/questions ahead of the meeting through the website *https://arc.cnf.io/sessions/h259/#!/dashboard* that will be opened for input on October 5, 2020.

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2020–21428 Filed 9–28–20; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit issued.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8030; email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: On August 20, 2020, the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on September 23, 2020 to:

Permit No. 2021–004

1. Grant Ballard

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2020–21501 Filed 9–28–20; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit modification request received and permit issued.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated and permits issued under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of a requested permit modification and permit issued.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–8224; email: *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation (NSF), as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 671), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection.

NSF issued a permit (ACA 2016–020) to Laura K.O. Smith, Owner, Operator Quixote Expeditions, on December 23, 2015. The issued permit allows the permit holder to conduct waste management activities associated with the operation of the ''Ocean Tramp,'' a reinforced ketch rigged sailing yacht in the Antarctic Peninsula region. Activities to be conducted by Quixote include: Passenger landings, hiking, photography, wildlife viewing, and possible station visits.

A modification to this permit, dated November 22, 2017, permitted coastal camping activities in select locations and resupply of fresh food to the Quixote Expeditions vessel as part of fly/cruise operations. Another modification, dated November 6, 2018, allowed the permit holder to add a second vessel to support Quixote Expeditions activities, to conduct ship-to-ship fuel transfers, to release comminuted food waste (excepting poultry) at sea, and to operate a remotely piloted aircraft for educational and commercial purposes. A recent modification to this permit, dated November 20, 2019, permitted the conduct waste management activities similar to prior seasons during the 2019–2020 field season.

On September 17, 2020, the permit holder submitted an update of provided NSF an update based on planned activities for the 2020–2021 field season and to request an extension of the permit expiration date. Quixote's proposed activities are similar as those detailed in the original permit and earlier modifications. The Environmental Officer has reviewed the modification request and has determined that the amendment is not a material change to the permit, and it will have a less than a minor or transitory impact.

Dates of Permitted Activities: September 23, 2020–March 30, 2021.

The permit modification was issued on September 23, 2020.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2020–21502 Filed 9–28–20; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–440; NRC–2020–0188]

Energy Harbor Nuclear Corp.; Energy Harbor Nuclear Generation LLC; Perry Nuclear Power Plant, Unit No. 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of an amendment to Facility Operating License No. NPF–58, issued to Energy Harbor Nuclear Corp. (EHNC) and Energy Harbor Nuclear Generation LLC, for operation of the Perry Nuclear Power Plant, Unit No. 1 (PNPP), located near Lake Erie in Lake County, Ohio. The proposed action would amend the expiration of Facility Operating License No. NPF–58 from March 18, 2026, to November 7, 2026. Specifically, the expiration date of PNPP's full-power operating license (FPOL) would be revised such that it would expire 40 years from the date of issuance of the FPOL, as is permitted by the NRC's regulations.

DATES: The environmental assessment (EA) and finding of no significant impact (FONSI) referenced in this document is available on September 29, 2020.

ADDRESSES: Please refer to Docket ID NRC–2020–0188 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov/* and search for Docket ID NRC–2020–0188. 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 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.

FOR FURTHER INFORMATION CONTACT: Scott P. Wall, Office of Nuclear Reactor Regulation; U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2855; email: *Scott.Wall@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering the issuance of an amendment to Facility Operating License No. NPF–58, issued to EHNC and Energy Harbor Nuclear Generation LLC (collectively, the licensees), for operation of PNPP, located near Lake Erie in Lake County, Ohio. The licensee requested the amendment by letter dated March 26, 2020 (ADAMS Accession No. ML20086K773), as supplemented by letter dated July 30, 2020 (ADAMS Accession No. ML20212L544). If approved, the amendment would revise the expiration date of the license such that it would expire 40 years from the date of the issuance of the FPOL, as is permitted by section 50.51 of title 10 of the *Code of*

Federal Regulations (10 CFR). In accordance with 10 CFR 51.21, the NRC prepared the following EA that analyzes the environmental impacts of the proposed licensing action. Based on the results of this EA, and in accordance with 10 CFR 51.31(a), the NRC has determined not to prepare an environmental impact statement for the proposed licensing action and is issuing a FONSI.

II. Environmental Assessment

Description of the Proposed Action

The proposed action would revise the expiration date of PNPP's Facility Operating License such that it would expire 40 years from the date of the issuance of the FPOL, as permitted by 10 CFR 50.51. The proposed action would revise the expiration date of the Facility Operating License No. NPF–58 from March 18, 2026, to November 7, 2026, which is 40 years from the date of issuance of the FPOL (November 7, 1986).

The proposed action is also described in the licensee's application dated March 26, 2020, as supplemented by letter dated July 30, 2020.

Need for the Proposed Action

On March 18, 1986, the NRC issued a low-power testing license (No. NPF–45) that authorized the licensee to operate PNPP at up to 5 percent of rated power. On November 7, 1986, the NRC issued a FPOL (No. NPF–58) that authorized the licensee to operate PNPP at up to 100 percent of rated power, with an expiration date 40 years from the date of the issuance of the low-power license.

The proposed action would allow the licensee to recapture the approximate 7.7-month period of low-power operation and extend the license expiration date to November 7, 2026. This action is consistent with NRC policy established in the Staff Requirements Memorandum (SRM) for SECY–98–296, ''Staff Requirements—SECY–98–296—Agency Policy Regarding Licensee Recapture of Low-Power Testing or Shutdown Time for Nuclear Power Plants,'' dated March 30, 1999 (ADAMS Accession No. ML20213A739) and SECY–98–296, ''Agency Policy Regarding Licensee Recapture of Low-Power Testing or Shutdown Time for Nuclear Power Plants,'' dated December 21, 1998, available at (ADAMS Accession No. ML992870025).

Environmental Impacts of the Proposed Action

The proposed action would amend the PNPP Facility Operating License such that it would expire 40 years from the date of the issuance of the facility's FPOL.

NUREG–0884, ''Final Environmental Statement Related to the Operation of Perry Nuclear Power Plant, [Unit Nos.] 1 and 2,'' dated August 1982 (ADAMS Accession No. ML15134A060), concluded that PNPP could operate with minimal environmental impact. The proposed action would not affect the design or operation of PNPP and would not involve any modifications to or increase the licensed power for the plant. Similarly, the proposed action would not significantly increase the probability or consequences of accidents or change the types of effluents released offsite. Because the proposed approximate 7.7-month extension of operation represents only a small fraction of the 40-year operating life considered in NUREG–0884, there would be no significant increase in the amount of any effluent released or waste generated, and no significant increase in occupational or public radiation exposure. The nominal additional quantities of effluents and waste generated during the proposed approximate 7.7-month period of extension would be in accordance with current operating requirements and regulatory limits. Therefore, the NRC concludes that there would be no significant radiological or non-radiological environmental impacts associated with the proposed action.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC considered denial of the license amendment request (*i.e.,* the ''no-action'' alternative). Denial of the license amendment request would result in no change in current environmental impacts. Accordingly, the environmental impacts of the proposed action and the no-action alternative would be similar.

Alternative Use of Resources

There are no unresolved conflicts concerning alternative uses of available resources under the proposed action.

Agencies or Persons Consulted

On August 5, 2020, the NRC notified State of Ohio representatives of the EA and FONSI. Additionally, in accordance with 10 CFR 50.91, the licensee provided copies of its application to the State of Ohio, and the NRC staff will consult with this State prior to issuance of the amendment. No additional Federal or State of Ohio agencies or persons were consulted regarding the environmental impact of the proposed action.

III. Finding of No Significant Impact

The licensee has requested an amendment to revise the expiration date of the PNPP license such that it would expire 40 years from the date of the issuance of the FPOL, as is permitted by 10 CFR 50.51. Specifically, the proposed action would revise the expiration date of Facility Operating License No. NPF–58 from March 18, 2026 to November 7, 2026, which is 40 years from the issuance of the FPOL on November 7, 1986.

The proposed action is in accordance with the licensee's application dated March 26, 2020, as supplemented by letter dated July 30, 2020.

The NRC is considering issuing the requested amendment. The proposed action would not significantly affect plant safety, would not have a significant adverse effect on the probability of an accident occurring, and would not have any significant radiological or non-radiological impacts. The reason the human environment would not be significantly affected is that the proposed action would not involve any construction or modification of the facility. Consistent with 10 CFR 51.21, the NRC conducted the EA for the proposed action, and this FONSI incorporates by reference the EA in Section II of this notice. Therefore, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

As required by 10 CFR 51.32(a)(5), the related environmental document which provides the latest description of environmental conditions at PNPP is NUREG–0884. Other than the licensee's letter dated March 26, 2020, as supplemented by letter dated July 30, 2020, there are no other environmental documents associated with this review. These documents are available for public inspection as indicated in Section I of this notice.

Dated: September 24, 2020.

For the Nuclear Regulatory Commission.

Scott P. Wall,

Senior Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–21513 Filed 9–28–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0202]

NuScale Power, LLC; NuScale Small Modular Reactor

AGENCY: Nuclear Regulatory Commission.

ACTION: Standard design approval; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued a standard design approval (SDA) to NuScale Power, LLC (NuScale) for the NuScale small modular reactor (SMR) standard design. The SDA allows the NuScale SMR standard design to be referenced in an application for a construction permit or operating license, or an application for a combined license or manufacturing license under its regulations.

DATES: The Standard Design Approval was issued on September 11, 2020.

ADDRESSES: Please refer to NRC–2020–0202 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0202. 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 reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The NuScale Power Standard Design, Standard Design Approval is available in ADAMS under Accession No. ML20247J564.

FOR FURTHER INFORMATION CONTACT: Gregory Cranston, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0546, email: *Gregory.Cranston@nrc.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Nuclear Regulatory Commission has issued a standard design approval (SDA) to NuScale Power, LLC, for the NuScale small modular reactor (SMR) standard design under subpart E, ''Standard Design Approvals,'' of title 10 of the *Code of Federal Regulations* (10 CFR) part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' This SDA allows the NuScale SMR standard design to be referenced in an application for a construction permit or operating license under 10 CFR part 50, ''Domestic Licensing of Production and Utilization Facilities,'' or an application for a combined license or manufacturing license under 10 CFR part 52. In addition, the NRC has issued the final safety evaluation report (FSER) (ADAMS Package Accession No. ML20023A318) that supports issuance of the SDA.

Issuance of this SDA signifies completion of the NRC staff's technical review of the NuScale SMR design. The NRC staff performed its technical review of the NuScale SMR design control document in accordance with the standards for review of standard design approval applications set forth in 10 CFR 52.139, ''Standards for Review of Applications.''

On the basis of its evaluation and independent analyses, as described in the FSER, the NRC staff concludes that NuScale's application for standard design approval meets the applicable portions of 10 CFR 52.137, ''Content of Applications; Technical Information,'' and the review standards identified in 10 CFR 52.139.

Copies of the NuScale SMR FSER and SDA have been placed in the NRC's PDR. The PDR is currently closed. However, you may order copies by submitting a 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.

Dated: September 23, 2020.

For the Nuclear Regulatory Commission.

Anna H. Bradford,

Director, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–21429 Filed 9–28–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of September 28, October 5, 12, 19, 26, November 2, 2020.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

Week of September 28, 2020

Wednesday, September 30, 2020

9:00 a.m.—Strategic Programmatic Overview of the Operating Reactors and New Reactors Business Lines and Results of the Agency Action Review Meeting (Public Meeting) (Contact: Candace de Messieres: 301–415–8395)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://www.nrc.gov/.*

Week of October 5, 2020—Tentative

Thursday, October 8, 2020

10:00 a.m.—Meeting with the Organization of Agreement States and the Conference of Radiation Control Program Directors (Public Meeting) (Contact: Celimar Valentin-Rodriguez: 301–415–7124)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://www.nrc.gov/.*

Week of October 12, 2020—Tentative

There are no meetings scheduled for the week of October 12, 2020.

Week of October 19, 2020—Tentative

Wednesday, October 21, 2020

10:00 a.m.—Briefing on Human Capital and Equal Employment Opportunity (Public Meeting) (Contact: Randi Neff: 301–287–0583)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://www.nrc.gov/.*

1:00 p.m.—All Employees Meeting with the Commissioners (Public Meeting)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://www.nrc.gov/.*

Week of October 26, 2020—Tentative

There are no meetings scheduled for the week of October 26, 2020.

Week of November 2, 2020—Tentative

Thursday, November 5, 2020

9:00 a.m.—Strategic Programmatic Overview of the Decommissioning and Low-Level Waste and Nuclear Materials Users Business Lines (Public Meeting) (Contact: Celimar Valentin- Rodriguez: 301–415–7124)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://www.nrc.gov/.*

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or by email at *Wendy.Moore@nrc.gov* or *Tyesha.Bush@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: September 25, 2020.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2020–21627 Filed 9–25–20; 4:15 pm]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89970; File No. SR–CboeEDGX–2020–045]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule

September 23, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 11, 2020, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the fee schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule applicable to its equities trading platform (''EDGX Equities'') by: (1) Amending certain standard rates; (2) adding a new fee code; (3) updating the Non-Displayed Add Volume Tiers; and (4) including a Remove Volume Tier.[3]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 13 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[4] no single registered equities exchange has more than 18% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays credits to members that provide liquidity and assesses fees to those that remove liquidity. The Exchange's fee schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Currently, for orders priced at or above $1.00, the Exchange provides a standard rebate of $0.0017 per share for orders that add liquidity and assesses a fee of $0.0027 per share for orders that remove liquidity. For orders priced below $1.00, the Exchange a standard rebate of $0.00003 per share for orders that add liquidity and assesses a fee of 0.30% of Dollar Value for orders that remove liquidity. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an

[3] The Exchange initially filed the proposed fee changes on September 1, 2020 (SR–CboeEDGX–2020–044). On September 11, 2020, the Exchange withdrew that filing and submitted this proposal.

[4] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (August 24, 2020), available at *https://markets.cboe.com/us/equities/market_statistics/.*

incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Proposed Amendment to Standard Rebate for Securities Under $1.00

As stated above, the Exchange currently offers a standard rebate of $0.00003 for orders in securities below $1.00 that add liquidity. The Exchange proposes to amend this standard rate by providing a standard rebate of $0.00009 for orders that add liquidity in securities priced under $1.00 and reflects this change in the Fee Codes and Associated Fee where applicable (*i.e.,* corresponding to fee codes 3, 4, B, V, and Y). The Exchange notes that the proposed standard rate is in line with, yet also competitive with, rates assessed by other equities exchanges on orders in securities priced below $1.00.[5] The Exchange notes, too, that its affiliated exchange, Cboe BZX Exchange, Inc. (''BZX Equities''), is simultaneously submitting a fee change to amend its same current standard rate for orders that add liquidity in securities under $1.00 in the same manner.

Proposed New Fee Code

The Exchange proposed to add a new type of fee code in the Fee Code and Associated Fees table in the Fee Schedule. Specifically, the proposed fee code ''ZM'' is appended to Retail[6] Day or Regular Hours Only (''RHO'')[7] Orders that remove liquidity on arrival and are assessed no fee. Currently, such orders in securities priced at or above $1.00 are assessed the standard fee of $0.0027 to remove liquidity and such orders in securities priced below $1.00 are assessed the standard fee of 0.30% of Dollar Value to remove liquidity.

Proposed Updates to the Non-Displayed Add Volume Tiers

Currently, the Exchange provides for three Non-Displayed Add Volume Tiers under footnote 1 of the Fee Schedule. These tiers offer enhanced rebates on Members' orders yielding fee codes ''DM''[8], ''HA''[9], ''MM''[10] and ''RP''[11] where a Member reaches certain required volume-based criteria offered in each tier. Specifically, the Non-Displayed Add Volume Tiers are as follows:

- Tier 1 provides an enhanced rebate of $0.0015 for a Member's qualifying orders (*i.e.,* yielding fee codes DM, HA, MM and RP) where a Member adds an ADV[12] greater than or equal to 1,000,000 shares as Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.
- Tier 2 provides an enhanced rebate of $0.0022 for a Member's qualifying orders where a Member adds an ADV greater than or equal to 2,500,000 shares as Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.
- Tier 3 provides an enhanced rebate of $0.0025 for a Member's qualifying orders where a Member adds an ADV greater than or equal to 7,000,000 shares as Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.

The Exchange proposes to update the criteria in each of the Non-Displayed Add Volume Tiers as follows below. The Exchange notes that the enhanced rebates currently provided in each tier remain the same.

- To meet the proposed criteria in Tier 1, a Member must have an ADAV greater than or equal to 0.01% of TCV for Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.
- To meet the proposed criteria in Tier 2, a Member must have an ADAV greater than or equal to 0.02% of TCV for Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.
- To meet the proposed criteria in Tier 3, a Member must have an ADAV greater than or equal to 0.05% of TCV for Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.

The Exchange notes that the proposed rule change also updates the language in each Tier to state ''where a Member has an ADAV'', which essentially states the same requirement as ''adds an ADV'', but is more appropriately aligned with the defined terms in the Fee Schedule.[13] Further, the Exchange does not believe that amending the current volume over a baseline number of shares criteria to, instead, be a percentage volume over TCV poses any significant increase or decrease in difficulty in reaching the Non-Displayed Add Volume Tiers, but only changes the format of the Non-Displayed Add Volume Tier criteria to be consistent with the format of the criteria in the other volume-based tiers offered under the Fee Schedule.[14]

Proposed Remove Volume Tier

The Exchange proposes to add a new Remove Volume Tier under footnote 1 of the Fee Schedule.[15] The proposed Remove Volume Tier offers a reduced remove fee of $0.0026 in securities at or above $1.00 and 0.28% of total dollar value for orders in securities below $1.00[16] for orders yielding fee code ''BB''[17], ''N''[18] and ''W''[19] where a Member has an ADAV[20] greater than or equal to 0.25% TCV[21] with displayed orders that yield fee codes B, V or Y. The proposed Remove Volume Tier is designed to incentivize Members to increase their orders that add displayed

[5] *See* NYSE Price List 2020, ''Transactions in stocks with a per share stock price less than $1.00'', which either does not assess a charge or assesses a charge of 0.3% for various orders in securities priced below $1.00; *and* Nasdaq Pricing, ''Rebates and Fees, Shares Executed Below $1.00'', which assesses no change for orders to add liquidity in securities priced below $1.00 and assesses a charge of 0.30% of total dollar volume for orders to remove liquidity in securities priced below $1.00.

[6] *See* EDGX Rule 11.21(a)(1). A ''Retail Order'' is an agency or riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. *See* EDGX Rule 11.21(a)(2). Retail Orders are submitted by a ''Retail Member Organization'' or ''RMO'', which is a member (or a division thereof) that has been approved by the Exchange to submit such orders.

[7] ''Day'' is an instruction the User may attach to an order stating that an order to buy or sell which, if not executed, expires at the end of Regular Trading Hours. Any Day Order entered into the System before the opening for business on the Exchange, or after the closing of Regular Trading Hours, will be rejected. *See* EDGX Rule 11.6(q)(2). ''Regular Hours Only (''RHO'') is an instruction a User may attach to an order designating it for execution only during Regular Trading Hours, which includes the Opening Process and Re-Opening Process following a halt suspension or pause. *See* EDGX Rule 11.6(q)(6).

[8] Appended to orders that add liquidity using MidPoint Discretionary order within discretionary range and are provided a rebate of $0.00100.

[9] Appended to non-displayed orders that add liquidity and are provided a rebate of $0.00100.

[10] Appended to non-displayed orders that add liquidity using Mid-Point Peg and are provided a rebate of $0.00100.

[11] Appended to non-displayed orders that add liquidity using Supplemental Peg and are provided a rebate of $0.00100.

[12] ''ADV'' means average daily volume calculated as the number of shares added to, removed from, or routed by, the Exchange, or any combination or subset thereof, per day. ADV is calculated on a monthly basis.

[13] *See supra* note 12; *and see infra* note 20.

[14] *See* EDGX Equities Fee Schedule, ''Add Volume Tiers'', ''Tape B Volume Tier'', and ''Retail Volume Tier''.

[15] As a result of the new Remove Volume Tier, it also updates the title of footnote 1 to ''Add/Remove Volume Tiers''.

[16] As a result, the Exchange proposes to update the statement under General Notes in the Fee Schedule to state that ''unless otherwise indicated, variable rates provided by tiers apply only to executions in securities priced at or above $1.00.

[17] Appended to orders that remove liquidity from EDGX (Tape B) and is assessed a standard fee of $0.00270.

[18] Appended to orders that remove liquidity from EDGX (Tape C) and is assessed a standard fee of $0.00270.

[19] Appended to orders that remove liquidity from BZX (Tape A) and is assessed a standard fee of $0.00270.

[20] ''ADAV'' means average daily added volume calculated as the number of shares added per day. ADAV is calculated on a monthly basis.

[21] ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

volume on the Exchange in order to receive a reduced fee on their qualifying, liquidity removing orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[22] in general, and furthers the objectives of Section 6(b)(4),[23] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members, issuers and other persons using its facilities. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The proposed rule changes reflect a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members.

Regarding the proposed change to the standard rates, the Exchange believes that amending the standard rate for orders that add volume in securities priced below $1.00 is reasonable because, as stated above, in order to operate in the highly competitive equities markets, the Exchange and its competing exchanges seek to offer similar pricing structures, including assessing comparable standard fees for orders in securities priced below $1.00. Thus, the Exchange believes the proposed standard rate change is reasonable as it is generally aligned with and competitive with the amounts assessed for the orders in securities below $1.00 on other equities exchanges. The Exchange also believes that amending this standard rate amount represents an equitable allocation of fees and is not unfairly discriminatory because they will continue to automatically apply to all Members' orders that add liquidity in securities less than $1.00 uniformly.

Regarding the proposed new fee code ZM appended to Retail Day/RHO Orders that remove liquidity on arrival, the Exchange notes that the competition for Retail Order flow is particularly intense, especially as it relates to exchange versus off-exchange venues, as prominent retail brokerages tend to route a majority of their limit orders to off-exchange venues.[24] Accordingly, competitive forces compel the Exchange to use exchange transaction fees and credits, particularly as they relate to competing for Retail Order flow, because market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange believes that its proposed change to adopt fee code ZM, which will assess no fee for Retail Day/RHO Orders that remove upon arrival is reasonable, equitable and not unfairly discriminatory. Specifically, the Exchange believes the proposal is reasonable as market participants will not be subject to a fee for the execution of such orders. This is consistent with, and competitive with, fees assessed for retail order flow on other equities exchanges, which provide pricing incentives to retail orders in the form of lower fees and/or higher rebates.[25] The Exchange notes too that it currently offers a rebate of $0.0032 per share for Retail Orders that add liquidity (*i.e.,* yielding fee code ''ZA'') as compared to the standard rebate of $0.0017 for liquidity adding orders, as well as Retail Volume Tiers which provide various enhanced rebates specifically for Members' Retail Order flow. The Exchange believes that adopting no charge on orders yielding fee code ZM is reasonable in that it is reasonably designed to incentivize an increase in removing Retail Order flow. Retail Orders are generally submitted in smaller sizes and tend to attract Market-Makers, as smaller size orders are easier to hedge, and Retail Order flow that removes liquidity additionally signals to liquidity providers to increase their overall provision of liquidity in the markets. Increased Market-Maker activity facilitates tighter spreads and an increase in overall liquidity provider activity provides for deeper, more robust levels of liquidity, both of which signal additional corresponding increase in order flow from other market participants, contributing towards a robust, well-balanced market ecosystem. Indeed, increased overall order flow benefits all investors by continuing to deepen the Exchange's liquidity pool, potentially providing even greater execution incentives and opportunities, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency and improving investor protection. The Exchange notes that, like all other fee codes, ZM and the accompanying free charge will be automatically and uniformly applied to all Members' qualifying orders. The Exchange additionally notes that while the proposed fee code and assessment of no fee is applicable only to Retail Orders, the Exchange does not believe this application is discriminatory as the Exchange offers similar rebates or reduced rates to non-Retail Order flow.[26]

The Exchange believes that the proposed Remove Volume Tier is reasonable because it provides an additional opportunity through a new tier for Members to receive a discounted rate by means of liquidity adding orders and that the proposed changes to the Non-Displayed Liquidity Tiers are reasonable because they merely update the format of the tiers' criteria to be consistent with other volume-based tiers currently offered by the Exchange, thus maintaining existing opportunities for Members to receive a discounted rate by means of non-displayed liquidity adding orders.[27] The Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges, including the Exchange, and are reasonable, equitable and non-discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Additionally, as noted above, the Exchange operates in highly competitive market. The Exchange is only one of several equity venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. It is also only one of several maker-taker exchanges. Competing equity exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange. These competing pricing schedules, including those of the Exchange's affiliated equities

[22] 15 U.S.C. 78f.

[23] 15 U.S.C. 78f(b)(4).

[24] *See* Securities Exchange Release No. 86375 (July 15, 2019), 84 FR 34960 (SR–CboeEDGX–2019–045).

[25] *See* Nasdaq Price List, Rebate to Add Displayed Designated Retail Liquidity, which offer rebates of $0.00325 and $0.0033 for Add Displayed Designated Retail Liquidity; *and* NYSE Price List, ''Fees and Credits Applicable to Executions in the Retail Liquidity Program'', which offers various reduced fees, including the assessment of no charges, for various types of retail order volume, and ''Transaction Fees and Credits For Tape B and C Securities'', which provides a rebate of $0.0030 per share specifically for retail orders.

[26] *See generally,* EDGX Equities Fee Schedule, Fee Codes and Associated Fees; *see also* ''Add Volume Tiers'' and ''Tape B Volume Tier'', both of which provide various enhanced rebates for non-Retail Order flow.

[27] *See supra* note 14.

exchanges,[28] are presently comparable to those that the Exchange provides, including the pricing of comparable criteria and reduced fees.

Moreover, the Exchange believes the Remove Volume Tier is a reasonable means to incentivize Members to continue to provide liquidity adding, displayed volume to the Exchange by offering them a different, additional opportunity than that of the current Add Volume Tiers—to receive a reduced fee on their liquidity removing orders by meeting the proposed criteria in submitting additional add volume order flow. In addition to this, the Exchange has recently observed that trading in subdollar names has grown significantly; nearly tripling since the beginning of 2020, and that competing equities exchanges have begun offering pricing incentives for subdollar orders.[29] Therefore, the Exchange believes that it is reasonable and equitable to provide the proposed reduced fee under the new Remove Volume Tier for qualifying subdollar orders. Also, as noted above, the Exchange's affiliated equities exchanges already have similar Remove Volume Tiers in place, which offer similar rebates for achieving comparable criteria, in addition to their Add Volume Tiers.[30]

In addition to this, the Exchange believes the proposed Non-Displayed Volume Tiers are reasonable in that the proposed changes to the tiers' criteria is designed to be more consistent with the format of the criteria (*i.e.,* percentage of volume based on TCV) currently offered under the other volume-based tiers in the Fee Schedule.[31] Also, as noted above, the Exchange's affiliated equities exchange, BZX Equities, currently has Non-Displayed Volume Tiers in place, which offer substantially similar enhanced rebates and criteria based on volume over TCV for its members.[32]

Overall, the Exchange believes that the proposed tiers, each based on a Member's liquidity adding orders, will benefit all market participants by incentivizing continuous liquidity and thus, deeper more liquid markets as well as increased execution opportunities. Particularly, the proposed Remove Volume Tier is designed to incentivize continuous displayed liquidity, which signals other market participants to take the additional execution opportunities provided by such liquidity, while the proposed Non-Displayed Add Volume Tiers remains designed to incentivize non-displayed liquidity, which further contributes to a deeper, more liquid market and provide even more execution opportunities for active market participants at improved prices. This overall increase in activity deepens the Exchange's liquidity pool, offers additional cost savings, supports the quality of price discovery, promotes market transparency and improves market quality, for all investors.

The Exchange believes that the proposal represents an equitable allocation of fees and rebates and is not unfairly discriminatory because all Members are eligible for the proposed Remove Volume Tier and Non-Displayed Add Volume Tiers and would have the opportunity to meet the tiers' criteria and would receive the proposed fee if such criteria is met. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying for the proposed tiers. While the Exchange has no way of predicting with certainty how the proposed tier will impact Member activity, the Exchange anticipates that approximately eight Members will be able to compete for and reach the proposed Remove Volume Tier. The Exchange also notes that while the proposed changes to the criteria in the Non-Displayed Add Volume Tiers do not significantly increase or decrease the level of criteria difficulty, thus do not significantly affect Members' current ability to compete for and reach the proposed tiers, approximately three additional Members will be able to compete for and reach these tiers, as amended. The Exchange anticipates that the tiers will include various liquidity providing Member types, such as traditional Market Makers, and wholesale or consolidator firms that mainly make markets for retail orders, each providing distinct types of order flow to the Exchange to the benefit of all market participants. The Exchange also notes that proposed tiers will not adversely impact any Member's pricing or ability to qualify for other reduced fee or enhanced rebate tiers. Should a Member not meet the proposed criteria under any of the proposed tiers, the Member will merely not receive that corresponding reduced fee. Furthermore, the proposed reduced fee in the Remove Volume Tier would uniformly apply to all Members that meet the required criteria under the proposed tier. The Exchange again notes that the enhanced rebates offered under the Non-Displayed Add Volume Tiers remain the same.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.''

The Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed change applies to all Members equally in that all Members are eligible for the proposed Remove Volume Tier and the proposed Non-Displayed Add Volume Tiers, have a reasonable opportunity to meet the tiers' criteria and will all receive the proposed fee if such criteria is met. Additionally, the proposed tiers are designed to attract additional order flow to the Exchange. The Exchange believes that the additional and updated tier criteria would incentivize market participants to direct liquidity adding order flow to the Exchange, bringing with it improved price transparency. Greater overall order

[28] *See* EDGA Equities Fee Schedule, footnote 7, ''Add/Remove Volume Tiers'', of which the Remove Volume Tiers offers an enhanced rebate of $0.0022 or $0.0028 for reaching a certain threshold of ADV over TCV; BYX Equities Fee Schedule, footnote 1, ''Add/Remove Volume Tiers'', of which the Remove Volume Tiers offer enhanced rebates between $0.0015 and $0.0018 for various criteria (Step-Up volume, ADAV of a set number of shares, ADV as a percentage of TCV, etc.); *and* BZX Equities Fee Schedule, footnote 1, ''Add Volume Tiers'', Non-Displayed Add Volume Tiers, which provide for substantially similar enhanced rebates and non-displayed volume based criteria.

[29] *See* NYSE Price List, ''Fees and Credits applicable to Designated Market Makers (''DMMs'')'', which provides, among various credits for orders in securities at or above $1.00, additional credit of $0.0004 for DMMs adding liquidity in securities under $1.00; *see also* Securities Exchange Release No. 89607 (August 18, 2020), 85 FR 52179 (August 24, 2020) (SR–NYSEArca–2020–75), which recently adopted in its fee schedule a step up tier for ETP Holders adding liquidity in Round Lots and Odd Lots in Tapes A, B and C securities with a per share price below $1.00 and amended the base rate for adding and removing liquidity in Round Lots and Odd Lots in Tapes A, B and C securities with a per share price below $1.00.

[30] *See supra* note 28.

[31] *See supra* note 14.

[32] *See supra* note 28.

flow and pricing transparency benefits all market participants on the Exchange by providing more trading opportunities, enhancing market quality, and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem, which benefits all market participants. Further, the proposed standard rebate for orders that add liquidity in securities below $1.00 and the proposed no charge for orders yielding fee code ZM will apply uniformly and automatically to all such Members' respective orders, as all other standard rates and fee codes apply today to qualifying orders. In addition to this, and as indicated above, the Exchange does not believe that not assessing a fee for Retail Orders yielding fee code ZM imposes any burden on intramarket competition as the Exchange offers many similar rebate opportunities for non-Retail Orders in it Fee Schedule.[33]

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including 12 other equities exchanges and off-exchange venues and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 18% of the market share. Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[34] and paragraph (f) of Rule 19b–4[35] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGX–2020–045 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–CboeEDGX–2020–045. 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–CboeEDGX–2020–045, and should be submitted on or before October 20, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–21406 Filed 9–28–20; 8:45 am]

BILLING CODE 8011–01–P

[33] *See supra* note 26.

[34] 15 U.S.C. 78s(b)(3)(A).

[35] 17 CFR 240.19b–4(f).

[36] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89973; File No. SR–FINRA–2020–029]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Proposed Rule Change Relating to Granularity of Timestamps in Trade Reports Submitted to FINRA's Equity Trade Reporting Facilities

September 23, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 17, 2020, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. 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

FINRA is proposing to require firms to report time fields in trade reports submitted to an equity trade reporting facility (or ''FINRA Facility'')[3] using the same timestamp granularity that they use to report to the consolidated audit trail (''CAT''), in accordance with an SEC order granting exemptive relief from certain CAT NMS Plan requirements.

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA 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, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

FINRA's equity trade reporting rules require members to report all time fields, including time of trade execution and, if applicable, time of trade cancellation, to the FINRA Facilities in seconds (*i.e.,* HH:MM:SS) and milliseconds, if the member's system captures time in milliseconds.[4] Pursuant to Rule 6860 of FINRA's CAT Compliance Rule,[5] Industry Members are required to report timestamps for Reportable Events, including trade executions, to the CAT's Central Repository in milliseconds, and if their system captures time in finer increments, to report in such finer increments up to nanoseconds (except as otherwise provided under Rule 6860 for Manual Order Events).[6] This requirement is consistent with the CAT NMS Plan,[7] the CAT Compliance Rules of the other Plan Participants and exemptive relief granted by the SEC relating to timestamp granularity.[8]

Thus, currently there is a difference in the timestamp granularity requirements applicable to member firms reporting to the FINRA Facilities (up to milliseconds) and to the CAT (up to nanoseconds). This difference in timestamp granularity has implications for exemptive relief granted by the SEC. On June 11, 2020, the SEC granted the Plan Participants exemptive relief from, in pertinent part, Section 6.4(d)(ii)(B) of the CAT NMS Plan, which states that each Participant, through its Compliance Rule, must require its Industry Members to report to the CAT a cancelled trade indicator when a trade is cancelled.[9] Specifically, since firms already report trade cancellations to the FINRA Facilities pursuant to FINRA's trade reporting rules, the Participants requested an exemption so that they could relieve firms of their obligation to report the same information to the CAT. Instead, the CAT will obtain trade cancellations from trade report data that FINRA reports to the CAT (''FINRA Facility Data'') and will link such data to the related CAT execution reports submitted by Industry Members. As part of the FINRA Facility Data, FINRA submits to the CAT the time of trade cancellation as reported by the firm to the FINRA Facility. As noted above, under current rules and systems limitations, this timestamp is in milliseconds.

Given the difference in timestamp granularity requirements for firms reporting to the FINRA Facilities and the CAT, it is possible that the CAT could receive the time of trade cancellation in milliseconds from FINRA, while the time of trade cancellation for the same event might

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Specifically, the equity FINRA Facilities are (1) the Alternative Display Facility, the FINRA/Nasdaq Trade Reporting Facilities and the FINRA/NYSE Trade Reporting Facility, through which member firms report OTC transactions in NMS stocks to FINRA, and (2) the OTC Reporting Facility, through which member firms report transactions in OTC Equity Securities to FINRA.

[4] *See* Rules 6282.04 and 7130.01 (relating to the ADF); 6380A.04 and 7230A.01 (relating to the FINRA/Nasdaq TRFs); 6380B.04 and 7230B.01 (relating to the FINRA/NYSE TRF); and 6622.04 and 7330.01 (relating to the ORF).

[5] ''Compliance Rule'' is defined under Section 1.1 of the CAT NMS Plan to mean ''with respect to a Participant, the rule(s) promulgated by such Participant as contemplated by Section 3.11.'' FINRA's CAT Compliance Rule is the FINRA Rule 6800 Series (Consolidated Audit Trail Compliance Rule).

[6] Terms used but not otherwise defined herein have the meaning set forth in the CAT NMS Plan and FINRA's CAT Compliance Rule. Specifically, ''Central Repository,'' ''Industry Member,'' ''Manual Order Event'' and ''Reportable Event'' are defined under Section 1.1 of the CAT NMS Plan and FINRA Rule 6810.

[7] Section 6.8(b) of the CAT NMS Plan states:

Each Participant shall, and through its Compliance Rule shall require its Industry Members to, report information required by SEC Rule 613 and this Agreement to the Central Repository in milliseconds. To the extent that any Participant's order handling or execution systems utilize timestamps in increments finer than the minimum required in this Agreement, such Participant shall utilize such finer increment when reporting CAT Data to the Central Repository so that all Reportable Events reported to the Central Repository can be adequately sequenced. Each Participant shall, through its Compliance Rule: (i) Require that, to the extent that its Industry Members utilize timestamps in increments finer than the minimum required in this Agreement in their order handling or execution systems, such Industry Members shall utilize such finer increment when reporting CAT Data to the Central Repository; and (ii) provide that a pattern or practice of reporting events outside of the required clock synchronization time period without reasonable justification or exceptional circumstances may be considered a violation of SEC Rule 613 and the CAT NMS Plan.

[8] *See* Securities Exchange Act Release No. 88608 (April 8, 2020), 85 FR 20743 (April 14, 2020). Pursuant to this exemption, Industry Members that capture timestamps in increments more granular than nanoseconds must truncate the timestamps, after the nanosecond level, for submission to the CAT and not round up or down in such circumstances. The exemption remains in effect for five years, until April 8, 2025, unless extended by the SEC.

[9] *See* Securities Exchange Act Release No. 89051 (June 11, 2020), 85 FR 36631 (June 17, 2020) (''FINRA Facility Data Exemption Order'').

FINRA notes that the FINRA Facility Data Exemption Order also grants exemptive relief from Section 6.4(d)(ii)(A)(2) of the CAT NMS Plan, which states that each Participant, through its Compliance Rule, must require its Industry Members to report the SRO-Assigned Market Participant Identifier of the clearing broker or prime broker, if applicable, for orders that are executed in whole or in part. This aspect of the Order is not at issue in the proposed rule change.

have been expressed in increments finer than milliseconds, had the firm reported such information directly to the CAT. In such instances, the CAT would not receive the same data it would have received absent the exemptive relief.[10] As a result, to ensure that the FINRA Facility Data provided to the CAT is equivalent to the data that would have otherwise been submitted by Industry Members, in the FINRA Facility Data Exemption Order, the SEC expressly conditioned the exemptive relief on the FINRA Facilities accepting timestamps up to nanoseconds.

Specifically, the FINRA Facility Data Exemption Order requires that FINRA amend its rules and technical specifications to permit the FINRA Facilities to accept timestamps up to the granularity under the CAT NMS Plan (which, as noted above, is currently up to nanoseconds) and to implement such changes by December 15, 2021 for the TRFs and ADF and by December 15, 2022 for the ORF. In the FINRA Facility Data Exemption Order, the SEC notes that if the Plan Participants do not meet all of the conditions set forth in the order, on the schedule set forth in the order, their ability to recover fees from Industry Members could be impacted pursuant to the terms of Section 11.6 of the CAT NMS Plan.[11]

Proposed Amendments to FINRA Trade Reporting Rules

FINRA is proposing to amend its equity trade reporting rules [12] to require Industry Members with an obligation to report order execution events to the Central Repository pursuant to FINRA's CAT Compliance Rule to report time fields (including time of execution and time of cancellation, if applicable) in trade reports submitted to a FINRA Facility using the same timestamp granularity, as set forth in Rule 6860 (currently up to nanoseconds), that they use to report to the Central Repository.

FINRA notes that, except as discussed below, all trades that are reported to a FINRA Facility must also be reported to the CAT. As such, firms with a trade reporting obligation under FINRA's trade reporting rules also have a CAT reporting obligation and are therefore already subject to the timestamp granularity requirements under the CAT Compliance Rule. Given that CAT Reporters must have systems that capture time in at least milliseconds to meet the requirement that they report to the CAT in milliseconds, FINRA expects such firms to report to the FINRA Facilities in milliseconds under FINRA's current trade reporting rules.[13] Once the proposed rule change is implemented, any firm capturing and reporting time to the CAT in increments finer than milliseconds would be required to report time to the FINRA Facilities in such finer increments up to nanoseconds.

There is one instance where firms have an obligation to report trades to a FINRA Facility without a corresponding CAT reporting obligation. Under FINRA trade reporting rules, firms must report trades in Restricted Equity Securities effected pursuant to Securities Act Rule 144A to the ORF.[14] Unlike trades in OTC Equity Securities, these 144A trades are not required to be reported within 10 seconds [15] and as such are not reportable to the CAT.[16] Therefore, in this limited instance, *i.e.,* where a firm reports a trade in a Restricted Equity Security effected pursuant to Rule 144A, the firm could report to the ORF in seconds or, if the firm's system captures time in milliseconds, the firm would be required to report in milliseconds. The firm would not be required under the proposed rule change to report in increments finer than milliseconds; however, they could voluntarily do so.

Because the FINRA Facilities do not currently accept timestamps more granular than milliseconds, FINRA is unable to estimate, based on trade report information, how many firms capture time in increments more granular than milliseconds or have trade reporting systems capable of reporting time to a FINRA Facility in such finer increments. However, FINRA reviewed reporting statistics for order execution events in NMS stocks and OTC equity securities reported by Industry Members to the CAT (referred to in the CAT Industry Member Technical Specifications as ''MEOTs'') during the month of July 2020. On an average day, 12,617,227 out of 32,667,792 Industry Member order execution events (or 38.6%) have a timestamp granularity finer than milliseconds. Of the 167 firms that reported order execution events on an average day, 79 firms (or 47.2%) used a timestamp granularity finer than milliseconds. Seven of those firms reported time in nanoseconds, and together they reported 1,792,160 order execution events (or 5.5% of the total number of order execution events).

Some of these firms may already send timestamps to a FINRA Facility in increments finer than milliseconds; [17] FINRA does not believe that these firms would need to make any systems changes to comply with the proposed rule change. Other firms that capture time in increments finer than milliseconds may truncate the timestamp before sending to the FINRA Facility; these firms would need to make systems changes to send the more granular timestamp to the FINRA Facility. As noted above, FINRA will provide ample advance notice prior to the implementation date of the proposed rule change to allow firms to make and test the necessary systems changes.

FINRA understands that the securities information processors (''SIPs'') currently accommodate timestamps up to nanoseconds [18] and at least some of the exchanges send quotation and transaction information to the SIPs in nanoseconds today. Once the proposed rule change is implemented, the FINRA Facilities will send transaction information to the SIPs with timestamps

[10] For example, a firm cancels a trade at 10:30:00.123456 and reports the cancellation to a FINRA Facility with a trade cancellation time of 10:30:00.123 (the timestamp is truncated at the millisecond level for reporting to the FINRA Facility). As a consequence of the FINRA Facility Data Exemption Order, the data in the CAT reflects the time of cancellation as 10:30:00.123, which is the time submitted in the FINRA Facility Data. Had the firm reported the trade cancellation directly to the CAT, the data in the CAT would reflect the time of cancellation as 10:30:00.123456.

[11] *See* FINRA Facility Data Exemption Order, citing CAT NMS Plan at Section 11.6 (effective June 22, 2020).

[12] *See* Rules 6282.04, 6380A.04, 6380B.04, 6622.04, 7130.01, 7230A.01, 7230B.01 and 7330.01. FINRA is proposing identical amendments to these rules.

[13] Small Industry Members that do not currently report to FINRA's Order Audit Trail System (''OATS'') are not required to begin reporting to the CAT until December 13, 2021. Accordingly, FINRA would not expect these non-OATS reporters to report to the FINRA Facilities in milliseconds until December 13, 2021, unless their systems currently capture milliseconds.

[14] *See* Rule 6622(a)(3).

[15] Pursuant to Rule 6622(a)(3), such trades must be reported by the end of the day on trade date or, if executed after the ORF closes, by 8:00 p.m. the next business day. These trades are reported for regulatory purposes only and are not publicly disseminated.

[16] The CAT NMS Plan and FINRA's CAT Compliance Rule apply to ''Eligible Securities,'' which are defined as all NMS Securities and all OTC Equity Securities. ''OTC Equity Security'' is defined, in turn, as ''any equity security, other than an NMS Security, subject to prompt last sale reporting rules of a registered national securities association and reported to one of such association's equity trade reporting facilities.'' *See* Rule 6810. Accordingly, order and trade events relating to Restricted Equity Securities, including trades effected pursuant to Rule 144A, are not reportable to CAT.

[17] If a FINRA Facility receives a timestamp more granular than milliseconds, the Facility will truncate at the millisecond level (the Facility will not reject the trade report, nor will it round the timestamp up or down).

[18] Today, where a firm reports time in seconds or milliseconds, the FINRA Facilities add zeroes to convert the times to nanoseconds before sending to the SIPs.

at the level of granularity as reported by the firm.[19] As such, FINRA believes that the proposed rule change will enhance the granularity and sequencing of trade reports both for purposes of FINRA's audit trail and the publicly disseminated SIP data, to the extent firms are reporting time in increments finer than milliseconds. FINRA notes that, because not all firms capture and report timestamps at the same granularity, there may be questions about the potential for reverse engineering based on timestamps published by the SIPs, *e.g.,* could market participants attempt to identify the trading activity of a firm that they believe has the technological capability of capturing timestamps in nanoseconds. However, as noted above, on average, seven firms currently capture (and report to CAT) time in nanoseconds and these firms reported on average close to 1.8 million order execution events to CAT per day. FINRA believes that as more firms capture timestamps in more granular increments, the potential for such reverse engineering should decrease over time.

If the Commission approves the proposed rule change, FINRA will announce the implementation date of the proposed rule change in a *Regulatory Notice.* The implementation date of the proposed rule change relating to the TRFs and ADF will be no later than December 15, 2021, and the implementation date of the proposed rule change relating to the ORF will be no later than December 15, 2022. To provide member firms sufficient time to make any systems changes necessary to comply with the proposed rule change, FINRA will provide ample advance notice of the implementation date, including publication of the *Regulatory Notice,* as well as updated technical specifications and testing schedule, at least 120 days prior to the implementation date.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[20] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and Section 15A(b)(9) of the Act,[21] which requires that FINRA rules not impose any burden on competition that is not necessary or appropriate.

FINRA believes that the proposed rule change is consistent with the Act because it is consistent with the SEC's FINRA Facility Exemption Order, which provides exemptive relief from certain provisions of the CAT NMS Plan, and the proposed rule change is necessary to comply with the express conditions of that order. In approving the CAT NMS Plan, the SEC noted that the Plan ''is necessary and appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanism of a national market system, or is otherwise in furtherance of the purposes of the Act.'' [22] Because the proposed rule change implements exemptive relief under the CAT NMS Plan, FINRA believes that the proposed rule change furthers the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act. In addition, FINRA believes that the proposed rule change will enhance the granularity and sequencing of trade reports both for purposes of FINRA's audit trail and the publicly disseminated SIP data, to the extent firms are reporting time in increments finer than milliseconds.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Assessment

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the potential economic impacts, including anticipated costs, benefits, and distributional and competitive effects, relative to the current baseline, and the alternatives FINRA considered in assessing how to best meet its regulatory objectives.

Regulatory Need

On June 11, 2020, the SEC granted the Plan Participants exemptive relief from, in pertinent part, Section 6.4(d)(ii)(B) of the CAT NMS Plan, which states that each Participant, through its Compliance Rule, must require its Industry Members to report to the CAT a cancelled trade indicator when a trade is cancelled. As firms already report trade cancellations to the FINRA Facilities pursuant to FINRA's trade reporting rules, the Participants requested an exemption so that they could relieve firms of their obligation to report the same information to the CAT. Given the exemptive relief, the CAT will obtain trade cancellations from trade report data that FINRA reports to the CAT and will link such data to the related CAT execution reports submitted by Industry Members.

There is, however, a difference in the timestamp granularity requirements applicable to member firms reporting to the FINRA Facilities (up to milliseconds) and to the CAT (up to nanoseconds). Given the difference in timestamp granularity requirements for firms reporting to the FINRA Facilities and the CAT, it is possible that the CAT could receive a cancelled trade timestamp in milliseconds from FINRA, while a cancelled trade timestamp for the same trade cancellation might have been expressed in increments finer than milliseconds. In such instances, the CAT would not receive the same data it would have received absent the exemptive relief. The FINRA Facility Data Exemption Order requires that FINRA amend its rules and technical specifications to permit the FINRA Facilities to accept timestamps up to the granularity under the CAT NMS Plan.

Economic Baseline

Pursuant to Rule 6860 of FINRA's CAT Compliance Rule, Industry Members are required to report timestamps for Reportable Events, including trade executions, to the CAT's Central Repository in milliseconds, and if their system captures time in finer increments, to report in such finer increments up to nanoseconds. The proposed rule change does not require firms to begin capturing time in more granular increments than milliseconds; however, if they are reporting timestamps to the CAT in increments finer than milliseconds, the proposed rule change requires that they also

[19] FINRA notes that the SIP NMS Plans require FINRA to send the trade execution time reported by its member firms to the SIPs. *See* Section IV(c) of the Consolidated Tape Association (CTA) Plan and Section VIII.B of the Nasdaq Unlisted Trading Privileges (UTP) Plan (stating that ''in the case of FINRA, the time of the transaction shall be the time of execution that a FINRA member reports to a FINRA trade reporting facility in accordance with FINRA rules''). As such, once the FINRA Facilities begin accepting, and member firms begin reporting, more granular timestamps in accordance with the proposed rule change, FINRA will be required to send all timestamps in the granularity reported by the firm (up to nanoseconds) to the SIPs for publication. Any change (*e.g.,* truncating a more granular timestamp to the millisecond or microsecond level before sending to the SIPs) would require amendment (or, at a minimum, interpretation) of the SIP NMS Plans by the Plan Participants jointly and is beyond the scope of this proposed rule change.

[20] 15 U.S.C. 78*o*–3(b)(6).

[21] 15 U.S.C. 78*o*–3(b)(9).

[22] *See* Securities Exchange Act Release No. 79318 (November 15, 2016), 81 FR 84696, 84697 (November 23, 2016).

report to the FINRA Facilities in such finer increment (up to nanoseconds).

During the month of July 2020, 202 market participant identifiers (''MPIDs'') submitted at least one trade cancellation message to a FINRA Facility. In total, 57,325 trade cancellation messages were submitted to the FINRA Facilities in July 2020 by these 202 MPIDs. Each of the 57,325 cancellation messages reported to the FINRA Facilities would then be reported to CAT by FINRA. Some of these cancellation messages are not publicly disseminated.[23] Out of the 202 MPIDs, 146 MPIDs submitted at least one trade cancellation message to a FINRA Facility that was publicly disseminated in July 2020. Of the total 57,325 cancellation messages, 14,539 were publicly disseminated.

Because the FINRA Facilities do not currently accept timestamps more granular than milliseconds, FINRA is unable to estimate, based on trade report information, how many firms capture time in increments more granular than milliseconds or have trade reporting systems capable of reporting time to a FINRA Facility in such finer increments. FINRA, however, has reviewed reporting statistics for order execution events[24] in NMS stocks and OTC equity securities reported by Industry Members to the CAT. On an average day in July 2020, 12,617,227 out of 32,667,792 Industry Member order execution events (or 38.6%) have a timestamp granularity finer than milliseconds. Of the 167 firms[25] that reported order execution events on an average day, 79 firms (or 47.2%) used a timestamp granularity finer than milliseconds (*i.e.,* microseconds or nanoseconds). Seven of those firms reported time in nanoseconds, and together these firms reported 1,792,160 order execution events (or 5.5% of the total number of order execution events).

Economic Impact

Benefits

Given the exemptive relief, firms reporting trade cancellations to the FINRA Facilities are not required to report the same information to CAT, as CAT will obtain trade cancellations from trade report data that FINRA reports to the CAT. Consequently, firms are not required to report trade cancellations to both the FINRA Facilities and CAT.

Once the proposed rule change is implemented, any firm capturing and reporting time to the CAT in increments finer than milliseconds would be required to report time to the FINRA Facilities in such finer increments up to nanoseconds. This may enhance the granularity and sequencing of trade reports for FINRA's audit trail, which, in turn, may improve FINRA's ability to surveil equity markets. In addition, as the FINRA Facilities send transaction information to the SIPs with timestamps at the level of granularity as reported, the granularity of the publicly disseminated SIP would improve. This would benefit market participants who currently use data from the SIP, as the timestamps would be more granular.

Costs

Some firms that capture time in increments finer than milliseconds may already send timestamps to a FINRA Facility in such finer increment. If a firm already submits timestamps to a FINRA Facility in increments finer than milliseconds, then the firm would not need to make any systems changes to comply with this proposed rule change. However, if a firm currently truncates more granular timestamps at the millisecond level before sending to a FINRA Facility, then the firm would incur costs to make system changes to report more granular timestamps, up to nanoseconds. On an average day in July 2020, seven firms reported 1,792,160 order execution events to the CAT with timestamps reported in nanoseconds. As not all firms capture and report timestamps at that same granularity, there is a risk that firms that report executions with nanosecond timestamps published in the SIP may be identified by potential reverse engineering. This may put firms that report executions with nanosecond timestamps at a competitive disadvantage, relative to firms that do not report executions in nanoseconds, because firms reporting in nanoseconds might be identified by their executions. This risk of potential reverse engineering may decline over time as more firms capture timestamps in more granular increments.

Alternatives Considered

No further alternatives are under consideration.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date, 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 such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2020–029 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–FINRA–2020–029. 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

[23] FINRA notes that where the original trade report was submitted for non-dissemination (*i.e.,* regulatory and/or clearing only) purposes, the cancellation of that report would not be disseminated.

[24] Order execution events are referred to in the CAT Industry Member Technical Specifications as ''MEOTs.''

[25] The number of firms is calculated by the number of unique Central Registration Depository (''CRD'') numbers.

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 also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2020–029 and should be submitted on or before October 20, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–21409 Filed 9–28–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89968; File No. SR–IEX–2020–15]

Self-Regulatory Organizations: Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to Transaction Fees Pursuant to IEX Rule 15.110 Concerning the CQ Remove Fee

September 23, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 11, 2020, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,[3] and Rule 19b–4 thereunder,[4] IEX is filing with the Commission a proposed rule change, pursuant to IEX Rule 15.110(a) and (c), to remove the Crumbling Quote Remove Fee (''CQ Remove Fee'' or ''CQRF''). Fee changes pursuant to this proposal are effective upon filing,[5] and will be implemented as described herein.

The text of the proposed rule change is available at the Exchange's website at *www.iextrading.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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule, pursuant to IEX Rule 15.110 (a) and (c), to eliminate the CQ Remove Fee, which is an additional fee on Members that that execute more than a certain threshold of orders that take liquidity during periods when the IEX crumbling quote indicator (''CQI'') is on for the security in question.

Background

The CQI is a transparent proprietary mathematical calculation (specified in IEX Rule 11.190(g)) designed to predict whether a particular quote is unstable or ''crumbling,'' meaning that the NBB is likely about to decline or the NBO is likely about to increase. The Exchange utilizes real time relative quoting activity of certain Protected Quotations[6] and the proprietary mathematical calculation (the ''quote instability calculation'') to assess the probability of an imminent change to the current Protected NBB to a lower price or Protected NBO to a higher price for a particular security (''quote instability factor''). When the quoting activity meets predefined criteria and the quote instability factor calculated is greater than the Exchange's defined quote instability threshold, the System[7] treats the quote as unstable and the CQI is on. During all other times, the quote is considered stable, and the CQI is off. The System independently assesses the stability of the Protected NBB and Protected NBO for each security. When the System determines that a quote, either the Protected NBB or the Protected NBO, is unstable, the determination remains in effect at that price level for up to two milliseconds.

IEX currently offers two non-displayed order types—Discretionary Peg[8] and primary peg[9]—that each leverage the protective features of the CQI by restricting such orders from exercising price discretion to a more aggressive price when the CQI is on. As described more fully below, the Commission recently approved a new IEX order type—D-Limit—that can be displayed or non-displayed and will also leverage the protective features of the CQI and is pending deployment. Prior to deployment of the D-Limit order type, the CQ Remove Fee has been the only IEX functionality that was designed to leverage the CQI to protect displayed orders.

In the absence of a displayed order type that could leverage the protective features of the CQI, the CQ Remove Fee was designed to incentivize market participants to send orders (including displayed orders) to provide liquidity to IEX by reducing the volume of orders involving latency arbitrage trading strategies that seek to exploit information advantages during narrow time windows when the CQI is on.

The Exchange currently charges the CQ Remove Fee to orders that remove resting liquidity when the CQI is on if such executions exceed the CQRF Threshold.[10] Executions of orders that remove resting liquidity during periods when the CQI is on are assessed a fee of $0.0030 per each incremental share

[26] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(1).

[4] 17 CFR 240.19b–4.

[5] 15 U.S.C. 78s(b)(3)(A)(ii).

[6] Pursuant to IEX Rule 11.190(g), references to ''Protected Quotations'' include quotations from the New York Stock Exchange LLC (''NYSE''); The Nasdaq Stock Market LLC (''Nasdaq''); NYSE Arca, Inc. (''NYSE Arca''); Nasdaq BX, Inc. (''Nasdaq BX''); Cboe BZX Exchange, Inc. (''Cboe BZX''); Cboe BYX Exchange, Inc. (''Cboe BYX''); Cboe EDGX Exchange, Inc. (''EDGX''); and Cboe EDGA Exchange, Inc. (''EDGA'').

[7] *See* IEX Rule 1.160(nn).

[8] *See* IEX Rule 11.190(b)(10). IEX has two other order types that are based on the DPeg order type: The Retail Liquidity Provider order and the Corporate Discretionary Peg order. *See* IEX Rule 11.190(b)(14) and (16).

[9] *See* IEX Rule 11.190(b)(8).

[10] The threshold is equal to 5% of the sum of a Member's total monthly executions on IEX, measured on a per logical port (*i.e.,* session) per MPID basis. *See* Investors Exchange Fee Schedule, available on the Exchange public website.

executed at or above $1.00 that exceeds the CQ Remove Fee Threshold.[11]

The CQ Remove Fee has resulted in a small incremental reduction in the use of latency arbitrage strategies on IEX. IEX believes the limited impact of the CQ Remove Fee is a result of the fact that the potential profits from the use of such strategies substantially exceed the profits lost from the CQ Remove Fee.[12]

Proposal

IEX proposes to eliminate the CQ Remove Fee, as of October 1, 2020, to coincide with the October 1, 2020 full deployment of the D-Limit order type.[13] As noted above, the CQ Remove Fee has been only minimally effective in reducing the use of latency arbitrage strategies targeting resting orders on IEX at potentially stale prices. With the launch of the D-Limit order type, which is designed to protect both displayed and non-displayed orders from the same type of latency arbitrage strategies as the CQ Remove Fee, market participants seeking protection from such strategies through non-pegged orders, including displayed orders, can use D-Limit orders instead of other limit orders.

Therefore, IEX proposes to amend the IEX Fee Schedule to delete references to the CQ Remove Fee and related references as follows:

- Delete the following lines from the ''Definitions'' in the ''Transaction fees'' section:
  - ''Quote instability'' is defined in IEX Rule 11.190(g).
  - ''CQRF Threshold'' means the Crumbling Quote Remove Fee Threshold. The threshold is equal to 5% of the sum of a Member's total monthly executions on IEX measured on a per logical port (*i.e.,* session) per MPID basis.
- Delete the following row from the ''Fee Code Modifiers'' table:

Q	Crumbling Quote Remove Fee: Removes liquidity during periods of quote instability at or within the NBBO above the CQRF Threshold, measured on an MPID basis.[1]	$0.0030

- Delete the following rows from the ''Fee Code Combinations and Associated Fees'' table:

IQ[1]	Removes non-displayed liquidity during periods of quote instability	$0.0009
LQ[1]	Removes displayed liquidity during periods of quote instability	$0.0003
ISQ[1]	Member removes non-displayed liquidity provided by such Member during periods of quote instability.	FREE
IQR[12]	Retail order removes non-displayed liquidity during periods of quote instability	FREE
LSQ[1]	Member removes displayed liquidity provided by such Member during periods of quote instability	FREE
LQR[12]	Retail order removes displayed liquidity during periods of quote instability	FREE
ISQR[12]	Retail order removes non-displayed liquidity provided by such Member during periods of quote instability.	FREE
LSQR[12]	Retail order removes displayed liquidity provided by such Member during periods of quote instability	FREE

- Delete Footnote 1 (in the ''Transaction fees'' section of the Fee Schedule):
  - [1] *Crumbling Quote Remove Fee:* Executions with Fee Code Q that exceed the CQRF Threshold are subject to the Crumbling Quote Remove Fee identified in the Fee Code Modifiers table. Executions with Fee Code Q that do not exceed the CQRF Threshold are subject to the fees identified in the Fee Codes and Associated Fees table.

IEX also proposes to make conforming changes to the Fee Schedule by renumbering Transaction Fee Footnote ''2'' to Footnote ''1'' and changing all current references to Footnote ''2'' to instead reference Footnote ''1,'' specifically for the following fee codes and fee code combinations.

- ''R'', ''IR'', ''LR'', ''ISR'', and ''LSR.''

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b)[14] of the Act in general, and furthers the objectives of Sections 6(b)(4)[15] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. Additionally, IEX believes that the elimination of the CQ Remove Fee is consistent with the investor protection objectives of Section 6(b)(5)[16] of the Act in particular in that it is designed to promote just and equitable principles of trade, to remove impediments to a free and open market and national market system, and in general to protect investors and the public interest.

As discussed in the Purpose Section, the CQ Remove Fee was designed to incentivize market participants to send orders (including displayed orders) to provide liquidity to IEX by reducing the volume of orders involving latency arbitrage trading strategies that seek to exploit information advantages during narrow time windows when the CQI is on. As discussed above, the CQ Remove Fee resulted in only a minimal reduction in the use of such latency arbitrage strategies, and with the launch of the D-Limit order type, which is designed to protect both displayed and non-displayed orders from the same type of latency arbitrage strategies as the CQ Remove Fee, market participants seeking protection from such strategies through non-pegged orders (including displayed orders) can use D-Limit orders. IEX believes that use of D-Limit orders, as compared to the CQ Remove Fee, will provide a more direct and effective means for market participants to obtain such protection. Therefore, the Exchange believes the proposal to eliminate the CQ Remove Fee is reasonable because, as discussed above, the CQ Remove Fee has been only modestly successful in achieving its intended purpose of disincentivizing latency arbitrage trading strategies that

[11] Executions below $1.00 are assessed a fee of 0.30% of the total dollar value (''TDV'') of the execution unless the Fee Code Combination results in a free execution. *See* Investors Exchange Fee Schedule, available on the Exchange public website.

[12] The Exchange is effectively limited in setting the CQ Remove Fee by Rule 610(c) of Regulation NMS. 17 CFR 242.610(c).

[13] Deployment of the D-Limit order type is scheduled to begin in test symbols on Friday, September 25, 2020 and conclude in all symbols on Thursday, October 1, 2020. *See* IEX Trading Alert #2020–024 (Discretionary Limit (D-Limit) Order Type Launch) issued on August 28, 2020, available at *https://iextrading.com/alerts/#/121.*

[14] 15 U.S.C. 78f.

[15] 15 U.S.C. 78f(b)(4).

[16] 15 U.S.C. 78f(b)(5).

seek to exploit information advantages during narrow time windows when the CQI is on. The Exchange has limited resources available to it to devote to the operation of pricing disincentives such as the CQ Remove Fee and as such, it is reasonable and equitable for the Exchange to reallocate those resources away from programs that are less effective. The Exchange also believes that proposed change is equitable and not unfairly discriminatory because elimination of the CQ Remove Fee will apply to all Members in the same manner.

Moreover, the Exchange notes that eliminating the CQ Remove Fee will mean that orders that take liquidity during periods of quote instability above the CQRF Threshold will be assessed the same fees that were assessed by the Exchange prior to the introduction of the CQ Remove Fee, pursuant to the IEX Fee Schedule that was filed with the Commission pursuant to the Act.[17] Thus, the Exchange believes the proposed change does not present any unique or novel issues under the Act that have not already been considered by the Commission.

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. With regard to intra-market competition, the Exchange notes that the removal of the CQ Remove Fee will apply equally to all Members. While the CQ Remove Fee was designed to disincentivize certain latency arbitrage trading strategies, as described in the Purpose and Statutory Basis sections, the Exchange believes that the new D-Limit order type will provide more direct and effective protection to Members and other market participants from such strategies. Consequently, the Exchange does not believe that elimination of the CQ Remove Fee will impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act.

With regard to inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and alternative trading systems. Because competitors are free to modify their own fees in response, subject to the SEC rule filing process as applicable, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which IEX fee changes could impose any burden on inter-market competition is extremely limited.

Further, as discussed in the Statutory Basis section, the elimination of the CQ Remove Fee will mean that orders that take liquidity during periods of quote instability above the CQRF Threshold will be assessed the same fees that were assessed by the Exchange prior to the introduction of the CQ Remove Fee, pursuant to the IEX Fee Schedule that was filed with the Commission pursuant to the Act.[18] Thus, the Exchange believes the proposed change does not present any unique or novel issues under the Act that have not already been considered by the Commission.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii)[19] of the Act.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[20] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–IEX–2020–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–IEX–2020–15. 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 offices 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–IEX–2020–15, and should be submitted on or before October 20, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–21404 Filed 9–28–20; 8:45 am]

BILLING CODE 8011–01–P

[17] *See* Securities Exchange Act Release No. 78550 (August 11, 2016), 81 FR 54873 (August 17, 2016) (SR–IEX–2016–09).

[18] *See* Securities Exchange Act Release No. 78550 (August 11, 2016), 81 FR 54873 (August 17, 2016) (SR–IEX–2016–09).

[19] 15 U.S.C. 78s(b)(3)(A)(ii).

[20] 15 U.S.C. 78s(b)(2)(B).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89969; File No. SR–PEARL–2020–15]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, to Exchange Rule 1014, Imposition of Fines for Minor Rule Violations

September 23, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on September 8, 2020, MIAX PEARL, LLC (''MIAX PEARL'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. On September 22, 2020, the Exchange filed Amendment No. 1 to the proposed rule change, which supersedes the original filing in its entirety.[3] The Commission is publishing this notice to solicit comments on Amendment No. 1 from interested persons and approving the proposal, as modified by Amendment No. 1, on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a change to add certain rules applicable to the trading of equity securities to the list of minor rule violations in Rule 1014.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX PEARL's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On December 13, 2016, the Commission issued an order granting the Exchange's application for registration as a national securities exchange.[4] On February 6, 2020, the Commission published for public comment an Exchange proposal to adopt rules governing the trading of equity securities.[5] On August 14, 2020, the Commission approved the Exchange's proposal to adopt rules governing the trading of equity securities.[6] MIAX PEARL anticipates to begin trading equity securities on September 25, 2020. On December 21, 2017, the Commission issued an order declaring effective the Exchange's MRVP.[7] The Exchange now proposes to add certain rules applicable to the trading of equity securities to the list of minor rule violations in Exchange Rule 1014.

Exchange Rule 1014 sets forth the list of rules under which a Member may be subject to a fine. Exchange Rule 1014 permits the Exchange to impose a fine of up to $5,000 on any member or a person associated with or employed by a member for a minor violation of an eligible rule. The Exchange proposes to amend Exchange Rule 1014 to add certain rules applicable to the trading of equity securities to the list of rules eligible for disposition pursuant to a minor fine under Exchange Rule 1014.[8]

The Exchange proposes that, as set forth in proposed Exchange Rule 1014(d)(15), violations of the following rules would be appropriate for disposition under the MRVP: Rule 2202 and Interpretations thereunder (requiring the submission of responses to Exchange requests for trading data within specified time period); Rule 2623 (requirement to identify short sale orders as such); Rule 2624 (requirement to comply with locked and crossed market rules); Rule 2104 (Communications with the Public); Rule 2202 and Interpretations thereunder (related to the requirement to furnish Exchange-related order, market and transaction data, as well as financial or regulatory records and information); and Rule 2606(a)(1) (requirements for Equities Market Makers to maintain continuous two-sided quotations).[9]

Violations of Exchange Rules 2202, Preamble (requiring the submission of responses to Exchange requests for trading data within specified time period), 2623, 2624, and 2104 would be subject to the following fines:

Occurrence *	Individual	Member firm
First time fined ..	$100	$500
Second time fined	300	1,000
Third time fined	500	2,500

* Within a ''rolling'' 12-month period.

Violations of Exchange Rules 2202, Interpretation .01 (related to the requirement to furnish Exchange-related order, market and transaction data, as well as financial or regulatory records and information) and 2606(a)(1) would be subject to fines $100 per violation. The Exchange notes that these proposed fine levels are based on those approved for LTSE and proposed by MEMX.[10]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange clarifies which fine amounts apply to violations of various provisions of Exchange Rule 2202.

[4] *See* Securities Exchange Act Release No. 79543 (December 13, 2016), 81 FR 92901 (December 20, 2016) (File No. 10–227).

[5] *See* Securities Exchange Act Release No. 88132 (February 6, 2020), 85 FR 8053 (February 12, 2020) (SR–PEARL–2020–03).

[6] *See* Securities Exchange Act Release No. 89563 (August 14, 2020), 85 FR 51510 (August 20, 2020) (''Approval Order'').

[7] *See* Securities Exchange Act Release No. 82385 (December 21, 2017), 82 FR 61613 (December 28, 2017) (File No. 4–715).

[8] FINRA's maximum fine for minor rule violations under FINRA Rule 9216(b) is $2,500. The Exchange will apply an identical maximum fine amount for eligible violations to achieve consistency with FINRA and also to amend its minor rule violation plan to include such fines. Like FINRA, the Exchange would be able to pursue a fine greater than $2,500 for violations of Rules 2202, 2606(a)(1), 2623, 2624, and 2104 in a regular disciplinary proceeding or Letter of Consent under Rule 1003 as appropriate. Any fine imposed in excess of $2,500 or not otherwise covered by Rule 19d–1(c)(2) of the Act would be subject to prompt notice to the Commission pursuant to Rule 19d–1 under the Act.

[9] MEMX, LLC's (''MEMX'') proposal to adopt a MRVP includes MEMX Rule 12.11 Interpretations and Policy .01 and Exchange Act Rule 604 (failure to properly display limit orders) MEMX Rules 4.5 through 4.16 (Consolidated Audit Trail Compliance Rules). *See* Securities Exchange Act Release No. 89485 (August 5, 2020), 85 FR 48577 (August 11, 2020) (File No. 4–764). The Exchange notes that it recently amended Exchange Rule 1014 to include Chapter XVII, its Consolidated Order Trail Compliance Rule. *See* Securities Exchange Act Release No. 89166 (June 26, 2020), 85 FR 39943 (July 2, 2020) (SR–PEARL–2020–07). The Exchange Rules does not include a rule identical to MEMX Rule 12.11.01 that could be included in this proposal. The Exchange notes that MEMX Rule 12.11.01 simply refers to their member's existing obligations under Exchange Act Rule 604 and a similar rule is also not included in Long Term Stock Exchange, Inc.'s (''LTSE'') MRVP. *See* Securities Exchange Act Release Nos. 87415 (October 29, 2019), 84 FR 59427 (November 4, 2019) (File No. 4–753).

[10] *Id.*

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5),[12] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

Minor rule fines provide a meaningful sanction for minor or technical violations of rules when the conduct at issue does not warrant stronger, immediately reportable disciplinary sanctions. The inclusion of a rule in the Exchange's MRVP does not minimize the importance of compliance with the rule, nor does it preclude the Exchange from choosing to pursue violations of eligible rules through a Letter of Consent if the nature of the violations or prior disciplinary history warrants more significant sanctions. Rather, the Exchange believes that the proposed rule change will strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities in cases where full disciplinary proceedings are unwarranted in view of the minor nature of the particular violation. Rather, the option to impose a minor rule sanction gives the Exchange additional flexibility to administer its enforcement program in the most effective and efficient manner while still fully meeting the Exchange's remedial objectives in addressing violative conduct. Specifically, the proposed rule change is designed to prevent fraudulent and manipulative acts and practices because it will provide the Exchange the ability to issue a minor rule fine for violations of certain rules related to the trading of equity securities where a more formal disciplinary action may not be warranted or appropriate consistent with the approach of other exchanges for the same conduct.

In connection with the fine level specified in the proposed rule change, adding language describing the fine levels would further the goal of transparency and add clarity to the Exchange's rules. Adopting the same caps as MEMX and LTSE for minor rule fines in connection with the included rules applicable to the trading of equity securities would also promote regulatory consistency across self-regulatory organizations.

The Exchange further believes that the proposed amendments to Rule 1014 are consistent with Section 6(b)(6) of the Act,[13] which provides that members and persons associated with members shall be appropriately disciplined for violation of the provisions of the rules of the exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction. As noted, the proposed rule change would provide the Exchange ability to sanction minor or technical violations of certain rules applicable to the trading of equity securities pursuant to the Exchange's rules.

Finally, the Exchange also believes that the proposed changes are designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[14] Rule 1014 does not preclude a member or a person associated with or employed by a member from contesting an alleged violation and receiving a hearing on the matter with the same procedural rights through a litigated disciplinary proceeding.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather is concerned solely with making certain equity related rules eligible for a minor rule fine disposition, thereby strengthening the Exchange's ability to carry out its oversight and enforcement functions and deter potential violative conduct.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 to 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–PEARL–2020–15 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–PEARL–2020–15. 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–PEARL–2020–15 and should be submitted on or before October 20, 2020.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78f(b)(6).

[14] 15 U.S.C. 78f(b)(7) and 78f(d).

applicable to a national securities exchange.[15] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[16] which requires that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also believes that the proposal is consistent with Sections 6(b)(1) and 6(b)(6) of the Act [17] which require that the rules of an exchange enforce compliance with, and provide appropriate discipline for, violations of Commission and Exchange rules. Finally, the Commission finds that the proposal is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act, as required by Rule 19d–1(c)(2) under the Act,[18] which governs minor rule violation plans.

As stated above, the Exchange proposes to amend Exchange Rule 1014 to add certain rules applicable to the trading of equity securities to the list of rules eligible for disposition pursuant to a minor fine under Exchange Rule 1014. The Commission believes that the amended MRVP will permit the Exchange to carry out its oversight and enforcement responsibilities as a self-regulatory organization (''SRO'') more efficiently in cases where full disciplinary proceedings are not necessary due to the minor nature of the particular violation.

In declaring the Exchange's amended MRVP effective, the Commission in no way minimizes the importance of compliance with Exchange rules and all other rules subject to the imposition of sanctions under Exchange Rule 1014. The Commission believes that the violation of an SRO's rules, as well as Commission rules, is a serious matter. However, Exchange Rule 1014 provides a reasonable means of addressing violations that do not rise to the level of requiring formal disciplinary proceedings, while providing greater flexibility in handling certain violations. The Commission expects that the Exchange will continue to conduct surveillance and make determinations based on its findings, on a case-by-case basis, regarding whether a sanction under the amended MRVP is appropriate, or whether a violation requires formal disciplinary action.

For the same reasons discussed above, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[19] for approving the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of the notice of the filing thereof in the **Federal Register**. The proposal merely amends Exchange Rule 1014 to add certain rules applicable to the trading of equity securities to the current list of rules eligible for disposition pursuant to a minor fine under Exchange Rule 1014. In addition, the Commission notes that the proposal is consistent with the minor rule violation plans of other SROs.[20] Accordingly, the Commission believes that a full notice-and-comment period is not necessary before approving the proposal.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act [21] and Rule 19d–1(c)(2) thereunder,[22] that the proposed rule change (SR–PEARL–2020–15), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–21405 Filed 9–28–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89971; File No. SR–PEARL–2020–16]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 2618, Risk Settings and Trading Risk Metrics

September 23, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 14, 2020, MIAX PEARL, LLC (''MIAX PEARL'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing a proposed rule change to provide Equity Members [3] certain optional risk settings under Exchange Rule 2618 when trading equity securities on the Exchange's equity trading platform (referred to herein as ''MIAX PEARL Equities'').

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX PEARL's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to provide Equity Members certain optional risk settings under Exchange Rule 2618 when trading equity securities on MIAX PEARL Equities.[4] To help Equity Members

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[15] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78f(b)(1) and 78f(b)(6).

[18] 17 CFR 240.19d–1(c)(2).

[19] 15 U.S.C. 78s(b)(2).

[20] *See* Securities Exchange Act Release Nos. 87415 (October 29, 2019), 84 FR 59427 (November 4, 2019) (File No. 4–753) (order declaring effective the LTSE MRVP); and 89485 (September 11, 2020), 85 FR 58081 (September 17, 2020) (File No. 4–764) (order declaring effective the MEMX MRVP).

[21] *Id.*

[22] 17 CFR 240.19d–1(c)(2).

[23] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Rule 1901 for the definition of Equity Member.

[4] The proposed rule changes are substantially similar to a recent rule amendment by Cboe BZX Exchange, Inc. (''BZX'') and Cboe EDGX Exchange, Inc. (''EDGX''). *See* Interpretation and Policy .03 to BZX Rule 11.13 *and* Interpretation and Policy .03 to EDGX Rule 11.10. *See* Securities Exchange Act Nos. 88599 (April 8, 2020) 85 FR 20793 (April 14, 2020) (the ''BZX Approval''); and 88783 (April 30, 2020), 85 FR 26991 (May 6, 2020) (the ''EDGX Notice''). *See also* Securities Exchange Act Release

Continued

manage their risk, the Exchange proposes to offer optional risk settings that would authorize the Exchange to take automated action if a designated limit for an Equity Member is breached. Such risk settings would provide Equity Members with enhanced abilities to manage their risk with respect to orders on the Exchange. Proposed paragraph (a)(2) of Rule 2618[5] sets forth the specific risk control the Exchange proposes to offer. Specifically, the Exchange proposes to offer the following risk setting:

- The ''Gross Notional Trade Value'', which refers to a pre-established maximum daily dollar amount for purchases and sales across all symbols, where both purchases and sales are counted as positive values. For purposes of calculating the Gross Notional Trade Value, only executed orders are included.[6]

The Gross Notional Trade Value risk setting is similar to credit controls measuring gross exposure provided for in paragraph (a)(1)(A) of Exchange Rule 2618 and allow limits to be set at the Market Participant Identifier (''MPID''), session, and firm level.[7] Therefore, the proposed risk management functionality would allow an Equity Member to manage its risk more comprehensively and across various level settings. Further, like our existing credit controls measuring gross exposure, the proposed risk setting would also be based on a notional execution value. The Exchange notes that the current gross notional control noted in paragraph (a)(1)(A) of Exchange Rule 2618 will continue to be available in addition to the proposed risk setting.

Proposed paragraph (a)(4) of Exchange Rule 2618 provides that an Equity Member that does not self-clear may allocate and revoke[8] the responsibility of establishing and adjusting the risk settings identified in proposed paragraph (a)(2) of Exchange Rule 2618 to a Clearing Member that clears transactions on behalf of the Equity Member, if designated in a manner prescribed by the Exchange. Specifically, Exchange Rule 2620(a): (i) Defines the term ''Clearing Member'';[9] (ii) outlines the process by which a Clearing Member shall affirm its responsibility for clearing any and all trades executed by the Equity Member designating it as its Clearing Firm; and (iii) provides that the rules of a Qualified Clearing Agency shall govern with respect to the clearance and settlement of any transactions executed by the Equity Member on the Exchange.

By way of background, Exchange Rule 2620(a) requires that all transactions passing through the facilities of the Exchange shall be cleared and settled through a Qualified Clearing Agency using a continuous net settlement system.[10] As reflected on Exchange Rule 2620(a), this requirement may be satisfied by direct participation, use of direct clearing services, or by entry into a corresponding clearing arrangement with another Member that clears through a Qualified Clearing Agency (*i.e.,* a Clearing Member). If an Equity Member clears transactions through another Equity Member that is a Clearing Member, such Clearing Member shall affirm to the Exchange in writing, through letter of authorization, letter of guarantee or other agreement acceptable to the Exchange, its agreement to assume responsibility for clearing and settling any and all trades executed by the Member designating it as its clearing firm.[11] Thus, while not all Equity Members are Clearing Members, all Equity Members are required either to clear their own transactions or to have in place a relationship with a Clearing Member that has agreed to clear transactions on their behalf in order to conduct business on the Exchange. Therefore, the Clearing Member that guarantees the Member's transactions on the Exchange has a financial interest in the risk settings utilized within the System[12] by the Member.

Paragraph (a) of Rule 2620 allows Clearing Members an opportunity to manage their risk of clearing on behalf of other Equity Members, if authorized to do so by the Equity Member trading on MIAX PEARL Equities. Such functionality is designed to help Clearing Members to better monitor and manage the potential risks that they assume when clearing for Equity Members of the Exchange. An Equity Member may allocate or revoke the responsibility of establishing and adjusting the risk settings identified in proposed paragraph (a)(2) of Exchange Rule 2618 to its Clearing Member in a manner prescribed by the Exchange. By allocating such responsibility, an Equity Member cedes all control and ability to establish and adjust such risk settings to its Clearing Member unless and until such responsibility is revoked by the Equity Member, as discussed in further detail below. Because the Equity Member is responsible for its own trading activity, the Exchange will not provide a Clearing Member authorization to establish and adjust risk settings on behalf of an Equity Member without first receiving consent from the Equity Member. The Exchange considers an Equity Member to have provided such consent if it allocates the responsibility to establish and adjust risk settings to its Clearing Member in a manner prescribed by the Exchange. By allocating such responsibilities to its Clearing Member, the Equity Member consents to the Exchange taking action, as set forth in proposed paragraph (a)(6) of Exchange Rule 2618, with respect to the Equity Member's trading activity. Specifically, if the risk setting(s) established by the Clearing Member are breached, the Equity Member consents that the Exchange will automatically block new orders submitted and cancel open orders until such time that the applicable risk setting is adjusted to a higher limit by the Clearing Member. An Equity Member may also revoke responsibility allocated to its Clearing Member pursuant to this paragraph at any time in a manner prescribed by the Exchange.

Nos. 89032 (June 9, 2020), 85 FR 36246 (June 15, 2020) (SR–CboeBZX–2020–44); *and* 89000 (June 3, 2020), 85 FR 35344 (June 9, 2020) (SR–CboeEDGX–2020–023).

[5] The Exchange proposes to renumber the current paragraph (2) under Exchange Rule 2618 as paragraph (7) to account for proposed paragraphs (a)(2) through (6) described in this proposed rule change.

[6] One difference between this proposed rule change and those of BZX and EDGX is that the Exchange does not propose at this time to offer a net credit risk setting, which refers to a pre-established maximum daily dollar amount for purchases and sales across all symbols, where purchases are counted as positive values and sales are counted as negative values. *See supra* note 4. The Exchange will submit a separate proposed rule change with the Commission to adopt a ''Net Notional Trade Value'' in the future.

[7] Another difference between this proposed rule change and those of BZX and EDGX is that both BZX and EDGX only allow the gross credit risk limits to be set at the MPD Level or to a subset of orders identified within that MPID (the ''risk group identifier'' level). *See supra* note 4. The Exchange believes allowing for limits to be set at the MPID, session, or firm level provides Equity Members greater flexibility in managing their risk exposure.

[8] As discussed below, if an Equity Member revokes the responsibility of establishing and adjusting the risk settings identified in proposed paragraph (a), the settings applied by the Equity Member would be applicable.

[9] The term ''Clearing Member'' refers to a Member that is a member of a Qualified Clearing Agency and clears transactions on behalf of another Member. *See* Exchange Rule 2620(a).

[10] The term ''Qualified Clearing Agency'' means a clearing agency registered with the Commission pursuant to Section 17A of the Act that is deemed qualified by the Exchange. *See* Exchange Rule 1901. The rules of any such clearing agency shall govern with the respect to the clearance and settlement of any transactions executed by the Member on the Exchange.

[11] An Equity Member can designate one Clearing Member per MPID associated with the Equity Member.

[12] *See* Exchange Rule 100 for a definition of ''System.''

Proposed paragraph (a)(3) Exchange Rule 2618 provides that either an Equity Member or its Clearing Member, if allocated such responsibility pursuant to proposed paragraph (a)(4) of Exchange Rule 2618, may establish and adjust limits for the risk settings provided in proposed paragraph (a)(2) of Exchange Rule 2618. An Equity Member or Clearing Member may establish and adjust limits for the risk settings in a manner prescribed by the Exchange. The risk management web portal page will also provide a view of all applicable limits for each Equity Member, which will be made available to the Equity Member and its Clearing Member, as discussed in further detail below.

Proposed paragraph (a)(5) of Exchange Rule 2618 would provide optional alerts to signal when an Equity Member is approaching its designated limit. If enabled, the alerts would generate when the Equity Member breaches certain percentage thresholds of its designated risk limit, as determined by the Exchange. Based on current industry standards, the Exchange anticipates initially setting these thresholds at seventy-five or ninety percent of the designated risk limit. Both the Equity Member and Clearing Member [13] would have the option to enable the alerts via the risk management tool on the web portal and designate email recipients of the notification. The proposed alert system is meant to warn an Equity Member and Clearing Member of the Equity Member's trading activity, and will have no impact on the Equity Member's order and trade activity if a warning percentage is breached. Proposed paragraph (a)(6) of Exchange Rule 2618 would authorize the Exchange to automatically block new orders submitted and cancel all open orders in the event that a risk setting is breached. The Exchange will continue to block new orders submitted until the Equity Member or Clearing Member, if allocated such responsibility pursuant to proposed paragraph (a)(4) of Exchange Rule 2618, adjusts the risk settings to a higher threshold. The proposed functionality is designed to assist Equity Members and Clearing Members in the management of, and risk control over, their credit risk. Further, the proposed functionality would allow the Equity Member to seamlessly avoid unintended executions that exceed their stated risk tolerance.

[13] A Clearing Member would have the ability to enable alerts regardless of whether it was allocated responsibilities pursuant to proposed paragraph (a)(4) of Exchange Rule 2618.

The Exchange does not guarantee that the proposed risk settings described in proposed paragraphs (a)(2) through (6) are sufficiently comprehensive to meet all of an Equity Member's risk management needs. Pursuant to Rule 15c3–5 under the Act,[14] a broker-dealer with market access must perform appropriate due diligence to assure that controls are reasonably designed to be effective, and otherwise consistent with the rule.[15] Use of the Exchange's risk settings included in proposed paragraphs (a)(2) through (6) of Exchange Rule 2618 will not automatically constitute compliance with Exchange or federal rules and responsibility for compliance with all Exchange and SEC rules remains with the Equity Member.

Lastly, as the Exchange currently has the authority to share any of an Equity Member's risk settings specified in paragraph (a) of Exchange Rule 2618 under Exchange Rule 2620(f) with the Clearing Member that clears transactions on behalf of the Equity Member. Existing Exchange Rule 2620(f) provides the Exchange with authority to directly provide Clearing Members that clear transactions on behalf of an Equity Member, to share any of the Equity Member's risk settings set forth under paragraph (a) of Exchange Rule 2618.[16] The purpose of such a provision under Exchange Rule 2620(f) was implemented to reduce the administrative burden on participants on MIAX PEARL Equities, including both Clearing Members and Equity Members, and to ensure that Clearing Members receive information that is up to date and conforms to the settings active in the System. Further, the provision was adopted because the Exchange believed such functionality would help Clearing Members to better monitor and manage the potential risks that they assume when clearing for Equity Members of the Exchange. Paragraph (f) of Exchange Rule 2620 would further authorize the Exchange to share any of an Equity Member's risk settings specified in proposed paragraph (a)(2) to Exchange Rule 2618 with the Clearing Member that clears transactions on behalf of the Equity Member.

The Exchange notes that the use by an Equity Member of the risk settings offered by the Exchange is optional. By using these proposed optional risk settings, an Equity Member therefore also opts-in to the Exchange sharing its designated risk settings with its Clearing Member. The Exchange believes that its proposal to offer an additional risk setting will allow Equity Members to better manage their credit risk. Further, by allowing Equity Members to allocate the responsibility for establishing and adjusting such risk settings to its Clearing Member, the Exchange believes Clearing Members may reduce potential risks that they assume when clearing for Equity Members of the Exchange. The Exchange also believes that its proposal to share a Member's risk settings set forth under proposed paragraph (a)(2) to Exchange Rule 2618 directly with Clearing Members reduces the administrative burden on participants on the Exchange, including both Clearing Members and Equity Members, and ensures that Clearing Members are receiving information that is up to date and conforms to the settings active in the System.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[17] in general, and furthers the objectives of Section 6(b)(5),[18] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Specifically, the Exchange believes the proposed amendment will remove impediments to and perfect the mechanism of a free and open market and a national market system because it provides additional functionality for an Equity Member to manage its credit risk. In addition, the proposed risk setting could provide Clearing Members, who have assumed certain risks of Equity Members, greater control over risk tolerance and exposure on behalf of their correspondent Equity Members, if

[14] 17 CFR 240.15c3–5.

[15] *See* Division of Trading and Markets, Responses to Frequently Asked Questions Concerning Risk Management Controls for Brokers or Dealers with Market Access, *available at https://www.sec.gov/divisions/marketreg/faq-15c-5-risk-management-controls-bd.htm.*

[16] By using the optional risk settings provided in paragraph (a)(1) of Exchange Rule 2618, an Equity Member opts-in to the Exchange sharing its risk settings with its Clearing Member. Any Equity Member that does not wish to share such risk settings with its Clearing Member can avoid sharing such settings by becoming a Clearing Member. *See* Securities Exchange Act Release No. 89563 (August 14, 2020), 85 FR 51510 (August 20, 2020) (SR–PEARL–2020–03) (''Equities Approval Order'').

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

allocated responsibility pursuant to proposed paragraph (a)(4) of Exchange Rule 2618, while also providing an alert system that would help to ensure that both Equity Members and its Clearing Member are aware of developing issues. As such, the Exchange believes that the proposed risk settings would provide a means to address potentially market-impacting events, helping to ensure the proper functioning of the market.

In addition, the Exchange believes that the proposed rule change is designed to protect investors and the public interest because the proposed functionality is a form of risk mitigation that will aid Equity Members and Clearing Members in minimizing their financial exposure and reduce the potential for disruptive, market-wide events. In turn, the introduction of such risk management functionality could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

Further, the Exchange believes that the proposed rule will foster cooperation and coordination with persons facilitating transactions in securities because the Exchange will provide alerts when an Equity Member's trading activity reaches certain thresholds, which will be available to both the Equity Member and Clearing Member. As such, the Exchange may help Clearing Members monitor the risk levels of correspondent Equity Members and provide tools for Clearing Members, if allocated such responsibility, to take action.

The proposal will permit Clearing Members who have a financial interest in the risk settings of Equity Members to better monitor and manage the potential risks assumed by Clearing Members, thereby providing Clearing Members with greater control and flexibility over setting their own risk tolerance and exposure. To the extent a Clearing Member might reasonably require an Equity Member to provide access to its risk settings as a prerequisite to continuing to clear trades on the Equity Member's behalf, the Exchange's proposal to share those risk settings directly reduces the administrative burden on participants on the Exchange, including both Clearing Members and Equity Members. Moreover, providing Clearing Members with the ability to see the risk settings established for Equity Members for which they clear will foster efficiencies in the market and remove impediments to and perfect the mechanism of a free and open market and a national market system. The proposal also ensures that Clearing Members are receiving information that is up to date and conforms to the settings active in the System. The Exchange believes that the proposal is consistent with the Act, particularly Section 6(b)(5),[19] because it will foster cooperation and coordination with persons engaged in facilitating transactions in securities and more generally, will protect investors and the public interest, by allowing Clearing Members to better monitor their risk exposure and by fostering efficiencies in the market and removing impediments to and perfect the mechanism of a free and open market and a national market system.

Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's Members because use of the risk settings is optional and are not a prerequisite for participation on the Exchange. The proposed risk settings are completely voluntary and, as they relate solely to optional risk management functionality, no Member is required or under any regulatory obligation to utilize them.

The proposed rule change is based on Interpretation and Policy .03 of EDGX Rule 11.10 and Interpretation and Policy .03 of BZX Rule 11.13, with four minor differences.[20] First, both BZX and EDGX only allow the gross credit risk limits to be set at the MPID level or to a subset of orders identified within that MPID (the ''risk group identifier'' level) while the Exchange proposes to allow the risk limits to be set at the MPID, session, and firm level. Second, the Exchange only proposes to adopt a Gross Notional Trade Value risk setting while EDGX and BZX adopted both gross notional and net notional risk settings. Third, EDGX proposed additional changes to its Rule 11.13(a) to allow their clearing members access to its members risk settings. The Exchange does not need to include similar changes in this proposal as Exchange Rule 2620(a) already provides Clearing Members this ability and includes text identical to that which EDGX recently adopted.[21] Lastly, the Exchange notes that it proposes to generate alerts when the Equity Member breaches certain percentage thresholds of its designated risk limit, as determined by the Exchange. Based on current industry standards, the Exchange anticipates initially setting these thresholds at seventy-five or ninety percent of the designated risk limit. The Exchange notes that EDGX stated these thresholds would be set at fifty, seventy, or ninety percent.

[19] 15 U.S.C. 78f(b)(5).

[20] *See supra* note 4.

[21] *Id.*

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange believes that the proposal may have a positive effect on competition because it would allow the Exchange to offer risk management functionality that is comparable to functionality that has been adopted by other national securities exchanges.[22] Further, by providing Equity Members and their Clearing Members additional means to monitor and control risk, the proposed rule may increase confidence in the proper functioning of the markets and contribute to additional competition among trading venues and broker-dealers. Rather than impede competition, the proposal is designed to facilitate more robust risk management by Equity Members and Clearing Members, which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [23] and Rule 19b–4(f)(6) thereunder.[24]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [25] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [26] permits the Commission to designate a

[22] *Id.*

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6)(iii).

shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange may implement the proposed risk controls on the anticipated launch date of MIAX PEARL Equities on September 25, 2020. The Exchange states that waiver of the operative delay would allow Equity Members to immediately utilize the proposed functionality to manage their risk. For this reason, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[27]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–PEARL–2020–16 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–PEARL–2020–16. 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 such 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–PEARL–2020–16, and should be submitted on or before October 20, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Assistant Secretary.

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[27] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89970; File No. SR–CboeEDGX–2020–045]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule

September 23, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 11, 2020, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the fee schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule applicable to its equities trading platform (''EDGX Equities'') by: (1) Amending certain standard rates; (2) adding a new fee code; (3) updating the Non-Displayed Add Volume Tiers; and (4) including a Remove Volume Tier.[3]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 13 registered equities exchanges, as well as a number of alternative trading

[3] The Exchange initially filed the proposed fee changes on September 1, 2020 (SR–CboeEDGX–2020–044). On September 11, 2020, the Exchange withdrew that filing and submitted this proposal.

systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[4] no single registered equities exchange has more than 18% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays credits to members that provide liquidity and assesses fees to those that remove liquidity. The Exchange's fee schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Currently, for orders priced at or above $1.00, the Exchange provides a standard rebate of $0.0017 per share for orders that add liquidity and assesses a fee of $0.0027 per share for orders that remove liquidity. For orders priced below $1.00, the Exchange a standard rebate of $0.00003 per share for orders that add liquidity and assesses a fee of 0.30% of Dollar Value for orders that remove liquidity. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Proposed Amendment to Standard Rebate for Securities Under $1.00

As stated above, the Exchange currently offers a standard rebate of $0.00003 for orders in securities below $1.00 that add liquidity. The Exchange proposes to amend this standard rate by providing a standard rebate of $0.00009 for orders that add liquidity in securities priced under $1.00 and reflects this change in the Fee Codes and Associated Fee where applicable (*i.e.,* corresponding to fee codes 3, 4, B, V, and Y). The Exchange notes that the proposed standard rate is in line with, yet also competitive with, rates assessed by other equities exchanges on orders in securities priced below $1.00.[5] The Exchange notes, too, that its affiliated exchange, Cboe BZX Exchange, Inc. (''BZX Equities''), is simultaneously submitting a fee change to amend its same current standard rate for orders that add liquidity in securities under $1.00 in the same manner.

Proposed New Fee Code

The Exchange proposed to add a new type of fee code in the Fee Code and Associated Fees table in the Fee Schedule. Specifically, the proposed fee code ''ZM'' is appended to Retail[6] Day or Regular Hours Only (''RHO'')[7] Orders that remove liquidity on arrival and are assessed no fee. Currently, such orders in securities priced at or above $1.00 are assessed the standard fee of $0.0027 to remove liquidity and such orders in securities priced below $1.00 are assessed the standard fee of 0.30% of Dollar Value to remove liquidity.

Proposed Updates to the Non-Displayed Add Volume Tiers

Currently, the Exchange provides for three Non-Displayed Add Volume Tiers under footnote 1 of the Fee Schedule. These tiers offer enhanced rebates on Members' orders yielding fee codes ''DM''[8], ''HA'',[9] ''MM''[10] and ''RP''[11] where a Member reaches certain required volume-based criteria offered in each tier. Specifically, the Non-Displayed Add Volume Tiers are as follows:

- Tier 1 provides an enhanced rebate of $0.0015 for a Member's qualifying orders (*i.e.,* yielding fee codes DM, HA, MM and RP) where a Member adds an ADV[12] greater than or equal to 1,000,000 shares as Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.
- Tier 2 provides an enhanced rebate of $0.0022 for a Member's qualifying orders where a Member adds an ADV greater than or equal to 2,500,000 shares as Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.
- Tier 3 provides an enhanced rebate of $0.0025 for a Member's qualifying orders where a Member adds an ADV greater than or equal to 7,000,000 shares as Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.

The Exchange proposes to update the criteria in each of the Non-Displayed Add Volume Tiers as follows below. The Exchange notes that the enhanced rebates currently provided in each tier remain the same.

- To meet the proposed criteria in Tier 1, a Member must have an ADAV greater than or equal to 0.01% of TCV for Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.
- To meet the proposed criteria in Tier 2, a Member must have an ADAV greater than or equal to 0.02% of TCV for Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.
- To meet the proposed criteria in Tier 3, a Member must have an ADAV greater than or equal to 0.05% of TCV for Non-Displayed orders that yield fee codes DM, HA, HI, MM or RP.

The Exchange notes that the proposed rule change also updates the language in each Tier to state ''where a Member has an ADAV'', which essentially states the same requirement as ''adds an ADV'', but is more appropriately aligned with the defined terms in the Fee Schedule.[13] Further, the Exchange does not believe that amending the current volume over a baseline number of shares criteria to, instead, be a percentage volume over TCV poses any significant increase or decrease in difficulty in reaching the Non-Displayed Add Volume Tiers, but only changes the format of the Non-Displayed Add Volume Tier criteria to be consistent with the format of the

[4] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (August 24, 2020), available at *https://markets.cboe.com/us/equities/market_statistics/*.

[5] *See* NYSE Price List 2020, ''Transactions in stocks with a per share stock price less than $1.00'', which either does not assess a charge or assesses a charge of 0.3% for various orders in securities priced below $1.00; *and* Nasdaq Pricing, ''Rebates and Fees, Shares Executed Below $1.00'', which assesses no change for orders to add liquidity in securities priced below $1.00 and assesses a charge of 0.30% of total dollar volume for orders to remove liquidity in securities priced below $1.00.

[6] *See* EDGX Rule 11.21(a)(1). A ''Retail Order'' is an agency or riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. *See* EDGX Rule 11.21(a)(2). Retail Orders are submitted by a ''Retail Member Organization'' or ''RMO'', which is a member (or a division thereof) that has been approved by the Exchange to submit such orders.

[7] ''Day'' is an instruction the User may attach to an order stating that an order to buy or sell which, if not executed, expires at the end of Regular Trading Hours. Any Day Order entered into the System before the opening for business on the Exchange, or after the closing of Regular Trading Hours, will be rejected. *See* EDGX Rule 11.6(q)(2). ''Regular Hours Only (''RHO'') is an instruction a User may attach to an order designating it for execution only during Regular Trading Hours, which includes the Opening Process and Re-Opening Process following a halt suspension or pause. *See* EDGX Rule 11.6(q)(6).

[8] Appended to orders that add liquidity using MidPoint Discretionary order within discretionary range and are provided a rebate of $0.00100.

[9] Appended to non-displayed orders that add liquidity and are provided a rebate of $0.00100.

[10] Appended to non-displayed orders that add liquidity using Mid-Point Peg and are provided a rebate of $0.00100.

[11] Appended to non-displayed orders that add liquidity using Supplemental Peg and are provided a rebate of $0.00100.

[12] ''ADV'' means average daily volume calculated as the number of shares added to, removed from, or routed by, the Exchange, or any combination or subset thereof, per day. ADV is calculated on a monthly basis.

[13] *See supra* note 12; *and see infra* note 20.

criteria in the other volume-based tiers offered under the Fee Schedule.[14]

Proposed Remove Volume Tier

The Exchange proposes to add a new Remove Volume Tier under footnote 1 of the Fee Schedule.[15] The proposed Remove Volume Tier offers a reduced remove fee of $0.0026 in securities at or above $1.00 and 0.28% of total dollar value for orders in securities below $1.00[16] for orders yielding fee code ''BB''[17], ''N''[18] and ''W''[19] where a Member has an ADAV[20] greater than or equal to 0.25% TCV[21] with displayed orders that yield fee codes B, V or Y. The proposed Remove Volume Tier is designed to incentivize Members to increase their orders that add displayed volume on the Exchange in order to receive a reduced fee on their qualifying, liquidity removing orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[22] in general, and furthers the objectives of Section 6(b)(4),[23] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members, issuers and other persons using its facilities. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The proposed rule changes reflect a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members.

Regarding the proposed change to the standard rates, the Exchange believes that amending the standard rate for orders that add volume in securities priced below $1.00 is reasonable because, as stated above, in order to operate in the highly competitive equities markets, the Exchange and its competing exchanges seek to offer similar pricing structures, including assessing comparable standard fees for orders in securities priced below $1.00. Thus, the Exchange believes the proposed standard rate change is reasonable as it is generally aligned with and competitive with the amounts assessed for the orders in securities below $1.00 on other equities exchanges. The Exchange also believes that amending this standard rate amount represents an equitable allocation of fees and is not unfairly discriminatory because they will continue to automatically apply to all Members' orders that add liquidity in securities less than $1.00 uniformly.

Regarding the proposed new fee code ZM appended to Retail Day/RHO Orders that remove liquidity on arrival, the Exchange notes that the competition for Retail Order flow is particularly intense, especially as it relates to exchange versus off-exchange venues, as prominent retail brokerages tend to route a majority of their limit orders to off-exchange venues.[24] Accordingly, competitive forces compel the Exchange to use exchange transaction fees and credits, particularly as they relate to competing for Retail Order flow, because market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange believes that its proposed change to adopt fee code ZM, which will assess no fee for Retail Day/RHO Orders that remove upon arrival is reasonable, equitable and not unfairly discriminatory. Specifically, the Exchange believes the proposal is reasonable as market participants will not be subject to a fee for the execution of such orders. This is consistent with, and competitive with, fees assessed for retail order flow on other equities exchanges, which provide pricing incentives to retail orders in the form of lower fees and/or higher rebates.[25] The Exchange notes too that it currently offers a rebate of $0.0032 per share for Retail Orders that add liquidity (*i.e.,* yielding fee code ''ZA'') as compared to the standard rebate of $0.0017 for liquidity adding orders, as well as Retail Volume Tiers which provide various enhanced rebates specifically for Members' Retail Order flow. The Exchange believes that adopting no charge on orders yielding fee code ZM is reasonable in that it is reasonably designed to incentivize an increase in removing Retail Order flow. Retail Orders are generally submitted in smaller sizes and tend to attract Market-Makers, as smaller size orders are easier to hedge, and Retail Order flow that removes liquidity additionally signals to liquidity providers to increase their overall provision of liquidity in the markets. Increased Market-Maker activity facilitates tighter spreads and an increase in overall liquidity provider activity provides for deeper, more robust levels of liquidity, both of which signal additional corresponding increase in order flow from other market participants, contributing towards a robust, well-balanced market ecosystem. Indeed, increased overall order flow benefits all investors by continuing to deepen the Exchange's liquidity pool, potentially providing even greater execution incentives and opportunities, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency and improving investor protection. The Exchange notes that, like all other fee codes, ZM and the accompanying free charge will be automatically and uniformly applied to all Members' qualifying orders. The Exchange additionally notes that while the proposed fee code and assessment of no fee is applicable only to Retail Orders, the Exchange does not believe this application is discriminatory as the Exchange offers similar rebates or reduced rates to non-Retail Order flow.[26]

The Exchange believes that the proposed Remove Volume Tier is reasonable because it provides an additional opportunity through a new tier for Members to receive a discounted

[14] *See* EDGX Equities Fee Schedule, ''Add Volume Tiers'', ''Tape B Volume Tier'', and ''Retail Volume Tier''.

[15] As a result of the new Remove Volume Tier, it also updates the title of footnote 1 to ''Add/Remove Volume Tiers''.

[16] As a result, the Exchange proposes to update the statement under General Notes in the Fee Schedule to state that ''unless otherwise indicated, variable rates provided by tiers apply only to executions in securities priced at or above $1.00.

[17] Appended to orders that remove liquidity from EDGX (Tape B) and is assessed a standard fee of $0.00270.

[18] Appended to orders that remove liquidity from EDGX (Tape C) and is assessed a standard fee of $0.00270.

[19] Appended to orders that remove liquidity from BZX (Tape A) and is assessed a standard fee of $0.00270.

[20] ''ADAV'' means average daily added volume calculated as the number of shares added per day. ADAV is calculated on a monthly basis.

[21] ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[22] 15 U.S.C. 78f.

[23] 15 U.S.C. 78f(b)(4).

[24] *See* Securities Exchange Release No. 86375 (July 15, 2019), 84 FR 34960 (SR–CboeEDGX–2019–045).

[25] *See* Nasdaq Price List, Rebate to Add Displayed Designated Retail Liquidity, which offer rebates of $0.00325 and $0.0033 for Add Displayed Designated Retail Liquidity; *and* NYSE Price List, ''Fees and Credits Applicable to Executions in the Retail Liquidity Program'', which offers various reduced fees, including the assessment of no charges, for various types of retail order volume, and ''Transaction Fees and Credits For Tape B and C Securities'', which provides a rebate of $0.0030 per share specifically for retail orders.

[26] *See generally,* EDGX Equities Fee Schedule, Fee Codes and Associated Fees; *see also* ''Add Volume Tiers'' and ''Tape B Volume Tier'', both of which provide various enhanced rebates for non-Retail Order flow.

rate by means of liquidity adding orders and that the proposed changes to the Non-Displayed Liquidity Tiers are reasonable because they merely update the format of the tiers' criteria to be consistent with other volume-based tiers currently offered by the Exchange, thus maintaining existing opportunities for Members to receive a discounted rate by means of non-displayed liquidity adding orders.[27] The Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges, including the Exchange, and are reasonable, equitable and non-discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Additionally, as noted above, the Exchange operates in highly competitive market. The Exchange is only one of several equity venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. It is also only one of several maker-taker exchanges. Competing equity exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange. These competing pricing schedules, including those of the Exchange's affiliated equities exchanges,[28] are presently comparable to those that the Exchange provides, including the pricing of comparable criteria and reduced fees.

Moreover, the Exchange believes the Remove Volume Tier is a reasonable means to incentivize Members to continue to provide liquidity adding, displayed volume to the Exchange by offering them a different, additional opportunity than that of the current Add Volume Tiers—to receive a reduced fee on their liquidity removing orders by meeting the proposed criteria in submitting additional add volume order flow. In addition to this, the Exchange has recently observed that trading in subdollar names has grown significantly; nearly tripling since the beginning of 2020, and that competing equities exchanges have begun offering pricing incentives for subdollar orders.[29] Therefore, the Exchange believes that it is reasonable and equitable to provide the proposed reduced fee under the new Remove Volume Tier for qualifying subdollar orders. Also, as noted above, the Exchange's affiliated equities exchanges already have similar Remove Volume Tiers in place, which offer similar rebates for achieving comparable criteria, in addition to their Add Volume Tiers.[30]

In addition to this, the Exchange believes the proposed Non-Displayed Volume Tiers are reasonable in that the proposed changes to the tiers' criteria is designed to be more consistent with the format of the criteria (*i.e.,* percentage of volume based on TCV) currently offered under the other volume-based tiers in the Fee Schedule.[31] Also, as noted above, the Exchange's affiliated equities exchange, BZX Equities, currently has Non-Displayed Volume Tiers in place, which offer substantially similar enhanced rebates and criteria based on volume over TCV for its members.[32]

Overall, the Exchange believes that the proposed tiers, each based on a Member's liquidity adding orders, will benefit all market participants by incentivizing continuous liquidity and thus, deeper more liquid markets as well as increased execution opportunities. Particularly, the proposed Remove Volume Tier is designed to incentivize continuous displayed liquidity, which signals other market participants to take the additional execution opportunities provided by such liquidity, while the proposed Non-Displayed Add Volume Tiers remains designed to incentivize non-displayed liquidity, which further contributes to a deeper, more liquid market and provide even more execution opportunities for active market participants at improved prices. This overall increase in activity deepens the Exchange's liquidity pool, offers additional cost savings, supports the quality of price discovery, promotes market transparency and improves market quality, for all investors.

The Exchange believes that the proposal represents an equitable allocation of fees and rebates and is not unfairly discriminatory because all Members are eligible for the proposed Remove Volume Tier and Non-Displayed Add Volume Tiers and would have the opportunity to meet the tiers' criteria and would receive the proposed fee if such criteria is met. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying for the proposed tiers. While the Exchange has no way of predicting with certainty how the proposed tier will impact Member activity, the Exchange anticipates that approximately eight Members will be able to compete for and reach the proposed Remove Volume Tier. The Exchange also notes that while the proposed changes to the criteria in the Non-Displayed Add Volume Tiers do not significantly increase or decrease the level of criteria difficulty, thus do not significantly affect Members' current ability to compete for and reach the proposed tiers, approximately three additional Members will be able to compete for and reach these tiers, as amended. The Exchange anticipates that the tiers will include various liquidity providing Member types, such as traditional Market Makers, and wholesale or consolidator firms that mainly make markets for retail orders, each providing distinct types of order flow to the Exchange to the benefit of all market participants. The Exchange also notes that proposed tiers will not adversely impact any Member's pricing or ability to qualify for other reduced fee or enhanced rebate tiers. Should a Member not meet the proposed criteria under any of the proposed tiers, the Member will merely not receive that corresponding reduced fee. Furthermore, the proposed reduced fee in the Remove Volume Tier would uniformly apply to all Members that meet the required criteria under the proposed tier. The Exchange again notes that the enhanced rebates offered under the Non-Displayed Add Volume Tiers remain the same.

[27] *See supra* note 14.

[28] *See* EDGA Equities Fee Schedule, footnote 7, ''Add/Remove Volume Tiers'', of which the Remove Volume Tiers offers an enhanced rebate of $0.0022 or $0.0028 for reaching a certain threshold of ADV over TCV; BYX Equities Fee Schedule, footnote 1, ''Add/Remove Volume Tiers'', of which the Remove Volume Tiers offer enhanced rebates between $0.0015 and $0.0018 for various criteria (Step-Up volume, ADAV of a set number of shares, ADV as a percentage of TCV, etc.); *and* BZX Equities Fee Schedule, footnote 1, ''Add Volume Tiers'', Non-Displayed Add Volume Tiers, which provide for substantially similar enhanced rebates and non-displayed volume based criteria.

[29] *See* NYSE Price List, ''Fees and Credits applicable to Designated Market Makers (''DMMs'')'', which provides, among various credits for orders in securities at or above $1.00, additional credit of $0.0004 for DMMs adding liquidity in securities under $1.00; *see also* Securities Exchange Release No. 89607 (August 18, 2020), 85 FR 52179 (August 24, 2020) (SR–NYSEArca–2020–75), which recently adopted in its fee schedule a step up tier for ETP Holders adding liquidity in Round Lots and Odd Lots in Tapes A, B and C securities with a per share price below $1.00 and amended the base rate for adding and removing liquidity in Round Lots and Odd Lots in Tapes A, B and C securities with a per share price below $1.00.

[30] *See supra* note 28.

[31] *See supra* note 14.

[32] *See supra* note 28.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.''

The Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed change applies to all Members equally in that all Members are eligible for the proposed Remove Volume Tier and the proposed Non-Displayed Add Volume Tiers, have a reasonable opportunity to meet the tiers' criteria and will all receive the proposed fee if such criteria is met. Additionally, the proposed tiers are designed to attract additional order flow to the Exchange. The Exchange believes that the additional and updated tier criteria would incentivize market participants to direct liquidity adding order flow to the Exchange, bringing with it improved price transparency. Greater overall order flow and pricing transparency benefits all market participants on the Exchange by providing more trading opportunities, enhancing market quality, and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem, which benefits all market participants. Further, the proposed standard rebate for orders that add liquidity in securities below $1.00 and the proposed no charge for orders yielding fee code ZM will apply uniformly and automatically to all such Members' respective orders, as all other standard rates and fee codes apply today to qualifying orders. In addition to this, and as indicated above, the Exchange does not believe that not assessing a fee for Retail Orders yielding fee code ZM imposes any burden on intramarket competition as the Exchange offers many similar rebate opportunities for non-Retail Orders in it Fee Schedule.[33]

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including 12 other equities exchanges and off-exchange venues and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 18% of the market share. Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''. Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[33] *See supra* note 26.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [34] and paragraph (f) of Rule 19b–4 [35] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeEDGX–2020–045 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–CboeEDGX–2020–045. 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

[34] 15 U.S.C. 78s(b)(3)(A).

[35] 17 CFR 240.19b–4(f).

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–CboeEDGX–2020–045, and should be submitted on or before October 20, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–21403 Filed 9–28–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89972; File No. 4–566]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17d–2; Notice of Filing and Order Approving and Declaring Effective an Amendment to the Plan for the Allocation of Regulatory Responsibilities Among Cboe BZX Exchange, Inc., Cboe BYX Exchange, Inc., NYSE Chicago, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., MEMX LLC, MIAX PEARL, LLC, Nasdaq BX, Inc., Nasdaq PHLX LLC, The Nasdaq Stock Market LLC, NYSE National, Inc., New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., Investors' Exchange LLC, and Long-Term Stock Exchange, Inc. Relating to the Surveillance, Investigation, and Enforcement of Insider Trading Rules

September 23, 2020.

Notice is hereby given that the Securities and Exchange Commission (''Commission'') has issued an Order, pursuant to Section 17(d) of the Securities Exchange Act of 1934 (''Act''),[1] approving and declaring effective an amendment to the plan for allocating regulatory responsibility (''Plan'') filed on September 18, 2020, pursuant to Rule 17d–2 of the Act,[2] by Cboe BZX Exchange, Inc. (''BZX''), Cboe BYX Exchange, Inc. (''BYX''), NYSE Chicago, Inc. (''CHX''), Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX''), Financial Industry Regulatory Authority, Inc. (''FINRA''), MEMX LLC (''MEMX''), MIAX PEARL, LLC (''MIAX PEARL''), Nasdaq BX, Inc. (''BX''), Nasdaq PHLX LLC (''PHLX''), The Nasdaq Stock Market LLC (''Nasdaq''), NYSE National, Inc. (''NYSE National''), New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), Investors' Exchange LLC (''IEX'') and Long-Term Stock Exchange, Inc. (''LTSE'') (collectively, ''Participating Organizations'' or ''Parties'').

I. Introduction

Section 19(g)(1) of the Act,[3] among other things, requires every self-regulatory organization (''SRO'') registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO's own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d)[4] or Section 19(g)(2)[5] of the Act. Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO (''common members''). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

Section 17(d)(1) of the Act[6] was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.[7] With respect to a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d–1 and Rule 17d–2 under the Act.[8] Rule 17d–1 authorizes the Commission to name a single SRO as the designated examining authority (''DEA'') to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO rules.[9] When an SRO has been named as a common member's DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d–1 deals only with an SRO's obligations to enforce member compliance with financial responsibility requirements. Rule 17d–1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17d–2 under the Act.[10] Rule 17d–2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect to their common members. Under paragraph (c) of Rule 17d–2, the Commission may declare such a plan effective if, after providing for notice and comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors, to foster cooperation and coordination among the SROs, to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system, and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17d–2 relieves an SRO of those regulatory responsibilities allocated by the plan to another SRO.

II. The Plan

On September 12, 2008, the Commission declared effective the Participating Organizations' Plan for allocating regulatory responsibilities

[36] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78q(d).

[2] 17 CFR 240.17d–2.

[3] 15 U.S.C. 78s(g)(1).

[4] 15 U.S.C. 78q(d).

[5] 15 U.S.C. 78s(g)(2).

[6] 15 U.S.C. 78q(d)(1).

[7] *See* Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and Urban Affairs to Accompany S. 249, S. Rep. No. 94–75, 94th Cong., 1st Session 32 (1975).

[8] 17 CFR 240.17d–1 and 17 CFR 240.17d–2, respectively.

[9] *See* Securities Exchange Act Release No. 12352 (April 20, 1976), 41 FR 18808 (May 7, 1976).

[10] *See* Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976).

pursuant to Rule 17d–2.[11] The Plan is designed to eliminate regulatory duplication by allocating regulatory responsibility over Common FINRA Members [12] (collectively ''Common Members'') for the surveillance, investigation, and enforcement of common insider trading rules (''Common Rules'').[13] The Plan assigns regulatory responsibility over Common FINRA Members to FINRA for surveillance, investigation, and enforcement of insider trading by broker-dealers, and their associated persons, with respect to Listed Stocks (as defined in the Plan), irrespective of the marketplace(s) maintained by the Participating Organizations on which the relevant trading may occur.

III. Proposed Amendment to the Plan

On September 18, 2020, the Parties submitted a proposed amendment to the Plan. The proposed amendment was submitted to add MIAX PEARL as a Participant to the Plan and to add Exchange Act Rules 14e–3 and 15(g) to the list of rules in Exhibit A. The text of the proposed amended 17d–2 plan is as follows (additions are *italicized;* deletions are [bracketed]):

* * * * *

* * * * *

Agreement for the Allocation of Regulatory Responsibility of Surveillance, Investigation and Enforcement for Insider Trading Pursuant to § 17(d) of the Securities Exchange Act of 1934, 15 U.S.C. § 78q (d), and Rule 17d–2 Thereunder

This agreement (the ''Agreement'') by and among Cboe BZX Exchange, Inc. (''BZX''), Cboe BYX Exchange, Inc. (''BYX''), NYSE Chicago, Inc. (''CHX''), Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX''), Financial Industry Regulatory Authority, Inc. (''FINRA''), MEMX LLC (''MEMX''), *MIAX PEARL, LLC (''MIAX PEARL''),*[1] Nasdaq BX, Inc. (''BX''), Nasdaq PHLX LLC (''PHLX''), The Nasdaq Stock Market LLC (''Nasdaq''), NYSE National, Inc. (''NYSE National''), New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), Investors' Exchange LLC (''IEX'') and Long-Term Stock Exchange, Inc. (''LTSE'') (each a ''Participating Organization'' and together, the ''Participating Organizations''), is made pursuant to § 17(d) of the Securities Exchange Act of 1934 (the ''Act''), 15 U.S.C. 78q(d), and Securities and Exchange Commission (''SEC'') Rule 17d–2, which allow for plans to allocate regulatory responsibility among self-regulatory organizations (''SROs''). Upon approval by the SEC, this

[1] MIAX PEARL's allocation of certain regulatory responsibilities to FINRA under this Agreement is limited to the activites of MIAX PEARL Equities, a facility of MIAX PEARL.

Agreement shall amend and restate the agreement among the Participating Organizations approved by the SEC on [August 1, 2019] *May 26, 2020.*

Whereas, the Participating Organizations desire to: (a) Foster cooperation and coordination among the SROs; (b) remove impediments to, and foster the development of, a national market system; (c) strive to protect the interest of investors; and (d) eliminate duplication in their regulatory surveillance, investigation and enforcement of insider trading;

Whereas, the Participating Organizations are interested in allocating to FINRA regulatory responsibility for Common FINRA Members (as defined below) for surveillance, investigation and enforcement of Insider Trading (as defined below) in NMS Stocks (as defined below) irrespective of the marketplace(s) maintained by the Participating Organizations on which the relevant trading may occur in violation of Common Insider Trading Rules (as defined below);

Whereas, the Participating Organizations will request regulatory allocation of these regulatory responsibilities by executing and filing with the SEC a plan for the above stated purposes (this Agreement, also known herein as the ''Plan'') pursuant to the provisions of § 17(d) of the Act, and SEC Rule 17d–2 thereunder, as described below; and

Whereas, the Participating Organizations will also enter into a Regulatory Services Agreement (the ''Insider Trading RSA''), of even date herewith, to provide for the investigation and enforcement of suspected Insider Trading against broker-dealers, and their associated persons, that are not Common FINRA Members in the case of Insider Trading in NMS Stocks..

Now, therefore, in consideration of the mutual covenants contained hereafter, and other valuable consideration to be mutually exchanged, the Participating Organizations hereby agree as follows:

1. *Definitions.* Unless otherwise defined in this Agreement, or the context otherwise requires, the terms used in this Agreement will have the same meaning they have under the Act, and the rules and regulations thereunder. As used in this Agreement, the following terms will have the following meanings:

a. ''Rule'' of an ''exchange'' or an ''association'' shall have the meaning defined in Section 3(a)(27) of the Act.

b. ''Common FINRA Members'' shall mean members of FINRA and at least one of the Participating Organizations.

c. ''Common Insider Trading Rules'' shall mean (i) the federal securities laws and rules thereunder promulgated by the SEC pertaining to insider trading, and (ii) the rules of the Participating Organizations that are related to insider trading, as provided on Exhibit A to this Agreement.

d. ''Effective Date'' shall have the meaning set forth in paragraph 27.

e. ''Insider Trading'' shall mean any conduct or action taken by a natural person or entity related in any way to the trading of securities by an insider or a related party based on or on the basis of material non-public information obtained during the performance of the insider's duties at the corporation, or otherwise misappropriated, that could be deemed a violation of the Common Insider Trading Rules.

f. ''Intellectual Property'' will mean any: (1) Processes, methodologies, procedures, or technology, whether or not patentable; (2) trademarks, copyrights, literary works or other works of authorship, service marks and trade secrets; or (3) software, systems, machine-readable texts and files and related documentation.

g. ''Plan'' shall mean this Agreement, which is submitted as a Plan for the allocation of regulatory responsibilities of surveillance*, investigation and enforcement* for insider trading pursuant to § 17(d) of the Act, 15 U.S.C. 78q(d), and SEC Rule 17d–2.

h. ''NMS Stock(s)'' shall have the meaning set forth in Rule 600(b)(47) of SEC Regulation NMS.

[11] *See* Securities Exchange Act Release No. 58536 (September 12, 2008), 73 FR 54646 (September 22, 2008). *See also* Securities Exchange Act Release Nos. 58806 (October 17, 2008), 73 FR 63216 (October 23, 2008); 61919 (April 15, 2010), 75 FR 21051 (April 22, 2010); 63103 (October 14, 2010), 75 FR 64755 (October 20, 2010); 63750 (January 21, 2011), 76 FR 4948 (January 27, 2011); 65991 (December 16, 2011), 76 FR 79714 (December 22, 2011); 78473 (August 3, 2016), 81 FR 52722 (August 9, 2016); 84392 (October 10, 2018), 83 FR 52243 (October 16, 2018); 86542 (August 1, 2019), 84 FR 38679 (August 7, 2019); 88948 (May 26, 2020), 85 FR 33239 (June 1, 2020).

[12] Common FINRA Members include members of FINRA and at least one of the Participating Organizations.

[13] Common rules are defined as: (i) Federal securities laws and rules promulgated by the Commission pertaining to insider trading, and (ii) the rules of the Participating Organizations that are related to insider trading. *See* Exhibit A to the Plan.

i. ''Listing Market'' shall mean an exchange that lists NMS Stocks.

2. *Assumption of Regulatory Responsibilities.* On the Effective Date of the Plan, FINRA will assume regulatory responsibilities for surveillance, investigation and enforcement of Insider Trading by broker-dealers, and their associated persons, for Common FINRA Members with respect to NMS Stocks, irrespective of the marketplace(s) maintained by the Participant Organizations on which the relevant trading may occur in violation of the Common Insider Trading Rules (''Regulatory Responsibilities'').

3. *Certification of Insider Trading Rules.*

a. *Initial Certification.* By signing this Agreement, the Participating Organizations, other than FINRA, hereby certify to FINRA that their respective lists of Common Insider Trading Rules contained in Exhibit A hereto are correct, and FINRA hereby confirms that such rules are Common Insider Trading Rules as defined in this Agreement.

b. *Yearly Certification.* Each year following the commencement of operation of this Agreement, or more frequently if required by changes in the rules of the Participating Organizations, each Participating Organization shall submit a certified and updated list of Common Insider Trading Rules to FINRA for review, which shall (i) add Participating Organization rules not included in the then-current list of Common Insider Trading Rules that qualify as Common Insider Trading Rules as defined in this Agreement; (ii) delete Participating Organization rules included in the current list of Common Insider Trading Rules that no longer qualify as Common Insider Trading Rules as defined in this Agreement; and (iii) confirm that the remaining rules on the current list of Common Insider Trading Rules continue to be Participating Organization rules that qualify as Common Insider Trading Rules as defined in this Agreement. FINRA shall review each Participating Organization's annual certification and confirm whether FINRA agrees with the submitted certified and updated list of Common Insider Trading Rules by each of the Participating Organizations.

4. *No Retention of Regulatory Responsibility.* The Participating Organizations do not contemplate the retention of any responsibilities with respect to the regulatory activities being assumed by FINRA under the terms of this Agreement.

5. *Fees.* FINRA shall charge Participating Organizations for performing the Regulatory Responsibilities, as set forth in the Schedule of Fees, attached as Exhibit B.

6. *Applicability of Certain Laws, Rules, Regulations or Orders.* Notwithstanding any provision hereof, this Agreement shall be subject to any statute, or any rule or order of the SEC. To the extent such statute, rule, or order is inconsistent with one or more provisions of this Agreement, the statute, rule, or order shall supersede the provision(s) hereof to the extent necessary to be properly effectuated and the provision(s) hereof in that respect shall be null and void.

7. *Exchange Committee; Reports.*

a. *Exchange Committee.* The Participating Organizations shall form a committee (the ''Exchange Committee''), which shall act on behalf of all of Participating Organizations in receiving copies of the reports described below and in reviewing issues that arise under this Agreement. Each Participating Organization shall appoint a representative to the Exchange Committee. The Exchange Committee representatives shall report to their respective executive management bodies regarding status or issues under this Agreement. The Participating Organizations agree that the Exchange Committee will meet regularly up to four (4) times a year, with no more than one meeting per calendar quarter. At these meetings, the Exchange Committee will discuss the conduct of the Regulatory Responsibilities and identify issues or concerns with respect to this Agreement, including matters related to the calculation of the cost formula and accuracy of fees charged and provision of information related to the same. The SEC shall be permitted to attend the meetings as an observer.

b. *Reports.* FINRA shall provide the reports set forth in Exhibit C hereto and any additional reports related to this Agreement reasonably requested by a majority vote of all representatives to the Exchange Committee at each Exchange Committee meeting, or more often as the Participating Organizations deem appropriate, but no more often than once every quarterly billing period.

8. *Customer Complaints.* If a Participating Organization receives a copy of a customer complaint relating to Insider Trading or other activity or conduct that is within FINRA's Regulatory Responsibilities as set forth in this Agreement, the Participating Organization shall promptly forward to FINRA, as applicable, a copy of such customer complaint.

9. *Parties to Make Personnel Available as Witnesses.* Each Participating Organization shall make its personnel available to FINRA to serve as testimonial or non-testimonial witnesses as necessary to assist FINRA in fulfilling the Regulatory Responsibilities allocated under this Agreement. FINRA shall provide reasonable advance notice when practicable and shall work with a Participating Organization to accommodate reasonable scheduling conflicts within the context and demands as the entity with ultimate regulatory responsibility. The Participating Organization shall pay all reasonable travel and other expenses incurred by its employees to the extent that FINRA requires such employees to serve as witnesses, and provide information or other assistance pursuant to this Agreement.

10. *Market Data; Sharing of Work-Papers, Data and Related Information.*

a. *Market Data.* FINRA shall obtain raw market data necessary to the performance of regulation under this Agreement from (a) the Consolidated Tape Association (''CTA'') and (b) the NASDAQ Unlisted Trading Privileges Plan.

b. *Sharing.* A Participating Organization shall make available to FINRA information necessary to assist FINRA in fulfilling the Regulatory Responsibilities assumed under the terms of this Agreement. Such information shall include *any* information collected by a Participating Organization in the course of performing its regulatory obligations under the Act, including information relating to an on-going disciplinary investigation or action against a member, the amount of a fine imposed on a member, financial information, or information regarding proprietary trading systems gained in the course of examining a member (''Regulatory Information''). This Regulatory Information shall be used by FINRA solely for the purposes of fulfilling its Regulatory Responsibilities.

c. *No Waiver of Privilege.* The sharing of documents or information between the parties pursuant to this Agreement shall not be deemed a waiver as against third parties of regulatory or other privileges relating to the discovery of documents or information.

d. *Intellectual Property.*

(i) *Existing Intellectual Property.* FINRA is and will remain the owner of all right, title and interest in and to the proprietary Intellectual Property it employs in the provision of regulation hereunder (including the SONAR system), and any derivative works thereof. To the extent certain elements of FINRA's systems, or portions thereof, may be licensed or leased from third parties, all such third party elements shall remain the property of such third

parties, as applicable. Likewise, any other Participating Organization is and will remain the owner of all right, title and interest in and to its own existing proprietary Intellectual Property.

(ii) *Enhancements to Existing Intellectual Property or New Developments.* In the event FINRA (a) makes any changes, modifications or enhancements to its Intellectual Property for any reason, or (b) creates any newly developed Intellectual Property for any reason, including as a result of requested enhancements or new development by the Exchange Committee (collectively, the ''New IP''), the Participating Organizations acknowledge and agree that FINRA shall be deemed the owner of the New IP created by it (and any derivative works thereof), and shall retain all right, title and interest therein and thereto, and each other Participating Organization hereby irrevocably assigns, transfers and conveys to FINRA without further consideration all of its right, title and interest in or to all such New IP (and any derivative works thereof).

(iii) *Fees for New IP.* FINRA will not charge the Participating Organizations any fees for any New IP created and used by FINRA; provided, however, that FINRA will be permitted to charge fees for software maintenance work performed on systems used in the discharge of its duties hereunder.

11. *Special or Cause Examinations.* Nothing in this Agreement shall restrict or in any way encumber the right of a party to conduct special or cause examinations of Common FINRA Members as any party, in its sole discretion, shall deem appropriate or necessary.

12. *Dispute Resolution Under this Agreement.*

a. *Negotiation.* The parties to this Agreement will attempt to resolve any disputes through good faith negotiation and discussion, escalating such discussion up through the appropriate management levels until reaching the executive management level. In the event a dispute cannot be settled through these means, the parties shall refer the dispute to binding arbitration.

b. *Binding Arbitration.* All claims, disputes, controversies, and other matters in question between the parties to this Agreement arising out of or relating to this Agreement or the breach thereof that cannot be resolved by the parties will be resolved through binding arbitration. Unless otherwise agreed by the parties, a dispute submitted to binding arbitration pursuant to this paragraph shall be resolved using the following procedures:

(i) The arbitration shall be conducted in the city of New York in accordance with the Commercial Arbitration Rules of the American Arbitration Association and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof; and

(ii) There shall be three arbitrators, and the chairperson of the arbitration panel shall be an attorney.

13. *Limitation of Liability.* As between the Participating Organizations, no Participating Organization, including its respective directors, governors, officers, employees and agents, will be liable to any other Participating Organization, or its directors, governors, officers, employees and agents, for any liability, loss or damage resulting from any delays, inaccuracies, errors or omissions with respect to its performing or failing to perform regulatory responsibilities, obligations, or functions, except (a) as otherwise provided for under the Act, (b) in instances of a Participating Organization's gross negligence, willful misconduct or reckless disregard with respect to another Participating Organization, (c) in instances of a breach of confidentiality obligations owed to another Participating Organization, or (d) in the case of any Participating Organization paying fees hereunder, for any payments due. The Participating Organizations understand and agree that the Regulatory Responsibilities are being performed on a good faith and best effort basis and no warranties, express or implied, are made by any Participating Organization to any other Participating Organization with respect to any of the responsibilities to be performed hereunder. This paragraph is not intended to create liability of any Participating Organization to any third party.

14. *SEC Approval.*

a. The parties agree to file promptly this Agreement with the SEC for its review and approval. FINRA shall file this Agreement on behalf, and with the explicit consent, of all Participating Organizations.

b. If approved by the SEC, the Participating Organizations will notify their members of the general terms of this Agreement and of its impact on their members.

15. *Subsequent Parties; Limited Relationship.* This Agreement shall inure to the benefit of and shall be binding upon the Participating Organizations hereto and their respective legal representatives, successors, and assigns. Nothing in this Agreement, expressed or implied, is intended or shall: (a) Confer on any person other than the Participating Organizations hereto, or their respective legal representatives, successors, and assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement, (b) constitute the Participating Organizations hereto partners or participants in a joint venture, or (c) appoint one Participating Organization the agent of the other.

16. *Assignment.* No Participating Organization may assign this Agreement without the prior written consent of all the other Participating Organizations, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that any Participating Organization may assign this Agreement to a corporation controlling, controlled by or under common control with the Participating Organization without the prior written consent of any other party.

17. *Severability.* Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

18. *Termination.*

a. Any Participating Organization may cancel its participation in this Agreement at any time, provided that it has given 180 days written notice to the other Participating Organizations (or in the case of a change of control in ownership of a Participating Organization, such other notice time period as that Participating Organization may choose), and provided that such termination has been approved by the SEC. The cancellation of its participation in this Agreement by any Participating Organization shall not terminate this Agreement as to the remaining Participating Organizations.

b. The Regulatory Responsibilities assumed under this Agreement by FINRA may be terminated by FINRA against any Participating Organization as follows. The Participating Organization will have thirty (30) days from receipt to satisfy the invoice. If the Participating Organization fails to satisfy the invoice within thirty (30) days of receipt (''Default''), FINRA will notify the Participating Organization of the Default. The Participating Organization will have thirty (30) days from receipt of the Default notice to satisfy the invoice.

c. FINRA will have the right to terminate the Regulatory Responsibilities assumed under this Agreement if a Participating

Organization has Defaulted in its obligation to pay the invoice on more than three (3) occasions in any rolling twenty-four (24) month period.

19. *Intermarket Surveillance Group (''ISG'').* In order to participate in this Agreement, all Participating Organizations to this Agreement must be members of the ISG.

20. *General.* The Participating Organizations agree to perform all acts and execute all supplementary instruments or documents that may be reasonably necessary or desirable to carry out the provisions of this Agreement.

21. *Liaison and Notices.* All questions regarding the implementation of this Agreement shall be directed to the persons identified below, as applicable. All notices and other communications required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been duly given upon (i) actual receipt by the notified party or (ii) constructive receipt (as of the date marked on the return receipt) if sent by certified or registered mail, return receipt requested, to the following addresses:

For Cboe BZX Exchange, Inc.: Greg Hoogasian, Chief Regulatory Officer, Cboe BZX Exchange, Inc., 400 S. LaSalle Street, Chicago, IL 60605, Telephone: (312) 786–7844, Facsimilie: (312) 786–7982, Email: *ghoogasian@cboe.com*

For Cboe BYX Exchange, Inc.: Greg Hoogasian, Chief Regulatory Officer, Cboe B[Z]*YX* Exchange, Inc., 400 S. LaSalle Street, Chicago, IL 60605, Telephone: (312) 786–7844, Facsimilie: (312) 786–7982, Email: *ghoogasian@cboe.com*

For NYSE Chicago, Inc.: Anthony Albanese, Chief Regulatory Officer, NYSE Group, Inc., 11 Wall Street, New York, NY 10005, Telephone: (212) 656–8297, Facsimile: (212) 656–2027, Email: *Anthony.Albanese@theice.com*

For Cboe EDGA Exchange, Inc.: Greg Hoogasian, Chief Regulatory Officer, Cboe [BZX]*EDGA* Exchange, Inc., 400 S. LaSalle Street, Chicago, IL 60605, Telephone: (312) 786–7844, Facsimilie: (312) 786–7982, Email: *ghoogasian@cboe.com*

For Cboe EDGX Exchange, Inc.: Greg Hoogasian, Chief Regulatory Officer, Cboe [BZX]*EDGX* Exchange, Inc., 400 S. LaSalle Street, Chicago, IL 60605, Telephone: (312) 786–7844, Facsimilie: (312) 786–7982, Email: *ghoogasian@cboe.com*

For Financial Industry Regulatory Authority, Inc.: Sam Draddy, Senior Vice President, Office of Fraud Detection and Market Intelligence, FINRA, 1735 K Street NW, Washington, DC 20006, Telephone: (240) 386–5042, Facsimile: (301) 407–4635, Email: *Sam.Draddy@finra.org*

For MEMX LLC: Scott Palmer, Chief Regulatory Officer, MEMX LLC, 111 Town Square Place, Suite 520, Jersey City, NJ 07310, Telephone: (201) 596–6995, Facsimilie: (201) 331–7904, Email: *spalmer@memx.com*

For MIAX PEARL, LLC: Edward Deitzel, Chief Regulatory Officer, Miami International Securities Exchange, LLC, 7 Roszel Road, Suite 1A, Princeton, NJ 08540, Telephone: (609) 897–1466, Facsimile:, Email: *edeitzel@miaxoptions.com*

For Nasdaq BX, Inc.: John A. Zecca, Executive Vice President and Chief Legal and Regulatory Officer, The Nasdaq Stock Market LLC, 805 King Farm Boulevard, Rockville, MD 20850, Telephone: (301) 978–8498, Facsimile: (301) 978–8472, Email: *John.Zecca@nasdaq.com*

For Nasdaq PHLX LLC: Joseph P. Cusick, Chief Regulatory Officer, Nasdaq PHLX LLC, FMC Tower, Level 8, 2929 Walnut Street, Philadelphia, PA 19104, Telephone: (215) 496–1576, Facsimile: (215) 496–5104, Email: *joseph.cusick@nasdaq.com*

For The Nasdaq Stock Market LLC: John A. Zecca, Executive Vice President and Chief Legal and Regulatory Officer, The Nasdaq Stock Market LLC, 805 King Farm Boulevard, Rockville, MD 20850, Telephone: (301) 978–8498, Facsimile: (301) 978–8472, Email: *John.Zecca@nasdaq.com*

For NYSE National, Inc.: Anthony Albanese, Chief Regulatory Officer, NYSE National, Inc., 11 Wall Street, New York, NY 10005, Telephone: (212) 656–8927, Facsimile: (212) 656–2027, Email: *Anthony.albanese@theice.com*

For New York Stock Exchange LLC: Anthony Albanese, Chief Regulatory Officer, NYSE, 11 Wall Street, New York, NY 10005, Telephone: (212) 656–8927 Facsimile: (212) 656–2027, Email: *Anthony.albanese@theice.com*

For NYSE American LLC: Anthony Albanese, Chief Regulatory Officer, NYSE American, 11 Wall Street, New York, NY 10005, Telephone: (212) 656–8927, Facsimile: (212) 656–2027, Email: *Anthony.albanese@theice.com*

For NYSE Arca, Inc.: Anthony Albanese, Chief Regulatory Officer, NYSE Arca, 11 Wall Street, New York, NY 10005, Telephone: (212) 656–8927, Facsimile: (212) 656–2027, Email: *Anthony.albanese@theice.com*

For Investors' Exchange LLC.: Claudia Crowley, Chief Regulatory Officer, IEX, 3 World Trade Center, 175 Greenwich Street 58th Floor, New York, NY 10007, Telephone: (646) 343–2041, Facsimile: (646) 365–6862, Email: *Claudia.crowley@iextrading.com*

For Long-Term Stock Exchange, Inc.: Gary Goldsholle, Chief Regulatory Officer, LTSE, 100 Greenwich St., Suite 11A, New York, NY 10006, Telephone: (202) 580–5752, Email: *Gary@longtermstockexchange.com*

22. *Confidentiality.* The parties agree that documents or information shared shall be held in confidence, and used only for the purposes of carrying out their respective regulatory obligations under this Agreement. No party shall assert regulatory or other privileges as against the other with respect to Regulatory Information that is required to be shared pursuant to this Agreement, as defined by paragraph 10, above.

23. *Regulatory Responsibility.* Pursuant to Section 17(d)(1)(A) of the Act, and Rule 17d–2 thereunder, the Participating Organizations jointly and severally request the SEC, upon its approval of this Agreement, to relieve the Participating Organizations, jointly and severally, of any and all responsibilities with respect to the matters allocated to FINRA pursuant to this Agreement for purposes of §§ 17(d) and 19(g) of the Act.

24. *Governing Law.* This Agreement shall be deemed to have been made in the State of New York, and shall be construed and enforced in accordance with the law of the State of New York, without reference to principles of conflicts of laws thereof. Each of the parties hereby consents to submit to the jurisdiction of the courts of the State of New York in connection with any action or proceeding relating to this Agreement.

25. *Survival of Provisions.* Provisions intended by their terms or context to survive and continue notwithstanding delivery of the regulatory services by FINRA, the payment of the Fees by the Participating Organizations, and any expiration of this Agreement shall survive and continue.

26. *Amendment.*

a. This Agreement may be amended to add a new Participating Organization, provided that such Participating Organization does not assume regulatory responsibility, solely by an amendment executed by FINRA and such new Participating Organization. All other Participating Organizations expressly consent to allow FINRA to add new Participating Organizations to this Agreement as provided above. FINRA will promptly notify all Participating Organizations of any such

amendments to add a new Participating Organization.

b. All other amendments must be approved by each Participating Organization. All amendments, including adding a new Participating Organization, must be filed with and approved by the SEC before they become effective.

27. *Effective Date.* The Effective Date of this Agreement will be the date the SEC declares this Agreement to be effective pursuant to authority conferred by § 17(d) of the Act, and SEC Rule 17d–2 thereunder.

28. *Counterparts.* This Agreement may be executed in any number of counterparts, including facsimile, each of which will be deemed an original, but all of which taken together shall constitute one single agreement between the parties.

In witness whereof, the parties hereto have each caused this Agreement for the Allocation of Regulatory Responsibility of Surveillance, Investigation and Enforcement for Insider Trading to be signed and delivered by its duly authorized representative.

Exhibit A: Common Insider Trading Rules

1. Securities Exchange Act of 1934 Section 10(b), and rules and regulations promulgated there under in connection with insider trading, including SEC Rule 10b–5 (as it pertains to insider trading), which states that:

Rule 10b–5—Employment of Manipulative and Deceptive Devices It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,

a. To employ any device, scheme, or artifice to defraud,

b. To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

c. To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

2. Securities Exchange Act of 1934 Section 17(a), and rules and regulations promulgated there under in connection with insider trading, including SEC Rule 17a–3 (as it pertains to insider trading).

3. *Securities Exchange Act of 1934 Rule 14e–3—Transactions in securities on the basis of material, nonpublic information in the context of tender offers.*

4. *Securities Exchange Act of 1934 Section 15(g) in connection with insider trading and protection of material, nonpublic information.*

5. The following SRO Rules as they pertain to violations of insider trading:

FINRA Rule 2010 (Standards of Commercial Honor and Principles of Trade)
FINRA Rule 2020 (Use of Manipulative, Deceptive or Other Fraudulent Devices)
FINRA Rule 3110 (Supervision)
FINRA Rule 4511 (General Requirements)
FINRA Rule 4512 (Customer Account Information)
MEMX Rule 3.1 (Business Conduct of Members)
MEMX Rule 3.2 (Violations Prohibited)
MEMX Rule 3.3 (Use of Fraudulent Devices)
MEMX Rule 4.1 (Requirements)
MEMX Rule 5.1 (Written Procedures)
MEMX Rule 5.3 (Records)
MEMX Rule 5.5 (Prevention of Misuse of Material, Nonpublic Information)
MEMX Rule 12.4 (Manipulative Transactions)
MIAX PEARL Equities Rule 2100 (Business Conduct of Members)
MIAX PEARL Equities Rule 2101 (Violations Prohibited)
MIAX PEARL Equities Rule 2102 (Use of Fraudulent Devices)
MIAX PEARL Equities Rule 2200 (General Requirements)
MIAX PEARL Equities Rule 2201 (Customer Account Information)
MIAX PEARL Equities Rule 2300 (Supervision)
MIAX PEARL Equities Rule 2303 (Prevention of Misuse of Material, Non-Public Information)
MIAX PEARL Equities Rule 2703 (Manipulative Transactions)
NYSE Rule 440 (Books and Records)
NYSE Rule 476(a) (Disciplinary Proceedings Involving Charges Against Members, Member Organizations, Principal Executives, Approved Persons, Employees, or Others)
NYSE Rule 2010 (Standards of Commercial Honor and Principles of Trade)
NYSE Rule 2020 (Use of Manipulative, Deceptive or Other Fraudulent Devices)
NYSE Rule 3110 (Supervision)
NYSE American General and Floor Rule 3(j) (General Prohibitions and Duty to Report)
NYSE American Rule 2.24–E (ETP Books and Records)
NYSE American Rule 476(a) (Disciplinary Proceedings Involving Charges Against Members, Member Organizations, Principal Executives, Approved Persons, Employees, or Others)
NYSE American Rule 2010 (Equities. Standards of Commercial Honor and Principles of Trade)
NYSE American Rule 2020 (Equities. Use of Manipulative, Deceptive or Other Fraudulent Devices)
NYSE American Rule 3110 (Equities. Supervision)
Nasdaq Rule General 9, Section 1(a) (Standards of Commercial Honor and Principles of Trade)
Nasdaq Rule General 9, Section 1(g) (Use of Manipulative, Deceptive or Other Fraudulent Devices)
Nasdaq Rule General 9, Section 20 (Supervision)
Nasdaq Rule General 9, Section 43 (General Requirements)
Nasdaq Rule General 9, Section 45 (Customer Account Information)
CHX Article 8, Rule 3 (Fraudulent Acts)
CHX Article 9, Rule 2 (Just & Equitable Trade Principles)
CHX Article 11, Rule 2 (Maintenance of Books and Records)
CHX Article 6, Rule 5 (Supervision of [Registered Persons] *Representatives* and Branch and Resident Offices)
[PHLX Rule Options 9, Section 1 (Conduct Inconsistent with Just and Equitable Principles of Trade)] *PSX Rule 3503(a) Conduct Inconsistent with Just and Equitable Principles of Trade*
PHLX Rule General 9, Section 20 (Supervision)
[PHLX Rule Options 6E, Section 1 (Maintenance, Retention and Furnishing of Books, Records and Other Information)]
PHLX Rule General 9, Section 21 (Supervisory Procedures Relating to ITSFEA and to Prevention of Misuse or Material Nonpublic Information)
PHLX Rule General 9, Section 1(b) (Manipulative Operations)
NYSE Arca Rule 2.28 (Books and Records)
NYSE Arca Rule 5.1–E(a)(2)(v)(D) (General Provisions and Unlisted Trading Privileges)
NYSE Arca Rule 11.1 (Adherence to Law *and Good Business Practice)*
NYSE Arca Rule 11.2(b) (Prohibited Acts (J&E))
NYSE Arca Rule 11.3 (Prevention of the Misuse of Material, Nonpublic Information)
NYSE Arca Rule 11.18 (Supervision)
NYSE Arca Rule 9.1–E(c) (Office Supervision)
NYSE Arca Rule 9.2–E(b) (Account Supervision)
NYSE Arca Rule 9.2–E(c) (Customer Records)

NYSE Arca Rule 9.2010–E (Standards of Commercial Honor and Principles of Trade)
NYSE Arca Rule 9.2020–E (Use of Manipulative, Deceptive or Other Fraudulent Devices)
NYSE National Rule 5.1(a)(2)(D)(iv) (Unlisted Trading Privileges)
NYSE National Rule 11.3.1 (Business Conduct of ETP Holders)
NYSE National Rule 11.3.2 (Violations Prohibited)
NYSE National Rule 11.3.3 (Use of Fraudulent Devices)
NYSE National Rule 11.4.1 (Requirements)
NYSE National Rule 11.5.1 (Written Procedures)
NYSE National Rule 11.5.3 (Records)
NYSE National Rule 11.5.5 (Prevention of the Misuse of Material, Nonpublic Information)
NYSE National Rule 11.12.4 (Manipulative Transactions)
BX Rule General 9, Section 1(a) (Standards of Commercial Honor and Principles of Trade)
BX Rule General 9, Section 1(i) (Use of Manipulative, Deceptive or Other Fraudulent Devices)
BX Rule General 9, Section 20 (Supervision)
BX Rule General 9, Section 30(a) and (b) (Books and Records; Financial Condition)
BZX Rule 3.1 (Business Conduct of Members)
BZX Rule 3.2 (Violations Prohibited)
BZX Rule 3.3 (Use of Fraudulent Devices)
BZX Rule 4.1 (Requirements)
BZX Rule 5.1 (Written Procedures)
BZX Rule 5.3 (Records)
BZX Rule 5.5 (Prevention of the Misuse of Material, Non-Public Information)
BZX Rule 12.4 (Manipulative Transactions)
BYX Rule 3.1 (Business Conduct of ETP Holders)
BYX Rule 3.2 (Violations Prohibited)
BYX Rule 3.3 (Use of Fraudulent Devices)
BYX Rule 4.1 (Requirements)
BYX Rule 5.1 (Written Procedures)
BYX Rule 5.3 (Records)
BYX Rule 5.5 (Prevention of the Misuse of Material, Non-Public Information)
BYX Rule 12.4 (Manipulative Transactions)
EDGA Rule 3.1 (Business Conduct of Members)
EDGA Rule 3.2 (Violations Prohibited)
EDGA Rule 3.3 (Use of Fraudulent Devices)
EDGA Rule 4.1 (Requirements)
EDGA Rule 5.1 (Written Procedures)
EDGA Rule 5.3 (Records)
EDGA Rule 5.5 (Prevention of *the* Misuse of Material, Nonpublic Information)
EDGX Rule 12.4 (Manipulative Transactions)
IEX Rule 3.110 (Business Conduct of Members)
IEX Rule 3.120 (Violations Prohibited)
IEX Rule 3.130 (Use of Fraudulent Devices)
IEX Rule 4.511 (General Requirements)
IEX Rule 4.512 (Customer Account Information)
IEX Rule 5.110 (Supervision)
IEX Rule 5.150 (Prevention of *the* Misuse of Material, Non-Public Information)
IEX Rule 10.140 (Manipulative Transactions)
LTSE Rule 3.110 (Business Conduct of Members)
LTSE Rule 3.120 (Violations Prohibited)
LTSE Rule 3.130 (Use of Fraudulent Devices)
LTSE Rule 4.511 (General Requirements)
LTSE Rule 4.512 (Customer Account Information)
LTSE Rule 5.110 (Supervision)
LTSE Rule 5.150 (Prevention of *the* Misuse of Material, Non-Public Information)
LTSE Rule 10.140 (Manipulative Transactions)

Exhibit B: Fee Schedule

1. *Fees.* FINRA shall charge each Participating Organization a Quarterly Fee in arrears for the performance of FINRA's Regulatory Responsibilities under the Plan (each, a ''Quarterly Fee,'' and together, the ''Fees'').

a. *Quarterly Fees.*

(1) Quarterly Fees for each Participating Organization will be charged by FINRA according to the Participating Organization's ''Percentage of Publicly Reported Trades'' occurring over three-month billing periods. The ''Percentage of Publicly Reported Trades'' shall equal a Participating Organization's total number of reported NMS Stock trades during the relevant period as specified in paragraph 1b. (the ''Numerator''), divided by the total number of all NMS Stock trades for the same period as specified in paragraph 1b. (the ''Denominator''). For purposes of clarification, ADF and Trade Reporting Facility (''TRF'') activity will be included in the Denominator. Additionally, with regard to TRFs, TRF trade volume will be charged to FINRA. Consequently, for purposes of calculating the Quarterly Fees, the volume for each Participant Organization's TRF will be calculated separately (that is, TRF volume will be broken out from the Participating Organization's overall Percentage of Publicly Reported Trades) and the fees for such will be billed to FINRA in accordance with paragraph 1a.(2), rather than to the applicable Participating Organization.

(2) The Quarterly Fees shall be determined by FINRA in the following manner for each Participating Organization:

(a) Less than 1.0%: If the Participating Organization's Percentage of Publicly Reported Trades for the relevant three-month billing period is less than 1.0%, the Quarterly Fee shall be $6,250, per quarter (''Static Fee'');

(b) Less than 2.0% but No Less than 1.0%: If the Participating Organization's Percentage of Publicly Reported Trades for the relevant three-month billing period is less than 2.0% but no less than 1.0%, the Quarterly Fee shall be $18,750, per quarter (''Static Fee'');

(c) 2.0% or Greater: If the Participating Organization's Percentage of Publicly Reported Trades for the relevant three-month billing period is 2.0% or greater, the Quarterly Fee shall be the amount equal to the Participating Organization's Percentage of Publicly Reported Trades multiplied by FINRA's total charge (''Total Charge'') for its performance of Regulatory Responsibilities for the relevant three-month billing period.

(3) Increases in Static Fees. FINRA will re-evaluate the Quarterly Fees on an annual basis during the annual budget process outlined in paragraph 1.c. below. During each annual re-evaluation, FINRA will have the discretion to increase the Static Fees by a percentage no greater than the percentage increase in the Final Budget over the preceding year's Final Budget. Any changes to the Static Fees shall not require an amendment to this Agreement, but rather shall be memorialized through the budget process.

(4) Increases in Total Charges. Any change in the Total Charges (whether a Final Budget increase or any mid year change) shall not require an amendment to this Agreement, but rather shall be memorialized through the budget process.

b. *Source of Data.* For purposes of calculation of the Percentage of Publicly Reported Trades for each Participating Organization, FINRA will use trades reported to the two SIPs (a) the Consolidated Tape Association (''CTA''), and (b) the Unlisted Trading Privileges Plan. In each case, FINRA will use the total trades as may be adjusted by the Participating Organization. Adjustments will include any separation or breakup of the number of trades as a result of reporting of bunched or bundled trades by a Participating Organization but will not

include any adjustments resulting from single-priced opening, reopening or closing auction trades. Each Participating Organization that reports bunched or bundled trades will report to FINRA any adjustments to its total number of NMS Stock trades on the 15th of the month following the end of the quarter.

c. *Annual Budget Forecast.* FINRA will notify the Participating Organizations of the forecasted costs of its insider trading program for the following calendar year by close of business on October 15 of the then-current year (the ''Forecasted Budget''). FINRA shall use best efforts to provide as accurate a forecast as possible. FINRA shall then provide a final submission of the costs following approval of such costs by its Board of Governors (the ''Final Budget''). Subject to paragraph 1d. below, in the event of a difference between the Forecasted Budget and the Final Budget, the Final Budget will govern.

d. *Increases in Fees over Five Percent.*

(1) In the event that any proposed increase to Fees by FINRA for a given calendar year (which increase may arise either during the annual budgetary forecasting process or through any mid-year increase) will result in a cumulative increase in such calendar year's Fees of more than five percent (5%) above the preceding calendar year's Final Budget (a ''Major Increase''), then senior management of any Participating Organization (a) that is a Listing Market or (b) for which the Percentage of Publicly Reported Trades is then currently twenty percent (20%) or greater, shall have the right to call a meeting with the senior management of FINRA in order to discuss any disagreement over such proposed Major Increase. By way of example, if FINRA provides a Final Budget for 2011 that represents an 4% increase above the Final Budget for 2010, the terms of this paragraph 1.d.(1) shall not apply; if, however, in April of 2011, FINRA notifies the Exchange Committee of an increase in Fees that represents an additional 3% increase above the Final Budget for 2010, then the increase shall be deemed a Major Increase, and the terms of this paragraph 1.d.(1) shall become applicable (*i.e.,* 4% and 3% represents a cumulative increase of 7% above the 2010 Final Budget).

(2) In the event that senior management members of the involved parties are unable to reach an agreement regarding the proposed Major Increase, then the matter shall be referred back to the Exchange Committee for final resolution. Prior to the matter being referred back to the Exchange Committee, nothing shall prohibit the parties from conferring with the SEC. Resolution shall be reached through a vote of no fewer than all Participating Organizations seated on the Exchange Committee, and a simple majority shall be required in order to reject the proposed Major Increase.

e. *Time Tracking.* FINRA shall track the time spent by staff on insider trading responsibilities under this Agreement; however, time tracking will not be used to allocate costs.

2. *Invoicing and Payment.* FINRA shall invoice each Participating Organization for the Quarterly Fee associated with the regulatory activities performed pursuant to this Agreement during the previous three-month billing period within forty five (45) days of the end of such previous 3-month billing period. A Participating Organization shall have thirty (30) days from date of invoice to make payment to FINRA on such invoice. The invoice will reflect the Participating Organization's Percentage of Publicly Reported Trades for that billing period.

3. *Disputed Invoices; Interest.* In the event that a Participating Organization disputes an invoice or a portion of an invoice, the Participating Organization shall notify FINRA in writing of the disputed item(s) within fifteen (15) days of receipt of the invoice. In its notification to FINRA of the disputed invoice, the Participating Organization shall identify the disputed item(s) and provide a brief explanation of why the Participating Organization disputes the charges. FINRA may charge a Participating Organization interest on any undisputed invoice or the undisputed portions of a disputed invoice that a Participating Organization fails to pay within thirty (30) days of its receipt of such invoice. Such interest shall be assessed monthly. Interest will mean one and one half percent per month, or the maximum allowable under applicable law, whichever is less.

4. *Taxes.* In the event any governmental authority deems the regulatory activities allocated to FINRA to be taxable activities similar to the provision of services in a commercial context, the other Participating Organizations agree that they shall bear full responsibility, on a joint and several basis, for the payment of any such taxes levied on FINRA, or, if such taxes are paid by FINRA directly to the governmental authority, the other Participating Organizations agree that they shall reimburse FINRA for the amount of any such taxes paid.

5. *Audit Right; Record Keeping.*

a. *Audit Right.*

(i) Once every rolling twelve (12) month period, FINRA shall permit no more than one audit (to be performed by one or more Participating Organizations) of the Fees charged by FINRA to the Participating Organizations hereunder and a detailed cost analysis supporting such Fees (the ''Audit''). The Participating Organization or Organizations that conduct this Audit will select a nationally-recognized independent auditing firm (or may use its regular independent auditor, providing it is a nationally-recognized auditing firm) (''Auditing Firm'') to act on its, or their behalf, and will provide reasonable notice to other Participating Organizations of the Audit. FINRA will permit the Auditing Firm reasonable access during FINRA's normal business hours, with reasonable advance notice, to such financial records and supporting documentation as are necessary to permit review of the accuracy of the calculation of the Fees charged to the Participating Organizations. The Participating Organization, or Organizations, as applicable, other than FINRA, shall be responsible for the costs of performing any such audit.

(ii) If, through an Audit, the Exchange Committee determines that FINRA has inaccurately calculated the Fees for any Participating Organization, the Exchange Committee will promptly notify FINRA in writing of the amount of such difference in the Fees, and, if applicable, FINRA shall issue a reimbursement of the overage amount to the relevant Participating Organization(s), less any amount owed by the Participating Organization under any outstanding, undisputed invoice(s). If such an Audit reveals that any Participating Organization paid less than what was required pursuant to the Agreement, then that Participating Organization shall promptly pay FINRA the difference between what the Participating Organization owed pursuant to the Agreement and what that Participating Organization originally paid FINRA. If FINRA disputes the results of an Audit regarding the accuracy of the Fees, it will submit the dispute for resolution pursuant to the dispute resolution procedures in paragraph 12 of the Agreement.

(iii) In the event that through the review of any supporting documentation provided during the Audit, any one or more Participating Organizations desire to discuss with FINRA the supporting documentation and any questions arising therefrom with regard to the manner in which regulation was conducted, the Participating Organization(s) shall call a

meeting with FINRA. FINRA shall in turn notify the Exchange Committee of this meeting in advance, and all Participating Organizations shall be welcome to attend (the ''Fee Analysis Meeting''). The parties to this Agreement acknowledge and agree that while FINRA commits to discuss the supporting documentation at the Fee Analysis Meeting, FINRA shall not be subject, by virtue of the above Audit rights or any discussions during the Fee Analysis Meeting or otherwise, to any limitation whatsoever, other than the Increase in Fee provisions set forth in paragraph 1.d. of this Exhibit, on its discretion as to the manner and means by which it conducts its regulatory efforts in its role as the SRO primarily liable for regulatory decisions under this Agreement. To that end, no disagreement among the Participating Organizations as to the manner or means by which FINRA conducts its regulatory efforts hereunder shall be subject to the dispute resolution procedures hereunder, and no Participating Organization shall have the right to compel FINRA to alter the manner or means by which it conducts its regulatory efforts. Further, a Participating Organization shall not have the right to compel a rebate or reassessment of fees for services rendered, on the basis that the Participating Organization would have conducted regulatory efforts in a different manner than FINRA in its professional judgment chose to conduct its regulatory efforts.

b. *Record Keeping.* In anticipation of any audit that may be performed by the Exchange Committee under paragraph 5.a. above, FINRA shall keep accurate financial records and documentation relating to the Fees charged by it under this Agreement.

Exhibit C: Reports

FINRA shall provide the following information in reports to the Exchange Committee, which information covers activity occurring under this Agreement:

1. *Alert Summary Statistics:* Total number of surveillance system alerts generated by quarter along with associated number of reviews and investigations. In addition, this paragraph shall also reflect the number of reviews and investigations originated from a source other than an alert. A separate table would be presented for the trading activity of the NMS Stocks listed on each Participating Organization's exchange.

2008	Surveillance alerts	Investigations
1st Quarter		
2nd Quarter		
3rd Quarter		
4th Quarter		
2008 Total		

2. *Aging of Open Matters:* Would reflect the aging for all currently open matters for the quarterly period being reported. A separate table would be presented for the trading activity of the NMS Stocks listed on each Participating Organization's exchange.

Example:

	Surveillance alerts	Investigations
0–6 months		
6–9 months		
9–12 months		
12+ months		
Total		

3. *Timeliness of Completed Matters:* Would reflect the total age of those matters that were completed or closed during the quarterly period being reported. FINRA will provide total referrals to the SEC.

	Surveillance alerts	Investigations
0–6 months		
6–9 months		
9–12 months		
12+ months		
Total		

4. *Disposition of Closed Matters:* Would reflect the disposition of those matters that were completed or closed during the quarterly period being reported. A separate table would be presented for the trading activity of the NMS Stocks listed on each Participating Organization's exchange.

Example:

	Surveillance YTD	Investigations YTD
No Further Review		
Letter of Caution/Admonition Fine		
Referred to Legal/Enforcement		
Referred to SEC/SRO		
Merged		
Other		
Total		

5. *Pending Reviews.* In addition to the above reports, the Chief Regulatory Officer (CRO) (or his or her designee) of any Participating Organization that is also a Listing Market may inquire about pending reviews involving stocks listed on that Participating Organization's market. FINRA will respond to such inquiries from a CRO; provided, however, that (a) the CRO must hold any information provided by FINRA in confidence and (b) FINRA will not be compelled to provide information in contradiction of any mandate, directive or order from the SEC, US Attorney's Office, the Office of any State Attorney General or court of competent jurisdiction.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. 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 4–566 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 4–566. 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 plan that are filed with the Commission, and all written communications relating to the proposed plan 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 plan also will be available for inspection and copying at the principal offices of the Participating Organizations. 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 *4–566* and should be submitted on or before October 20, 2020.

V. Discussion

The Commission finds that the Plan, as proposed to be amended, is consistent with the factors set forth in Section 17(d) of the Act [14] and Rule 17d–2 thereunder [15] in that it is necessary or appropriate in the public interest and for the protection of investors, fosters cooperation and coordination among SROs, and removes impediments to and fosters the development of the national market system. The Commission continues to believe that the Plan, as amended, should reduce unnecessary regulatory duplication by allocating regulatory responsibility for the surveillance, investigation, and enforcement of Common Rules to FINRA. Accordingly, the proposed amendment to the Plan promotes efficiency by consolidating these regulatory functions in a single SRO.

Under paragraph (c) of Rule 17d–2, the Commission may, after appropriate notice and comment, declare a plan, or any part of a plan, effective. In this instance, the Commission believes that appropriate notice and comment can take place after the proposed amendment is effective. The amendment adds MIAX PEARL as a Participant to the Plan, and adds Exchange Act Rules 14e–3 and 15(g) to the list of rules in Exhibit A.[16] The Commission believes that the current amendment to the Plan does not raise any new regulatory issues that the Commission has not previously considered, and therefore believes that the amended Plan should become effective without any undue delay.

[14] 15 U.S.C. 78q(d).

[15] 17 CFR 240.17d–2.

[16] The Commission notes that the most recent prior amendment to the Plan, which, among other things, added MEMX as a Party to the Plan, was published for comment and the Commission did not receive any comments thereon. *See supra* note 11.

VI. Conclusion

This order gives effect to the amended Plan submitted to the Commission that is contained in File No. 4–566.

It is therefore ordered, pursuant to Section 17(d) of the Act,[17] that the Plan, as amended, filed with the Commission pursuant to Rule 17d–2 on September 18, 2020, is hereby approved and declared effective.

It is further ordered that the Participating Organizations are relieved of those regulatory responsibilities allocated to FINRA under the amended Plan to the extent of such allocation.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

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[17] 15 U.S.C. 78q(d).

[18] 17 CFR 200.30–3(a)(34).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89974; File No. SR–CboeBZX–2020–071]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule

September 23, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 11, 2020, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the fee schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule applicable to its equities trading platform (''BZX Equities'') to: (1) Amend certain standard rates; (2) update the Add Volume Tiers; (3) update the Supplemental Incentive Program Tiers; (4) include a Remove Volume Tier; and (5) include additional Lead Market Maker (''LMM'') Add Volume Tiers.[3]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 13 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[4] no single registered equities exchange has more than 18% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a

[3] The Exchange initially filed the proposed fee changes on September 1, 2020 (SR–CboeBZX–2020–069). On September 11, 2020, the Exchange withdrew that filing and submitted this filing.

[4] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (August 24, 2020), available at *https://markets.cboe.com/us/equities/market_statistics/.*

''Maker-Taker'' model whereby it pays credits to members that provide liquidity and assesses fees to those that remove liquidity. The Exchange's fee schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Currently, for orders priced at or above $1.00, the Exchange provides a standard rebate of $0.0025 per share for orders that add liquidity and assesses a fee of $0.0030 per share for orders that remove liquidity. For orders priced below $1.00, the Exchange does not assess a fee for orders that add liquidity and assesses a fee of 0.30% of total dollar value for orders that remove liquidity. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Proposed Amendment to Standard Rates

As stated above, the Exchange currently assesses a standard rebate of $0.0025 per share for orders that add liquidity in securities priced at $1.00 or more. Also, for orders in securities below $1.00, it does not assess a standard fee for orders that add liquidity and assesses a fee of .30% of total dollar value per share for orders that remove liquidity. The Exchange proposes to amend the standard rate for orders that add liquidity in securities priced at $1.00 or more from a standard rebate of $0.0025 per share to $0.0020 per share and reflects this change in the Fee Codes and Associated Fee where applicable (*i.e.,* corresponding to fee codes B, V, and Y). The Exchange also proposes to amend the standard rates for orders in securities priced under $1.00 that add liquidity by providing for a standard rebate of $0.00009 per share, and reflects this change in footnote 7 which is appended to corresponding fee codes that add liquidity (*i.e.,* B, V and Y). The Exchange notes that these standard rates are in line with, yet also competitive with, rates assessed by other equities exchanges on orders in securities priced at $1.00 or more [5] and in securities priced below $1.00.[6] The Exchange notes, too, that its affiliated exchange, Cboe EDGX Exchange, Inc. (''EDGX Equities''), is simultaneously submitting a fee change to amend its same current standard rates for orders in securities under $1.00 that add liquidity in the same manner.

Proposed Updates to the Add Volume Tiers

The Exchange currently offers five Add Volume Tiers under footnote 1 of the Fee Schedule. The Add Volume Tiers provide Members with opportunities to receive incrementally increasing enhanced rebates for their liquidity adding orders that yield fee codes ''B'' [7], ''V'' [8], and ''Y'' [9], upon reaching incrementally more difficult criteria under each tier. Specifically, the Add Volume Tiers currently offer the following:

- Tier 1 offers an enhanced rebate of $0.0028 for qualifying orders (*i.e.,* yielding fee codes B, V or Y) where a Member has an ADAV [10] as a percentage of TCV [11] greater than or equal to 0.20%;
- Tier 2 offers an enhanced rebate of $0.0029 for qualifying orders where a Member has an ADAV as a percentage of TCV greater than or equal to 0.30%;
- Tier 3 offers an enhanced rebate of $0.0030 for qualifying orders where a Member has an ADAV as a percentage of TCV greater than or equal to 0.50%;
- Tier 4 offers an enhanced rebate of $0.0031 for qualifying orders where a Member has an ADAV as a percentage of TCV greater than or equal to 1.00%; and
- Tier 5 offers an enhanced rebate of $0.0032 for qualifying orders where a Member has an ADAV as a percentage of TCV greater than or equal to 1.25%.

The Exchange proposes to amend the rebates offered and the criteria under each Add Volume Tier, as well as proposes an additional Tier 6, as follows:

- Proposed Tier 1 offers an enhanced rebate of $0.0025 for qualifying orders where a Member has an ADAV greater than or equal to 1,000,000;
- Proposed Tier 2 offers an enhanced rebate of $0.0027 for qualifying orders where a Member has an ADAV as a percentage of TCV greater than or equal to 0.10%;
- Proposed Tier 3 offers an enhanced rebate of $0.0028 for qualifying orders where a Member has an ADAV as a percentage of TCV greater than or equal to 0.20%;
- Proposed Tier 4 offers an enhanced rebate of $0.0029 for qualifying orders where a Member has an ADAV as a percentage of TCV greater than or equal to 0.25%;
- Proposed Tier 5 offers an enhanced rebate of $0.0030 for qualifying orders where a Member has an ADAV as a percentage of TCV greater than or equal to 0.40%; and
- Proposed new Tier 6 offers an enhanced rebate of $0.0031 for qualifying orders where a Member has an ADAV as a percentage of TCV greater than or equal to 0.85%.

The proposed rule change to Tiers 1 through 5 eases the difficulty in reaching the tiers' criteria while amending the enhanced rebates to correspond with the ease in criteria and proposed Tier 6 offers Members an additional opportunity to receive a rebate on their qualifying orders. The proposed restructuring of the current Add Volume Tiers and the new criteria and reduced fee offered in proposed Tier 6 are designed to provide Members with increased incentives to receive enhanced rebates on their liquidity adding displayed orders by increasing their add volume order flow in order to achieve the proposed eased and/or additional criteria.

Proposed Updates to the Supplemental Incentive Program Tiers

The Exchange currently offers three different Supplemental Incentive Program Tiers under footnote 1 of the Fee Schedule, wherein a Member may receive an additional rebate for qualifying orders where a Member adds

[5] *See* NYSE Price List 2020, ''Transactions in stocks with a per share stock price of $1.00 or more'', which assesses a fee of ranging from no charge to $0.0018 for various orders in securities priced at $1.00 or more; *and* Nasdaq Pricing 7, Section 118(a)(1), which assesses a charge ranging from no charge to $0.0035 or a credit ranging from $0.00005 to $0.00325 for various orders in securities priced at $1.00 or more.

[6] *See* NYSE Price List 2020, ''Transactions in stocks with a per share stock price less than $1.00'', which either does not assess a charge or assesses a charge of 0.3% for various orders in securities priced below $1.00; *and* Nasdaq Price List, ''Rebates and Fees, Shares Executed Below $1.00'', available at *http://www.nasdaqtrader.com/Trader.aspx?id=PriceListTrading2,* which assesses no charge for orders to add liquidity in securities priced below $1.00 and assesses a charge of 0.30% of total dollar volume for orders to remove liquidity in securities priced below $1.00. *See also* Securities Exchange Release No. 89607 (August 18, 2020), 85 FR 52179 (August 24, 2020) (SR–NYSEArca–2020–75), which recently amended in its fee schedule the base rate for adding and removing liquidity in Round Lots and Odd Lots in Tapes A, B and C securities with a per share price below $1.00.

[7] Appended to displayed orders that adds liquidity to BZX (Tape B) and is assessed a standard rebate of $0.0025.

[8] Appended to displayed orders that adds liquidity to BZX (Tape A) and is assessed a standard rebate of $0.0025.

[9] Appended to displayed orders that adds liquidity to BZX (Tape C) and is assessed a standard rebate of $0.0025.

[10] ''ADAV'' means average daily added volume calculated as the number of shares added per day. ADAV is calculated on a monthly basis.

[11] ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

a certain Tape ADV [12] as a percentage of that Tape's TCV. Specifically, the Supplemental Incentive Program Tiers offered are as follows:

• Supplemental Incentive Program—Tape A Tier offers an additional rebate of $0.0001 for orders yielding fee code V [13] where a Member adds a Tape A ADV greater than or equal to 0.50% of the Tape A TCV;

• Supplemental Incentive Program—Tape B Tier offers an additional rebate of $0.0001 for orders yielding fee code B [14] where a Member adds a Tape B ADV greater than or equal to 0.50% of the Tape B TCV; and

• Supplemental Incentive Program—Tape C Tier offers an additional rebate of $0.0001 for orders yielding fee code Y [15] where a Member adds a Tape C ADV greater than or equal to 0.50% of the Tape C TCV;

The proposed rule change amends each of the tiers' criteria by reducing the percentage of Tape ADV over Tape TCV from 0.50% to 0.30%. The proposed rule change also updates the language in each Tier to state ''where a Member has a Tape A/B/C ADAV'', which essentially states the same requirement as ''adds an ADV,'' but is more appropriately aligned with the defined terms in the Fee Schedule.[16] The proposed rule change to the Supplemental Incentive Program Tiers does not alter any of the additional rebate amounts currently offered. As such, the reduction in percentage of Tape ADAV over TCV, thus easing the tiers' criteria, is designed to further incentivize Members to submit displayed order flow to Tapes A, B and C to receive the current additional rebates provided under the Supplemental Incentive Program Tiers.

Proposed Remove Volume Tier

The Exchange proposes to add a new Remove Volume Tier under footnote 1 of the Fee Schedule.[17] The proposed Remove Volume Tier offers a reduced fee of $0.0029 for orders in securities at or above $1.00 and 0.28% of total dollar value for orders in securities below $1.00 [18] yielding fee code ''N'', [19] ''W'' [20] and ''BB'' [21] where a Member has an ADAV greater than or equal to 0.20% TCV with displayed orders that yield fee codes B, V or Y. The proposed Remove Volume Tier is designed to incentivize Members to increase their orders that add displayed volume on the Exchange in order to receive a reduced fee on their qualifying, liquidity removing orders.

Proposed Updates to the LMM Add Volume Tiers

Under the Exchange's LMM Program, the Exchange offers daily incentives for LMMs in securities listed on the Exchange for which the LMM meets certain Minimum Performance Standards.[22] Such daily incentives are determined based on the number of Cboe-listed securities for which the LMM meets such Minimum Performance Standards and the average auction volume across such securities. Generally, the more LMM Securities [23] for which the LMM meets the Minimum Performance Standards and the higher the auction volume across those securities, the greater the total daily payment to the LMM. Currently, the Exchange offers an LMM Add Volume Tier under footnote 14 of the Fee Schedule, which provides an additional rebate of $0.0001 for LMM orders yielding B, V and Y [24] where an LMM 1) adds an ADV [25] greater than or equal to 0.20% of the TCV, 2) has an Average Aggregate Daily Auction Volume in LMM Securities greater than or equal to 500,000, and 3) is enrolled in at least 75 LMM Securities.

The Exchange proposes to include three additional LMM Add Volume Tiers as follows:[26]

• Proposed LMM Add Volume Tier 2 provides an additional rebate of $0.0006 for orders yielding fee codes V [27] and ''HV'' [28] where an LMM 1) is enrolled is enrolled in at least 50 LMM Securities, and 2) has a Tape A ADAV greater than or equal to 0.10% of the Tape A TCV;

• Proposed LMM Add Volume Tier 3 provides an additional rebate of $0.0003 for orders yielding fee codes B [29] and ''HB'' [30] where an LMM 1) is enrolled is enrolled in at least 50 LMM Securities, and 2) has a Tape B ADAV greater than or equal to 0.20% of the Tape B TCV;

• LMM Add Volume Tier 4 provides an additional rebate of $0.0006 for orders yielding fee codes Y [31] and ''HY'' [32] where an LMM (1) is enrolled in at least 50 LMM Securities, and (2) has a Tape C ADAV greater than or equal to 0.10% of the Tape C TCV.

The proposed additional tiers also explicitly include that the proposed additional rebates apply to orders in securities priced below $1.00 and makes clear in the general heading language that both displayed and non-displayed orders will count toward meeting the tiers' criteria. The proposed additional LMM Add Volume tiers are designed to provide LMM Members with opportunities to receive additional rebates for both their displayed and non-displayed orders, thus further incentivizing Members to enroll and participate in the LMM Program, as well LMM Members to continue to add volume to Tape A, B and C.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[33]

[12] ''ADV'' means average daily volume calculated as the number of shares added or removed, combined, per day. ADV is calculated on a monthly basis.

[13] *See supra* note 8.

[14] *See supra* note 7.

[15] *See supra* note 9.

[16] *See supra* notes 10 and 12.

[17] As a result of the new Remove Volume Tier, it also updates the title of footnote 1 to ''Add/Remove Volume Tiers''.

[18] As a result, the Exchange proposes to update the statement under General Notes in the Fee Schedule to state that ''unless otherwise indicated, variable rates provided by tiers apply only to executions in securities priced at or above $1.00.

[19] Appended to orders that remove liquidity from BZX (Tape C) and is assessed a standard fee of $0.00300.

[20] Appended to orders that remove liquidity from BZX (Tape A) and is assessed a standard fee of $0.00300.

[21] Appended to orders that remove liquidity from BZX (Tape B) and is assessed a standard fee of $0.00300.

[22] As defined in Rule 11.8(e)(1)(E), the term ''Minimum Performance Standards'' means a set of standards applicable to an LMM that may be determined from time to time by the Exchange. Such standards will vary between LMM Securities depending on the price, liquidity, and volatility of the LMM Security in which the LMM is registered. The performance measurements will include: (A) Percent of time at the NBBO; (B) percent of executions better than the NBBO; (C) average displayed size; and (D) average quoted spread. For additional detail, see Original LMM Filing.

[23] As defined in Rule 11.8(e)(1)(D), the term ''LMM Security'' means a Listed Security that has an LMM. As defined in Rule 11.8(e)(1)(B), the term ''Listed Security'' means any ETP or any Primary Equity Security or Closed-End Fund listed on the Exchange pursuant to Rule 14.8 or 14.9.

[24] *See supra* notes 7, 8 and 9.

[25] Like the proposed clarification in the Supplement Incentive Tiers, the proposed rule change also updates the language in LMM Add Volume Tier 1 to state ''where a Member has a Tape A/B/C ADAV'', which essentially states the same requirement as ''adds an ADV'', but is more appropriately aligned with the defined terms in the Fee Schedule. *See supra* note 15.

[26] As a result of the proposed additional LMM Add Volume Tiers, the Exchange updates the current LMM Add Volume Tier to be LMM Add Volume Tier 1.

[27] *See supra* note 8.

[28] Appended to non-displayed orders that add liquidity (Tape A) and are assessed a standard rebate of $0.0015.

[29] *See supra* note 7.

[30] Appended to non-displayed orders that add liquidity (Tape B) and are assessed a standard rebate of $0.0015.

[31] *See supra* note 9.

[32] Appended to non-displayed orders that add liquidity (Tape C) and are assessed a standard rebate of $0.0015.

[33] 15 U.S.C. 78f.

in general, and furthers the objectives of Section 6(b)(4),[34] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members, issuers and other persons using its facilities. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The proposed rule changes reflect a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members. The Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges, including the Exchange, and are reasonable, equitable and non-discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Additionally, as noted above, the Exchange operates in highly competitive market. The Exchange is only one of several equity venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. It is also only one of several maker-taker exchanges. Competing equity exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange. These competing pricing schedules, moreover, are presently comparable to those that the Exchange provides, including the pricing of comparable criteria and/or fees and rebates.

Regarding the proposed change to the standard rates, the Exchange believes that amending the standard rates for orders that add volume in securities prices at $1.00 or more and in securities priced below $1.00 is reasonable because, as stated above, in order to operate in the highly competitive equities markets, the Exchange and its competing exchanges seek to offer similar pricing structures, including assessing comparable standard rates for orders in securities priced at or above, as well as priced below, $1.00.[35] Thus, the Exchange believes the proposed standard rate changes are reasonable as they are generally aligned with and competitive with the amounts assessed for the orders in securities above/below $1.00 on other equities exchanges. The Exchange also believes that amending the standard rate amounts represents an equitable allocation of fees and is not unfairly discriminatory because they will continue to automatically and uniformly apply to all Members' orders that add liquidity in securities at $1.00 or more and in securities less than $1.00.

Regarding the proposed updates and additions to the Add Volume, Supplemental Incentive and LMM Add Volume Tiers, as well as the new Remove Volume Tier, the Exchange believes that the proposed tiers are reasonable because they each provide an additional opportunity (either by amending existing tiers or adding new tiers) for Members to receive a discounted rate or enhanced rebates by means of liquidity adding orders. The Exchange notes the proposed tiers are available to all Members and are competitively achievable for all Members that submit the requisite order flow, in that, all firms are eligible for the proposed tiers and those that submit the requisite order flow could compete to meet the proposed tiers. Each Member will uniformly receive the respective proposed enhanced rebates, additional rebates or reduced fee if the corresponding tier criteria is met. The Exchange also believes that the proposed tiers are reasonable, equitable and not unfairly discriminatory because, as noted above, competing equity exchanges offer similar tiered pricing structures to that of the proposed Add Volume,[36] Supplemental Incentive,[37] Remove Volume,[38] and LMM Add Volume Tiers,[39] including as amended, which are presently comparable in pricing and criteria to the proposed tiers.

In particular, the Exchange believes the proposed Add Volume Tiers are reasonable because they amend existing opportunities by easing the level of difficulty in each of the existing five tiers, thus maintaining the current structure of step-up in difficulty in achieving each ascending tier, and provide an additional, also incrementally more challenging, opportunity in proposed Tier 6. The proposed ease in criteria and additional tier will incentivize Members to increase add volume order flow in order to receive the corresponding enhanced rebates for Members' qualifying orders. The Exchange further believes that the proposed rule changes to the Add Volume Tiers are reasonable as they represent proportional decreases in difficulty per adjacent tiers. In line with easing the relative level of difficulty in each of the Add Volume Tiers, the Exchange believes that providing a reduced enhanced rebate per tier is reasonable as it is commensurate with the proposed criteria. That is, the reduction in enhanced rebates reasonably reflects the scaled difficulty in achieving the add volume criteria over a baseline of 1,000,000 in proposed Tier 1, up through the incrementally increasing ADAV threshold as a percentage of TCV in Tiers 2 through 6. Also, the proposed reduced enhanced rebates (and proposed additional enhanced rebate in Tier 6) corresponding to the proposed criteria in the Add Volume Tiers do not represent a significant departure from the enhanced rebates currently offered under the tiers, and merely incrementally shifts the range of enhanced rebates offered to most appropriately align with the

[34] 15 U.S.C. 78f(b)(4).

[35] *See supra* notes 5 and 6.

[36] *See* EDGA Equities Fee Schedule, footnote 7, ''Add/Remove Volume Tiers''; BYX Equities Fee Schedule, footnote 1, ''Add/Remove Volume Tiers''; and EDGX Equities Fee Schedule, footnote 1, ''Add Volume Tiers'', each of which provide for similar add volume criteria for which members may receive comparable reduced fees on their orders (EDGA/BYX) or enhanced rebates ranging from $0.0023 to $0.0028 (EDGX) for meeting such thresholds.

[37] *See* NYSE Price List, ''Credit Applicable to Supplemental Liquidity Providers (''SLPs'')'', which provides additional credits up to $0.0005 for various types of Tape liquidity; *and* Nasdaq Equity 7, Section 118(a)(1), which provides supplemental credit of $0.00005 for various types of Tape liquidity.

[38] *See* EDGA Equities Fee Schedule, footnote 7, ''Add/Remove Volume Tiers'', of which the Remove Volume Tiers offers an enhanced rebate of $0.0022 or $0.0028 for reaching a certain threshold of ADV over TCV; *and* BYX Equities Fee Schedule, footnote 1, ''Add/Remove Volume Tiers'', of which the Remove Volume Tiers offer enhanced rebates between $0.0015 and $0.0018 for various criteria (Step-Up volume, ADAV of a set number of shares, ADV as a percentage of TCV, etc.).

[39] *See* Nasdaq Phlx Equity 7 Pricing Schedule, Section 3(c), which provides up to an additional credit of $0.0003 for various order and quoting volume thresholds for the exchange's qualified market makers (''QMMs''); *and* NYSE Price List, ''Fees and Credits applicable to Designated Market Makers (''DMMs'')'', which provides, among various credits for orders in securities at or above $1.00, additional credit of $0.0004 for DMMs adding liquidity in securities under $1.00. *See also* Securities Exchange Release No. 89607 (August 18, 2020), 85 FR 52179 (August 24, 2020) (SR–NYSEArca–2020–75), which recently adopted in its fee schedule a step up tier for ETP Holders adding liquidity in Round Lots and Odd Lots in Tapes A, B and C securities with a per share price below $1.00 and amended the base rate for adding and removing liquidity in Round Lots and Odd Lots in Tapes A, B and C securities with a per share price below $1.00.

corresponding shift in criteria difficulty per each tier.

Similarly, the Exchange believes the proposed amendments to the Supplemental Incentive Tiers are reasonable because they, too, amend existing opportunities by uniformly easing the level of difficulty in each of the three existing Supplemental Incentive Tiers, which currently provide for the same criteria thresholds per Tape. Therefore, by uniformly easing the criteria per each tier, while maintaining the existing additional rebate amounts, the proposed rule change to the Supplemental Tiers is reasonably designed to incentivize Members to increase their add volume order flow per each Tape.

The Exchange believes the Remove Volume Tier is a reasonable means to incentivize Members to continue to provide liquidity adding, displayed volume to the Exchange by offering them a different, additional opportunity than that of the Add Volume Tiers—to receive a reduced fee on their liquidity removing orders by meeting the proposed criteria in submitting additional add volume order flow. In addition to this, the Exchange has recently observed that trading in subdollar names has grown significantly; nearly tripling since the beginning of 2020, and that competing equities exchanges have begun offering pricing incentives for subdollar orders.[40] Therefore, the Exchange believes that it is reasonable and equitable to provide the proposed reduced fee under the new Remove Volume Tier for qualifying subdollar orders. Also, as indicated above, the Exchange's affiliated equities exchanges already have similar Remove Volume in place, which offer similar rebates for achieving comparable criteria, in addition to their Add Volume Tiers.[41]

The Exchange believes the proposed additional LMM Add Volume Tiers are reasonable in that they offer LMM Members on the Exchange an additional opportunity to receive an added rebate for their provision of liquidity, both displayed and non-displayed, per Tape. As with the proposed Remove Volume Tier, the Exchange believes that it is reasonable and equitable to provide the proposed additional rebates under the new LMM Add Volume Tiers for qualifying subdollar orders as a result of the recent expansive growth in the subdollar market segment, as well as competitive pricing offered by other equities exchanges for subdollar orders.[42] The Exchange believes the proposed additional rebates for both liquidity adding displayed and non-displayed orders to the Tapes will incentivize increased overall order flow to the Book and price-improvement opportunities. The Exchange also notes that the proposed LMM Add Volume Tiers reflect a competitive pricing structure designed to incentivize market participants to enroll in LMP Securities, which the Exchange believes will enhance market quality in all securities listed on the Exchange and encourage issuers to list new products and transfer existing products to the Exchange. The Exchange further believes that the proposed criteria and corresponding additional rebates per tier are reasonable and equitable. Generally, Tape B experiences less variability in terms of broader market share, whereas Tape A and C tend to experience more volatility. As a result, the Exchange has observed that LMM Members generally submit less Tape volume in connection with Tape A and Tape C. For example, the average Tape ADAV as a percentage of Tape TCV in Tape A and Tape C from LMM Members in the last month was approximately ten basis points lower than their average Tape ADAV over Tape TCV in Tape B. As a result, the Exchange believes Members are more easily able to meet a volume requirement for Tape B, and therefore, it is equitable to provide for a slightly higher ADAV Tape B threshold of Tape B TCV than that for Tape A and C, that corresponds to a slightly lower additional rebate than that which corresponds to Tape A and C.

Overall, the Exchange believes that easing the current tiers' criteria and adding new tier criteria, each based on a Member's liquidity adding orders, will benefit all market participants by incentivizing continuous liquidity and thus, deeper more liquid markets as well as increased execution opportunities. Particularly, the majority of the proposed tiers are designed to incentivize continuous displayed liquidity, which signals other market participants to take the additional execution opportunities provided by such liquidity, while the proposed incentives to provide non-displayed liquidity will further contribute to a deeper, more liquid market and provide even more execution opportunities for active market participants at improved prices. This overall increase in activity deepens the Exchange's liquidity pool, offers additional cost savings, supports the quality of price discovery, promotes market transparency and improves market quality, for all investors.

In addition to this, the Exchange believes that the proposal represents an equitable allocation of rebates and is not unfairly discriminatory because all Members will continue to be eligible for the Add Volume and Supplemental Incentive Tiers, as amended, and in the same way will be eligible for the proposed Remove Volume Tier and additional Add Volume and LMM Add Volume Tiers. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying for the proposed tiers. While the Exchange has no way of predicting with certainty how the proposed tiers will impact Member activity, the Exchange anticipates that for the proposed Add Volume Tiers approximately between seven and thirteen Members will be able to compete for and achieve the proposed criteria across proposed Add Volume Tiers 1 and 2; at least three Members will be able to compete for and achieve the amended criteria in each Add Volume Tier 3 and 4; and at least six Members will be able to compete for and achieve the amended/new criteria across Add Volume Tiers 5 and 6. The Exchange anticipates that for the proposed Supplemental Incentive Tiers at least three Members will be able to compete for and achieve the proposed criteria in each of the three additional tiers. The Exchange anticipates that for the proposed Remove Volume Tier at least ten Members will be able to compete for and achieve the proposed criteria. Finally, the Exchange anticipates that for the proposed Add Volume LMM Tiers at least two LMM Members will be able to compete for and achieve the proposed criteria in each of the three additional tiers. The Exchange anticipates that the tiers will include various liquidity providing Member types, such as traditional Market Makers, and wholesale or consolidator firms that mainly make markets for retail orders, each providing distinct types of order flow to the Exchange to the benefit of all market participants. The Exchange also notes that the proposed tiers will not

[40] *See* NYSE Price List, ''Fees and Credits applicable to Designated Market Makers (''DMMs'')'', which provides, among various credits for orders in securities at or above $1.00, additional credit of $0.0004 for DMMs adding liquidity in securities under $1.00; *see also* Securities Exchange Release No. 89607 (August 18, 2020), 85 FR 52179 (August 24, 2020) (SR–NYSEArca–2020–75), which recently adopted in its fee schedule a step up tier for ETP Holders adding liquidity in Round Lots and Odd Lots in Tapes A, B and C securities with a per share price below $1.00 and amended the base rate for adding and removing liquidity in Round Lots and Odd Lots in Tapes A, B and C securities with a per share price below $1.00.

[41] *See supra* note 38.

[42] *See supra* note 40.

adversely impact any Member's pricing or their ability to qualify for other rebate tiers. Rather, should a Member not meet the proposed criteria for a tier, the Member will merely not receive the corresponding additional rebate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [43]

The Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed changes apply to all Members equally in that all Members are eligible for the proposed Add Volume Tiers, Supplemental Incentive Tiers, Remove Volume Tier and LMM Add Volume Tiers (and have the same opportunity to become an LMM Member), have a reasonable opportunity to meet the tiers' criteria and will all receive the corresponding proposed enhanced rebates, additional rebates and reduced fee if such criteria are met. Additionally, the proposed tier changes are designed to attract additional order flow to the Exchange. The Exchange believes that the updated tier criteria and the additional tier criteria would incentivize market participants to direct liquidity adding order flow to the Exchange, bringing with it additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefits all market participants on the Exchange by enhancing market quality and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem. In addition to this, the Exchange notes that the proposed amendments to the standard rebates for orders in securities above/below $1.00 will continue to apply automatically to all such Members' orders uniformly.

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including 12 other equities exchanges and off-exchange venues and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 18% of the market share.[44] Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [45] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[46] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [47] and paragraph (f) of Rule 19b–4 [48] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2020–071 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2020–071. 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

[43] Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

[44] *See supra* note 4.

[45] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[46] *NetCoalition* v. *SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[47] 15 U.S.C. 78s(b)(3)(A).

[48] 17 CFR 240.19b–4(f).

post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2020–071 and should be submitted on or before October 20, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[49]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–21410 Filed 9–28–20; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before October 29, 2020.

ADDRESSES: Comments should refer to the information collection by title and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW, 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION:

Copies: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Officer.

The STEP Client Report form is completed by state administrators in states that receive an SBA STEP grant in order to report data on the quarterly progress of STEP grant recipients and their clients. These data are used to understand how states have improved the trade and export activities and revenue outcomes of clients. Data from the STEP Client Report provides SBA with critical information about the impact of various strategies used to advance trade and export activities in each state. These data also provide an understanding of the specific ways in which funded activities meet SBA's goal of improving small business trade and export productivity. These data may inform strategies that can be replicated by other small businesses.

Title: SBA STEP Client Report Form.

OMB Control Number: N/A.

Description of Respondents: This form will be completed by the directors at approximately 90 STEP grant recipients.

Estimated Annual Responses: 360.

Estimated Annual Hour Burden: 360.

Curtis Rich,

Management Analyst.

[FR Doc. 2020–21494 Filed 9–28–20; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before October 29, 2020.

ADDRESSES: Comments should refer to the information collection by title and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW, 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION:

Copies: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Officer.

The SBA secondary market is an evolving 36.9 billion dollar market designed to facilitate the availability of capital to lenders serving the small business community. Pursuant to section 5(h)(1)(C) of the Small Business Act, 15 U.S.C. 634(h)(1)(C), when a secondary market loan is transferred from one investor to another, the sellers of the loan or pool certificate must disclose to certain information to the buyer. This information includes a constant annual prepayment rate based on the seller's analysis pf prepayment histories of SBA guaranteed loans with similar maturities, and also information regarding the terms, conditions and yield of the transferred security.

Title: Form of Detached Assignment for U.S. Small Business Administration Loan Pool or Guaranteed Interest Certificate.

OMB Control Number: 3245–0212.

Description of Respondents: Secondary Market Lenders.

Estimated Annual Responses: 7,500.

Estimated Annual Hour Burden: 11,250.

Curtis Rich,

Management Analyst.

[FR Doc. 2020–21445 Filed 9–28–20; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

[49] 17 CFR 200.30–3(a)(12).

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before October 29, 2020.

ADDRESSES: Comments should refer to the information collection by title and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW, 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION:

Copies: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Officer.

In recognition of the small business community's contributions to the nation's economy, the President of the United States designates one week each year as Small Business Week. As part of that week's activities the Small Business Administration (SBA) issues recognition awards to various small business owners, entrepreneurs and advocates. Award nominees and nominators submit this information to SBA for use in evaluating their eligibility for an award, verifying accuracy of information submitted, and determining whether there are any actual or potential conflicts of interest.

Summary of Information Collections

Title: Small Business Administration Award Nomination.

Description of Respondents: Small Business Owners and Advocates who have been nominated for an SBA recognition award.

Form Number: 3300–3314.

Estimated Annual Responses: 600.

Estimated Annual Hour Burden: 900.

Curtis Rich,

Management Analyst.

[FR Doc. 2020–21451 Filed 9–28–20; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

Interest Rates

The Small Business Administration publishes an interest rate called the optional ''peg'' rate (13 CFR 120.214) on a quarterly basis. This rate is a weighted average cost of money to the government for maturities similar to the average SBA direct loan. This rate may be used as a base rate for guaranteed fluctuating interest rate SBA loans. This rate will be 0.88 percent for the October–December quarter of FY 2021.

Pursuant to 13 CFR 120.921(b), the maximum legal interest rate for any third party lender's commercial loan which funds any portion of the cost of a 504 project (see 13 CFR 120.801) shall be 6% over the New York Prime rate or, if that exceeds the maximum interest rate permitted by the constitution or laws of a given State, the maximum interest rate will be the rate permitted by the constitution or laws of the given State.

Dianna L. Seaborn,

Director, Office of Financial Assistance.

[FR Doc. 2020–21427 Filed 9–28–20; 8:45 am]

BILLING CODE 8026–03–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2020–0046]

Charging Standard Administrative Fees for Non-Program Information

AGENCY: Social Security Administration.

ACTION: Notice of updated schedule of standard administrative fees.

SUMMARY: On August 22, 2012, we announced in the **Federal Register** a schedule of standard administrative fees we charge to the public. We charge these fees to recover our full costs when we provide information and related services for non-program purposes. We are announcing an update to the previously published schedule of standard administrative fees. The updated standard fee schedule is part of our continued effort to standardize fees for non-program information requests. Standard fees provide consistency and ensure we recover the full cost of supplying information when we receive a request for a purpose not directly related to the administration of a program under the Social Security Act (Act).

DATES: The changes described above are applicable for requests we receive on or after October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Karen Hunter, Social Security Administration, Office of Finance, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–5861. For information on eligibility or filing for benefits, visit our website, *socialsecurity.gov,* or call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778.

SUPPLEMENTARY INFORMATION: Section 1106 of the Act and the Privacy Act [1] authorize the Commissioner of Social Security to promulgate regulations regarding the fees related to providing information. Our regulations and operating instructions identify when we will charge fees for information.[2] Under our regulations, whenever we determine a request for information is for any purpose not directly related to the administration of the Social Security programs, we require the requester to pay the full cost of providing the information.[3] To inform the public of these fees, on August 22, 2012,[4] we announced in the **Federal Register** a schedule of standard administrative fees we charge to the public. We last updated the schedule of standard fees on September 4, 2018.[5]

New Information: We are required to review and update standard administrative fees at least every two years.[6] Based on the most recent cost analysis, the following table provides the new schedule of standard administrative fees per request:

Copying an Electronic Folder: $41.

Copying a Paper Folder: $83.

Regional Office Certification [7]*:* $64.

Record Extract: $34.

Third Party Manual SSN Verification: $36.

Office of Central Operations Certification [8]*:* $30.

W–2/W–3 Requests [9]*:* $90.

Form SSA–7050, Request for Social Security Earning Information: $92.

Requests for Copy of Original Form SS–5, Application for a Social Security Card: $21.

Requests for Copy of Numident Record (Computer Extract of the SS–5): $20.

[1] 42 U.S.C. 1306 and 5 U.S.C. 552a(f)(5), respectively.

[2] See 20 CFR 401.95, 402.170, and 402.175; Program Operations Manual System (POMS) GN 03311.005.

[3] See 42 U.S.C. 1306(c) and 20 CFR 402.175.

[4] 77 FR 50757.

[5] 83 FR 45002.

[6] See the Office of Management and Budget Circular No. A–25, *User Charges.*

[7] Requests received in a field office, regional office, or headquarters component.

[8] Requests received in the Office of Central Operations.

[9] W–2/W–3 Fee is $90 per request, not dependent on the number of years or number of individuals within request.

A requester can obtain certified and non-certified detailed yearly Social Security earnings information by completing Form SSA–7050, *Request for Social Security Earning Information.* We charge $92 for each Form SSA–7050 for detailed yearly Social Security earnings information. For an additional $30, we will certify the detailed earnings information. Detailed earnings information includes the names and addresses of employers. Yearly earnings totals are available in two ways, depending on the requester's need for certification. A requester can continue to obtain non-certified yearly earnings totals (Form SSA–7004, *Request for Social Security Statement*) through our free online service, *my* Social Security, a personal online account for Social Security information and services. Online Social Security Statements display uncertified yearly earnings, free of charge, and do not show any employer information. A requester can obtain certified yearly Social Security earnings totals by completing the Form SSA–7050. The cost for certified yearly earnings totals is $122 ($92 plus an additional $30 for certification).

We will continue to evaluate all standard fees at least every two years to ensure we capture the full costs associated with providing information for non-program-related purposes. We require nonrefundable advance payment by check, money order, or credit card. We do not accept cash. We will only accept one form of payment in the full amount of the standard fee for each request, and will not divide the fee amount between more than one form of payment. If we revise any of the standard fees, we will publish another notice in the **Federal Register**. For other non-program requests for information not addressed here or within the current schedule of standard administrative fees, we will continue to charge fees calculated on a case-by-case basis to recover our full cost of supplying the information.

Additional Information

Additional information is available on our Business Services website at *https://www.ssa.gov/thirdparty/business.html* or by written request to: Social Security Administration, Office of Public Inquiries and Communications Support, 1100 West High Rise, 6401 Security Boulevard, Baltimore, MD 21235.

The Commissioner of the Social Security Administration, Andrew Saul, having reviewed and approved this document, is delegating the authority to electronically sign this document to Faye I. Lipsky, who is the primary Federal Register Liaison for SSA, for purposes of publication in the **Federal Register**.

Faye I. Lipsky,

Federal Register Liaison, Office of Legislation and Congressional Affairs, Social Security Administration.

[FR Doc. 2020–21520 Filed 9–28–20; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 11214]

Notice of Determinations

Culturally Significant Object Being Imported for Exhibition—Determinations: Exhibition of "The Holy Trinity" Painting by Peter Paul Rubens

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that one object being imported from abroad pursuant to an agreement with the foreign owner or custodian for temporary exhibition within the 17th Century Flemish Paintings Gallery of *The J. Paul Getty Museum* at the *Getty Center*, Los Angeles, California, and at possible additional exhibitions or venues yet to be determined, is of cultural significance, and, further, that its temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Program Administrator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Educational and Cultural Affairs, Department of State.

[FR Doc. 2020–21431 Filed 9–28–20; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 11216]

Updating the State Department's List of Entities and Subentities Associated With Cuba (Cuba Restricted List)

ACTION: Updated publication of list of entities and subentities; notice.

SUMMARY: The Department of State is publishing an update to its List of Restricted Entities and Subentities Associated with Cuba (Cuba Restricted List) with which direct financial transactions are generally prohibited under the Cuban Assets Control Regulations (CACR). The Department of Commerce's Bureau of Industry and Security (BIS) generally will deny applications to export or reexport items for use by entities or subentities on the Cuba Restricted List.

DATES: September 29, 2020.

FOR FURTHER INFORMATION CONTACT: Emily Belson, Office of Economic Sanctions Policy and Implementation, 202–647–6526; Robert Haas, Office of the Coordinator for Cuban Affairs, tel.: 202–453–8456, Department of State, Washington, DC 20520.

SUPPLEMENTARY INFORMATION:

Background

On June 16, 2017, the President signed National Security Presidential Memorandum-5 on Strengthening the Policy of the United States Toward Cuba (NSPM–5). As directed by NSPM–5, on November 9, 2017, the Department of the Treasury's Office of Foreign Assets Control (OFAC) published a final rule in the **Federal Register** amending the CACR, 31 CFR part 515, and the Department of Commerce's Bureau of Industry and Security (BIS) published a final rule in the **Federal Register** amending, among other sections, the section of the Export Administration Regulations (EAR) regarding Cuba, 15 CFR 746.2. The regulatory amendment to the CACR added § 515.209, which generally prohibits direct financial transactions with certain entities and subentities identified on the State Department's Cuba Restricted List. The regulatory amendment to 15 CFR 746.2, notes BIS will generally deny applications to export or re-export items for use by entities or subentities identified on the Cuba Restricted List. The State Department is now updating the Cuba Restricted list, as published below and available on the State Department's website (*https://www.state.gov/cuba-sanctions/cuba-restricted-list/*)

This update includes one additional subentity and an alias thereof. This is the seventh update to the Cuba Restricted List since it was published November 9, 2017 (82 FR 52089). Previous updates were published November 15, 2018 (see 83 FR 57523), March 9, 2019 (see 84 FR 8939), April 24, 2019 (see 84 FR 17228), July 26, 2019 (see 84 FR 36154), November 19, 2019 (see 84 FR 63953), June 12, 2020 (see 85 FR 35972), and a correction June 19, 2020 (85 FR 37146). The State Department will continue to update the Cuba Restricted List periodically.

The publication of the updated Cuba Restricted List further implements the directive in paragraph 3(a)(i) of NSPM–5 for the Secretary of State to identify the entities or subentities, as appropriate, that are under the control of, or act for or on behalf of, the Cuban military, intelligence, or security services or personnel, and publish a list of those identified entities and subentities with which direct financial transactions would disproportionately benefit such services or personnel at the expense of the Cuban people or private enterprise in Cuba.

Electronic Availability

This document and additional information concerning the Cuba Restricted List are available from the Department of State's website (*https://www.state.gov/cuba-sanctions/cuba-restricted-list/*).

List of Restricted Entities and Subentities Associated With Cuba as of September 29, 2020

Below is the U.S. Department of State's list of entities and subentities under the control of, or acting for or on behalf of, the Cuban military, intelligence, or security services or personnel with which direct financial transactions would disproportionately benefit such services or personnel at the expense of the Cuban people or private enterprise in Cuba. For information regarding the prohibition on direct financial transactions with these entities, please see 31 CFR 515.209. All entities and subentities were listed effective November 9, 2017, unless otherwise indicated.

** * * Entities or subentities owned or controlled by another entity or subentity on this list are not treated as restricted unless also specified by name on the list. * * **

Ministries

MINFAR—Ministerio de las Fuerzas Armadas Revolucionarias
MININT—Ministerio del Interior

Holding Companies

CIMEX—Corporación CIMEX S.A.
Compañía Turística Habaguanex S.A.
GAESA—Grupo de Administración Empresarial S.A.
Gaviota—Grupo de Turismo Gaviota
UIM—Unión de Industria Militar

Hotels in Havana and Old Havana

Aparthotel Montehabana
Gran Hotel Bristol Kempinski *Effective November 15, 2019*
Gran Hotel Manzana Kempinski
H10 Habana Panorama
Hostal Valencia
Hotel Ambos Mundos
Hotel Armadores de Santander
Hotel Beltrán de Santa Cruz
Hotel Conde de Villanueva
Hotel del Tejadillo
Hotel el Bosque
Hotel el Comendador
Hotel el Mesón de la Flota
Hotel Florida
Hotel Habana 612
Hotel Kohly
Hotel Los Frailes
Hotel Marqués de Prado Ameno
Hotel Marqués de Cardenas de Montehermoso *Effective June 12, 2020*
Hotel Palacio Cueto *Effective July 26, 2019*
Hotel Palacio del Marqués de San Felipe y Santiago de Bejucal
Hotel Palacio O'Farrill
Hotel Park View
Hotel Raquel
Hotel Regis *Effective June 12, 2020*
Hotel San Miguel
Hotel Santa Isabel *Effective April 24, 2019*
Hotel Telégrafo
Hotel Terral
Iberostar Grand Packard Hotel *Effective November 15, 2018*
Memories Miramar Havana
Memories Miramar Montehabana
SO/Havana Paseo del Prado *Effective November 15, 2018*

Hotels in Santiago de Cuba

Villa Gaviota Santiago

Hotels in Varadero

Blau Marina Varadero Resort
also Fiesta Americana Punta Varadero *Effective November 15, 2018*
also Fiesta Club Adults Only *Effective March 12, 2019*
Grand Aston Varadero Resort *Effective November 15, 2019*
Grand Memories Varadero
Hotel El Caney Varadero *Effective April 24, 2019*
Hotel Las Nubes *Effective November 15, 2018*
Hotel Oasis *Effective November 15, 2018*
Iberostar Bella Vista *Effective November 15, 2018*
Iberostar Laguna Azul
Iberostar Playa Alameda
Meliá Marina Varadero
Meliá Marina Varadero Apartamentos *Effective April 24, 2019*
Meliá Peninsula Varadero
Memories Varadero
Naviti Varadero
Ocean Varadero El Patriarca
Ocean Vista Azul
Paradisus Princesa del Mar
Paradisus Varadero
Sol Sirenas Coral

Hotels in Pinar del Rio

Hotel Villa Cabo de San Antonio
Hotel Villa Maria La Gorda y Centro Internacional de Buceo

Hotels in Baracoa

Hostal 1511
Hostal La Habanera
Hostal La Rusa
Hostal Rio Miel
Hotel El Castillo
Hotel Porto Santo
Villa Maguana

Hotels in Cayos de Villa Clara

Angsana Cayo Santa María *Effective November 15, 2018*
Dhawa Cayo Santa María
Grand Aston Cayo Las Brujas Beach Resort and Spa *Effective November 19, 2019*
Golden Tulip Aguas Claras *Effective November 15, 2018*
Hotel Cayo Santa María
Hotel Playa Cayo Santa María
Iberostar Ensenachos
Las Salinas Plana & Spa *Effective November 15, 2018*
La Salina Noreste *Effective November 15, 2018*
La Salina Suroeste *Effective November 15, 2018*
Meliá Buenavista
Meliá Cayo Santa María
Meliá Las Dunas
Memories Azul
Memories Flamenco
Memories Paraíso
Ocean Casa del Mar
Paradisus Los Cayos *Effective November 15, 2018*
Royalton Cayo Santa María
Sercotel Experience Cayo Santa María *Effective November 15, 2018*
Sol Cayo Santa María
Starfish Cayo Santa María *Effective November 15, 2018*
Valentín Perla Blanca *Effective November 15, 2018*
Villa Las Brujas
Warwick Cayo Santa María also Labranda Cayo Santa María Hotel *Effective November 15, 2018*

Hotels in Holguín

Blau Costa Verde Beach & Resort also Fiesta Americana Holguín Costa Verde *Effective November 15, 2018*

Hotel Playa Costa Verde
Hotel Playa Pesquero
Memories Holguín
Paradisus Río de Oro Resort & Spa
Playa Costa Verde
Playa Pesquero Premium Service
Sol Rio de Luna y Mares
Villa Cayo Naranjo
Villa Cayo Saetia
Villa Pinares de Mayari

Hotels in Jardines del Rey

Cayo Guillermo Resort Kempinski *Effective July 26, 2019*
Grand Muthu Cayo Guillermo *Effective November 15, 2018*
Gran Muthu Imperial Hotel *Effective November 15, 2019*
Gran Muthu Rainbow Hotel *Effective November 15, 2019*
Hotel Playa Coco Plus
Iberostar Playa Pilar
Meliá Jardines del Rey
Memories Caribe
Pestana Cayo Coco also Hotel Playa Paraiso *Effective June 12, 2020*

Hotels in Topes de Collantes

Hostal Los Helechos
Kurhotel Escambray *Effective November 15, 2018*
Los Helechos
Villa Caburni

Tourist Agencies

Crucero del Sol
Gaviota Tours

Marinas

Marina Gaviota Cabo de San Antonio (Pinar del Rio)
Marina Gaviota Cayo Coco (Jardines del Rey)
Marina Gaviota Las Brujas (Cayos de Villa Clara)
Marina Gaviota Puerto Vita (Holguín)
Marina Gaviota Varadero (Varadero)

Stores in Old Havana

Casa del Abanico
Colección Habana
Florería Jardín Wagner
Joyería Coral Negro—Additional locations throughout Cuba
La Casa del Regalo
San Ignacio 415
Soldadito de Plomo
Tienda El Navegante
Tienda Muñecos de Leyenda
Tienda Museo El Reloj Cuervo y Sobrinos

Entities Directly Serving the Defense and Security Sectors

ACERPROT—Agencia de Certificación y Consultoría de Seguridad y Protección Alias Empresa de Certificación de Sistemas de Seguridad y Protección *Effective November 15, 2018*
AGROMIN—Grupo Empresarial Agropecuario del Ministerio del Interior
APCI—Agencia de Protección Contra Incendios
CAHOMA—Empresa Militar Industrial Comandante Ernesto Che Guevara Casa Editorial Verde Olivo *Effective July 26, 2019*
CASEG—Empresa Militar Industrial Transporte Occidente
CID NAV—Centro de Investigación y Desarrollo Naval
CIDAI—Centro de Investigación y Desarrollo de Armamento de Infantería
CIDAO—Centro de Investigación y Desarrollo del Armamento de Artillería e Instrumentos Ópticos y Ópticos Electrónicos
CORCEL—Empresa Militar Industrial Emilio Barcenas Pier
CUBAGRO—Empresa Comercializadora y Exportadora de Productos Agropecuarios y Agroindustriales
DATYS—Empresa Para El Desarrollo De Aplicaciones, Tecnologías Y Sistemas
DCM TRANS—Centro de Investigación y Desarrollo del Transporte
DEGOR—Empresa Militar Industrial Desembarco Del Granma
DSE—Departamento de Seguridad del Estado Editorial Capitán San Luis *Effective July 26, 2019*
EMIAT—Empresa Importadora Exportadora de Abastecimientos Técnicos
Empresa Militar Industrial Astilleros Astimar
Empresa Militar Industrial Astilleros Centro
Empresa Militar Industrial Yuri Gagarin
ETASE—Empresa de Transporte y Aseguramiento
Ferretería TRASVAL
GELCOM—Centro de Investigación y Desarrollo Grito de Baire Impresos de Seguridad
MECATRONICS—Centro de Investigación y Desarrollo de Electrónica y Mecánica
NAZCA—Empresa Militar Industrial Granma
OIBS—Organización Integración para el Bienestar Social
PLAMEC—Empresa Militar Industrial Ignacio Agramonte
PNR—Policía Nacional Revolucionaria
PROVARI—Empresa de Producciones Varias
SEPSA—Servicios Especializados de Protección
SERTOD—Servicios de Telecomunicaciones a los Órganos de la Defensa *Effective November 15, 2018*
SIMPRO—Centro de Investigación y Desarrollo de Simuladores
TECAL—Empresa de Tecnologías Alternativas
TECNOPRO—Empresa Militar Industrial ''G.B. Francisco Cruz Bourzac''
TECNOTEX—Empresa Cubana Exportadora e Importadora de Servicios, Artículos y Productos Técnicos Especializados
TGF—Tropas de Guardafronteras
UAM—Unión Agropecuaria Militar
ULAEX—Unión Latinoamericana de Explosivos
XETID—Empresa de Tecnologías de la Información Para La Defensa
YABO—Empresa Militar Industrial Coronel Francisco Aguiar Rodríguez

Additional Subentities of CIMEX

ADESA/ASAT—Agencia Servicios Aduanales (Customs Services)
American International Services (Remittances) *Effective September 29, 2020*
alias AIS Remesas *Effective September 29, 2020*
Cachito (Beverage Manufacturer)
Contex (Fashion)
Datacimex
ECUSE—Empresa Cubana de Servicios
FINCIMEX *Effective June 19, 2020*
Inmobiliaria CIMEX (Real Estate)
Inversiones CIMEX
Jupiña (Beverage Manufacturer)
La Maisón (Fashion)
Najita (Beverage Manufacturer)
Publicitaria Imagen (Advertising)
Residencial Tarara S.A. (Real Estate/ Property Rental) *Effective November 15, 2018*
Ron Caney (Rum Production)
Ron Varadero (Rum Production)
Telecable (Satellite Television)
Tropicola (Beverage Manufacturer)
Zona Especializada de Logística y Comercio (ZELCOM)

Additional Subentities of GAESA

Aerogaviota *Effective April 24, 2019*
Almacenes Universales (AUSA)
ANTEX—Corporación Antillana Exportadora
Compañía Inmobiliaria Aurea S.A. *Effective November 15, 2018*
Dirección Integrada Proyecto Mariel (DIP)
Empresa Inmobiliaria Almest (Real Estate)
GRAFOS (Advertising)
RAFIN S.A. (Financial Services)
Sociedad Mercantin Inmobiliaria Caribe (Real Estate)
TECNOIMPORT
Terminal de Contenedores de la Habana (TCH)
Terminal de Contenedores de Mariel, S.A.
UCM—Unión de Construcciones Militares
Zona Especial de Desarrollo Mariel (ZEDM)

Zona Especial de Desarrollo y Actividades Logísticas (ZEDAL)

Additional Subentities of Gaviota

AT Comercial
Centro de Buceo Varadero *Effective June 12, 2020*
Centro Internacional de Buceo Gaviota Las Molas *Effective June 12, 2020*
Delfinario Cayo Naranjo *Effective June 12, 2020*
Diving Center—Marina Gaviota *Effective April 24, 2019*
Gaviota Hoteles Cuba *Effective March 12, 2019*
Hoteles Habaguanex *Effective March 12, 2019*
Hoteles Playa Gaviota *Effective March 12, 2019*
Manzana de Gomez
Marinas Gaviota Cuba *Effective March 12, 2019*
PhotoService
Plaza La Estrella *Effective November 15, 2018*
Plaza Las Dunas *Effective November 15, 2018*
Plaza Las Morlas *Effective November 15, 2018*
Plaza Las Salinas *Effective November 15, 2018*
Plaza Las Terrazas del Atardecer *Effective November 15, 2018*
Plaza Los Flamencos *Effective November 15, 2018*
Plaza Pesquero *Effective November 15, 2018*
Producciones TRIMAGEN S.A. (Tiendas Trimagen)

Additional Subentities of Habaguanex

Sociedad Mercantil Cubana Inmobiliaria Fenix S.A. (Real Estate)

* * *Activities in parentheticals are intended to aid in identification, but are only representative. All activities of listed entities and subentities are subject to the applicable prohibitions.** *

Peter Haas,

Acting Assistant Secretary, Bureau of Economic and Business Affairs, Department of State.

[FR Doc. 2020–21449 Filed 9–28–20; 8:45 am]

BILLING CODE 4710–29–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0263]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Collection Approval of Information Collection: Safe Disposition of Life Limited Aircraft Parts

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew this information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 13, 2020. The collection involves maintaining and recording ''the current status of life-limited parts of each airframe, engine, propeller, rotor, and appliance. The information to be collected is necessary for maintaining and recording that the part is airworthy.

DATES: Written comments should be submitted by October 29, 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: David A. Hoyng by email at: *david.a.hoyng@faa.gov* or *9-AWA-AFS-300-Maintenance@faa.gov;* phone: (325) 260–8658 or (202) 267–1675.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0665.

Title: Safe Disposition of Life Limited Aircraft Parts.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 13, 2020 (FAA–2020–0263, **Federal Register** Volume 85, Number 50 [Pages 14721–14722], Online via [*www.gpo.gov*] [FR Doc No: 2020–05179]).

The FAA has found life-limited parts that exceeded their life-limits installed on type-certificated products during accident investigations and in routine surveillance. Although such installation of life-limited parts violates existing FAA regulations, concerns have arisen regarding the disposition of these life-limited parts when they have reached their life limits. Concerns over the use of life-limited aircraft parts led Congress to pass a law requiring the safe disposition of these parts. The Wendell H. Ford Investment and Reform Act for the 21st Century (Pub. L. 106–181), added section 44725 to Title 49, United States Code.

Current Requirements

The type design of an aircraft, aircraft engine, or propeller includes the Instructions for Continued Airworthiness (ICA), which includes the Airworthiness Limitations that describe life limits for parts installed on the product. See, for instance, 14 CFR 21.3(c) and 21.50. In order for an aviation product to comply with its type design, the life-limited parts installed on it must fall within the acceptable ranges described in the Airworthiness Limitations section of the Instructions for Continued Airworthiness. For this reason, installation of a life-limited part after the mandatory replacement time has been reached would be a violation of the maintenance regulations. Section 43.13(b) requires that maintenance work be completed so that the product worked on ''will be at least equal to its original or properly altered condition. * * *'' The product is not at least equal to its original or properly altered condition if a life-limited part has reached or exceeded its life limit. Existing regulations require that specific markings be placed on all life-limited parts at the time of manufacture. This includes permanently marking the part with a part number (or equivalent) and a serial number (or equivalent). See 14 CFR 45.14. Persons who install parts must have adequate information to determine a part's current life status. In particular, documentation problems may mislead an installer concerning the life remaining for a life-limited part. This rule further provides for the data needs of subsequent installers to ensure they know the life remaining on a part and prevent the part being used beyond its life limit. Existing regulations provide for records on life-limited parts that are installed on aircraft. The regulations require that each owner or operator under § 91.417(a)(2)(ii) and each certificate holder under § 121.380(a)(2)(iii) or § 135.439(a)(2)(ii), maintain records showing ''the current status of life-limited parts of each airframe, engine, propeller, rotor, and appliance.'' These regulations do not

govern the disposition of the part when it is removed from the aircraft. If the part is intended to be reinstalled, however, a record of the life status of the part will be needed at the time of reinstallation to show that the part is within its life limit and to create the required record under §§ 91.417(a)(2)(ii), 121.380(a)(2)(iii), or 135.439(a)(2)(ii), as applicable. Therefore, when a life-limited part is removed from an aircraft and that part is intended to be reinstalled in an aircraft, industry practice is to make a record of the part's current status at the time of removal. Repair stations, air carriers, and fixed base operators (FBO's) have systems in place to keep accurate records of such parts to ensure that they can reinstall the parts and have the required records to show that the part is airworthy. If the part is not intended to be reinstalled, however, under existing regulations and practice there is no record required or routinely made when a part is removed from an aircraft. The part may be at the end of its life limit and not eligible for installation. Or, the part may not have reached the end of its life limit, but is so close that reinstallation would not be practicable. In these cases industry practices vary. For instance, the part might be put in a bin and later sold as scrap metal, it might be used as a training aid, or it might be mutilated. This renewal of the OMB control action requires the continued information collection.

Respondents: Industry associations, air carriers, manufacturers, repair stations, representatives of employees, a foreign civil air authority, and individuals estimated to 8,000.

Frequency: As identified in previous rulemaking proposals for an annual frequency of information collection requirements is 100,000 procedures.

Estimated Average Burden per Response: 30 minutes per procedure.

Estimated Total Annual Burden: As identified in previous rule making estimates for this information collection the FAA refined its estimate of annual burden, and has determined that there is no more than a minimal paperwork burden on any respondent for the record keeping and reporting requirements of 30 minutes duration, at $54 per hour per procedure.

Issued in Washington, DC, on September 24, 2020.

David Hoyng,

Aviation Safety Inspector—LLP SME, Air Carrier Branch/Aircraft Maintenance Division/Office of Safety Standards.

[FR Doc. 2020–21523 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0060]

Agency Information Collection Activities: Requests for Comments; Clearance of New Approval of Information Collection: Pilot Professional Development

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval new information collection. The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published on October 7, 2016. The collection involves the development and approval of new and revised training curriculum for certificate holders using part 121 pilot training and qualification programs.

DATES: Written comments should be submitted by October 29, 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: Sheri Pippin by email at: *sheri.pippin@faa.gov;* phone: 424–405–7256.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–XXXX.

Title: Pilot Professional Development.

Form Numbers: None.

Type of Review: This is a new information collection.

Background: The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published on October 7, 2016 (81 FR 69908). On February 25, 2020, the FAA published the Pilot Professional Development final rule. This action amends the requirements primarily applicable to air carriers conducting domestic, flag, and supplemental operations to enhance the professional development of pilots in those operations. This action requires air carriers conducting domestic, flag, and supplemental operations to provide new-hire pilots with an opportunity to observe flight operations and become familiar with procedures before serving as a flightcrew member in operations; to revise the upgrade curriculum; and to provide leadership and command and mentoring training for all pilots in command. This final rule will mitigate incidents of unprofessional pilot behavior and reduce pilot errors that can lead to a catastrophic event.

Summary: The final rule requires the development and approval of new and revised training curriculums for the following:

- Leadership and command and mentoring ground training for pilots currently serving as PIC (§ 121.429) and recurrent PIC leadership and command and mentoring training (§§ 121.409(b) and 121.427);
- Leadership and command training and recurrent leadership and command training for pilots serving as SIC in operations that require three or more pilots (§ 121.432(a));
- Upgrade training curriculum requirements (§§ 121.420 and 121.426);
- Part 121 appendix H requirements; and
- Approval of Qualification Standards Document for certificate holders using an Advanced Qualification Program (AQP) (§ 121.909).

The final rule also requires some additional recordkeeping related to maintaining records of pilots completing the following:

- Leadership and command and mentoring ground training for pilots currently serving as PIC (§ 121.429);
- Leadership and command training and recurrent leadership and command training for pilots serving as SIC in operations that require three or more pilots (§ 121.432(a));
- Recurrent PIC leadership and command and mentoring ground training (§ 121.427); and
- Operations familiarization for new-hire pilots (§ 121.435).

Use: This information will be used to ensure safety-of-flight by making certain that adequate training is obtained and maintained by those who operate under part 121. The FAA will review the respondents' training programs and

training courseware through routine certification, inspection and surveillance of certificate holders using part 121 pilot training and qualification programs to ensure compliance and adherence to regulations and, where necessary, to take enforcement action.

Respondents: As of February 2017, there were 79 certificate holders who use part 121 pilot training and qualification programs. They collectively employed 39,122 PICs and 42,227 SICs.

Frequency: Information is collected on occasion. Responses will vary based on type of operation.

Estimated Average Burden per Response: Burden per Operator varies per operation.

Estimated Total Annual Burden: 206 hours.

Issued in Washington, DC, on September 24, 2020.

Sandra L. Ray,

Aviation Safety Inspector, FAA, Policy Integration Branch, AFS–270.

[FR Doc. 2020–21482 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0228]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Pilots Convicted of Alcohol or Drug-Related Motor Vehicle Offenses Subject to State Motor Vehicle Administrative Procedure

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 4, 2020. The collection involves receiving and maintaining correspondence required to be sent to the FAA from pilots who have been involved in a drug or alcohol related motor vehicle action. The information to be collected will be used to and/or is necessary because the FAA is concerned about those airmen abusing or dependent on drugs or alcohol in regard to the safety of the National Airspace System.

DATES: Written comments should be submitted by October 29, 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: Christopher Marks by email at: *Christopher.Marks@faa.gov;* phone: 405–954–2789.

SUPPLEMENTARY INFORMATION: *Public Comments Invited:* You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0543.

Title: Pilots Convicted of Alcohol or Drug-Related Motor Vehicle Offenses Subject to State Motor Vehicle Administrative Procedure.

Form Numbers: No official form numbers used.

Type of Review: Renewal of an information collection.

Background: The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 4, 2020 (85 FR 12817). After a study and audit conducted from the late 1970's through the 1980's by the Department of Transportation, Office of the Inspector General, (DOT/OIG), the DOT/OIG recommended the FAA find a way to track alcohol abusers and those dependent on the substance that may pose a threat to the National Airspace (NAS). Through a Congressional act issued in November of 1990, the FAA established a Driving Under the Influence (DUI) and Driving While Intoxicated (DWI) Investigations Branch. The final rule for this program is found in Title 14 Code of Federal Regulations (CFR)—Part 61 § 61.15.

This regulation calls for pilots certificated by the FAA to send information regarding Driving Under the Influence (or similar charges) of alcohol and/or drugs to the FAA within 60 days from either an administrative action against their driver's license and/or criminal conviction. Part of the regulation also calls for the FAA to seek certificate action should an airman be involved in multiple, separate drug/alcohol related motor vehicle incidents within a three-year period. Information sent by the airmen is used to confirm or refute any violations of these regulations, as well as by the Civil Aerospace Medical Institute (CAMI) for medical qualification purposes. Collection by CAMI is covered under a separate OMB control number 2120–0034.

An airman is required to provide a letter via mail or facsimile, with the following information: Name, address, date of birth, pilot certificate number, the type of violation which resulted in the conviction or administrative action, and the state which holds the records or action.

Respondents: 589 FAA airmen with drug and alcohol related motor vehicle actions provide approximately 862 reports per year over the last three years.

Frequency: On occasion.

Estimated Average Burden per Response: 30 minutes.

Estimated Total Annual Burden: 431 hours.

Issued in Oklahoma City, OK on September 23, 2020.

Christopher Marks,

Security Specialist, Office of Security & Hazardous Materials Safety/Enforcement Standards & Policy Division, AXE–900.

[FR Doc. 2020–21418 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2020–0064]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document supplements the August 11, 2020, notice to the public (85 FR 48631) regarding the July 28, 2020, petition by BNSF Railway Company (BNSF) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 213. The Federal Railroad Administration (FRA) assigned the petition Docket Number FRA–2020–0064.

In support of its petition, BNSF referenced data and analysis from BNSF's ongoing Track Inspection Test Program, Docket Number FRA–2018–0091, however the specific data was not included in the petition. FRA requested that BNSF provide all applicable data, and FRA has posted the data to Docket

Number FRA–2020–0064 (Document No. FRA–2020–0064–0005). Based on this new information, FRA is extending the public comment period for 45 days.

A copy of the petition, as well as any written communications concerning the petition, if any, are available for review online at *www.regulations.gov.*

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing for 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 November 13, 2020 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/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. 2020–21467 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2020–0027–N–23]

Proposed Agency Information Collection Activities; Comment Request

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

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of the Information Collection Request (ICR) abstracted below. Before submitting this ICR to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified in the ICR.

DATES: Interested persons are invited to submit comments on or before November 30, 2020.

ADDRESSES: Submit comments and recommendations for the proposed ICR to Ms. Hodan Wells, Information Collection Clearance Officer at email: *hodan.wells@dot.gov* or telephone: (202) 493–0440. Please refer to the assigned OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days' notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. Specifically, FRA invites interested parties to comment on the following ICR regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal regulations mandate. In summary, FRA reasons that comments received will advance three objectives: (1) Reduce reporting burdens; (2) organize information collection requirements in a ''user-friendly'' format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Training, Qualification, and Oversight for Safety-Related Railroad Employees.

OMB Control Number: 2130–0597.

Abstract: In 2014, FRA published a final rule establishing minimum training standards for all safety-related railroad employees, as required by the Rail Safety Improvement Act of 2008. The final rule requires each railroad or contractor that employs one or more safety-related employees to develop and submit a training program to FRA for approval and to designate the minimum training qualifications for each occupational category of employee. Additionally, the rule requires most employers to conduct periodic oversight of their own employees and annual written reviews of their training programs to close performance gaps.

FRA will use the information collected to ensure each employer—railroad or contractor—conducting operations subject to part 243 develops, adopts, submits, and complies with a training program for each category and subcategory of safety-related railroad employee. Each program must have training components identified so that FRA will understand how the program works when it reviews the program for approval. Further, FRA will review the required training programs to ensure they include: Initial, ongoing, and on-the-job criteria; testing and skills evaluation measures designed to foster continual compliance with Federal standards; and the identification of critical safety defects and plans for immediate remedial actions to correct them.

In response to petitions for reconsideration, FRA has extended the effective date for developing the required training program under § 243.101 for employers with 400,000 or more total annual employee work hours

to January 1, 2020, and for employers with fewer than 400,000 total annual employee work hours to May 1, 2021.

Type of Request: Extension with change (revised estimates) of a currently approved collection.

Affected Public: Businesses.

Form(s): N/A.

Respondent Universe: 1,155 railroads/contractors/training organizations/learning institutions.

Frequency of Submission: On occasion.

Reporting Burden:

CFR section [1]	Respondent universe	Total annual responses	Average time per responses	Total annual burden hours	Total cost equivalent [2]
243.101(a)(2)—Training program required for each employer not covered by (a)(1) and subject to this part by May 1, 2021.	1,046 railroads/contractors.	298 training programs.	250 hours	74,500	$5,736,500
—(b) Submission by new employers commencing operations after Jan. 1, 2020 not covered by (a)(2).	10 new railroads/contractors.	10 training programs.	20	200	24,000
—(e) Contractor's duty to validate approved program to a railroad. (Revised requirement).	400 railroads/contractors.	50 documents	15 minutes	12.5	963
—(f) Railroad's duty to retain copies of contractor's validation document (Revised requirement).	10 new railroads	10 copies	2 minutes	.3	23
243.103(d)—Training components identified in program; modifications to components of the training programs.	1,155 railroads/contractors.	70 modified training programs.	5	350	26,950
243.109(b)—Previously approved programs requiring an informational filing when modified.	1,155 railroads/contractors/learning institutions.	10 informational filings.	8	80	6,160
—(c) New portions or substantial revisions to an approved training program.	10 railroads/contractors.	10 revised training programs.	16	160	12,320
—(c) New portions or substantial revisions to an approved training program found non-conforming to this part by FRA—revisions required.	5 railroads/contractors.	5 revised training programs.	8	40	3,080
—(d)(1)(i) Copy of additional submissions, resubmissions, and informational filings to labor organization presidents.	10 railroads/contractors.	25 copies	10 minutes	4.2	323
—(d)(1)(ii) Railroad statement affirming that a copy of submissions, resubmissions, or informational filings has been served to labor organization presidents.	228 railroads/contractors.	76 affirming statements.	10 minutes	12.7	978
—(d)(2) Labor comments on railroad training program submissions, resubmissions, or informational filings.	228 railroads' labor organizations.	3 comments	30 minutes	1.5	116
243.111(g)—Safety-related railroad employees instructed by training organizations and learning institutions (TO/LI)—recordkeeping.	109 TO/LI	5,450 records	5 minutes	454.2	34,973
—(h) TO/LI to provide student's training transcript or training record to any employer upon request by the student.	109 TO/LI	545 records	5 minutes	45.4	3,496
243.201(a)(2)—Designation of existing safety-related railroad employees by job category (for employers not covered by (a)(1) and subject to this part by January 1, 2022).	1,039 railroads/contractors.	346 designation lists.	15 minutes	86.5	6,661
—(b) New employers operating after January 1, 2020, not covered by (a)(2), designation of safety-related employees by job category—Lists.	10 new railroads/contractors.	10 designation lists	15 minutes	2.5	193
—(c) Training records of newly hired employees or those assigned new safety-related duties.	4,800 employees	4,800 records	15 minutes	1,200	92,400
—(d)(1)(i) Requests for relevant qualification or training record from an entity other than current employer.	4,800 employees	960 record requests.	5 minutes	80	6,160
243.203—(a)-(e) Recordkeeping—Systems set up to meet FRA requirements.	1,155 railroads/contractors/TOLI.	1,046 recordkeeping systems.	30 minutes	523	40,271
—(f) Transfer of records to successor employer.	1,155 railroads/contractors/TOLI.	3 records	30 minutes	1.5	116
243.205(c)—Railroad identification of supervisory employees who conduct periodic oversight tests by category/subcategory.	300 contractors	100 identifications	5 minutes	8.3	639

CFR section [1]	Respondent universe	Total annual responses	Average time per responses	Total annual burden hours	Total cost equivalent [2]
—(f) Notification by RR of contractor employee non-compliance with Federal laws/regulations/orders to employee and employee's employer.	300 contractors	90 employee notices.	10 minutes	15	1,155
—(f) Notification by RR of contractor employee non-compliance with Federal laws/regulations/orders to employee and employee's employer.	300 contractors	270 employer notices.	10 minutes	45	3,465
—(i) and (j) Employer records of periodic oversight.	1,046 railroads/contractors.	150,000 records	5 minutes	12,500	962,500
243.207(a)—Written annual review of safety data (Railroads with 400,000 annual employee work hours or more).	22 railroads	22 reviews	16	352	27,104
—(b) Railroad copy of written annual review at system headquarters.	22 railroads	22 review copies ...	5 minutes	1.8	139
—(e) Railroad notification to contractor of relevant training program adjustments.	22 railroads	2 notifications	15 minutes	.5	39
243.209(a)–(b)—Railroad maintained list of contractors utilized.	746 railroads	746 lists	30 minutes	373	28,721
—(c) Railroad duty to update list of contractors utilized and retain record for at least 3 years showing if a contractor was utilized in last 3 years.	746 railroads	75 updated lists	15 minutes	18.8	1,444
Total	1,155 railroads/contractors/training organizations/ learning institutions.	165,054 responses	N/A	91,069	7,020,889

[1] *Note:* The current inventory exhibits a total burden of 282,824 hours while that of this requesting notice is 91,069 hours. FRA determined many of the estimates were initial estimates and outdated. Moreover, other estimates were not derived from PRA requirements, thus leading to the increased figures in the current inventory, which were decreased accordingly in this notice. Also, totals may not add due to rounding.

[2] The dollar equivalent cost is derived from the Surface Transportation Board's Full Year Wage A&B data series using the appropriate employee group hourly wage rate that includes a 75-percent overhead charge.

Total Estimated Annual Responses: 165,054.

Total Estimated Annual Burden: 91,069 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $7,020,889.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that a respondent is not required to respond to, conduct, or sponsor a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Deputy Chief Counsel.

[FR Doc. 2020–21527 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2020–0076]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on September 18, 2020, BNSF Railway Company (BNSF) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 213, Track Safety Standards. FRA assigned the petition Docket Number FRA–2020–0076.

Specifically, BNSF requests a waiver of compliance from 49 CFR 213.113, *Defective rails,* to permit an alternate means of affecting the remedial actions set forth in remedial action code C (49 CFR 213.113(c)). BNSF proposes that following the application of joint bars in accordance with remedial action code C, the track segment be operated as follows:

- Trains may continue to run at the maximum allowable speed for the track class until a maximum of 15 million gross tons (MGT) have traversed the track segment;
- after 15 MGT have traversed the segment, operating speed will be reduced to 50 miles per hour (mph) thereafter until the defective rail is replaced; and
- if the rail defect progresses to a 100% fracture, operating speed will be reduced to 10 mph thereafter until the defective rail is replaced.

BNSF states that the relief will promote railroad safety by allowing rail inspection vehicles to maintain ideal inspection frequencies, which will ensure that BNSF track will be inspected more frequently and defects remedied and repaired more quickly.

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 November 13, 2020 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/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. 2020–21466 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Competitive Funding Opportunity: Pilot Program for Transit-Oriented Development Planning

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of Funding Opportunity (NOFO).

SUMMARY: The Federal Transit Administration (FTA) announces the opportunity to apply for approximately $6.22 million of Fiscal Year (FY) 2020 funding under the Pilot Program for Transit-Oriented Development Planning (Catalog of Federal Domestic Assistance #20.500). FTA may award additional funds if they are made available to the program prior to the announcement of project selections. As required by Federal public transportation law and subject to funding availability, funds will be awarded competitively to support comprehensive planning associated with new fixed guideway and core capacity improvement projects.

DATES: Complete proposals must be submitted electronically through the *GRANTS.GOV* ''APPLY'' function by 11:59 p.m. EDT on October 26, 2020. Prospective applicants should initiate the process by registering on the *GRANTS.GOV* website promptly to ensure completion of the application process before the submission deadline. Instructions for applying can be found on FTA's website at *https://www.transit.dot.gov/TODPilot* and in the ''FIND'' module of *GRANTS.GOV.* The *GRANTS.GOV* funding opportunity ID is FTA–2020–014–TPE. Mail and fax submissions will not be accepted.

FOR FURTHER INFORMATION CONTACT: Dwayne Weeks, FTA Office of Planning and Environment, (202) 493–0316, or *Dwayne.Weeks@dot.gov.* A TDD is available at 1–800–877–8339 (TDD/FIRS).

SUPPLEMENTARY INFORMATION:

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A. Program Description

Section 20005(b) of the Moving Ahead for Progress in the 21st Century Act (MAP–21; Pub. L. 112–141, July 6, 2012), with funding authorized by 49 U.S.C. 5338(a)(2)(B), authorizes FTA to award funds under the Pilot Program for Transit-Oriented Development (TOD) Planning (TOD Pilot Program). The TOD Pilot Program grants are competitively awarded to local communities to integrate land use and transportation planning with a new fixed guideway or core capacity improvement transit capital project as defined in Federal public transportation law (49 U.S.C. 5309(a)). (See section C of this NOFO for more information about eligibility.)

The TOD Pilot Program is intended to fund comprehensive planning that supports economic development, ridership, multimodal connectivity and accessibility, increased transit access for pedestrian and bicycle traffic, and mixed-use development near transit stations. The TOD Pilot Program also encourages identification of infrastructure needs and engagement with the private sector.

FTA is seeking comprehensive planning projects covering an entire transit capital project corridor, rather than proposals that involve planning for individual station areas or only a small section of the corridor. To ensure that any proposed planning work both reflects the needs and aspirations of the local community, and also results in concrete, specific deliverables and outcomes, transit project sponsors must partner with entities with land use planning authority in the transit project corridor to conduct the planning work.

B. Federal Award Information

Federal public transportation law (49 U.S.C. 5338(a)(2)(B)) authorizes FTA to make grants for eligible comprehensive planning projects under Section 20005(b) of MAP–21. FTA intends to award all available funding ($6.22 million) to selected applicants responding to this NOFO. Due to funding limitations, applicants that are selected for funding may receive less than the amount originally requested.

Only proposals from eligible recipients for eligible activities will be considered for funding. FTA anticipates minimum grant awards of $250,000 and maximum grant awards of $2,000,000.

C. Eligibility Information

1. Eligible Applicants

Applicants under the TOD Pilot Program must be State or local governmental authorities and FTA grant recipients (*i.e.,* existing direct and designated recipients) as of the publication date of this NOFO. An applicant must be the project sponsor of an eligible transit capital project as defined below in section C, subsection 3 or an entity with land use planning authority in the project corridor of an eligible transit capital project. Except in cases where an applicant is both the sponsor of an eligible transit project and has land use authority in at least a portion of the transit project corridor, the transit project sponsor and at least one entity in the project corridor with land use planning authority must partner on the proposed comprehensive planning project. Documentation of this partnership must be included with the application; see section D, subsection 2 of this NOFO for further information.

Only one application per transit capital project corridor may be submitted to FTA. Multiple applications submitted for a single transit capital project corridor indicate that partnerships are not in place and FTA will reject all of the applications.

2. Cost Sharing or Matching

The maximum Federal funding share is 80 percent.

Eligible sources of local match include the following: Cash from non-

Government sources (other than revenues from providing public transportation services); revenues derived from the sale of advertising and concessions; amounts received under a service agreement with a State or local social service agency or private social service organization; revenues generated from value capture financing mechanisms; funds from an undistributed cash surplus; replacement or depreciation cash fund or reserve; or new capital. In-kind contributions are permitted. Transportation Development Credits (formerly referred to as Toll Revenue Credits) may not be used to satisfy the local match requirement. FTA may prioritize projects proposed with a higher non-Federal share.

3. Other Eligibility Criteria

i. Eligible Transit Projects

Any comprehensive planning work proposed for funding under the TOD Pilot Program must be associated with an eligible transit capital project. Although not required to be part of the Capital Investment Grant program, to be eligible, the proposed transit capital project must be a new fixed guideway project or a core capacity improvement project as defined by Federal public transportation law (49 U.S.C. 5309(a)).

A fixed guideway is a public transportation facility:

(A) Using and occupying a separate right-of-way for the exclusive use of public transportation;

(B) using rail;

(C) using a fixed catenary system;

(D) for a passenger ferry system; or

(E) for a bus rapid transit system.

A new fixed guideway capital project is defined in statute to be:

(A) A new fixed guideway project that is a minimum operable segment or extension to an existing fixed guideway system; or

(B) a fixed guideway bus rapid transit project that is a minimum operable segment or an extension to an existing bus rapid transit system.

A fixed guideway bus rapid transit project is defined more specifically in statute as a bus capital project:

(A) In which the majority of the project operates in a separated right-of-way dedicated for public transportation use during peak periods;

(B) that represents a substantial investment in a single route in a defined corridor or subarea; and

(C) that includes features that emulate the services provided by rail fixed guideway public transportation systems, including:

(i) Defined stations;

(ii) traffic signal priority for public transportation vehicles;

(iii) short headway bidirectional services for a substantial part of weekdays and weekend days; and

(iv) any other features the Secretary may determine are necessary to produce high-quality public transportation services that emulate the services provided by rail fixed guideway public transportation systems.

A core capacity improvement project is defined in statute as a substantial corridor-based capital investment in an existing fixed guideway system that increases the capacity of the corridor by not less than 10 percent. The term does not include project elements designed to maintain a state of good repair of the existing fixed guideway system.

Comprehensive planning work in a corridor for a transit capital project that does not meet the statutory definition above of either a new fixed guideway project or a core capacity improvement project is not eligible under the TOD Pilot Program.

ii. Eligible Activities

Any comprehensive planning efforts funded under the TOD Pilot Program must address all six aspects of the general authority stipulated in Section 20005(b)(2) of MAP–21:

i. Enhances economic development, ridership, and other goals established during the project development and engineering processes;

ii. facilitates multimodal connectivity and accessibility;

iii. increases access to transit hubs for pedestrian and bicycle traffic;

iv. enables mixed-use development;

v. identifies infrastructure needs associated with the eligible project; and

vi. includes private sector participation.

MAP–21 also requires the comprehensive planning effort to advance the metropolitan planning organization's metropolitan transportation plan. Further, MAP–21 requires applicants to establish performance criteria for the comprehensive planning effort.

Following are examples of the types of substantial deliverables that may result from the comprehensive planning work. Substantial deliverables are reports, plans and other materials that represent the key accomplishments of the comprehensive planning effort and that must be submitted to FTA as each is completed. Substantial deliverables may include, but are not restricted to, the following:

i. A comprehensive plan report that includes corridor development policies and station development plans, a proposed timeline, and recommended financing strategies for these plans;

ii. A strategic plan report that includes corridor specific planning strategies and program recommendations to support comprehensive planning;

iii. Revised TOD-focused zoning codes and/or resolutions;

iv. A report evaluating and recommending financial tools to encourage TOD implementation such as land banking, value capture, and development financing;

v. Policies to encourage TOD, including actions that reduce regulatory barriers that unnecessarily raise the costs of housing development or impede the development of affordable housing; and/or

vi. Local or regional resolutions to implement TOD plans and/or establish TOD funding mechanisms.

iii. Ineligible Activities

Applications should not include the following activities:

i. TOD planning work only in a single transit capital project station area;

ii. Transit project development activities that would be reimbursable under an FTA capital grant, such as project planning, the design and engineering of stations and other facilities, environmental analyses needed for the transit capital project, or costs associated with specific joint development activities;

iii. Capital projects, such as land acquisition, construction, and utility relocation; and

iv. Site- or parcel-specific planning, such as the design of individual structures.

D. Application and Submission Information

1. Address To Request Application Package

Applications must be submitted electronically through *GRANTS.GOV.* General information for submitting applications through *GRANTS.GOV* can be found at *https://www.transit.dot.gov/funding/grants/applying/applying-fta-funding* along with specific instructions for the forms and attachments required for submission. Mail and fax submissions will not be accepted.

2. Content and Form of Application Submission

Proposals must include a completed SF 424 Mandatory form (downloaded from *GRANTS.GOV*) and the following attachments to the completed SF 424:

i. A completed Applicant and Proposal Profile supplemental form for the TOD Pilot Program (supplemental form) found on the FTA website at

https://www.transit.dot.gov/TODPilot. The information on the supplemental form will be used to determine applicant and project eligibility for the program, and to evaluate the proposal against the selection criteria described in part E of this notice;

ii. A map of the proposed study area showing the transit project alignment and stations, major roadways, major landmarks, and the geographic boundaries of the proposed comprehensive planning activities;

iii. Documentation of a partnership between the transit project sponsor and an entity in the project corridor with land use planning authority to conduct the comprehensive planning work, if the applicant does not have both of these responsibilities. Documentation may consist of a memorandum of agreement or letter of intent signed by all parties that describes the parties' roles and responsibilities in the proposed comprehensive planning project; and

iv. Documentation of any funding commitments for the proposed comprehensive planning work.

Information such as the applicant's name, Federal amount requested, local match amount, description of the study area, are requested in varying degrees of detail on both the SF 424 form and supplemental form. Applicants must fill in all fields unless stated otherwise on the forms. Applicants should use both the ''Check Package for Errors'' and the ''Validate Form'' buttons on both forms to check all required fields, and ensure that the Federal and local amounts specified are consistent. In the event of errors with the supplemental form, FTA recommends saving the form on your computer and ensuring that JavaScript is enabled in your PDF reader. The information listed below MUST be included on the SF 424 and supplemental forms for TOD Pilot Program funding applications.

The SF 424 and supplemental form will prompt applicants to address the following items:

1. Provide the name of the lead applicant and, if applicable, the specific co-sponsors submitting the application.

2. Provide the applicant's Dun and Bradstreet Data Universal Numbering System (DUNS) number.

3. Provide contact information including: Contact name, title, address, phone number, and email address.

4. Specify the Congressional district(s) where the planning project will take place.

5. Identify whether the planning project is located in a qualified opportunity zone designated pursuant to *26* U.S.C. 1400Z–1.

6. Identify the project title and project scope to be funded, including anticipated substantial deliverables and the milestones at when they will be provided to FTA.

7. Identify and describe an eligible transit project that meets the requirements of section C, subsection 3 of this notice.

8. Provide evidence of a partnership between the transit project sponsor and at least one agency with land use authority in the transit capital project corridor, as described earlier in this subsection.

9. Address the six aspects of general authority under MAP–21 Section 20005(b)(2).

10. Address each evaluation criterion separately, demonstrating how the project responds to each criterion as described in section E.

11. Provide a line-item budget for the total planning effort, with enough detail to indicate the various key components of the comprehensive planning project.

12. Identify the Federal amount requested.

13. Document the matching funds, including amount and source of the match (may include local or private sector financial participation in the project). Describe whether the matching funds are committed or planned, and include documentation of the commitments.

14. Address whether other Federal funds have been sought or received for the comprehensive planning project.

15. Provide a schedule and process for the development of the comprehensive plan that includes anticipated dates for incorporating the planning work effort into the region's unified planning work program, completing major tasks and substantial deliverables, and completing the overall planning effort.

16. Describe how the comprehensive planning work advances the metropolitan transportation plan of the metropolitan planning organization.

17. Propose performance criteria for the development and implementation of the comprehensive planning work.

18. Identify potential State, local or other impediments to the products of the comprehensive planning work and its implementation, and how the work will address them.

FTA will not consider any additional materials submitted by applicants in its evaluation of proposals. The total length of the completed supplemental form and documentation of partnerships and funding commitments should be no more than 15 pages.

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant is required to: (1) Register in SAM before submitting an application; (2) provide a valid unique entity identifier; and (3) continue to maintain an active SAM registration with current information at all times during which the applicant has an active Federal award or an application or plan under consideration by FTA. These requirements do not apply if the applicant: (1) Is an individual; (2) is excepted from the requirements under 2 CFR 25.110(b) or (c); or (3) has an exception approved by FTA under 2 CFR 25.110(d). FTA may not make an award until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has not fully complied with the requirements by the time FTA is ready to make an award, FTA may determine that the applicant is not qualified to receive an award and use that determination as a basis for making a Federal award to another applicant. Registration in SAM may take as little as 3–5 business days, but since there could be unexpected steps or delays, FTA recommends allowing ample time, up to several weeks, for completion of all steps. For additional information on obtaining a unique entity identifier, please visit *www.sam.gov.*

4. Submission Dates and Times

Project proposals must be submitted electronically through *http://www.GRANTS.GOV* by 11:59 p.m. EDT on October 26, 2020. *GRANTS.GOV* attaches a time stamp to each application at the time of submission. Proposals submitted after the deadline will not be considered under any circumstances. Mail and fax submissions will not be accepted.

Within 48 hours after submitting an electronic application, the applicant should receive two email messages from *GRANTS.GOV:* (1) Confirmation of successful transmission to *GRANTS.GOV;* and (2) confirmation of successful validation by *GRANTS.GOV.* FTA will then validate the application and will attempt to notify any applicants whose applications could not be validated. If the applicant does not receive confirmation of successful validation or a notice of failed validation or incomplete materials, the applicant must address the reason for the failed validation, as described in the email notice, and resubmit before the submission deadline. If making a resubmission for any reason, include all original attachments regardless of which attachments were updated and check

the box on the supplemental form indicating this is a resubmission. An application that is submitted at the deadline and cannot be validated will be marked as incomplete, and such applicants will not receive additional time to re-submit.

Any addenda that FTA releases on the application process will be posted at *https://www.transit.dot.gov/TODPilot.* Important: FTA urges applicants to submit their applications at least 96 hours prior to the due date to allow time to receive the validation messages and to correct any problems that may have caused a rejection notification. *GRANTS.GOV* scheduled maintenance and outage times are announced on the *GRANTS.GOV* website at *http://www.GRANTS.GOV.* Deadlines will not be extended due to scheduled maintenance or outages.

Applicants are encouraged to begin the registration process on the *GRANTS.GOV* site well in advance of the submission deadline. Registration is a multi-step process, which may take several weeks to complete before an application can be submitted. Registered applicants may still be required to take steps to keep their registration up to date before submissions can be made successfully: (1) Registration in the System for Award Management (SAM) is renewed annually and (2) persons making submissions on behalf of the Authorized Organization Representative (AOR) must be authorized in *GRANTS.GOV* by the AOR to make submissions. Instructions on the *GRANTS.GOV* registration process are listed in Appendix A.

5. Funding Restrictions

See section C of this NOFO for detailed eligibility requirements. FTA emphasizes that any comprehensive planning projects funded through the TOD Pilot Program must be associated with an eligible transit project, specifically a new fixed guideway project or a core capacity improvement project as defined in Federal transit statute, 49 U.S.C. 5309(a). Projects are not required to be within the Capital Investment Grant Program.

E. Application Review Information

1. Criteria

FTA will evaluate proposals that include all components identified in section D of this notice according to the following three criteria:

a. Demonstrated Need

FTA will evaluate each project to determine the need for funding based on the following factors:

i. Potential state, local or other impediments to implementation of the products of the comprehensive planning effort, and how the workplan will address them;

ii. How the proposed work will advance TOD implementation in the corridor and region;

iii. Justification as to why Federal funds are needed for the proposed work; and

iv. Extent to which the transit project corridor could benefit from TOD planning.

b. Strength of the Work Plan, Schedule and Process

FTA will evaluate the strength of the work plan, schedule and process included in an application based on the following factors:

i. Extent to which the schedule contains sufficient detail, identifies all steps needed to implement the work proposed, and is achievable;

ii. The proportion of the project corridor covered by the work plan;

iii. Extent of partnerships, including with non-public sector entities;

iv. The partnerships' technical capability to develop, adopt and implement the comprehensive plans, based on FTA's assessment of the applicant's description of the policy formation, implementation, and financial roles of the partners, and the roles and responsibilities of proposed staff; and

v. Whether the performance measures identified in the application relate to the goals of the comprehensive planning work.

c. Funding Commitments

FTA will assess the status of local matching funds for the planning work. Applications demonstrating that matching funds for the proposed comprehensive planning work are committed will receive higher ratings from FTA on this factor. Proposed comprehensive planning projects for which matching funding sources have been identified, but are not yet committed, will be given lower ratings under this factor by FTA, as will proposed comprehensive planning projects for which in-kind contributions constitute the primary or sole source of matching funds.

2. Review and Selection Process

In addition to other FTA staff that may review the proposals, a technical evaluation committee will evaluate proposals based on the published evaluation criteria. Members of the technical evaluation committee and other FTA staff may request additional information from applicants, if necessary. Based on the findings of the technical evaluation committee, the FTA Administrator will determine the final selection of projects for program funding. Among the factors, in determining the allocation of program funds FTA may consider geographic diversity, diversity in the size of the grantees receiving funding, projects located in or that support public transportation service in a qualified opportunity zone designated pursuant to 26 U.S.C. 1400Z–1, or the applicant's receipt of other competitive awards. FTA may prioritize projects proposed with a higher local share.

Addressing the deteriorating conditions and disproportionately high fatality rates on our rural transportation infrastructure is of critical interest to the Department, as rural transportation networks face unique challenges in safety, infrastructure condition, and passenger and freight usage. Consistent with the DOT's new Rural Opportunities to Use Transportation for Economic Success (R.O.U.T.E.S.) initiative, the Department will consider how the applicant will address the challenges faced by rural areas. FTA will also evaluate the potential for the project to accelerate the introduction of innovative technologies or practices such as integrated fare payment systems permitting complete trips or advancements to propulsion systems. Innovation can also include practices such as new public transportation operational models, financial or procurement arrangements, or value capture.

In addition to the criteria and considerations outlined in this section, the FTA Administrator will take into account the following key Departmental objectives:

(A) Supporting economic vitality at the national and regional level;

(B) Leveraging Federal funding to attract other, non-Federal sources of infrastructure investment, including value capture;

(C) Using innovative approaches to improve safety and expedite project delivery;

(D) Encourage State and local and tribal governments to reduce regulatory barriers that unnecessarily raise the costs of housing development or impede the development of affordable housing; and

(E) Holding grant recipients accountable for their performance and achieving specific, measurable outcomes identified by grant applicants.

Prior to making an award, FTA is required to review and consider any information about the applicant that is

in the Federal Awardee Performance and Integrity Information Systems (FAPIIS) accessible through SAM. An applicant may review and comment on information about itself that a Federal awarding agency previously entered. FTA will consider any comments by the applicant, in addition to the other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in the 2 CFR 200.205 Federal awarding agency review of risk posed by applicants.

F. Federal Award Administration Information

1. Federal Award Notices

The FTA Administrator will announce the final project selections on the FTA website. Project recipients should contact their FTA Regional Offices for additional information regarding allocations for projects under the TOD Pilot Program. FTA will issue specific guidance to recipients regarding pre-award authority at the time of selection; see subsection 3 below for further information.

2. Administrative and National Policy Requirements

i. Pre-Award Authority.

FTA will issue specific guidance to recipients regarding pre-award authority at the time of selection. FTA does not provide pre-award authority for competitive funds until projects are selected and even then, there are Federal requirements that must be met before costs are incurred. Funds under this NOFO cannot be used to reimburse applicants for otherwise eligible expenses incurred prior to FTA award of a Grant Agreement until FTA has issued pre-award authority for selected projects, or unless FTA has issued a ''Letter of No Prejudice'' for the project before the expenses are incurred. For more information about FTA's policy on pre-award authority, please see the FY 2020 Apportionment Notice published on June 3, 2020. *https://www.govinfo.gov/content/pkg/FR-2020-06-03/pdf/2020-11946.pdf.*

ii. In connection with any program or activity conducted with or benefiting from funds awarded under this notice, recipients of funds must comply with all applicable requirements of Federal law, including, without limitation, the Constitution of the United States; statutory, regulatory, and public policy requirements, including without limitation, those protecting free speech, religious liberty, public welfare, the environment, and prohibiting discrimination; the conditions of performance, non-discrimination requirements, and other assurances made applicable to the award of funds in accordance with regulations of the Department of Transportation; and applicable Federal financial assistance and contracting principles promulgated by the Office of Management and Budget. In complying with these requirements, recipients, in particular, must ensure that no concession agreements are denied or other contracting decisions made on the basis of speech or other activities protected by the First Amendment. If the Department determines that a recipient has failed to comply with applicable Federal requirements, the Department may terminate the award of funds and disallow previously incurred costs, requiring the recipient to reimburse any expended award funds.

iii. Grant Requirements.

If selected, awardees will apply for a grant through FTA's Transit Award Management System (TrAMS). Recipients of TOD Pilot Program funds are subject to the grant requirements of the Section 5303 Metropolitan Planning program, including those of FTA Circular 8100.1C and Circular 5010.1E. All competitive grants, regardless of award amount, will be subject to the Congressional Notification and release process. Technical assistance regarding these requirements is available from each FTA regional office.

iv. Planning.

FTA encourages applicants to notify the appropriate metropolitan planning organizations in areas likely to be served by the funds made available under this program. Selected projects must be incorporated into the unified planning work programs of metropolitan areas before they are eligible for FTA funding or pre-award authority.

v. Standard Assurances.

The applicant assures that it will comply with all applicable Federal statutes, regulations, executive orders, directives, FTA circulars, and other Federal administrative requirements in carrying out any project supported by the FTA grant. The applicant acknowledges that it is under a continuing obligation to comply with the terms and conditions of the grant agreement issued for its project with FTA. The applicant understands that Federal laws, regulations, policies, and administrative practices might be modified from time to time and may affect the implementation of the project. The applicant agrees that the most recent Federal requirements will apply to the project, unless FTA issues a written determination otherwise. The applicant must submit the Certifications and Assurances before receiving a grant if it does not have current certifications on file.

3. Reporting

Post-award reporting requirements include submission of Federal Financial Reports and Milestone Progress Reports in FTA's electronic grants management system on a quarterly basis. Awardees must also submit copies of the substantial deliverables identified in the work plan to the FTA regional office at the corresponding milestones.

G. Federal Awarding Agency Contacts

For program-specific questions, please contact Dwayne Weeks, Office of Planning and Environment, (202) 493–0316, email: *Dwayne.Weeks@dot.gov.* A TDD is available at 1–800–877–8339 (TDD/FIRS). Any addenda that FTA releases on the application process will be posted at *https://www.transit.dot.gov/TODPilot.* To ensure applicants receive accurate information about eligibility or the program, the applicant is encouraged to contact FTA directly, rather than through intermediaries or third parties. FTA staff may also conduct briefings on the FY 2020 competitive grants selection and award process upon request. Contact information for FTA's regional offices can be found on FTA's website at *www.transit.dot.gov.*

For issues with *GRANTS.GOV* please contact *GRANTS.GOV* by phone at 1–800–518–4726 or by email at *support@grants.gov.*

H. Technical Assistance and Other Program Information

This program is not subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.''

K. Jane Williams,

Deputy Administrator.

[FR Doc. 2020–21473 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0070]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Automated Vehicle Transparency and Engagement for Safe Testing (AV TEST) Initiative

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a new information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below will be submitted to the Office of Management and Budget (OMB) for review and approval. The ICR describes the nature of the information collection and its expected burden.

The information collection described in this document is for NHTSA's planned Automated Vehicle Transparency and Engagement for Safe Testing (AV TEST) Initiative, which involves the collection of voluntarily-submitted information from entities involved in the testing of vehicles equipped with automated driving systems (ADS) and from States and local authorities involved in the regulation of ADS testing. The purpose of this collection is to provide information to the public about ADS testing operations in the United States and applicable State and local laws, regulations, and guidelines.

A **Federal Register** Notice with a 60-day comment period soliciting comments on the information collection was published on July 2, 2020 (85 FR 39975). NHTSA received 20 comments and a brief summary and NHTSA's response to those comments is provided in this document.

DATES: Comments must be submitted on or before October 29, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection, including suggestions for reducing burden, should be submitted to the Office of Management and Budget at *www.reginfo.gov/public/do/PRAMain.* To find this particular information collection, select ''Currently under Review—Open for Public Comment'' or use the search function.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Michael Frenchik, Office of Data Acquisition, Safety Systems Management Division (NSA–0130), Room W53–303, 1200 New Jersey Avenue SE, Washington, DC 20590. Mr. Frenchik's telephone number is (202) 366–0641. National Highway Traffic Safety Administration. U.S. Department of Transportation, 1200 New Jersey Avenue, SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), a Federal agency must receive approval from the Office of Management and Budget (OMB) before it collects certain information from the public and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. In compliance with these requirements, this notice announces that the following information collection request will be submitted OMB.

A **Federal Register** notice with a 60-day comment period soliciting public comments on the following information collection was published on July 2, 2020.

Title: Automated Vehicle Transparency and Engagement for Safe Testing (AV TEST) Initiative.

OMB Control Number: 2127–NEW.

Form Number: NHTSA Form 1586—AV TEST Tracker eForm; NHTSA Form 1587—AV TEST Onboarding Form.

Type of Request: Request for approval of a new information collection.

Type of Review Requested: Regular.

Length of Approval Requested: Three years from the date of approval.

Summary of the Collection of Information: The U.S. Department of Transportation (DOT), National Highway Traffic Safety Administration (NHTSA) was established by Congress to save lives, prevent injuries, and reduce economic costs due to motor vehicle crashes through education, research, safety standards, and enforcement activity. DOT and NHTSA are fully committed to reaching an era of crash-free roadways through the deployment of innovative lifesaving technologies. The prevalence of automotive crashes in the United States underscores the urgency to develop and deploy lifesaving technologies that can dramatically decrease the number of fatalities and injuries on our Nation's roadways.

NHTSA believes that Automated Driving System (ADS) technology, including technology contemplating no human driver at all, has the potential to significantly improve roadway safety in the United States. This technology remains substantially in development phases with companies across the United States performing varying levels of development, research, and testing relating to the performance of various aspects of ADS vehicle technologies. While much of these development operations occur in private facilities and closed-course test tracks, many stakeholders have progressed to conducting ADS vehicle testing on public roads or in public demonstrations. Moreover, to regulate such operations in their jurisdictions, many local authorities, such as States and cities, have passed laws governing ADS vehicle testing on public roads. These statutes, regulations, and ordinances vary, ranging from operational requirements to mandating the submission of periodic reports detailing ADS vehicle operation.

Description of the Need for the Information and Proposed Use of the Information: The AV TEST Initiative seeks to enhance public education and engagement with public ADS vehicle testing by coalescing information regarding respondents' various testing operations or requirements into a centralized resource. This information collection seeks voluntarily-provided information from entities performing ADS testing about their operations and information from local authorities about requirements or recommendations for such operations. NHTSA will maintain a digital platform on its website that collects information from respondents and makes the information about ADS operations and applicable State and local requirements and recommendations available to members of the public.

The program will support two main objectives. The first objective is to provide the public with access to geographic visualizations of testing at the national, State, and local levels. This information will be displayed on a graphic of the United States, with projects overlaid on the geographic areas in which the testing project is taking place. By clicking on a testing location, members of the public will be able see additional information about the operation and the ADS operator. Additional information may include basic information about the ADS operator, a brief statement about the entity, specific details of the testing activity, high-level (non-confidential) descriptions of the vehicles and technology, photos of the test vehicles, the dates on which testing occurs, frequency of vehicle operations, the number of vehicles participating in the project, the specific streets or areas comprising the testing routes,

information about safety drivers and their training, information about engagement with the community and/or local government, weblinks to the company's websites with brief introductory statements, and a link to the company's Voluntary Safety Self-Assessment (VSSA).[1]

The second objective is to provide members of the public with information collected from States and local authorities that regulate ADS operations. State and local authorities will be asked to provide weblinks for specific ADS-related topics, such as statutes, regulations, or guidelines for ADS operations, privacy-related issues, emergency response policies and training, or other activities that cultivate ADS testing. The implementation of this program will provide a central resource for the aforementioned information concerning ADS testing across the United States.

Affected Public: There are two information collection components to this request. The first affects entities engaged in testing of ADS vehicles, including original manufacturers of ADS vehicles and ADS vehicle equipment, and operators of ADS vehicles. The second affects local authorities regulating testing of ADS vehicles within their jurisdictions, including States, cities, counties, and other municipalities.

Estimated Number of Respondents: NHTSA anticipates that the Initiative will include up to 60 State or local government respondents and 40 private industry respondents (ADS developer, ADS vehicle manufacturer, or ADS operator respondents) per year.

Frequency: Participation is completely voluntary and each participant will choose its respective degree of involvement and the frequency of its submissions. Therefore, the frequency of a participant's response may vary due to a variety of factors, such as the degree of the entity's participation in the initiative or the frequency with which each entity modifies its ADS testing operations or, in the case of local authorities, amends its regulations governing such operations.

Number of Responses: Participation is completely voluntary and each participation will choose the number and frequency of its submissions. Therefore, the number of responses from a participant will vary due to a variety of factors, such as the degree of the entity's participation in the initiative or the frequency with which each entity modifies its ADS testing operations or, in the case of local authorities, amends its regulations governing such operations.

Estimated Total Annual Burden Hours: NHTSA estimates that each State or local participant will spend approximately 30 hours per year providing information to the AV TEST Initiative and estimates that each private industry participant will spend approximately 48 hours per year providing information to the AV TEST Initiative. While NHTSA's estimate for the burden hours per private industry participant remained the same from the July 2, 2020 notice, NHTSA has increased the burden estimate for State and local participants. Since publishing the original notice, NHTSA conducted a pilot involving 9 State and local participants and 9 ADS operators. NHTSA's revised estimates are based upon direct work with the participants in the pilot phase of the AV TEST Initiative. One of the pilot participants, Maryland Department of Transportation, also commented on the July 2 notice.

Specific estimates provided by a majority of participants in the initiative's pilot program confirmed NHTSA's original estimate that, on average, private industry participants would spend approximately 48 hours per year, or 4 hours per month, on data entry for the AV TEST Initiative. This estimate also factors in time for new participants to learn how to use the data-entry platform and submit initial information. While NHTSA's estimate for private industry participants has remained 48 hours per year, NHTSA has revised its estimate for State and local participants based on specific estimates provided by pilot participants, as well as NHTSA's observation of pilot participants in gathering and submitting data. Although the July 2 notice estimated that State and local participants would spend approximately 10 hours per year on data submission to the AV TEST Initiative, NHTSA now estimates the annual burden to be 30 hours per participant.

NHTSA estimates that the annual burden of participation will be approximately 48 hours for private industry respondents that include ADS operators, developers, or vehicle manufacturers. This total number of hours represents approximately four hours per month to perform data entry for testing projects (4 hours × 12 months = 48). Therefore, for the estimated 40 private industry participants, the total burden is estimated to be 1,920 hours per year (40 respondents × 48 hours).

NHTSA estimates that the annual burden of participation will likely be approximately 30 hours annually for State or local authorities. The increase from 10 hours to 30 hours per year was based on specific estimates provided by a majority of participants in the Initiative's pilot program, including a public comment by Maryland Department of Transportation.[2] Therefore, for the estimated 60 State or local authority participants, the total burden is estimated to be 1,800 hours per year (60 respondents × 30 hours). The total annual burden for the entire information collection request is estimated to 3,720 hours (1,920 hours + 1,800 hours).

The labor cost associated with this collection of information is derived by (1) applying the appropriate average hourly labor rate published by the Bureau of Labor Statistics, (2) dividing by either 0.701[3] (70.1%), for private industry workers, or 0.623 (62.3%), for State and local government workers, to obtain the total cost of compensation, and (3) multiplying by the estimated burden hours for each respondent type.

Labor costs associated with original manufacturers of ADS vehicles or ADS vehicle equipment and operators of ADS vehicles are estimated to be $60.96 per hour for ''Project Management Specialists,'' Occupation Code 13–1198, ($42.73[4] per hour ÷ 0.701). The estimated labor cost per private industry respondent is estimated to be $2,926.08 per year ($60.96 × 48 hours). Therefore, the total annual labor cost for private industry to participate in the AV TEST Initiative is estimated to be $117,043.

Labor costs associated with State and local authorities, such as States, counties, and cities are estimated to be $60.84 per hour for ''Legal Support Workers,'' Occupation Code 23–2099, ($37.90[5] per hour ÷ 0.623). The labor cost per State and local respondent is

[1] Voluntary Self-Assessments are described in Automated Driving Systems 2.0: A Vision for Safety, available at *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/13069a-ads2.0_090617_v9a_tag.pdf.* VSSAs are covered by the PRA Clearance with OMB Control Number 2127–0723.

[2] This estimate takes into consideration Maryland Department of Transportation's public comment to the 60-Day Notice and Request for Comment: AV TEST Initiative (*https://beta.regulations.gov/document/NHTSA-2020-0070-0006*).

[3] *See* Table 1. Employer Costs for Employee Compensation by ownership (Dec. 2019), available at *https://www.bls.gov/news.release/ecec.t01.htm* (accessed May 4, 2020).

[4] *See* May 2019 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 336100—Motor Vehicle Manufacturing, available at *https://www.bls.gov/oes/current/naics4_336100.htm#15-0000* (accessed May 4, 2020).

[5] *See* May 2019 National Occupational Employment and Wage Estimates by ownership, Federal, state, and local government, available at *https://www.bls.gov/oes/current/999001.htm#23-0000* (accessed May 4, 2020).

estimated to be $1,825.20 per year ($60.84 × 30 hours). Therefore, the total annual labor cost for State and local authorities to participate in the AV TEST Initiative is estimated to be $109,512 per year.

The total annual labor costs for all respondents, private industry and State and local authorities together, are estimated to be $226,555 per year. See Table 1 below for a summary of estimated annual burden hours and estimated labor costs.

TABLE 1—SUMMARY OF ESTIMATED BURDEN HOURS AND ESTIMATED LABOR COSTS

Respondent type	Number of respondents	Annual hours per respondent	Labor cost per hour	Annual labor cost per respondent	Total annual estimated burden hours	Total annual labor costs
Original Manufacturer of ADS Vehicles or ADS Vehicle Equipment and Operators of ADS Vehicles	40	48	$60.96	$2,926.08	1,920	$117,043
State or Local Authority	60	30	60.84	1,825.20	1,800	109,512
Total All Respondents	100				3,720	226,555

Estimated Total Annual Burden Cost: NHTSA estimates that there will be no costs to respondents other than labor costs associated with burden hours.

Summary of Public Comments: On July 2, 2020, NHTSA published a notice in the **Federal Register** Notice with a 60-day comment period soliciting comments on the information collection (85 FR 39975). NHTSA received a total of 20 comments from organizations and individuals. A summary of the comments is provided below and is arranged by topic area.

Mandatory Data Collection and Evaluation of Submissions: Several commenters, such as the National Transportation Safety Board (NTSB) and the Center for Auto Safety, were opposed to the voluntary nature of the Initiative. Although the commenters were in favor of NHTSA collecting information about ADS testing, they believe that NHTSA should make the submission of the information mandatory. Additionally, commenters suggested that NHTSA require more specific information that would allow NHTSA to evaluate the safety of the ADS testing.

The objective of AV TEST Initiative is to provide members of the public with a centralized database of high-level information about ADS testing activities and State and local laws, recommendations, and initiatives. It is, therefore, outside of the scope of the project to make any reporting mandatory or to expand the collection to include technical information or information that NHTSA would use to evaluate the safety of ADS operations. NHTSA shares the commenters' view that detailed technical material often provides valuable information and, in fact, the agency frequently engages with industry participants regarding technical aspects of their ADS development. Also, as noted in *Automated Driving Systems 2.0: A Vision for Safety,* NHTSA encourages ADS developers to make certain information available to members of the public in Voluntary Self-Assessments (VSSAs). NHTSA has outlined 12 areas related to ADS safety and performance to be included in the documents. Entities that choose to participate in AV TEST will be presented with a data entry field to provide a link to their VSSA if they have one and would like to include it with their AV TEST submission.

Data Standardization, Uniformity, and Completeness: Several commenters urged NHTSA to take steps to standardize submissions, including establishing standard terminology to increase uniformity of submissions. NHTSA appreciates this comment and would like to highlight a few of ways that NHTSA has designed the system to balance improving the quality of data collection and maximizing participation.

First, the AV TEST Initiative uses a data entry website that provides a structured data collection environment for contributors. Participating stakeholders are required to complete a minimum set of data fields when submitting information.[6] If a participant does not fill in a required field, they will be prompted to complete it before the submission can be sent to NHTSA for publication. Requiring certain data elements ensures a minimum level of completion for each submission and improves the quality of the data that is placed on the public website. While certain data fields are required, others are not. This allows the system to accommodate a wider range of ADS testing operations, vehicles, and jurisdictions. One commenter, General Motors LLC, advised that significant variance could exist for the types and amounts of data maintained by companies. As such, NHTSA believes that additional standardization of submission requirements or minimum information thresholds for participation may unintentionally exclude interested parties from participation.

Second, NHTSA agrees with commenters who suggested providing standard terminology and has integrated definitions for the requested data elements into the AV TEST tracker to ensure participants have a consistent understanding of the terminology being used by NHTSA. NHTSA is also providing a list of terms and definitions on the public website so that users can better understand the information presented.

Third, NHTSA has designed the data entry website to use drop-down options for many of the data fields to ensure greater uniformity across submissions. For example, the data field for road type provides the following drop-down options: freeway, highway, parking lot, rural, street, business campus, path/sidewalk, university, unknown, or not specified. NHTSA believes this feature will improve data uniformity while providing sufficient flexibility for unique operations. For features that do not have drop-down options, NHTSA has also taken steps to minimize error. For example, the data field for number of vehicles at a test site has character restrictions.

Accessibility and Vulnerable Populations: Several organizations submitted comments underscoring the potential impact of ADS technologies on accessibility and mobility, as well as the impact on children. Commenters suggested that NHTSA provide opportunity for participants to submit information related to accessibility of ADS operations as well as specific information related to the transportation of children.

NHTSA agrees with the comments and believes information about

[6] For a submission for an ADS operation, the required fields include: Country, State/Province, City, Public or Private Road, Road Type, Latitude and Longitude, Base Vehicle Type, Operation Status, a field asking whether the vehicle has a safety operator, and a field for the participant to indicate the type of operation (*e.g.,* providing service).

engagement with the community is an integral part of the AV TEST Initiative—particularly those with accessibility issues and members of vulnerable populations. Currently, NHTSA does not restrict participants from conveying this information, particularly for ADS test sites that are available for public use. However, NHTSA will encourage participants to provide information on accessibility and mobility for those with special needs. NHTSA will do this by creating new categories of weblinks that can be submitted to NHTSA. For example, NHTSA has added a ''Disability or Accessibility'' category, just as it has done for Emergency Response and VSSA information.

Establish Sunset for AV TEST tracker: Maryland Department of Transportation (MDOT) suggested NHTSA consider establishing a time to sunset the AV TEST tracker to eliminate data collection redundancy. NHTSA does not agree with MDOT's assertion that the AV TEST Initiative would present a data collection redundancy for vehicles that comply with all applicable FMVSS. In fact, some of the operations reported to NHTSA during its pilot phase of the AV TEST Initiative are for ADS operations involving the use of FMVSS-certified vehicles equipped with ADS. The type of information that will be collected through the AV TEST Initiative is not duplicative of data collected through NHTSA's existing crash data systems because NHTSA crash data systems only collect data on vehicles involved in crashes and vehicle-related deaths and injuries. NHTSA does not currently have a mechanism to collect information about ADS operations.

However, NHTSA notes that data submitted as part of the AV TEST Initiative may become stale. For example, because the AV TEST Initiative is voluntary, an ADS operator could provide information on an ADS operation and never update NHTSA when the operation is completed. Although we will provide a mechanism for participants to change the status of test sites from active to inactive or completed, participants may not update the status of an operation. As the AV TEST Initiative progresses, NHTSA will consider reaching out to program participants about operations that has not been updated for an extended period of time. In addition, we have provided participants the ability to remove out-of-date information and archive the data, which removes it from the AV TEST web page.

Estimated Total Annual Burden Hours: MDOT estimates States will spend more than 10 hours per year on supporting their AV TEST profiles. While MDOT acknowledged that that the 10-hour estimate may be appropriate for States solely focused on entering adopted legislation/regulation information once or twice per year, MDOT expects to 120 hours responding to the AV TEST Initiative. MDOT stated that it will update the AV TEST database for multi-modal transportation business units and estimates it will need 10 hours per month for this exercise. With respect to this subject, the Commercial Vehicle Safety Alliance, whose members include many State and local jurisdictions, advised that it ''deferred to its member jurisdictions'' on the burden presented by this collection.

NHTSA appreciates the comments on this topic and, in particular, the level of investment in the AV TEST Initiative that MDOT's comment anticipates and hopes that other participants will similarly dedicate resources as necessary and appropriate to further the goals of the program. The majority of participants in the pilot program estimated that they have and will continue to allocate approximately 2–3 hours per month to AV TEST related activities. Therefore, NHTSA calculates that State and local organizations will dedicate approximately 2.5 hours per month, or 30 hours annually, on their submissions with variances due to a range of factors, such as the availability of resources or each entity's approaches to the program. Nevertheless, NHTSA appreciates MDOT's comment that some jurisdiction participants may dedicate more time than what NHTSA estimates for the average participant.

Categories of Eligible Participants: Valeo, an automotive supplier, commented expressing a desire to participate in the program and share information regarding its automated vehicle development activities. Valeo specifically requested that NHTSA enable Tier 1 suppliers to participate in the AV TEST Initiative in the future. Additionally, the American Automobile Association (AAA) recommends that future versions of the AV TEST Initiative web platform include information provided by consumer and safety groups that evaluate vehicle technologies with the goal of educating consumers on the safety benefits, capabilities, and limitations of these applications.

In response, NHTSA appreciates AAA and Valeo's comments and is encouraged by the interest generated by the program at multifaceted levels of the automotive industry and the public. NHTSA's original 60-day notice contemplated that the collection could also include motor vehicle equipment manufacturers, which could encompass Tier 1 suppliers conducting AV test operations on public roads. As the AV TEST Initiative progresses, NHTSA will evaluate opportunities to enhance the scope of project and may consider allowing submission of information from organizations engaged in evaluating emerging vehicle technologies.

Number of Respondents: Several commenters expressed a concern that the voluntary nature of AV TEST would minimize industry participation, with one commenter believing that NHTSA's original estimate of at least 40 private participants was too high. Based on the number of entities that have already expressed interest in participating, NHTSA continues to anticipate that its estimate of 40 private participants is realistic, with even higher levels of participation possible as AV TEST becomes more established and entities engaged in ADS testing activities increase.

ADS Policy: NHTSA also received comments from safety advocates and individual members of the public highlighting concerns regarding driving automation. One comment stated that ''NHTSA should be focusing on proven safety systems currently available that can prevent or mitigate the crashes . . .'' such as a number of crash avoidance technologies included in the NTSB's Most Wanted Lists of Transportation Safety Improvements since 2016. Another commenter suggested that vehicles equipped with ADS technologies should be removed from roadways until NHTSA can ensure ''malware and terrorists cannot hack these computers driven moving time bombs.'' In addition, one commenter requested that ADS technology testing be limited to roadways that are built solely for ADS-equipped vehicles rather than public roads.

NHTSA appreciates the commenters' input and will keep this input in mind when considering future approaches to ADS technologies.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information

on respondents, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Chou-Lin Chou,

Associate Administrator, National Center for Statistics and Analysis.

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2020–0025]

Pipeline Safety: Overpressure Protection on Low-Pressure Natural Gas Distribution Systems

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice; Issuance of advisory bulletin.

SUMMARY: The Pipeline and Hazardous Materials Safety Administration (PHMSA) is issuing this advisory bulletin to remind owners and operators of natural gas distribution pipelines of the possibility of failure due to an overpressurization on low-pressure distribution systems. PHMSA is also reminding such owners and operators of existing federal integrity management regulations for gas distribution systems.

ADDRESSES: PHMSA guidance, including the advisory bulletin, can be found on PHMSA's website at *https://www.phmsa.dot.gov/guidance.*

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Natural Gas Distribution Systems

Natural gas distribution systems deliver natural gas to customers for heating, cooking, and other domestic and industrial uses. A basic natural gas distribution system has four elements: (1) Mains that transport gas underground; (2) service lines that deliver natural gas from the main to the customer; (3) regulators that control the pressure of gas to a designated value; and (4) meters that measure the quantity of natural gas used by each customer. Customer piping takes natural gas from the meter to the customer's heating equipment and other appliances.

There are two types of natural gas distribution systems used to supply natural gas to the customer: High-pressure distribution systems and low-pressure distribution systems. In a high-pressure distribution system, the gas pressure in the main is higher than the pressure provided to the customer. A pressure regulator installed at each meter reduces the pressure from the main to a pressure that can be used by the customer's equipment and appliances. These regulators incorporate an overpressure protection device to prevent overpressurization of the customer's piping and appliances should the regulator fail. Additionally, as of April 14, 2017, all new or replaced service lines connected to a high-pressure distribution system must have excess flow valves. (§ 192.383).[1] Excess flow valves can reduce the risk of overpressurization in natural gas distribution pipelines by shutting off unplanned, excessive gas flows. Because each customer's service line in a high-pressure distribution system is protected by an excess flow valve and a pressure regulator, it is highly unlikely that an overpressurization condition in the main would impact customers.

In a low-pressure natural gas distribution system, however, the natural gas in a distribution pipeline flows predominantly at the same pressure as the pressure contained within the customer's service line piping. Natural gas is typically supplied to distribution pipeline mains from a high-pressure source that connects to, and flows through, a regulator station. The regulator station functions to reduce the pressure to a level that allows the gas to flow continuously at a low pressure all the way to premises of the customers where the gas is ultimately consumed. Since there are no regulators at the customer meter set in a low-pressure system, an overpressure condition occurring on the distribution system can affect all customers served by the system in the event that the regulator(s) that controls the pressure for the system fails. This scenario is what happened in the September 13, 2018, accident in Merrimack Valley that prompted the subsequent National Transportation Safety Board (NTSB) report and recommendations.

II. CMA's Accident in Merrimack Valley

A. Accident Synopsis

On September 13, 2018, a series of structure fires and explosions occurred after high-pressure natural gas entered a low-pressure natural gas distribution system operated by Columbia Gas of Massachusetts (CMA), a subsidiary of NiSource, Inc.[2] CMA delivers natural gas to about 325,000 customers in Massachusetts. According to an investigation of the accident conducted by the National Transportation Safety Board,[3] the fires and explosions damaged 131 structures, including at least 5 homes that were destroyed in the city of Lawrence and the towns of Andover and North Andover. CMA shut down the low-pressure natural gas distribution system serving 10,894 customers, including some outside the affected area who had their service shut off as a precaution. An 18-year-old male was killed when a home exploded, and the house's chimney fell onto the vehicle where he was sitting. Another person in the vehicle at the time of the explosion was seriously injured, as was someone on the second floor of the house. In total, 22 people, including 3 firefighters, were transported to hospitals for treatment of their injuries.

B. Background on CMA's Natural Gas Main Replacement Project

The low-pressure natural gas distribution system in the Merrimack Valley was installed in the early 1900s and was constructed with cast iron mains. The system was designed with 14 regulator stations to control the pressure of natural gas entering the downstream distribution pipeline mains. Each regulator station contained two regulators in series—a ''worker regulator'' and a ''monitor regulator''—each with a sensing line connected to a downstream section of main for the purpose of providing a pressure measurement back to the regulator station so that the system could be maintained at a specified pressure level of 0.5 pounds per square inch. The

[1] PHMSA published the final rule, ''Pipeline Safety: Expanding the Use of Excess Flow Valves in Gas Distribution Systems to Applications Other Than Single-Family Residences,'' on October 14, 2016, but delayed the effective date by six months to give operators time to comply with the new provisions. (81 FR 70987). A copy of this final rule is available in the docket PHMSA–2011–0009 at *https://www.regulations.gov.*

[2] CMA is expected to be officially transferred by NiSource, Inc., to Eversource Energy in November 2020.

[3] ''Pipeline Accident Report: Overpressurization of Natural Gas Distribution System, Explosions, and Fires in Merrimack Valley, Massachusetts; September 13, 2018.'' The National Transportation Safety Board. Accident Report: NTSB/PAR–19/02. Adopted September 24, 2019.

''worker'' regulator is the primary regulator that maintains the natural gas pressure, and the ''monitor'' regulator provides a redundant backup to the ''worker'' regulator. Each of the regulator stations reduced the natural gas pressure from about 75 pounds per square inch gauge (psig) to 12 inches of water column (w.c.), or about 0.5 psig, for distribution through the mains and delivery to customers.[4]

Beginning in 2016, CMA initiated an effort to replace 7,595 feet of low-pressure cast iron and bare steel mains with 4,845 feet of low-pressure and high-pressure polyethylene (plastic) mains. CMA contracted with Feeney Brothers, a pipeline services firm, to complete the replacement project. A work package, which included materials such as isometric drawings and procedural details for disconnecting and connecting pipes, was prepared for each of the planned construction activities. However, no package was prepared for the relocation of the Winthrop Avenue sensing lines serving the Winthrop Avenue regulator station.

The first stage of the project involved the installation of the plastic main, which was completed in late 2016. The regulator sensing lines at the Winthrop Avenue regulator station remained attached to the cast iron main that would ultimately be decommissioned.

CMA connected the plastic pipe to the distribution system, which allowed it to be monitored for pressure changes. The second stage of the project began in 2018 and involved the installation of tie-ins to the new plastic main, after which the legacy cast iron mains would be decommissioned and abandoned in their existing location. On the day of the accident, the sensing lines were still connected to the abandoned cast iron main.

At the Winthrop Avenue regulator station, about 0.5 mile south of the work area, the sensing lines connected to the abandoned cast iron mains continued providing data input to the two pressure regulators used to control the system pressure.[5] Once the contractor crew isolated the cast iron main, the natural gas pressure began to drop in the cast iron main and the sensing lines continued to provide those readings to the regulator station. As the pressure dropped, the pressure regulators responded by opening further to inject more gas to into the downstream system to the newly installed plastic system. Because there were no sensing lines connecting the regulator station to the newly installed plastic mains, the legacy sensing lines continued to provide ''zero'' pressure readings to Winthrop Avenue regulators, thereby causing them to fully open and provide a continuous flow of gas into the new low-pressure plastic system, resulting in an extreme overpressurization of the distribution system. This immediately resulted in multiple fires, explosions, and injuries.

C. National Transportation Safety Board (NTSB) Accident Investigation and Recommendations

Since the accident, the National Transportation Safety Board (NTSB) issued several safety recommendations. On November 14, 2018, NTSB recommended that the operator, NiSource Inc.:

- Revise the engineering plan and constructability review process across all of its subsidiaries to ensure that all applicable departments review construction documents for accuracy, completeness, and correctness, and that the documents or plans be sealed by a professional engineer prior to commencing work (P–18–6);
- Review and ensure that all records and documentation of its natural gas systems are traceable, reliable, and complete (P–18–7);
- Apply management of change process to all changes to adequately identify system threats that could result in a common mode failure (P–18–8); and
- Develop and implement control procedures during modifications to gas mains to mitigate the risks identified during management of change operations. Gas main pressures should be continually monitored during these modifications and assets should be placed at critical locations to immediately shut down the system if abnormal operations are detected (P–18–9).

In response, NiSource Inc. has taken actions that satisfied the NTSB's recommendations, which are now classified as ''Closed.''

On September 24, 2019, the National Transportation Safety Board (NTSB) issued its accident report and identified the probable cause of, and contributing factors to, CMA's accident in Merrimack Valley. NTSB found that the probable cause of the accident was CMA's weak engineering management that failed to adequately plan, review, sequence, and oversee the construction project that abandoned the cast iron main without first relocating the regulator sensing lines to the new plastic main. NTSB also found that a contributing cause of the accident was a low-pressure natural gas distribution system that was designed and operated without adequate overpressure protection. As a result of its investigation, NTSB made several recommendations to NiSource, Inc., the Commonwealth of Massachusetts and several other States, and PHMSA. NTSB made two recommendations to PHMSA. The first (P–19–14) called for PHMSA to ''revise Title 49 *Code of Federal Regulations* Part 192 to require overpressure protection for low-pressure natural gas distribution systems that cannot be defeated by a single operator error or equipment failure.'' Having investigated multiple overpressurization accidents over the past 50 years, NTSB concluded that low-pressure natural gas distribution systems that use only sensing lines and regulators to detect and prevent overpressurization are not optimal to prevent overpressurization accidents.

NTSB's second recommendation (P–19–15) called for PHMSA to ''issue an alert to all low-pressure natural gas distribution system operators of the possibility of a failure of overpressure protection, and the alert should recommend that operators use a failure modes and effects analysis (FMEA) or equivalent structured and systematic method to identify potential failures and take action to mitigate those identified failures.'' NTSB found that CMA's constructability review[6] process was not sufficiently robust to detect the omission of a work order to relocate the sensing lines; and that CMA's engineering risk management processes were deficient. NTSB explained that for regulator sensing lines, CMA only considered excavation damage as a risk to be mitigated. NTSB concluded that a comprehensive and formal risk assessment, such as FMEA, would have identified the human error that caused the redundant regulators to open and over pressurize the low-pressure system.

In response to NTSB's recommendation P–19–15, PHMSA is issuing this advisory bulletin to remind owners and operators of low-pressure natural gas distribution systems of the possibility of a failure of overpressure protection devices. Currently, there are Federal regulations in place that specify several minimum safety standards requiring operators to account for the possibility of overpressure events in the

[4] In the pipeline industry, it is customary to measure anything less than 1 psig in inches of water column. A measurement of 1 inch w.c. equals 0.0361 psig.

[5] *Sensing lines* are also called *control lines* or *static lines.*

[6] ''Constructability reviews'' are a recognized and generally accepted good engineering practice commonly used for the execution of professional design services and are intended to provide an independent and structured review of construction plans and specifications to ensure there are no conflicts, errors, or omissions.

design and operation of their systems. Specifically, the Distribution Integrity Management Program (DIMP) regulations at 49 CFR 192.1005 require operators of natural gas distribution systems to develop and implement an integrity management program for pipelines they own, operate, or maintain. Under DIMP, operators must identify existing and potential threats to the integrity of their systems, and to rank the risks so that known issues can be evaluated by the risks they pose. PHMSA agrees with the NTSB that low-pressure distribution system operators need to be reminded of their obligation to identify all threats to their systems and take mitigative measures in accordance with the risks to their systems. The diversity of designs and operating conditions of those systems mean that the risks associated with overpressure conditions may be best managed by a combination of design elements and engineering practices tailored to the unique attributes and conditions of their specific systems that pipeline operators are best positioned to identify and implement. Therefore, PHMSA is reminding operators of low-pressure distribution systems of their existing obligations under the DIMP regulations to consider and implement such tailored approaches to mitigate or eliminate the risk of an overpressurization event.

D. Distribution Integrity Management Program Regulatory Provisions

PHMSA first adopted integrity management regulations for hazardous liquid pipelines in 2000, then for gas transmission pipelines in 2003. Subsequently, the Pipeline Integrity, Protection, Enforcement, and Safety Act of 2006 (PIPES Act of 2006; Pub. L. 109–468) mandated that PHMSA prescribe minimum safety standards to extend integrity management to gas distribution pipeline systems. The 2006 legislation directed PHMSA to require operators of distribution pipelines to identify and assess risks on their distribution lines, to remediate conditions that present a potential threat to pipeline integrity, and to monitor program effectiveness. In response to that mandate, PHMSA implemented new requirements in 49 CFR part 192, subpart P, that rely on operator-specific programs to improve the overall integrity of pipeline systems and reduce risk (74 FR 63905; December 4, 2009). PHMSA concluded that this performance-based approach was a more effective method for improving pipeline system safety—given the diversity of distribution systems and the particular threats to which different systems may each be exposed—than imposing a ''one-size-fits-all'' prescriptive requirement.

The DIMP regulations require operators of natural gas distribution systems to develop, write, and implement an integrity management program for pipelines they own, operate, or maintain. An integrity management plan is a written set of policies and procedures that each operator must develop and implement to ensure compliance. Pursuant to § 192.1007,[7] an integrity management plan must include procedures for implementing the following elements:

- Periodically assess and improve the integrity management program; and
- Report performance results to PHMSA and, where applicable, also to state public utility commissions.

a. *Knowledge (192.1007(a)).* This section requires an operator to develop an understanding of its distribution pipeline. An operator must identify the characteristics of its pipeline's design and operations, and of the environment in which it operates, which are necessary to assess applicable threats and risks. This must include considering information gained from past design, operations, and maintenance. This section further requires that operators develop their understanding from reasonably available information. Operators have considerable knowledge of their pipeline to support routine operations and maintenance, but this information may be distributed throughout the company, in possession of groups responsible for individual functions. Operators must assemble this information to the extent necessary to support the development and implementation of their IM program.

PHMSA recognizes that there may be gaps in the knowledge an operator possesses when it develops its initial IM plan. Operators must identify these gaps and the additional information needed to improve their understanding. Operators are required to provide a plan for gaining that information over time through the normal activities of operating and maintaining pipeline systems (*e.g.,* collecting information about underlying components when portions of the pipeline must be excavated for other reasons). Operators must also develop a process by which the program will be periodically reviewed and refined, as needed.

b. *Identify threats ((§ 192.1007(b)).* Identification of the threats that affect, or could potentially affect, a distribution pipeline remains critical to ensuring integrity. Knowledge of applicable threats allows operators to evaluate the safety risks they pose and to rank those risks, allowing safety resources to be applied where they will be most effective. This section requires that operators consider the general categories of threats that must be reported on annual reports. Operators are required to consider reasonably available information to identify threats that affect their pipeline or that could potentially affect it (*e.g.,* landslides in a hilly area with loose soils even if no landslide has been experienced). The section specifies that operators should minimally consider data sources resulting from normal operation and maintenance in evaluating threats.

c. *Evaluate and rank risk (192.1007(c)).* This section requires that an operator evaluate the identified threats to determine their relative importance and rank the risks associated with its pipeline. Operators must consider the likelihood of threats and the consequences of a failure that might result from each threat. Consideration of consequences is important to help ensure that risks are properly ranked. A potential accident of relatively low probability but that would produce significant consequences should be considered to be of higher risk than an accident with somewhat greater likelihood, but one that is not expected to produce major consequences.

d. *Identify and implement measures to address risks (§ 192.1007(d)).* This section requires operators to determine and implement measures designed to reduce the risk of failure of gas distribution pipeline systems.

e. *Measure performance, monitor results, and evaluate effectiveness (§ 192.1007(e)).* This section requires operators to develop performance measures, including some that are specified for use by all operators. Measuring performance periodically enables operators to determine whether actions being taken to address threats are effective, or whether different or additional actions are needed. An operator must also periodically re-evaluate the threats and risks to its gas distribution pipeline.

f. *Periodic evaluation and improvement (§ 192.1007(f)).* This section requires operators to re-evaluate risks across the entire pipeline system periodically and to consider the relevance of threats in one specific location as compared to other locations.

[7] ''Pipeline Safety: Integrity Management Program for Gas Distribution Pipelines.'' Final Rule. (74 FR 63905; Dec. 4, 2009). *https://www.federalregister.gov/documents/2009/12/04/E9-28467/pipeline-safety-integrity-management-program-for-gas-distribution-pipelines#h-22*

Operators must consider the results of their performance monitoring in these evaluations, which must be performed at least once every five years. An operator must determine an appropriate period for conducting a complete program evaluation based on the complexity of its system. An operator should conduct a program evaluation any time there are changes in factors that would increase the risk associated with a failure.

While DIMP regulations have been in place since 2009, some operators may not be sufficiently aware of their pipeline attributes, nor adequately or consistently assessing threats as part of their DIMP programs. Early in the investigation, NTSB determined that several of NiSource's engineering processes were deficient. For example, the NTSB found that CMA's inadequate planning, documentation, and recordkeeping processes led to the omission of the relocation of sensing lines during a construction project. Further, NTSB found that CMA's constructability review process was not sufficiently robust to detect the omission of a work order to relocate sensing lines. It was the abandonment of the cast iron main without first relocating the sensing lines that led directly to the accident. Thus, it is necessary to identify and evaluate the physical and operational characteristics of each pipeline system to evaluate risks adequately. It is also important that an operator focus its DIMP on identifying the conditions that can cause failures and address them before a failure occurs. Therefore, PHMSA is reminding owners and operators of their continuing obligation to comply with DIMP regulations and is alerting operators that PHMSA considers the possibility of an overpressure protection failure to be a high-risk threat. PHMSA reminds operators of low-pressure systems that they must consider reasonably available information about possible threats to their gas distribution system, including such sources as the NTSB report, industry publications, and this advisory bulletin.

As part of the DIMP plans, PHMSA recommends that operators enhance their processes and procedures by including a failure modes and effects analysis, or equivalent structured and systematic method of risk analysis. Including a failure mode and effect analysis or equivalent methodology can help identify and mitigate the possibility of an overpressure failure event. PHMSA also urges operators to develop and implement procedures for construction-related work that are specific to low-pressure distribution systems, such as repairs, uprates in pressure, or replacement of pipeline or pressure regulation facilities.

II. Advisory Bulletin (ADB–2020–02)

To: Owners and Operators of Natural Gas Distribution Systems

Subject: Overpressure Protection on Low-pressure Natural Gas Distribution Systems.

Advisory: PHMSA is reminding all owners and operators of low-pressure natural gas distribution systems of the risk of failure of overpressure protection systems. This advisory bulletin is intended to clarify for the public existing pipeline safety standards and highlight the importance of evaluating and implementing overpressure protection design elements and operational practices within their compliance programs. The contents of this advisory bulletin do not have the force and effect of law. They are not meant to bind the public in any way, even as pipeline owners and operators must comply with the underlying safety standards.

PHMSA encourages operators to review the NTSB's Pipeline Accident Report concerning Columbia Gas of Massachusetts' (CMA) overpressurization event in the Merrimack Valley on September 13, 2018. It may be instructive regarding a host of potential safety problems that operators of low-pressure natural gas distribution systems may need to address. A copy of NTSB's accident report is contained within Docket No. PHMSA–2020–0025 for this advisory bulletin.

PHMSA also reminds pipeline operators of their obligations to comply with the gas DIMP regulations at 49 CFR part 192, subpart P. Under DIMP, gas distribution operators must have knowledge of their pipeline systems; identify threats to their systems; evaluate and rank risks; and identify, evaluate, and implement measures to address those risks. CMA's accident in Massachusetts highlights the need for operators of low-pressure systems to review thoroughly their current DIMP for the threat of overpressurization and to make any necessary changes or modifications to become fully compliant with the Federal Pipeline Safety Regulations (§ 192.1007(f)).

Written Procedures (§ 192.1005)

Developing and implementing comprehensive written procedures with sufficient specificity is one of the most effective ways to prevent overpressurization of a low-pressure gas system. Therefore, PHMSA reminds operators of low-pressure systems to review their written integrity management plans to help ensure that they comply with § 192.1005 and to ensure that they specifically address the risk of an overpressurization event. PHMSA further recommends, in addition to having procedures for operations, maintenance, and emergencies (§ 192.605), that operators develop written procedures for all activities involving new construction or pipe replacement projects for low-pressure distribution systems. PHMSA recommends that these procedures account for the additional precautions needed to protect those systems from an overpressurization event. These procedures should include:

- Clear roles and responsibilities across all departments involved in the planning and execution of construction or pipe replacement projects;
- Description and delineated scope of work to be conducted, with a materials list, necessary schematics, and maps of the location of the work;
- Requirements to review and ensure that all records and documentation of the affected gas system(s) are traceable, reliable, and complete;
- The sequential process of how the work is to be carried out and who or what group is responsible for each step;
- Application of a ''management of change'' process to identify all changes that could threaten system integrity, particularly where there is a risk emanating from a common mode of failure, including a list of individuals and groups necessary for review along with their comment and approval before work commences; and
- Implement a review process sufficiently robust to detect the omission of critical process and procedural steps that could prevent possible overpressurization events.

Knowledge of Distribution System (§ 192.1007(a))

PHMSA reminds operators that they are required to develop procedures in their DIMP that demonstrate an understanding of their gas distribution systems (§ 192.1007(a)). An operator must identify the characteristics of its pipeline design and operations, and of the environment in which it operates, in the process of assessing applicable threats and risks. Section 192.1007(a) requires that operators develop their understanding from reasonably available information. This must include information gained from past design, operations, and maintenance. If an operator acquires a pipeline and the historical records were not obtained or are not reasonably available, the records do not need to be re-created. However,

operators must assemble this information to the extent necessary to support the development and implementation of their integrity management programs. Underlying procedures must also identify additional information necessary to improve their understanding and provide a plan for gaining that information over time through the normal activities of operating and maintaining pipeline systems (*e.g.,* collecting information about buried components when portions of the pipeline must be excavated for other reasons). Operators must also develop a process by which the program will be periodically reviewed and refined, as needed. The outcome of the process should be that all affected departments of an operator's organization are aware of any planned construction work, have had the opportunity to review and provide comments on potential failure modes and to adopt a process for providing final approval of construction procedures.

Identifying Threats and Ranking Risk (§ 192.1007(b)–(c))

PHMSA reminds operators of their obligation under DIMP regulations (part 192, subpart P) to consider available information when identifying all potential and existing threats to the integrity of their systems (§ 192.1007(b)). In accordance with § 192.1007(b), operators are required to consider seven specific threats, including equipment failure and incorrect operation. Further, PHMSA reminds operators to evaluate the risks associated with their distribution pipelines, determine the relative importance of each threat, and rank the risks posed to their pipeline systems (§ 192.1007(c)). PHMSA reminds operators that consideration of consequences is important to help ensure that risks are properly ranked. A potential accident of relatively low likelihood but one that would produce significant consequences may be a higher risk than an accident with somewhat greater likelihood, but one that is not expected to produce major consequences.

Given the catastrophic consequences of the Merrimack Valley accident, PHMSA considers the possibility of an overpressure protection system failure to be a high-risk threat for low-pressure distribution systems where there are not adequate provisions to protect such systems. Therefore, PHMSA recommends that operators consider the single point of failure that could lead to an overpressurization of a low-pressure system as a high-risk threat and to review and adjust their DIMP plans accordingly. NTSB's Pipeline Accident Report sufficiently documents the occurrence of overpressurization of low-pressure distribution systems such that the threat of overpressurization should be considered a real and present threat. If the threat of overpressurization of low-pressure distribution systems is not considered an existing threat by an operator, justification for the elimination of this threat from consideration should be documented.

In performing a risk analysis required by DIMP (§ 192.1007), PHMSA recommends operators use a failure modes and effectiveness analysis (FMEA) model or an equivalent structured and systematic method to identify and mitigate risks. Failure modes and effects analysis (FMEA) is a generally accepted and recognized engineering practice used to identify and assess potential failures, including common mode failures. As NTSB concluded, a comprehensive and formal risk assessment, such as FMEA, would have identified the human error that caused the redundant regulators to open and over-pressurize the low-pressure system. Operators may already be leveraging FMEA or other similarly robust methodologies to perform the risk analysis and should continue to do so. PHMSA recommends that operators consider adopting FMEA or another qualitative tool that may help to identify possible failures or consequences of those failures that would not be identified otherwise.

Identify and Implement Measures To Address Risk (§ 192.1007(d))

PHMSA reminds operators that they must determine and implement measures designed to reduce the risk of failure on their pipeline systems (§ 192.1007(d)). If additional actions have not been taken to reduce risks, justification should be documented (*e.g.,* current overpressure protection design was determined to be sufficient; risks were deemed to be low).

There are several ways that operators can protect low-pressure distribution systems from overpressure events. Some notable examples include:

- Installing a full-capacity relief valve downstream of the low-pressure regulator station, including in applications where there is only worker-monitor pressure control;
- Installing a ''slam shut'' device;
- Using telemetered pressure recordings at district regulator stations to signal failures immediately to operators at control centers; and
- Completely and accurately documenting the location for all control (*i.e.,* sensing) lines on the system.

Measure Performance, Monitor Results, and Evaluate Effectiveness (§ 192.1007(e))

PHMSA reminds operators that they must monitor performance measures from an established baseline to evaluate the effectiveness of DIMP (§ 192.1007(e)). Section 192.1007(e)(vi) requires that these performance measures include any additional measures determined necessary to control identified threats. PHMSA reminds operators to modify their DIMP as appropriate, considering the potential failure of overpressure protection systems as a high-risk threat.

Issued in Washington, DC, on September 24, 2020, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2020–21508 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2020–0115]

Pipeline Safety: Inside Meters and Regulators

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Notice; issuance of advisory bulletin.

SUMMARY: PHMSA is issuing this advisory bulletin to alert owners and operators of natural gas distribution pipelines to the consequences of failures of inside meters and regulators. PHMSA is also reminding operators of existing Federal regulations covering the installation and maintenance of inside meter and regulators, including the integrity management regulations for distribution systems to reduce the risks associated with failures of inside meter and regulator installations.

ADDRESSES: PHMSA guidance, including this advisory bulletin, can be found on PHMSA's website at *https://www.phmsa.dot.gov/guidance.* You may also view this advisory bulletin and related documents at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Technical Questions: Michael Thompson, Transportation Specialist, by phone at 503–883–3495.

General Questions: Ashlin Bollacker, Technical Writer, by phone at 202–366–4203.

SUPPLEMENTARY INFORMATION:

Background

On August 10, 2016, a natural gas-fueled explosion and fire caused the partial collapse of a 14-unit apartment building located at 8701 Arliss Street (Building 8701) in the Flower Branch Apartment Complex of Silver Spring, Maryland. The explosion and fire also heavily damaged an adjacent apartment building, which shared a common wall with Building 8701. As a result of this accident, 7 residents died, 65 residents were transported to the hospital, and 3 firefighters were treated and released from the hospital. The property damage from the accident exceeded $1 million.

National Transportation Safety Board (NTSB) determined that the probable cause of the explosion was the failure of an indoor mercury service regulator with an unconnected vent line. The unconnected vent line allowed natural gas to flow into the meter room, where the gas accumulated and ignited from an unknown ignition source. A contributing factor to the accident was the mercury service regulator being located in a space where leak detection by odor was not readily available.

A ''service regulator'' is defined in § 192.3 as a ''device on a service line that controls the pressure of gas delivered from a higher pressure to the pressure provided to the customer. A service regulator may serve one customer or multiple customers through a meter header or manifold.'' Service regulators are installed to a meter inlet to control the gas pressure into a building. They reduce the high pressure used to transport natural gas through the delivery systems to the lower pressures used in homes and businesses. Service regulators include a relief valve that opens if the pressure of the regulated gas exceeds a specified pressure to allow the excess gas to vent to the outside atmosphere. Mercury service regulators present an increased risk of failure due to their age.[1]

Building 8701 received natural gas from a distribution system owned and operated by Washington Gas Light Company (WGL). WGL delivers natural gas to more than one million residential, commercial, and industrial customers throughout Washington, DC, and the surrounding regions in Maryland and Virginia. According to WGL, the mercury service regulators installed in Building 8701 were also installed in all 26 buildings of the Flower Branch apartment complex between 1955 and 1956. Since the accident, all of the mercury service regulators in the Flower Branch apartment complex have been removed and replaced.

NTSB Accident Investigation Findings and Recommendations to PHMSA

On April 24, 2019, NTSB adopted its report, ''Building Explosion and Fire, Silver Spring, Maryland, August 10, 2016,'' [2] determined the probable cause of the explosion, and issued safety recommendations. In its report, NTSB stated that several residents of Buildings 8701 and 8703 reported to investigators that they smelled gas in the weeks and months leading up to the explosion. On July 25, 2016, before the accident, several residents called the building manager, 9–1–1, and local fire personnel about gas odor. However, there was no evidence that residents, building management, or any emergency personnel notified the operator, WGL, of the gas odor. The investigation revealed that, had anyone notified WGL of a gas odor call made two weeks earlier, the accident may have been prevented. Notifying WGL would have allowed a service technician to enter the meter room of the building, identify the unconnected vent line, and remedy the situation. NTSB noted, however, that the use of gas odorants alone does not sufficiently mitigate the risk of death and injuries caused by gas system leaks, such as the leak that occurred in this accident.

As discussed above, NTSB determined that the probable cause of the explosion was the failure of an indoor mercury service regulator with an unconnected vent line. The unconnected vent line allowed natural gas to flow into the meter room, where the gas accumulated and ignited from an unknown ignition source. NTSB issued Safety Recommendations P–19–001 and P–19–002 to PHMSA based on the finding in the Silver Spring investigation that, had service regulators been located outside Building 8701, the explosion would have been avoided because gas would have vented to the atmosphere and dissipated. In light of these recommendations, PHMSA believes that operators should ensure compliance with the applicable pipeline safety regulations and should evaluate each service installation to determine the appropriate location of the service regulators. If access is an issue to check and maintain inside regulators properly, operators should do what is necessary to have the customer provide access for the operator to check the regulator and conduct the leakage and atmospheric corrosion surveys.

Minimum Federal Safety Standards for Customer Meters, Service Regulators and Service Lines

The Federal Pipeline Safety Regulations prescribe minimum safety standards for customer meters, service regulators, and service lines. They require operators to take into consideration the possibility of corrosion, overpressure events, and physical damage in the design, installation, and maintenance of these facilities. The Federal Pipeline Safety Regulations at 49 CFR 192.353 require that each meter and service regulator, whether inside or outside a building, must be installed in a readily accessible location and be protected from corrosion and other damage, including vehicular damage. For regulators located inside a building, each service regulator must be located as near as practical to the point of service line entrance. Each meter must be located in a ventilated place and not less than 3 feet from any source of ignition or any source of heat that might damage the meter. Section 192.355(b) states: ''[s]ervice regulator vents and relief vents must terminate outdoors, and the outdoor terminus must . . . [b]e located at a place where gas from the vent can escape freely into the atmosphere and away from any opening into the building.'' Section 192.357(d) requires regulators that might release gas to be vented to the outside atmosphere.

Federal Pipeline Safety Regulations include requirements that operators conduct leakage surveys of their systems, including meter and service regulators located inside buildings (§ 192.723). In scheduling such surveys, operators must consider the nature of their operations and the local conditions. At a minimum, operators must conduct surveys: (1) In business districts at intervals not exceeding 15 months, but at least once each calendar year; and (2) outside business districts as frequently as necessary, but at least once every five calendar years at intervals not exceeding 63 months. The regulations also require that operators inspect each pipeline or portion of pipeline that is exposed to the atmosphere for evidence of atmospheric corrosion in accordance with § 192.481. Further, if atmospheric corrosion is found during an inspection, the operator

[1] The design of mercury service regulators includes materials such as leather diaphragms and rubber valve seats that are subject to age-related deterioration.

[2] NTSB/PAR–19/01. The details of this accident investigation and the resulting safety recommendations may be accessed at *https://ntsb.gov/investigations/AccidentReports/Reports/PAR1901.pdf.*

must provide protection against the corrosion as required by § 192.479.

PHMSA is reminding operators of these existing requirements for inside meters and regulators. This advisory bulletin notes that, if access is an issue to check and maintain inside regulators properly, operators should endeavor to have the customer provide access for the operator to check the regulator and conduct the leakage and atmospheric corrosion surveys.

Distribution Integrity Management Program (DIMP) Regulations

In addition to these requirements for inside meters and regulators, PHMSA is also reminding operators of their obligation to continually assess risks to their systems and address those risks in accordance with DIMP regulations at § 192.1007. A DIMP program requires that operators demonstrate knowledge of their system (§ 192.1007(a)). Additionally, a DIMP program requires that operators identify existing and potential threats (§ 192.1007(b)). Identification of the threats that affect, or could potentially affect, a distribution pipeline is key to assuring its integrity. Knowledge of applicable threats allows operators to evaluate the risks they pose and to rank those risks, allowing safety resources to be applied where they will be most effective. Section 192.1007(c) requires that an operator evaluate the identified threats to determine their relative importance and rank the risks associated with its pipeline. Operators must consider the likelihood of threats as well as the consequences of a failure that might result from each threat. The integrity management programs must include measures designed and implemented to reduce the risk of failure from identified threats (§ 192.1007(d)). Measuring performance periodically and conducting a complete program re-evaluation at least every five years allows operators to determine whether actions being taken to address threats are effective, or whether different or additional actions are needed (§ 192.1007(e)–(f)). An operator should conduct a program evaluation any time there are changes in factors that would affect the risk of failure.

While the DIMP Regulations have been in place since 2009, some operators may not be sufficiently aware of their pipeline attributes, or may not be adequately or consistently assessing threats as part of their DIMP programs. For example, NTSB found that WGL's inadequate procedures led to the exclusion of the requirement that technicians verify the connection of vent lines for indoor service regulators during service and maintenance activities, and as such, vent lines could be inadvertently left disconnected following service work. NTSB concluded that WGL relied on unvalidated information to determine the location and condition of mercury service regulators. Therefore, the NTSB recommended that throughout the WGL network, WG implement an audit program to verify the data on the service forms used to determine the location and condition of mercury service regulators to ensure the accuracy of this safety-critical data.

Because it is so essential that operators identify the conditions that can cause failures and address them before a failure can occur, PHMSA is reminding operators of their obligations to comply with DIMP regulations. This advisory bulletin serves as a reminder to operators to identify and evaluate the physical and operational characteristics of each pipeline system. Operators following these requirements should help to ensure the safety of customer meters and regulators.

II. Advisory Bulletin (ADB–2020–01)

To: Owners and Operators of Gas Distribution Systems.

Subject: Requirements for Inside Meters and Regulators.

Advisory: To further enhance PHMSA's safety efforts and implement NTSB's April 24, 2019, Recommendations P–19–001 and P–19–002, PHMSA is issuing this advisory bulletin to remind operators of the requirements for inside meters and regulators. PHMSA is also reminding operators of existing Federal DIMP regulations to reduce the possibility of the failure of inside meter and regulator installations. Further, PHMSA advises operators to review NTSB's report concerning the August 10, 2016, accident as it may serve as prudent guidance regarding potential safety problems that operators may need to act on if it addresses a relevant factor on their system. This advisory bulletin is intended to clarify and describe the existing pipeline safety standards for operators and the public. The contents of this advisory bulletin do not have the force and effect of law and are not meant to bind the public in any way. However, pipeline operators must comply with the underlying pipeline safety standards at 49 CFR part 192.

PHMSA is reminding operators of §§ 192.353, 192.355, and 192.357, which provide requirements regarding the location and safety of customer meters and regulators. While the regulations allow service regulators to be located inside or outside structures, the requirements for indoor regulators are more stringent than those located outdoors. Section 192.353(a) requires that each meter and service regulator, whether inside or outside of a building, be installed in a readily accessible location and be protected from corrosion and other damage, including vehicular damage. Section 192.353(b) requires each service regulator installed within a building to be located as near as practical to the point of service line entrance, and § 192.353(c) requires that each meter installed within a building must be located in a ventilated place and not less than 3 feet from any source of ignition or any source of heat that might damage the meter. In addition, § 192.355(b) requires that the service regulator vents and relief vents must terminate outdoors, and the outdoor terminus must be located at a place where gas from the vent can escape freely into the atmosphere and away from any opening into the building. Section 192.357(d) requires regulators that might release gas to be vented to the outside atmosphere.

The Federal Pipeline Safety Regulations include requirements that operators conduct leakage and atmospheric corrosion surveys of their systems, including service regulators located inside or outside a building (§§ 192.723 and 192.481). If access is an issue to check and maintain inside meter and regulators properly, operators should endeavor to have the customer provide access for the operator to check these facilities and conduct the leakage and atmospheric corrosion surveys.

PHMSA is also reminding operators of their obligation to continually assess risks to their systems and address those risks as required by the DIMP regulations (§ 192.1007). PHMSA reminds pipeline operators of their responsibilities to continuously improve their knowledge of their pipeline systems, identify integrity threats, evaluate and rank risks, and identify, evaluate, and implement preventative and mitigative measures as required by the Federal Pipeline Safety Regulations. PHMSA recommends that operators thoroughly review their current DIMP for the threat of the failure of inside meter and regulator installations and make any changes necessary to become compliant with the Federal Pipeline Safety Regulations. For example, based on the requirements in § 192.1007(a) for operators to know their systems, PHMSA would expect operators to know the location (inside or outside) of all meters and regulators installed on their distribution system. Operators must evaluate the risks associated with these facilities, determine the relative importance of each threat, and rank the

risks posed to their pipeline (§ 192.1007(c)). PHMSA urges operators to consider the points-of-failure identified in NTSB's accident investigation report as they relate to operators' inside meter and regulator installations and to adjust their DIMP accordingly. These measures must include an effective leak management program unless all leaks are repaired when found (§ 192.1007(d)). As part of their leak management program, operators must consider all risks, including the risk of failure or damage to inside meter and regulator installations. If risks are identified, risk reduction measures must be put in place to address them, or if additional actions have not been taken to reduce risks, justification must be documented.

Issued in Washington, DC, on September 24, 2020, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2020–21507 Filed 9–28–20; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Agency Information Collection Activities; Proposed Renewal; Comment Request; Renewal Without Change of Anti-Money Laundering Programs; Due Diligence Programs for Correspondent Accounts for Foreign Financial Institutions and for Private Banking Accounts

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, FinCEN invites comments on the proposed renewal, without change, of a currently approved information collection found in existing Bank Secrecy Act regulations. Specifically, the regulations require banks, brokers or dealers in securities, futures commission merchants, introducing brokers in commodities, and mutual funds to establish due diligence programs that include risk-based, and, where necessary, enhanced, policies, procedures, and controls reasonably designed to detect and report money laundering conducted through or involving, any correspondent accounts established or maintained for foreign financial institutions. The regulations also require that these same financial institutions establish due diligence programs that include policies, procedures, and controls reasonably designed to detect and report money laundering conducted through or involving any private banking accounts established by the financial institutions. The due diligence programs are required to be part of the financial institutions' anti-money laundering programs. Although no changes are proposed to the information collection itself, this request for comments covers a future expansion of the scope of the annual hourly burden and cost estimate associated with these regulations. This request for comments is made pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments are welcome, and must be received on or before November 30, 2020.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal E-rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Refer to Docket Number FINCEN–2020–0012 and the specific Office of Management and Budget (OMB) control number 1506–0046.
- *Mail:* Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINCEN–2020–0012 and OMB control number 1506–0046.

Please submit comments by one method only. Comments will also be incorporated into FinCEN's review of existing regulations, as provided by Treasury's 2011 Plan for Retrospective Analysis of Existing Rules. All comments submitted in response to this notice will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory Support Section at 1–800–767–2825 or electronically at *frc@fincen.gov.*

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Provisions

The legislative framework generally referred to as the Bank Secrecy Act (BSA) consists of the Currency and Financial Transactions Reporting Act of 1970, as amended by the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act) (Pub. L. 107–56) and other legislation. The BSA is codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, 31 U.S.C. 5311–5314 and 5316–5332, and notes thereto, with implementing regulations at 31 CFR chapter X.

The BSA authorizes the Secretary of the Treasury, *inter alia,* to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or counter-intelligence activities to protect against international terrorism, and to implement anti-money laundering (AML) programs and compliance procedures.[1] Regulations implementing the BSA appear at 31 CFR chapter X. The authority of the Secretary to administer the BSA has been delegated to the Director of FinCEN.[2]

Section 312 of the USA PATRIOT Act added subsection (i) to 31 U.S.C. 5318 of the BSA. Section 312 mandates that each financial institution that establishes, maintains, administers, or manages a correspondent account or a private banking account in the United States for non-U.S. persons subject such accounts to certain anti-money laundering compliance measures. In particular, a financial institution must establish appropriate, specific, and, where necessary, enhanced, due diligence (EDD) or enhanced scrutiny policies, procedures, and controls that are reasonably designed to detect and report instances of money laundering through those accounts. The regulations implementing the due diligence requirements for maintaining foreign correspondent accounts and private banking accounts are found at 31 CFR 1010.610 and 31 CFR 1010.620, respectively, and apply to covered financial institutions defined as banks, brokers or dealers in securities, futures commission merchants, introducing brokers in commodities, and mutual funds.[3]

(a) *31 CFR 1010.610—Due diligence programs for correspondent accounts for foreign financial institutions.*

Under 31 CFR 1010.610(a), covered financial institutions are required to establish due diligence policies, procedures, and controls that include each of the following for any correspondent account established, maintained, administered, or managed: (i) Determining whether any such foreign correspondent account is subject to EDD; (ii) assessing the money laundering risks presented by each such foreign correspondent account; and (iii) applying risk-based procedures and controls to each such foreign

[1] Section 358 of the USA PATRIOT Act added language expanding the scope of the BSA to intelligence or counter-intelligence activities to protect against international terrorism.

[2] Treasury Order 180–01 (re-affirmed Jan. 14, 2020).

[3] 31 CFR 1010.605(e).

correspondent account reasonably designed to detect and report known or suspected money laundering activity, including a periodic review of the correspondent account activity sufficient to determine consistency with information obtained about the type, purpose, and anticipated activity of the account.

Under 31 CFR 1010.610(b), covered financial institutions are required to establish EDD policies, procedures, and controls when establishing, maintaining, administering, or managing a correspondent account for certain foreign banks, as defined in 31 CFR 1010.610(c).[4] The EDD must reflect the risk assessment of the account and must include, as appropriate: (i) Obtaining information relating to the foreign bank's AML program; (ii) monitoring transactions to, from, or through the correspondent account in a manner reasonably designed to detect money laundering and suspicious activity; (iii) obtaining information from the foreign bank about the identity of persons with authority to direct transactions through the correspondent account if it is a payable-through account, as well as information about the sources and beneficial owners of funds or other assets in the payable-through account; (iv) determining whether the foreign bank maintains correspondent accounts for other foreign banks that use the foreign correspondent account established or maintained by the covered financial institution and, if so, taking reasonable steps to obtain information relevant to assess and mitigate money laundering risks, including, as appropriate, by obtaining the identity of the other foreign banks; and (v) obtaining the identity of certain owners of any such foreign bank that is not publicly traded and the nature and extent of the ownership interest.

Under 31 CFR 1010.610(d), covered financial institutions are required to establish special procedures when due diligence or EDD cannot be performed, including when the covered financial should refuse to open the account, suspend transaction activity, file a suspicious activity report, or close the account.

(b) *31 CFR 1010.620—Due diligence programs for private banking accounts.*

Under 31 CFR 1010.620, covered financial institutions are required to establish due diligence policies, procedures, and controls that, at a minimum, are designed to ensure that the financial institutions take reasonable steps to: (i) Ascertain the identify of all nominal and beneficial owners of a private banking account; [5] (ii) ascertain whether any nominal or beneficial owner is a senior foreign political figure; (iii) ascertain the source(s) of funds deposited into a private banking account and the purpose and expected use of the account; and (iv) review the activity of the account to ensure that it is consistent with the information obtained about the client's source of funds and with the stated purpose and expected use of the account, as needed to guard against money laundering, and to report any known or suspected money laundering or suspicious activity conducted to, from, or through a private banking account.

Under 31 CFR 1010.620(c), in the case of a private banking account for which a senior foreign political figure is a nominal or beneficial owner, covered financial institutions are required to conduct enhanced scrutiny of the account that is reasonably designed to detect and report transactions that may involve the proceeds of foreign corruption.[6]

Under 31 CFR 1010.620(d), covered financial institutions are required to establish special procedures when appropriate due diligence cannot be performed, including when the covered financial institution should refuse to open the account, suspend transaction activity, file a suspicious activity report, or close the account.

II. Paperwork Reduction Act of 1995 (PRA) [7]

Title: Due diligence programs for correspondent accounts for foreign financial institutions and private banking accounts (31 CFR 1010.610 and 31 CFR 1010.620).

OMB Control Number: 1506–0046.

Report Number: Not applicable.

Abstract: FinCEN is issuing this notice to renew the OMB control number for the due diligence programs for correspondent accounts for foreign financial institutions and for private banking accounts.

Affected Public: Businesses or other for-profit institutions, and non-profit institutions.

Type of Review:

- Renewal without change of a currently approved information collection.
- Propose for review and comment a renewal of the portion of the PRA burden that has been subject to notice and comment in the past (the ''traditional annual PRA burden'').
- Propose for review and comment a future expansion of the scope of the PRA burden (the ''supplemental annual PRA burden'').

Frequency: As required.

Estimated Number of Respondents: 16,938 financial institutions.[8]

Estimated Recordkeeping Burden: In Part 1 of this notice, FinCEN describes the breakdown of the estimated number of financial institutions, by type. In Part 2, FinCEN proposes for review and comment a renewal of the estimate of the traditional annual PRA hourly burden, which includes a scope and methodology similar to that used in the past, with the incorporation of a more robust cost estimate. The scope and methodology used in the past was limited to maintaining and updating the due diligence programs as part of the AML programs. In Part 3, FinCEN proposes for review and comment a methodology to estimate the hourly burden and the cost of a future estimate of a supplemental annual PRA burden that includes the burden and cost of maintaining records related to the regulatory requirements to conduct due diligence and EDD for foreign correspondent accounts, and to conduct due diligence and enhanced scrutiny for private banking accounts. Finally, in Part 4, FinCEN solicits input from the public about: (a) The accuracy of the estimate of the traditional annual PRA burden; (b) the method proposed for the calculation of the future supplemental annual PRA burden; (c) the criteria, metrics, and most appropriate questions FinCEN should consider when researching the information to estimate

[4] The EDD procedures are required for any correspondent account maintained for a foreign bank that operates pursuant to: (i) An offshore banking license; (ii) a banking license issued by a foreign country that has been designated as non-cooperative with international anti-money laundering principles or procedures by an intergovernmental group or organization of which the United States is a member and with which designation the U.S. representative to the group or organization concurs; or (iii) a banking license issued by a foreign country that has been designated by the Secretary as warranting special measures due to money laundering concerns.

[5] Private banking account means an account (or any combination of accounts) maintained at a covered financial institution that: (i) Requires a minimum aggregate deposit of funds or other assets of not less than $1,000,000; (ii) is established on behalf of or for the benefit of one or more non-U.S. persons who are direct or beneficial owners of the account; and (iii) is assigned to, or is administered or managed by, in whole or in part, an officer, employee, or agent of a covered financial institution acting as a liaison between the covered financial institution and the direct or beneficial owner of the account. 31 CFR 1010.605(m).

[6] *See* 31 CFR 1010.620(c)(2) for the definition of the term ''proceeds of foreign corruption.''

[7] Public Law 104–13, 44 U.S.C. 3506(c)(2)(A).

[8] Table 1 below sets forth a breakdown of the types of financial institutions covered by this notice.

the future traditional and supplemental annual PRA burden, according to the methodology proposed; and (d) any other comments about the regulations and the current and proposed future hourly burden and cost estimates of these requirements.

Part 1. Breakdown of the Financial Institutions Covered By This Notice

The breakdown of financial institutions, by type, covered By this notice is reflected in Table 1 below:

TABLE 1—BREAKDOWN OF FINANCIAL INSTITUTIONS COVERED BY THIS NOTICE, BY TYPE OF FINANCIAL INSTITUTION

Type of financial institution	Number of financial institutions
Banks	[9] 10,542
Brokers or dealers in securities	[10] 3,640
Futures commission merchants	[11] 61
Introducing brokers in commodities	[12] 1,104
Mutual funds	[13] 1,591
Total number of financial institutions	16,938

Part 2. Traditional Annual PRA Burden and Cost

Due to the practical challenges of obtaining the total number of correspondent accounts maintained by covered financial institutions for foreign financial institutions subject to regular due diligence requirements, the number of correspondent accounts maintained for foreign banks subject to EDD requirements, and the number of private banking accounts, the scope of the traditional annual PRA burden was limited to the annual burden of (a) maintaining and updating a due diligence programs as part of the AML program, and (b) securing approval of the program by an appropriate level of senior management.

FinCEN continues estimating the annual hourly burden of maintaining and updating the due diligence program for foreign correspondent accounts and private banking accounts at two hours per covered financial institution. This estimate covers the burden of (i) maintaining and updating the due diligence program to take into consideration any regulatory changes and any potential modifications required by changes in the types of foreign correspondent accounts or private banking accounts maintained, or by changes in the operations or organizational structure of the foreign financial institutions for which a covered financial institution maintains accounts, as well as changes to the organizational structure of private banking accounts (one hour), and (ii) presenting the updated due diligence program to the appropriate level of senior management of the financial institution for approval (one hour).

FinCEN's estimate of the traditional annual PRA burden, therefore, is 33,876 hours, as detailed in Table 2 below:

TABLE 2—BURDEN ASSOCIATED WITH UPDATING AND MAINTAINING THE DUE DILIGENCE PROGRAM AND OBTAINING SENIOR MANAGEMENT APPROVAL OF THE PROGRAM

Type of financial institution	Number of financial institutions (see Table 1)	Time per financial institution		Total burden hours per step		Grand total burden hours
		Maintenance	Approval	Maintenance	Approval	
Banks	10,542	1 hour	1 hour	10,542	10,542	21,084
Brokers or dealers in securities	3,640	1 hour	1 hour	3,640	3,640	7,280
Futures commission merchants	61	1 hour	1 hour	61	61	122
Introducing brokers in commodities	1,104	1 hour	1 hour	1,104	1,104	2,208
Mutual funds	1,591	1 hour	1 hour	1,591	1,591	3,182
Total burden hours				16,938	16,938	33,876

To calculate the hourly costs of the burden estimate, FinCEN identified four roles and corresponding staff positions involved in maintaining, updating, and obtaining senior management approval of the due diligence program: (i) Board of directors or senior management of the financial institution; (ii) general supervision (providing process oversight); (iii) direct supervision (reviewing operational-level work and cross-checking all or a sample of the work product against supporting documentation); and (iv) clerical work (engaging in research and administrative review, and recordkeeping).

FinCEN calculated the fully-loaded hourly wage for each of these four roles by using the median wage estimated by the U.S. Bureau of Labor Statistics (BLS),[14] and computing an additional benefits cost as follows:

[9] According to the Federal Deposit Insurance Corporation (FDIC) there were 5,103 FDIC-insured banks as of March 31, 2020. According to the Federal Reserve Board (FRB), there were 203 other entities supervised by the FRB, as of June 16, 2020, that fall within the definition of bank (20 Edge Act institutions, 15 agreement corporations, and 168 foreign banking organizations). According to the National Credit Union Administration there were 5,236 federally regulated credit unions as of December 31, 2019.

[10] According to the Securities and Exchange Commission (SEC), there were 3,640 brokers or dealers in securities registered with the SEC, as of March 31, 2020.

[11] According to the Commodities and Futures Trading Commission (CFTC), there were 61 futures commission merchants registered with the CFTC, as of March 31, 2020.

[12] According to the CFTC, there were 1,104 introducing brokers in commodities registered with the CFTC as of March 31, 2020.

[13] According to the SEC, there were approximately 1,591 mutual funds in 2017, based on forms filed with the SEC. The SEC provided the estimate to FinCEN for the last renewal of OMB control number 1506–0033, 83 FR 46012 (Sept. 11, 2018). FinCEN was unable to obtain a more recent estimate.

[14] The U.S. Bureau of Labor Statistics, Occupational Employment Statistics-National, May 2019, available at *https://www.bls.gov/oes/tables.htm*. The most recent data from the BLS corresponds to May 2019. For the benefits component of total compensation, see U.S. Bureau of Labor Statistics, Employer's Cost per Employee Compensation as of December 2019, available at *https://www.bls.gov/news.release/ecec.nr0.htm*. The ratio between benefits and wages for financial activities is $15.95 (hourly benefits)/$32.05 (hourly wages) = 0.50. The benefit factor is 1 plus the benefit/wages ratio, or 1.50. Multiplying each hourly wage by the benefit factor produces the fully-loaded hourly wage per position.

TABLE 3—FULLY-LOADED HOURLY WAGE BY ROLE AND BLS JOB POSITION FOR ALL FINANCIAL INSTITUTIONS COVERED BY THIS NOTICE

Role	BLS-code	BLS-name	Median hourly wage	Benefit factor	Fully-loaded hourly wage
Board of directors/senior management	11–1010	Chief Executive	$88.68	1.50	*$133.00
General supervision	11–3031	Financial Manager	62.45	1.50	93.68
Direct supervision	13–1041	Compliance Officer	33.20	1.50	49.80
Clerical work (research, review, and recordkeeping).	43–3099	Financial Clerk	20.40	1.50	30.60

(*) $133.02 rounded to $133.00.

FinCEN estimates that, *in general and on average,*[15] each role would spend different amounts of time on each portion of the traditional annual PRA burden, as follows:

For annually maintaining and updating the due diligence program, the cost of each hour of burden would be (i) one burden hour at $133.00 (representing the cost of board of directors or senior management review and approval), and (ii) one hour at $48.00 representing the actual update of the content of the program broken down by each role as shown in Table 4 below:

TABLE 4—WEIGHTED AVERAGE HOURLY COST OF MAINTAINING AND UPDATING THE DUE DILIGENCE PROGRAM

General supervision		Direct supervision		Clerical work		Weighted average hourly cost
% Time	Hourly cost	% Time	Hourly cost	% Time	Hourly cost	
10%	$9.37	60%	$29.88	30%	$9.18	$48.00

$48.43 rounded to $48.00

The total estimated cost of the traditional annual PRA burden is $3,065,778, as reflected in Table 5 below:

TABLE 5—TOTAL COST OF TRADITIONAL ANNUAL PRA BURDEN

Steps	Hourly burden	Hourly cost	Total cost
Maintaining and updating the program (divided between the roles listed in Table 4)	[16] 16,938	[17] $48.00	$813,024
Board of directors/senior management approval of the program	[18] 16,938	[19] 133.00	2,252,754
Total cost			3,065,778

Part 3. Supplemental Annual PRA Burden

In the future, FinCEN intends to add a supplemental annual PRA burden calculation that will include the estimated hourly burden and cost to maintain records to document compliance with the due diligence and EDD procedures for foreign correspondent accounts, and due diligence procedures and enhanced scrutiny requirements for private banking accounts.

(a) *Due diligence procedures for foreign correspondent accounts.*

As noted in Section I above, for all correspondent accounts established or maintained for foreign financial institutions, covered financial institutions are required to establish due diligence policies, procedures, and controls that include: (i) Determining whether each account is subject to EDD; (ii) assessing the money laundering risks presented by each account; and (iii) applying risk-based procedures and controls to each account that are reasonably designed to detect and report known or suspected money laundering activity, including a periodic review of the account activity sufficient to determine consistency with information obtained about the type, purpose, and anticipated activity of the account.

(b) *EDD procedures for certain foreign bank accounts.*

As noted in Section I above, covered financial institutions are required to establish EDD policies, procedures, and controls when establishing, maintaining, administering, or managing a correspondent account for certain foreign banks, as defined in 31 CFR 1010.610(c). The enhanced scrutiny must reflect the risk assessment of the account and must include, as appropriate: (i) Obtaining information relating to the AML program of the foreign bank; (ii) monitoring transactions to, from, or through the correspondent account in a manner reasonably designed to detect money laundering and suspicious activity; (iii) obtaining information from the foreign bank about the identity of persons with authority to direct transactions through the correspondent accounts if they are payable-through accounts, as well as information about the sources and beneficial owners of funds or other assets in the payable-through accounts; (iv) determining whether the foreign bank maintains correspondent accounts for other foreign banks that use the foreign correspondent account established or maintained by the covered financial institution and, if so,

[15] By ''in general,'' FinCEN means without regard to outliers (*e.g.,* financial institutions with foreign correspondent account relationships with complexities that are uncommonly higher or lower than those of the population at large). By ''on average,'' FinCEN means the mean of the distribution of each subset of the population.

[16] See Table 2.

[17] See Table 4.

[18] See Table 2.

[19] See Table 3.

taking reasonable steps to obtain information relevant to assess and mitigate money laundering risks, including, as appropriate, by obtaining the identity of the other foreign banks; and (v) obtaining the identity of certain owners of any such foreign bank that is not publicly traded and the nature and extent of the ownership interest.

(c) *Due diligence procedures for private banking accounts.*

As noted in Section I above, covered financial institutions are required to establish due diligence policies, procedures, and controls that, at a minimum, are designed to ensure that the financial institutions take reasonable steps to: (i) Ascertain the identity of all nominal and beneficial owners of a private banking account; (ii) ascertain whether any nominal or beneficial owner is a senior foreign political figure; (iii) ascertain the source(s) of funds deposited into a private banking account and the purpose and expected use of the account; and (iv) review the activity of the account to ensure that it is consistent with the information obtained about the client's source of funds and with the stated purpose and expected use of the account, as needed to guard against money laundering, and to report any known or suspected money laundering or suspicious activity conducted to, from, or through a private banking account.

(d) *Enhanced scrutiny for private banking accounts.*

As noted in Section I above, in the case of a private banking account for which a senior foreign political figure is a nominal or beneficial owner, covered financial institutions are required to conduct enhanced scrutiny that is reasonably designed to detect and report transactions involving the account that may involve the proceeds of foreign corruption.

FinCEN does not have the necessary information to provide a tentative estimate for these supplemental PRA hourly burdens and costs within the current notice. In addition, FinCEN does not have all the necessary information to precisely estimate the traditional annual PRA burden. For that reason, FinCEN is relying on estimates used in prior renewals of this OMB control number and the applicable regulations. FinCEN further recognizes that after receiving public comments as a result of this notice, future traditional annual PRA hourly burden and cost estimates may vary significantly. FinCEN intends to conduct more granular studies of the actions included in the proposed scope of the supplemental annual PRA burden in the near future, to arrive at more precise estimates of net BSA hourly burden and cost.[20] The data obtained in these studies also may result in a significant variation of the estimated traditional annual PRA burden.

Estimated Recordkeeping Burden: The average estimated annual PRA burden, measured in hours per respondent, is two hours (one burden hour to annually maintain and update the due diligence program, and one hour to annually obtain senior management approval of the due diligence program).

Estimated Number of Respondents: 16,938, as set out in Table 1.

Estimated Total Annual Responses: 16,938 revised due diligence programs for foreign correspondent accounts and private banking accounts annually; and 16,938 due diligences programs for foreign correspondent accounts and private banking accounts approved by senior management annually, as set out in Table 2.

Estimated Total Annual Recordkeeping Burden: The estimated total annual PRA burden is 33,876 hours, as set out in Table 2.

Estimated Total Annual Recordkeeping Cost: The estimated total annual PRA cost is $3,065,778, as set out in Table 5.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Records required to be retained under the BSA must be retained for five years.

Part 4. Request for Comments

(a) Specific request for comments on the traditional annual PRA hourly burden and cost.

FinCEN invites comments on any aspect of the traditional annual PRA burden, as set out in Part 2 of this notice. In particular, FinCEN seeks comments on the adequacy of: (i) FinCEN's assumptions underlying its estimate of the burden; (ii) the estimated number of hours required by each portion of the burden; and (iii) the organizational levels of the financial institution engaged in each portion of the burden, their estimated hourly remuneration, and the estimated proportion of participation by each role. FinCEN encourages commenters to include any publicly available sources for alternative estimates or methodologies.

(b) Specific request for comments on the proposed criteria for determining the scope of a supplemental annual PRA hourly burden and cost estimate.

FinCEN invites comments on any aspect of the criteria for a future estimate of the supplemental annual PRA burden, as set out in Part 3 of this notice.

(c) Specific request for comments on the appropriate criteria, methodology, and questionnaire required to obtain information to more precisely estimate the supplemental annual PRA hourly burden and cost.

FinCEN invites comments on the most appropriate and comprehensive means to question financial institutions about the annual hourly burden and cost attributable solely to the recordkeeping necessary to comply with the due diligence and EDD requirements for foreign correspondent accounts, and due diligence procedures and enhanced scrutiny requirements for private banking accounts (*i.e.,* the hourly burden and cost of complying with the recordkeeping requirements imposed exclusively by the BSA, which are not used to satisfy contractual obligations, other regulatory requirements, or business purposes of the financial institution).

The supplemental annual PRA hourly burden and cost estimate of the recordkeeping necessary to comply with the due diligence and EDD requirements for foreign correspondent accounts, and due diligence and enhanced scrutiny for private banking accounts must take into consideration only the effort involved in obtaining those data elements that are used exclusively for complying with requirements under 31 CFR 1010.610 and 31 CFR 1010.620, respectively. Given the complexity in determining what portion of the effort to include in the estimate, FinCEN seeks comments from the public regarding any questions we should consider posing in future notices, in addition to the specific questions for comment outlined directly below. Also, due to the evident

[20] Net hourly burden and cost are the burden and cost a financial institution incurs to comply with requirements that are unique to the BSA, and that do not support any other business purpose or regulatory obligation of the financial institution. Burden for purposes of the PRA does not include the time and financial resources needed to comply with an information collection, if the time and resources are for things a business (or other person) does in the ordinary course of its activities if the agency demonstrates that the reporting activities needed to comply are usual and customary. 5 CFR 1320.3(b)(2). For example, depending on the nature of the correspondent account or private banking account, a financial institution may be collecting and maintaining some of the same information on the foreign financial institution correspondent account holder or the private banking account holder that is required by the regulatory requirements under 31 CFR 1010.610 and 31 CFR 1010.620, respectively, in order to satisfy other obligations including (i) protecting the financial institution from fraud against itself or its customers, (ii) complying with other non-BSA regulatory requirements such as those imposed by the specific Federal functional regulator, or (iii) improving the financial institution's marketing efforts, or the credit analysis of any lending facilities granted to the foreign financial institution.

difficulty involved in estimating the number of correspondent accounts maintained for foreign financial institutions, the number of correspondent accounts maintained for foreign banks for which EDD is required, the number of private banking accounts, and the number of private banking accounts for which a senior foreign political figure is a nominal or beneficial owner and therefore subject to enhanced scrutiny, FinCEN welcomes any suggestions as to how to derive these estimates by using publicly available financial information.

(d) Specific questions for comment associated with the due diligence and EDD procedures for foreign correspondent accounts:

(1) *Due diligence procedures.*

- On average, how many correspondent accounts does your financial institution maintain for foreign financial institutions that require due diligence?
- Does your financial institution maintain foreign correspondent accounts for banks that require EDD?
- On average, how many correspondent accounts does your financial institution maintain for foreign banks that require EDD?
- Does your financial institution have a process to track foreign correspondent accounts for reasons other than to comply with the BSA requirements?
- On average, during the on-boarding process, how long does it take your financial institution to conduct the research necessary to determine if a correspondent account requires due diligence or EDD?
- Does your financial institution have a review and approval process involving senior management regarding the determination to conduct due diligence versus EDD? On average, how long does the review process take and how many approvals are necessary?
- On average, how long does it take your financial institution to conduct the research and document an initial risk assessment of a correspondent account?
- Does your financial institution have a review and approval process involving senior management to evaluate the conclusions reached in the original risk assessment? On average, how long does the review process take and how many approvals are necessary?
- On average, how frequently does your financial institution conduct periodic reviews of each correspondent account?
- On average, how long does it take your financial institution to conduct and document the periodic review of a correspondent account?
- Does your financial institution have a review and approval process involving senior management to evaluate the conclusions reached in the periodic review of a correspondent account? On average, how long does the review process take and how many approvals are necessary?

(2) *EDD procedures.*

- On average, how long does it take your financial institution to conduct research and document an initial risk assessment of a correspondent account that requires EDD?
- Does your financial institution have a review and approval process involving senior management to evaluate the conclusions reached in the original risk assessment? On average, how long does the review process take and how many approvals are necessary?
- On average, how long does it take your financial institution to obtain a foreign bank's AML program when a correspondent account requires EDD? Does your financial institution conduct a review of each applicable AML program?
- On average, how often does your financial institution conduct and document review of transaction activity through a correspondent account?
- On average, how long does it take your financial institution to conduct and document review of transaction activity through a correspondent account?
- Does your financial institution have a review and approval process involving senior management to evaluate the conclusions reached as a result of a transaction activity review on a particular correspondent account? On average, how long does the review process take and how many layers of management review are there?
- On average, how long does it take your financial institution to obtain information from a foreign bank about the identity of persons with authority to direct transactions through the correspondent account if it is a payable-through account, as well as information about the sources and beneficial owners of funds or other assets in the payable-through account?
- On average, how many individuals have the authority to direct transactions through a correspondent account?
- Does your financial institution have a way of identifying if a new person is permitted to conduct transaction activity through a correspondent account, so that your financial institution can obtain the proper information?
- Does your financial institution have a review and approval process involving senior management to evaluate information obtained on persons with authority to direct transactions through a correspondent account?
- Does your financial institution maintain correspondent accounts for foreign banks that permit other foreign banks to use the correspondent account maintained with your financial institution?
- On average, how many correspondent accounts does your financial institution maintain for foreign banks that permit other foreign banks to access the correspondent account?
- Does your financial institution have a way of determining if a foreign bank permits another foreign bank to access the correspondent account maintained with your financial institution?
- On average, how long does it take your financial institution to obtain information from a foreign bank about other foreign banks with access to the correspondent account maintained with your financial institution?
- What additional information does your financial institution obtain to assess and mitigate risk as it relates to other foreign banks permitted to access the correspondent account you maintain with a foreign bank?
- Does your financial institution have a review and approval process involving senior management to evaluate applicable information on other foreign banks with access a correspondent account you maintain with a foreign bank? On average, how long does the review process take and how many approvals are necessary?
- On average, how many non-publicly traded foreign banks does your financial institution maintain correspondent accounts for?
- On average, how long does it take your financial institution to obtain the identity of owners of a non-publicly traded foreign bank and obtain applicable information on the nature and extent of the ownership interest?
- Does your financial institution have a review and approval process involving senior management to evaluate applicable information on a non-publicly traded foreign bank? On average, how long does the review process take and how many approvals are necessary?

(e) Specific questions for comment associated with the due diligence and enhanced scrutiny for private banking accounts:

(1) *Due diligence procedures.*

- On average, how many private banking accounts does your financial institution maintain that requires due diligence?
- Does your financial institution maintain private banking accounts for

which a senior foreign political figure is a nominal or beneficial owner?

• On average, how many private banking accounts does your financial institution maintain for which a senior foreign political figure is a nominal or beneficial owner?

• Does your financial institution have a process to track private banking accounts for reasons other than to comply with the BSA requirements?

• On average, during the on-boarding process, how long does it take your financial institution to conduct the research necessary to determine if a private banking account requires enhanced scrutiny because a senior foreign political figure is a nominal or beneficial owner?

• On average, how long does it take your financial institution to conduct the research and/or obtain documents to ascertain the identity of all nominal and beneficial owners of a private banking account?

• On average, how long does it take your financial institution to research, obtain, and document the source of funds deposited into a private banking account and the purpose and expected use of the account?

• On average, how frequently does your financial institution conduct periodic reviews of each private banking account?

• On average, how long does it take your financial institution to conduct and document the periodic review of a private banking account?

• Does your financial institution have a review and approval process involving senior management to evaluate the conclusions reached in the periodic review of a private banking account? On average, how long does the review process take and how many approvals are necessary?

(2) *Enhanced scrutiny for senior foreign political figures.*

• On average, how long does it take your financial institution to conduct enhanced scrutiny of a private banking account for which a senior foreign political figure is a nominal or beneficial owner?

• On average, how often does your financial institution conduct enhanced scrutiny of such private banking account?

• Does your financial institution have a review and approval process involving senior management to evaluate the conclusions reached as a result of conducting enhanced scrutiny on such a private banking account? On average, how long does the review process take and how many approvals are necessary?

(f) General request for comments.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (i) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (ii) the accuracy of the agency's estimate of the burden of the collection of information; (iii) ways to enhance the quality, utility, and clarity of the information to be collected; (iv) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (v) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Michael Mosier,

Deputy Director, Financial Crimes Enforcement Network.

[FR Doc. 2020–21441 Filed 9–28–20; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Rural Health Advisory Committee; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Veterans' Rural Health Advisory Committee will hold a virtual meeting Monday, October 5, 2020, through Wednesday, October 7, 2020. The meeting will be accessible through the zoom link *https://zoom.us/j/93537309124* and phone number is 1–646–558–8656, Participant Code # 93537309124. The meeting will begin and end each day as follows:

Date	Time
October 5, 2020	11:00 a.m. to 2:00 p.m.
October 6, 2020	11:00 a.m. to 2:00 p.m.
October 7, 2020	11:00 a.m. to 2:00 p.m.

The meeting sessions are open to the public.

The purpose of the Committee is to advise the Secretary of VA on rural health care issues affecting Veterans. The Committee examines programs and policies that impact the delivery of VA rural health care to Veterans and discusses ways to improve and enhance VA access to rural health care services for Veterans.

The agenda will include updates from Department leadership; the Executive Director, VA Office of Rural Health; and the Committee Chair; as well as presentations by subject matter experts on general rural health care access.

Public comments will be received at 2:00 p.m. on October 7, 2020. Interested parties should contact Ms. Judy Bowie, by email at *VRHAC@va.gov,* or by mail at 810 Vermont Avenue NW (10P1R), Washington, DC 20420. Individuals wishing to speak are invited to submit a 1–2-page summary of their comment for inclusion in the official meeting record. Any member of the public seeking additional information should contact Ms. Bowie at the phone number or email address noted above.

Dated: September 23, 2020.

LaTonya L. Small,

Federal Advisory Committee Management Office.

[FR Doc. 2020–21397 Filed 9–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nomination for Appointment to the Advisory Committee on Disability Compensation

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA), Advisory Committee on Disability Compensation (the Committee), is seeking nominations of qualified candidates to be considered for appointment as a member of the Advisory Committee for the 2020—2021 membership cycle.

DATES: Nominations for membership on the Committee must be received by October 16, 2020, no later than 4:00 p.m., eastern standard time. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nomination packages should be emailed to the Designated Federal Officer (DFO), Sian Roussel at *sian.roussel@va.gov.*

SUPPLEMENTARY INFORMATION: In carrying out the duties set forth, the Committee responsibilities include:

(1) Advising the Secretary and Congress on the maintenance and periodic readjustment of the VA Schedule for Rating Disabilities.

(2) Providing a biennial report to Congress assessing the needs of Veterans with respect to disability compensation and outlining recommendations, concerns, and observations on the maintenance and periodic readjustment of the VA Schedule for Rating Disabilities.

(3) Meeting with VA officials, Veterans Service Organizations, and other stakeholders to assess the Department's efforts on the maintenance and periodic readjustment of the VA Schedule for Rating Disabilities.

Management and support services for the Committee are provided by VBA.

Authority: The Committee is authorized by 38 U.S.C. 546 and operates under the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. 2.

Membership Criteria: VBA is requesting nominations for upcoming vacancies on the Committee. The Committee is currently composed of 13 members. As required by statute, the members of the Committee are appointed by the Secretary from the general public, including:

(1) Individuals with experience with the provision of disability compensation by VA;

(2) Individuals who are leading medical and scientific experts in relevant fields.

In accordance with § 546, the Secretary determines the number, terms of service, and pay and allowances of members of the Committee, except that a term of service of any such member may not exceed four years. The Secretary may reappoint any member for additional terms of service.

Professional Qualifications: In addition to the criteria above, VA seeks: (1) Diversity in professional and personal qualifications; (2) Experience in military service and military deployments (please identify branch of service and rank); (3) Current work with Veterans; (4) Disability compensation subject matter expertise; (5) Experience working in large and complex organizations. Requirements for Nomination Submission: Nominations should be typewritten (one nomination per nominator).

Requirements for Nomination Submission:

The nomination package should include:

(1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes that qualify the nominee for service in this capacity), and a statement from the nominee indicating a willingness to serve as a member of the Committee;

(2) the nominee's contact information, including name, mailing address, telephone numbers, and email address;

(3) the nominee's curriculum vitae, and

(4) a summary of the nominee's experience and qualifications relative to the membership criteria and professional qualifications listed above.

Individuals selected for appointment to the Committee shall be invited to serve a two-year term. Committee members will receive a stipend for attending Committee meetings, including per diem and reimbursement for travel expenses incurred.

The Department makes every effort to ensure that the membership of its Federal advisory committees is fairly balanced in terms of points of view represented. Every effort is made to ensure that a broad representation of geographic areas, gender, and racial and ethnic minority groups, and that the disabled are given consideration for membership. Appointment to this Committee shall be made without discrimination because of a person's race, color, religion, sex (including gender identity, transgender status, sexual orientation, and pregnancy), national origin, age, disability, or genetic information. Nominations must state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude membership.

Dated: September 23, 2020.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2020–21413 Filed 9–28–20; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 85 Tuesday,

No. 189 September 29, 2020

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 512

Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS–5527–F]

RIN 0938–AT89

Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements two new mandatory Medicare payment models under section 1115A of the Social Security Act—the Radiation Oncology Model (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model). The RO Model will promote quality and financial accountability for providers and suppliers of radiotherapy (RT). The RO Model will be a mandatory payment model and will test whether making prospective episode payments to hospital outpatient departments (HOPD) and freestanding radiation therapy centers for RT episodes of care preserves or enhances the quality of care furnished to Medicare beneficiaries while reducing Medicare program spending through enhanced financial accountability for RO Model participants. The ETC Model will be a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants, in order to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model adjusts Medicare payments on certain dialysis and dialysis-related claims for participating ESRD facilities and clinicians caring for beneficiaries with ESRD—or Managing Clinicians—based on their rates of home dialysis transplant waitlisting, and living donor transplants. We believe that these two models will test ways to further our goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

DATES: These regulations are effective on November 30, 2020.

FOR FURTHER INFORMATION CONTACT:

Rebecca Cole, (410) 786–1589, *Rebecca.Cole@cms.hhs.gov,* for questions related to General Provisions.

RadiationTherapy@cms.hhs.gov, or 1–844–711–2664 Option 5, for questions related to the Radiation Oncology Model.

ETC-CMMI@cms.hhs.gov, for questions related to the ESRD Treatment Choices Model.

SUPPLEMENTARY INFORMATION:

Current Procedural Terminology (CPT) Copyright Notice

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The purpose of this final rule is to implement and test two new mandatory models under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center), and to implement certain general provisions that will be applicable to both the RO Model and the ETC Model. Section 1115A of the Social Security Act (the Act) authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs. Under the Medicare fee-for-service (FFS) program, Medicare generally makes a separate payment to providers and suppliers for each item or service furnished to a beneficiary during the course of treatment. Because the amount of payments received by a provider or supplier for such items and services varies with the volume of items and services furnished to a beneficiary, some providers and suppliers may be financially incentivized to inappropriately increase the volume of items and services furnished to receive higher payments. Medicare FFS may also detract from a provider's or supplier's incentive to invest in quality improvement and care coordination activities if it means those activities will result in payment for fewer items and services. As a result, care may be fragmented, unnecessary, or duplicative.

The goal for these models is to preserve or enhance the quality of care furnished to beneficiaries while reducing program spending through enhanced financial accountability for model participants. The Model performance period for the RO Model will begin on January 1, 2021, and end December 31, 2025. We will implement the payment adjustments under the ETC Model beginning January 1, 2021 and ending June 30, 2027.

These models will offer participants the opportunity to examine and better understand their own care processes and patterns with regard to beneficiaries receiving RT services for cancer, and beneficiaries with ESRD, respectively. We chose these focus areas for the models because, as discussed in sections III. and IV. of this final rule, we believe that participants in these models will have a significant opportunity to redesign care and improve the quality of care furnished to beneficiaries receiving these services.

We believe the models will further the agency's goal of increasing the extent to which CMS initiatives pay for value and outcomes, rather than for volume of services alone, by promoting the alignment of financial and other incentives for health care providers caring for beneficiaries receiving treatment for cancer or ESRD. Payments that are made to health care providers for assuming financial accountability for the cost and quality of care create incentives for the implementation of care redesign among model participants and other providers and suppliers.

CMS is testing several models, including voluntary models focused specifically on cancer and ESRD. The RO and ETC Models will require the participation of providers and suppliers that might not otherwise participate in these models, and will be tested in multiple geographic areas.

The models will allow CMS to test models with provider and supplier participation when there are differences in: (1) Historic care and utilization patterns; (2) patient populations and care patterns; (3) roles within their local markets; (4) volume of services; (5) levels of access to financial, community, or other resources; and (6) levels of population and health care provider density. As noted in the proposed rule, we believe that participation in these models by a large number of providers and suppliers with diverse characteristics will result in a robust data set for evaluating the models' proposed payment approaches and will stimulate the rapid development of new evidence-based knowledge. Testing these models in this manner will also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize quality improvement for beneficiaries receiving

services for RT and ESRD, which could inform future model design.

We solicited public comment on our proposals, and on any alternatives considered. CMS has made a number of modifications to the formatting and language used in the regulation text (for example, to revise ''pursuant to'' to ''under''; and ''shall'' to ''must'') to improve readability. These formatting and language changes are not intended to be substantive. Any substantive change(s) to this final rule is noted in the specific section(s) affected by the change(s).

2. Summary of the Major Provisions

a. General Provisions

The general provisions will be applicable only to participants in the RO Model and the ETC Model. We identified the general provisions based on similar requirements that have been repeatedly memorialized in various documents governing participation in existing model tests. We have made these provisions applicable to both the RO Model and ETC Model, with one exception related to termination of model participants, so that we may eliminate repetition in our regulations at 42 CFR part 512. The general provisions address beneficiary protections, model evaluation and monitoring, audits and record retention, rights in data and intellectual property, monitoring and compliance, remedial action, model termination by CMS, limitations on review, and miscellaneous provisions on bankruptcy and other notifications. These provisions are not intended to comprehensively encompass all the provisions that will apply to each model. Both the RO Model and the ETC Model have unique aspects that will require additional, more tailored provisions, including with respect to payment and quality measurement. Such model-specific provisions are described elsewhere in this final rule.

b. Radiation Oncology (RO) Model

In this rule, we are finalizing the creation and testing of a new payment model for radiation oncology, the RO Model. The intent of the RO Model is to promote quality and financial accountability for episodes of care centered on RT services. While preserving or enhancing the quality of care for Medicare beneficiaries, the RO Model will test whether prospective episode-based payments to physician group practices (PGPs), HOPDs, and freestanding radiation therapy centers for RT episodes of care will reduce Medicare expenditures. We anticipate the RO Model will benefit Medicare beneficiaries by encouraging more efficient care delivery and incentivizing higher value care across episodes of care. The RO Model will have a performance period of 5 calendar years, beginning January 1, 2021, and ending December 31, 2025. The RO Model will capture all complete RO episodes that end during the performance period, which means that the data collection, RO episode payments, and reconciliation will continue into calendar year 2026.

(1) Summary of the RO Provisions

(a) RO Model Overview

RT is a common treatment for patients undergoing cancer treatment and is typically furnished by a physician at either an HOPD or a freestanding radiation therapy center. The RO Model will include prospective payments for certain RT services furnished during a 90-day RO episode for included cancer types for certain Medicare beneficiaries. The included cancer types will be determined by the following criteria: All are commonly treated with radiation; make up the majority of all incidence of cancer types; and have demonstrated pricing stability. (See section III.C.5.a. of this final rule for more information.) This Model will not account for total cost of all care provided to the beneficiary during the 90 days of an RO episode. Rather, the payment will cover only select RT services furnished during an RO episode. Payments for RO episodes will be split into two components—the professional component (PC) and the technical component (TC). This division reflects the fact that RT professional and technical services are sometimes furnished by separate RT providers and RT suppliers and paid for through different payment systems (namely, the Medicare Physician Fee Schedule and Outpatient Prospective Payment System).

For example, under the RO Model, a participating HOPD must have at least one PGP to furnish RT services at the HOPD. A PGP will furnish the PC as a Professional participant and an HOPD will furnish the TC as a Technical participant. Both will be participants in the RO Model, furnishing separate components of the same RO episode. An RO participant may also elect to furnish both the PC and TC as a Dual participant through one entity, such as a freestanding radiation therapy center. The RO Model will test the cost-saving potential of prospective episode payments for certain RT services furnished during an RO episode and whether shorter courses of RT (that is, fewer doses, also known as fractions) will encourage more efficient care delivery and incentivize higher value care.

(b) RO Model Scope

We are finalizing criteria for the types of cancer included under the RO Model and list 16 cancer types that meet our criteria. These cancer types are commonly treated with RT and, therefore, RT services for such cancer types can be accurately priced for purposes of a prospective episode payment model. RO episodes will include most RT services furnished in HOPDs and freestanding radiation therapy centers during a 90-day period.

We are finalizing that participation in the RO Model will be mandatory for all RT providers and RT suppliers within selected geographic areas. We will use Core-Based Statistical Areas (CBSAs) delineated by the Office of Management and Budget [1] as the geographic area for the randomized selection of RO participants. We will link RT providers and RT suppliers to a CBSA by using the five digit ZIP Code of the location where RT services are furnished, permitting us to identify RO Model participants while still using CBSA as a geographic unit of selection. In addition, we will exclude certain providers and suppliers from participation under the RO Model as described in section III.C.3.c. of this final rule.

We are including beneficiaries that meet certain criteria under the RO Model. For example, these criteria will require that a beneficiary have a diagnosis of at least one of the cancer types included in the RO Model and that the beneficiary receive RT services from a participating provider or supplier in one of the selected CBSAs. Beneficiaries who meet these criteria will be included in RO episodes.

(c) RO Model Overlap With Other CMS Programs and Models

We expect that there could be situations where a Medicare beneficiary included in an RO episode under the RO Model is also assigned, aligned, or attributed to another Innovation Center model or CMS program. Overlap could also occur among RT providers and RT suppliers at the individual or organization level, such as where a radiation oncologist or his or her PGP participates in multiple Innovation Center models. We believe that the RO Model is compatible with existing models and programs that provide opportunities to improve care and

[1] See *https://www.census.gov/programs-surveys/metro-micro/about/omb-bulletins.html.*

reduce spending, especially episode payment models like the Oncology Care Model. However, we will work to resolve any potential overlaps between the RO Model and other CMS models or programs that could result in repetitive services, or duplicative payment of services, and duplicative counting of savings or other reductions in expenditures.

(d) RO Model Episodes and Pricing Methodology

We are setting a separate payment amount for the PC and the TC of each cancer type included in the RO Model. The payment amounts will be determined based on national base rates, trend factors, and adjustments for each participant's case-mix, historical experience, and geographic location. The payment amount will also be adjusted for withholds for incorrect payments, quality, and starting in the third performance year (PY3), patient experience. The standard beneficiary coinsurance amounts (typically 20 percent of the Medicare-approved amount for services) and sequestration will remain in effect. RO participants will have the ability to earn back a portion of the quality and patient experience withholds based on their reporting of clinical data, their reporting and performance on quality measures, and as of PY3, performance on the beneficiary-reported Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Radiation Therapy Survey.

(e) RO Model Quality Measures and Reporting Requirements

We are adopting four quality measures and will collect the CAHPS® Cancer Care Radiation Therapy Survey for the RO Model. Three of the four measures are National Quality Forum (NQF)-endorsed process measures that are clinically appropriate for RT and are approved for the Merit-based Incentive Payment System (MIPS).[2] [3] We selected all measures based on clinical appropriateness for RT services spanning a 90-day period. These measures will be applicable to the full range of included cancer types and provide us the ability to accurately measure changes or improvements in the quality of RT services. Further, we believe that these measures will allow the RO Model to apply a pay-for-performance methodology that incorporates performance measurement with a focus on clinical care and beneficiary experience with the aim of identifying a reduction in expenditures with preserved or enhanced quality of care for beneficiaries.

RO participants will be paid for reporting clinical data in accordance with our reporting requirements (as discussed in section III.C.8.e. of this final rule), and paid for performance on aggregated quality measure data on three quality measures and pay-for-reporting on one quality measure (for PY1 and PY2) (as discussed in section III.C.8.f. of this final rule). We are adding a set of patient experience measures based on the CAHPS® Cancer Care Survey for Radiation Therapy for inclusion as pay-for-performance measures. We will also require Professional participants and Dual participants to report all quality data for all applicable patients receiving RT services from RO participants based on numerator and denominator specifications for each measure (for example, not just Medicare beneficiaries or beneficiaries receiving care for RO episodes).

(f) RO Model Data Sharing Process

We will collect quality and clinical data for the RO Model. We intend to share certain data with RO participants to the extent permitted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and other applicable law. We are establishing data privacy compliance standards for RO participants. We are establishing requirements around the public release of patient de-identified information by RO participants. We will offer RO participants the opportunity to request a claims data file that contains patient-identifiable data on the RO participant's patient population for clinical treatment, care management and coordination, and quality improvement activities. Also, we will permit the data to be reused by RO participants for provider incentive design and implementation, and we believe it may be of use in RO participants' review of our calculation of their participant-specific episode payment amounts and reconciliation payment amounts or repayment amounts, as applicable. Thus, we expect that the data offered under the RO Model will be used by RO participants and CMS to better understand Model effects, establish benchmarks, and monitor participant compliance. Again, as previously described, the data uses and sharing will be allowed only to the extent permitted by the HIPAA Privacy Rule and other applicable law.

When using or disclosing such data, the RO participant will be required to make ''reasonable efforts to limit'' the information to the ''minimum necessary'' as defined by 45 CFR 164.502(b) and 164.514(d) to accomplish the intended purpose of the use, disclosure, or request. The RO participant will be required to further limit its disclosure of such information to what is permitted by applicable law, including the regulations promulgated under the HIPAA and the Health Information Technology for Economic and Clinical Health (HITECH) laws at 45 CFR part 160 and subparts A and E of part 164. Further discussion of data sharing can be found in section III.C.13. of this final rule.

(g) RO Model Beneficiary Protections

We are requiring Professional participants and Dual participants to notify RO beneficiaries of the beneficiary's inclusion in this Model through a standardized written notice to each RO beneficiary during the treatment planning service. We intend to provide a notification template, which RO participants may personalize with contact information and logos, but must otherwise not be changed. Further explanation of the beneficiary notification can be found in section III.C.15. of this final rule.

(h) RO Model Program Policy Waivers

We believe it will be necessary to waive certain requirements of title XVIII of the Act solely for purposes of carrying out the testing of the RO Model under section 1115A(b) of the Act. We will issue these waivers using our waiver authority under section 1115A(d)(1) of the Act. Each of the waivers is discussed in detail in section III.C.10. of this final rule, and codified in our regulations at § 512.280.

c. ESRD Treatment Choices (ETC) Model

The ETC Model will be a mandatory payment model, focused on encouraging greater use of home dialysis and kidney transplants for ESRD Beneficiaries among ESRD facilities and Managing Clinicians located in Selected Geographic Areas. The ETC Model will include two payment adjustments. The first payment adjustment, the Home Dialysis Payment Adjustment (HDPA), will be a positive adjustment on certain home dialysis and home dialysis-related claims during the initial 3 years of the model. The second payment adjustment, the Performance Payment Adjustment (PPA), will be a positive or negative adjustment on dialysis and dialysis-related Medicare payments, for both home dialysis and in-center dialysis,

[2] NQF endorsement summaries: *http://www.qualityforum.org/News_And_Resources/Endorsement_Summaries/Endorsement_Summaries.aspx.*

[3] See the CY 2018 QPP final rule (82 FR 53568).

based on ESRD facilities' and Managing Clinicians' rates of home dialysis, and of kidney transplant waitlisting and living donor transplantation, among attributed beneficiaries during the applicable MY. We are implementing the payment adjustments under the ETC Model beginning January 1, 2021, and ending June 30, 2027.

(1) Summary of the ETC Model Provisions

(a) ETC Model Overview

Beneficiaries with ESRD generally require some form of renal replacement therapy, the most common being hemodialysis (HD), followed by peritoneal dialysis (PD), or a kidney transplant. Most beneficiaries with ESRD receive HD treatments in an ESRD facility; however, other renal replacement modalities—including dialyzing at home or receiving a kidney transplant—may be better options than in-center dialysis for more beneficiaries than currently use them. We are finalizing the ETC Model to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians—clinicians who furnish and bill the Monthly Capitation Payment (MCP) for managing ESRD Beneficiaries—to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. We believe ESRD facilities and Managing Clinicians are the key providers and suppliers managing the dialysis care and treatment modality options for ESRD Beneficiaries and have a vital role to play in beneficiary modality selection and assisting beneficiaries through the transplant process. We are adjusting payments for home dialysis and home dialysis-related claims with claim service dates from January 1, 2021, through December 31, 2023 through the HDPA. We also will assess the rates of home dialysis and of kidney transplant waitlisting and living donor transplantation, among beneficiaries attributed to ETC Participants during the period beginning January 1, 2021, and ending June 30, 2026, with the PPA based on those rates applying to claims for dialysis and dialysis-related services with claim service dates beginning July 1, 2022, and ending June 30, 2027.

(b) ETC Model Scope

The ETC Model will be a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants for ESRD Beneficiaries. The rationale for a mandatory model for ESRD facilities and Managing Clinicians within Selected Geographic Areas is that we seek to test the effect of payment incentives on availability and choice of treatment modality among a diverse group of providers and suppliers. We will randomly select Hospital Referral Regions (HRRs) for inclusion in the Model, and also include all HRRs with at least 20 percent of ZIP Codes located in Maryland in addition to those selected through randomization in conjunction with the Maryland Total Cost of Care Model currently being tested in the state of Maryland. Managing Clinicians and ESRD facilities located in these Selected Geographic Areas will be required to participate in the ETC Model and will be assessed on their rates of home dialysis, and of kidney transplant waitlisting and living donor transplantation, among their attributed beneficiaries during each MY; CMS will then adjust certain of their Medicare payments upward or downward during the corresponding Performance Payment Adjustment Period (PPA Period). Managing Clinicians and ESRD facilities located in the Selected Geographic Areas will also receive a positive adjustment on their home dialysis and home dialysis-related claims for the first 3 years of the ETC Model to support home dialysis provision before the PPA begins to apply.

(c) Home Dialysis Payment Adjustment (HDPA)

We will make upward adjustments to certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and will make upward adjustments to the MCP paid to participating Managing Clinicians on home dialysis-related claims. The HDPA will apply to claims with claim service dates beginning on January 1, 2021, and ending on December 31, 2023.

(d) Home Dialysis and Transplant Performance Assessment and Performance Payment Adjustment (PPA)

We will assess ETC Participants' rates of home dialysis, and transplant waitlisting and living donor transplantation, during a MY, which will include 12 months of performance data. Each MY will overlap with the previous MY, if any, and the subsequent MY, if any, for a period of 6 months. Each MY will have a corresponding PPA Period—a 6-month period, which will begin 6 months after the conclusion of the MY. We will adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY. We will be measuring rates of home dialysis, and of transplant waitlisting and living donor transplantation, for ESRD facilities and Managing Clinicians using Medicare claims data, Medicare administrative data including enrollment data, and the Scientific Registry of Transplant Recipients (SRTR) data. We will measure home dialysis rates for ESRD facilities and Managing Clinicians in the ETC Model by calculating the number of dialysis treatment beneficiary years during the MY in which attributed beneficiaries received dialysis at home, plus one half the total number of dialysis treatment beneficiary years during the MY in which attributed beneficiaries received self dialysis in center. We will measure transplant rates for ESRD facilities and Managing Clinicians by calculating the number of attributed beneficiary years during the MY for which attributed beneficiaries were on the kidney transplant waitlist and by calculating the number of attributed beneficiary years during the MY for which attributed beneficiaries received living donor transplants. The ETC Model will make upward and downward adjustments to certain payments to participating ESRD facilities under the ESRD PPS and to the MCP paid to participating Managing Clinicians based upon the ETC Participant's home dialysis rate and transplant rate. The magnitude of the positive and negative PPAs for ETC Participants will increase over the course of the Model. These PPAs will apply to claims with claim service dates beginning July 1, 2022, and ending June 30, 2027.

(e) ETC Model Overlaps With Other Innovation Center Models and CMS Programs

The ETC Model will overlap with several other CMS programs and models, including initiatives specifically focusing on dialysis care. We believe the ETC Model will be compatible with other dialysis-focused CMS programs and models. However, we will work to resolve any potential overlaps between the ETC Model and other CMS models or programs that could result in repetitive services or duplicative payment for services. The payment adjustments made under the ETC Model will be counted as expenditures under the Medicare Shared Savings Program and other shared savings initiatives. Additionally, ESRD facilities will remain subject to the quality requirements in ESRD

Quality Incentive Program (QIP), and Managing Clinicians who are MIPS eligible clinicians will remain subject to MIPS unless otherwise excluded.

(f) ETC Model Medicare Payment Waivers

In order to make the proposed payment adjustments under the ETC Model, namely the HDPA and PPA, we will need to waive certain Medicare program requirements. In particular, we will waive certain requirements of the Act for the ESRD PPS, ESRD QIP, and Medicare Physician Fee Schedule only to the extent necessary to make the payment adjustments under the ETC Model for ETC Participants. In addition, we will waive certain requirements such that the payment adjustments made under the ETC Model will not change beneficiary cost-sharing from the regular Medicare program cost-sharing for the related Part B services that were paid for beneficiaries who receive services from ETC Participants.

It will also be necessary to waive certain Medicare payment requirements of section 1861(ggg) of the Act and implementing regulations at 42 CFR 410.48, regarding the use of the Kidney Disease Education (KDE) benefit, solely for the purposes of testing the ETC Model. The purpose of such waivers will be to give ETC Participants additional access to the tools necessary to ensure beneficiaries select their preferred kidney replacement modality. As education is a key component of assisting beneficiaries with making such selections, we will waive select requirements regarding the provision of the KDE benefit, including waiving the requirement that certain health care provider types must furnish the KDE service to allow additional staff to furnish the service, waiving the requirement that the KDE service be furnished to beneficiaries with Stage IV CKD to allow ETC Participants to furnish these services to beneficiaries in later stages of kidney disease, and waiving certain restrictions on the KDE curriculum to allow the content to be tailored to each beneficiary's needs.

We will issue these waivers using our waiver authority under section 1115A(d)(1) of the Act.

(g) ETC Model Monitoring and Quality Measures

Consistent with the monitoring requirements in the general provisions, we will closely monitor the implementation and outcomes of the ETC Model throughout its duration. The purpose of this monitoring will be to ensure that the ETC Model is implemented safely and appropriately, the quality or experience of care for beneficiaries is not harmed, and adequate patient and program integrity safeguards are in place.

As part of the monitoring strategy, we will be using two quality measures for the ETC Model: The Standardized Mortality Ratio and the Standardized Hospitalization Ratio. These measures are NQF-endorsed, and are currently calculated at the ESRD facility level for Dialysis Facility Reports and the ESRD QIP, respectively. Therefore, we will require no additional reporting of quality measures by ETC Participants. We intend to propose a beneficiary experience measure in future rulemaking.

(h) ETC Model Beneficiary Protections

The ETC Model will not allow beneficiaries to opt out of the payment adjustments for their ESRD facility or Managing Clinician; however, the Model will not restrict a beneficiary's freedom to choose an ESRD facility or Managing Clinician, or any other provider or supplier, and ETC Participants will be subject to the general provisions protecting beneficiary freedom of choice and access to medically necessary covered services. We also will require that ETC Participants notify beneficiaries of the ETC Participant's participation in the ETC Model by prominently displaying informational materials in ESRD facilities and Managing Clinician offices or facilities where beneficiaries receive care. Additionally, ETC Participants will be subject to the general provisions regarding descriptive model materials and activities.

B. Background

In the July 18, 2019 **Federal Register** (84 FR 34478), we published the proposed rule titled ''Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' that would implement two new mandatory Medicare payment models under section 1115A of the Act—the Radiation Oncology Model (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model).

As we stated in the proposed rule, we believe that these two models will test ways to further our goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

We received approximately 330 timely pieces of correspondence in response to our solicitation of public comments on the proposed rule. While we are finalizing several of the provisions from the proposed rule, there are a number of provisions from the proposed rule that we intend to address later and a few that we do not intend to finalize. We also note that some of the public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading. However, we note that in this final rule we are not addressing most comments received with respect to the provisions of the proposed rule that we are not finalizing at this time. Rather, we will address them at a later time, in a subsequent rulemaking document, as appropriate.

II. General Provisions

A. Introduction

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to such programs' beneficiaries. The Innovation Center has designed and tested numerous models governed by participation agreements, cooperative agreements, model-specific addenda to existing contracts with CMS, and regulations. While each of these models has a specific payment methodology, quality metrics, and certain other applicable policies, each model also has general provisions that are very similar, including provisions on monitoring and evaluation; compliance with model requirements and applicable laws; and beneficiary protections.

This section of the final rule finalizes the implementation of some general provisions that will be applicable to both the RO Model and the ETC Model. These general provisions are only applicable to model participants in the RO Model and the ETC Model. The general provisions being finalized here are based on similar provisions that have been repeatedly memorialized in various documents governing participation in existing model tests.

As we noted in the proposed rule, we believe it promotes efficiency to publish in section II. of this final rule certain general provisions in each of these areas that apply to both the RO Model and the ETC Model. This avoids the need to restate the same provisions separately for the two models in this final rule. We will codify these general provisions in a new subpart of the Code of Federal

Regulations (42 CFR part 512, subpart A). These provisions are not intended to comprehensively encompass all the provisions that will apply to each model. Both the RO Model and the ETC Model have unique aspects that require additional, more tailored provisions, including with respect to payment and quality measurement. Such model-specific provisions are described elsewhere in this final rule.

We received approximately 35 timely public comments on the general provisions of the proposed rule. These comments were submitted by individuals and entities with an interest in radiation oncology and kidney diseases. We note that some of these public comments were outside the scope of the proposed rule. These out-of-scope public comments are not addressed with the policy responses in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in this section of the final rule under the appropriate headings.

B. Basis and Scope

In § 512.100(a), we proposed to apply the general provisions in section II. of the proposed rule only to the RO Model and the ETC Model, each of which we proposed to refer to as an ''Innovation Center model'' for purposes of these general provisions. As proposed, this paragraph indicated that these general provisions would not, except as specifically noted in part 512, affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, and program integrity (such as those in parts 413, 414, 419, 420, and 489 of chapter IV of 42 CFR and those in parts 1001–1003 of chapter V of 42 CFR).

In § 512.100(b), we proposed to apply the general provisions to model participants in the RO Model (with one exception described later in this final rule) and the ETC Model. We proposed to define the term ''model participant'' to mean an individual or entity that is identified as a participant in an Innovation Center model under the terms of part 512; as proposed, the term ''model participant'' would include, unless otherwise specified, the terms ''RO participant'' or ''ETC Participant'' as those terms are defined in subparts B and C of part 512. We proposed to define ''downstream participant'' to mean an individual or entity that has entered into a written arrangement with a model participant pursuant to which the downstream participant engages in one or more Innovation Center model activities. We proposed that a downstream participant may include, but would not be limited to, an individual practitioner, as defined for purposes of the RO Model. We proposed to define ''Innovation Center model activities'' to mean any activities impacting the care of model beneficiaries related to the test of the Innovation Center model performed under the terms of proposed part 512. While not used in the general provisions, as this term is used for purposes of both the RO Model and the ETC Model, we proposed to define ''U.S. Territories'' to mean American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, the Commonwealth of the Northern Mariana Islands, Palau, Puerto Rico, U.S. Minor Outlying Islands, and the U.S. Virgin Islands.

We solicited public comment on our proposals regarding the basis and scope of these general provisions. We received no comments on these proposals and therefore we are finalizing these proposals without modification in our regulations at § 512.100(a). We similarly did not receive comments on our proposed definitions of model participant, downstream participant, or U.S. Territories, and are finalizing these definitions as proposed in our regulation at § 512.110.

C. Definitions

In our regulation at § 512.110, we proposed to define certain terms relevant to the general provisions. We describe these definitions in context throughout section II. of this final rule. To the extent we have received comments on the definitions we proposed, we have responded to those comments throughout section II. of this final rule.

D. Beneficiary Protections

As we design and test new models at the Innovation Center, we believe it is necessary to have certain protections in place to ensure that beneficiaries retain their existing rights and are not harmed by the participation of their health care providers in Innovation Center models. Therefore, as noted in the proposed rule, we believe it is necessary to propose certain provisions regarding beneficiary choice, the availability of services, and descriptive model materials and activities.

For purposes of the general provisions, we proposed to define the term ''beneficiary'' to mean an individual who is enrolled in Medicare FFS. As we noted in the proposed rule, this definition aligns with the scope of the RO Model and the ETC Model, which include only Medicare FFS beneficiaries. We also proposed to define the term ''model beneficiary'' to mean a beneficiary attributed to a model participant or otherwise included in an Innovation Center model under the terms of proposed part 512; as proposed, the term ''model beneficiary'' as defined in this section would include, unless otherwise specified, the term ''RO Beneficiary'' and beneficiaries attributed to ETC participants under § 512.360. As stated in the proposed rule, we believed it was necessary to propose this definition of model beneficiary so as to differentiate between Medicare FFS beneficiaries generally and those specifically included in an Innovation Center model. We received no comments on these proposed definitions and therefore are finalizing these definitions in our regulation at § 512.110 without modification.

1. Beneficiary Freedom of Choice

A beneficiary's ability to choose his or her provider or supplier is an important principle of Medicare FFS and is codified in section 1802(a) of the Act. To help ensure that this protection is not undermined by the testing of the two Innovation Center models, we proposed to require in § 512.120(a)(1) that model participants and their downstream participants not restrict a beneficiary's ability to choose his or her providers or suppliers. We proposed that this policy would apply with respect to all Medicare FFS beneficiaries, not just model beneficiaries, because we believe it is important to ensure that the Innovation Center model tests do not interfere with the general guarantees and protections for all Medicare FFS beneficiaries.

Also, in § 512.120(a)(2), we proposed to codify that the model participant and its downstream participants must not commit any act or omission, nor adopt any policy, that inhibits beneficiaries from exercising their freedom to choose to receive care from any Medicare-participating provider or supplier, or from any health care provider who has opted out of Medicare. As we noted in the proposed rule, we believe this requirement is necessary to ensure that Innovation Center models do not prevent beneficiaries from obtaining the general rights and guarantees provided under Medicare FFS. However, because we believe that it is important for model participants to have the opportunity to explain the benefits of care provided by them to model beneficiaries, we further proposed that the model participant and its downstream participants would be permitted to communicate to model

beneficiaries the benefits of receiving care with the model participant, if otherwise consistent with the requirements of part 512 and applicable law.

In § 512.110, we proposed to define the terms ''provider'' and ''supplier,'' as used in part 512, in a manner consistent with how these terms are used in Medicare FFS generally. Specifically, we proposed to define the term ''provider'' to mean a ''provider of services'' as defined under section 1861(u) of the Act and codified in the definition of ''provider'' at 42 CFR 400.202. We similarly proposed to define the term ''supplier'' to mean a ''supplier'' as defined in section 1861(d) of the Act and codified at 42 CFR 400.202. As stated in the proposed rule, we believe it is necessary to define ''provider'' and ''supplier'' in this way as a means of noting to the general public that we are using the generally applicable Medicare definitions of these terms for purposes of part 512.

We solicited comments on our proposals related to beneficiary freedom of choice. In this section of this final rule, we summarize and respond to the public comments received on the beneficiary freedom of choice proposal.

Comment: A few commenters thanked CMS for the explicit clarification of beneficiary rights—notably, that beneficiaries maintain their right to choose a health care provider that is not participating in either the RO Model or the ETC Model.

Response: We thank the commenters for their support and for their comments in support of our proposals to maintain beneficiaries' freedom of choice and other beneficiary protections.

Comment: A few commenters requested that CMS strengthen the proposed beneficiary protections so that beneficiaries are adequately educated about any Innovation Center model in which they are included. Specifically, one of the commenters requested that CMS solicit external feedback on the contents of any beneficiary notification letter prior to requiring its use by model participants. A few commenters also expressed concern that RO Model beneficiaries, specifically, would not have access to the same range of benefits as other Medicare beneficiaries.

Response: We disagree with the commenters that additional safeguards are needed to ensure that model beneficiaries will be adequately educated about the Innovation Center models. Specifically, we believe that several of our finalized provisions will provide adequate education to model beneficiaries regarding the models in which the beneficiaries are included, including §§ 512.225 and 512.330 relating to beneficiary notifications for the RO Model and ETC Model, respectively, as well as § 512.120(c) relating to the requirements for materials and activities used to educate, notify, or contact beneficiaries regarding the Innovation Center model (referred to in this final rule as descriptive model materials and activities). We would note that § 512.120(c) allows model participants to provide additional descriptive model materials and activities to model beneficiaries that could describe in greater detail the Innovation Center Model and its expected impacts on model beneficiaries. We note that this provision requires that all descriptive model materials and activities must not be materially inaccurate or misleading, and all such materials and activities may be reviewed by CMS. With respect to the template beneficiary notifications that RO participants and ETC Participants must furnish, we will not provide a formal process for soliciting feedback on the content of such notifications because such a process may interfere with the model operation timelines. However, we are open to receiving such feedback on an informal basis. We believe the provisions regarding beneficiary notifications and descriptive model materials and activities strike an appropriate balance between the amount of information that may be desired by beneficiaries and the burden of ensuring that such information is accurate and not misleading.

Additionally, as described in this final rule, under our regulations at § 512.120(a) and (b), model beneficiaries will retain the right to receive care from the providers and suppliers of their choice as well as access to the same range of benefits as other Medicare FFS beneficiaries who are not receiving care from an Innovation Center model participant. As such, we believe that our proposed beneficiary protections will establish strong beneficiary safeguards for the two Innovation Center models. However, as described in section II.H. of this final rule, we are also finalizing our proposal to monitor model participant compliance with model terms and other applicable program laws and policies, including requirements related to beneficiary access to services and the providers and suppliers of their choice. If needed, we will propose any modifications to the applicable beneficiary protections through future rulemaking.

After considering public comments, we are finalizing our proposals on beneficiary freedom of choice without modification in our regulation at § 512.120(a). We received no comments on the proposed definitions of provider and supplier and therefore are finalizing these definitions without modification in our regulation at § 512.110.

2. Availability of Services

Models tested under the authority of section 1115A of the Act are designed to test potential improvements to the delivery of and payment for health care to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care for the beneficiaries of these programs. As such, as we noted in the proposed rule, an important aspect of testing Innovation Center models is that beneficiaries continue to access and receive needed care. Therefore, in § 512.120(b)(1), we proposed that model participants and downstream participants are required to continue to make medically necessary covered services available to beneficiaries to the extent required by law. Consistent with the limitation on Medicare coverage under section 1862(a)(1)(A) of the Act, we proposed to define ''medically necessary'' to mean reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member. Also, we proposed to define ''covered services'' to mean the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act, which aligns with Medicare coverage standards and the definition of ''covered services'' used in other models tested by the Innovation Center. Also, we proposed that model beneficiaries and their assignees, as defined in 42 CFR 405.902, would retain their rights to appeal Medicare claims in accordance with 42 CFR part 405, subpart I. As noted in the proposed rule, we believe that model beneficiaries and their assignees should not lose the right to appeal claims for Medicare items and services furnished to them solely because the beneficiary's provider or supplier is participating in an Innovation Center model.

Also, in § 512.120(b)(2) we proposed to prohibit model participants and downstream participants from taking any action to avoid treating beneficiaries based on their income levels or based on factors that would render a beneficiary an ''at-risk beneficiary'' as that term is defined for purposes of the Medicare Shared Savings Program at 42 CFR 425.20, a practice commonly referred to as ''lemon dropping.'' For example, 42 CFR 425.20 defines an ''at-risk

beneficiary'' to include, without limitation, a beneficiary who has one or more chronic conditions or who is entitled to Medicaid because of disability. As such, a model participant or downstream participant would be prohibited from taking action to avoid treating beneficiaries with chronic conditions such as obesity or diabetes, or who are entitled to Medicaid because of disability. As noted in the proposed rule, we believe it is necessary to specify prohibitions on avoiding treating at-risk beneficiaries, including those with obesity or diabetes, or who are eligible for Medicaid because of disability, to prevent potential lemon dropping of beneficiaries. Further, we believe prohibiting lemon dropping is a necessary safeguard to counter any incentives created by the Innovation Center models for model participants to avoid treating potentially high-cost beneficiaries who are most in need of quality care. This prohibition has been incorporated into the governing documentation of many current models being tested by the Innovation Center for this same reason. Also, in § 512.120(b)(3), we proposed an additional provision to prohibit model participants from taking any action to selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the model participant's or downstream participant's financial or quality performance, a practice commonly referred to as ''cherry-picking.'' For example, a model participant or downstream participant would be prohibited from targeting only healthy, well-educated, or wealthy beneficiaries for voluntary alignment, the receipt of permitted beneficiary incentives or other interventions, or the reporting of quality measures.

We solicited comments on our proposals related to availability of services and on whether prohibiting cherry-picking would prevent model participants from artificially inflating their financial or quality performance results. In this section of this final rule, we summarize and respond to the public comments received on these proposals.

Comment: A commenter applauded CMS's proposals to prohibit model participants from ''cherry-picking'' beneficiaries. This commenter requested additional details on how CMS plans to identify model participants that have ''cherry-picked'' or ''lemon-dropped'' beneficiaries.

Response: We appreciate the commenter's support of our proposal to prohibit cherry-picking in Innovation Center models. We will identify model participants that may have ''cherry-picked'' or ''lemon-dropped'' beneficiaries through various modes of monitoring set forth in section II.H. (general provisions), section III.C.14. (the RO Model), and section IV.C.10. (ETC Model) of this final rule. In addition, beneficiary complaints may alert us to potentially inappropriate beneficiary selection or avoidance of certain beneficiaries.

After considering public comments, we are finalizing our proposed provisions on the availability of services without modification in our regulation at § 512.120(b). We received no comments on whether prohibiting cherry-picking will prevent model participants from artificially inflating their financial or quality performance results and therefore are not finalizing additional provisions against cherry-picking in this final rule.

3. Descriptive Model Materials and Activities

In order to protect beneficiaries from potentially being misled about Innovation Center models, we proposed at § 512.120(c)(1) to prohibit model participants and their downstream participants from using or distributing descriptive model materials and activities that are materially inaccurate or misleading. For purposes of part 512, we proposed to define the term ''descriptive model materials and activities'' to mean general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, social media, or other materials or activities distributed or conducted by or on behalf of the model participant or its downstream participants when used to educate, notify, or contact beneficiaries regarding the Innovation Center model. Further, we proposed that the following communications would not be descriptive model materials and activities: Communications that do not directly or indirectly reference the Innovation Center model (for example, information about care coordination generally); information on specific medical conditions; referrals for health care items and services; and any other materials that are excepted from the definition of ''marketing'' as that term is defined at 45 CFR 164.501. The potential for model participants to receive certain payments under the two Innovation Center models may be an incentive for model participants and their downstream participants to engage in marketing behavior that may confuse or mislead beneficiaries about the Innovation Center model or their Medicare rights. Therefore, as noted in the proposed rule, we believe it is necessary to ensure that those materials and activities that are used to educate, notify, or contact beneficiaries regarding the Innovation Center model are not materially inaccurate or misleading because these materials might be the only information that a model beneficiary receives regarding the beneficiary's inclusion in the model. Additionally, we understand that not all communications between the model participant or downstream participants and the model beneficiaries would address the model beneficiaries' care under the model. As such, we would note that this proposed prohibition would in no way restrict the ability of a model participant or its downstream participants to engage in activism or otherwise alert model beneficiaries to the drawbacks of mandatory models in which they would otherwise decline to participate, provided that such statements are not materially inaccurate or misleading. We did not propose to regulate information or communication unrelated to an Innovation Center model because it would not advance the purpose of the proposed prohibition, which is to protect model beneficiaries from being misled about their inclusion in an Innovation Center model or their Medicare rights generally. Accordingly, we proposed to define the term ''descriptive model materials and activities'' such that materials unrelated to the Innovation Center model are not subject to the requirements of § 512.120(c)(1).

Also, in § 512.120(c)(4) we proposed to reserve the right to review, or have our designee review, descriptive model materials and activities to determine whether the content is materially inaccurate or misleading; this review would not be a preclearance by CMS, but would take place at a time and in a manner specified by CMS once the materials and activities are in use by the model participant. As noted in the proposed rule, we believe it would be necessary for CMS to have this ability to review descriptive model materials and activities in order to protect model beneficiaries from receiving misleading or inaccurate materials regarding the Innovation Center model. Furthermore, to facilitate our ability to conduct this review and to monitor Innovation Center models generally, we proposed at § 512.120(c)(3) to require model participants and downstream participants, to retain copies of all written and electronic descriptive model materials and activities and to retain appropriate records for all other descriptive model materials and

activities in a manner consistent with § 512.135(c) (record retention).

Also in § 512.120(c)(2), we proposed to require model participants and downstream participants to include the following disclaimer on all descriptive model materials and activities: ''The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document.'' We proposed to require the use of this disclaimer so that the public, and beneficiaries in particular, are not misled into believing that model participants or their downstream participants are speaking on behalf of the agency.

We solicited comments on our proposals related to descriptive model materials and activities. We also solicited comment on whether we should propose a different disclaimer that alerts beneficiaries that we prohibit misleading information and gives beneficiaries contact information so they could reach out to us if they suspect the information they have received regarding an Innovation Center model is inaccurate.

In this section of this final rule, we summarize and respond to the public comments received on these proposals.

Comment: A commenter requested that CMS review all marketing materials from model participants prior to those materials being made available to beneficiaries in order to prevent confusion or the dissemination of misleading information. This commenter also supported the proposal that descriptive model materials and activities include the proposed disclaimer.

Response: We thank the commenter for supporting our proposal to require model participants include a disclaimer on all descriptive model materials and activities so that the public, and model beneficiaries in particular, are not misled into believing that model participants are speaking on behalf of CMS. We also appreciate the commenter's recommendation that CMS review all marketing materials from model participants prior to their distribution; however, we believe that our proposal to reserve the right to review such materials once distributed strikes the appropriate balance. Specifically, our final rule protects beneficiaries from receiving misleading information regarding Innovation Center models without unduly delaying the release of useful information or increasing the burden on model participants and CMS by requiring a thorough review of all marketing materials from all model participants prior to their release.

After considering public comments, we are finalizing our proposed provisions on descriptive model materials and activities without modification in our regulation at § 512.120(c). We did not receive any comments on whether we should propose a different disclaimer that alerts beneficiaries that we prohibit misleading information and gives them contact information so they could reach out to us if they suspect the information they have received regarding an Innovation Center model is inaccurate. Furthermore, we received no comments on these proposed definition of descriptive model materials and activities and therefore are finalizing this definition without modification in our regulation at § 512.110.

E. Cooperation With Model Evaluation and Monitoring

Section 1115A(b)(4) of the Act requires the Secretary to evaluate each model tested under the authority of section 1115A of the Act and to publicly report the evaluation results in a timely manner. The evaluation must include an analysis of the quality of care furnished under the model and the changes in program spending that occurred due to the model. Models tested by the Innovation Center are rigorously evaluated. For example, when evaluating models tested under section 1115A of the Act, we require the production of information that is representative of a wide and diverse group of model participants and includes data regarding potential unintended or undesirable effects, such as cost-shifting. The Secretary must take the evaluation into account if making any determinations regarding the expansion of a model under section 1115A(c) of the Act.

In addition to model evaluations, the Innovation Center regularly monitors model participants for compliance with model requirements. For the reasons described in section II.H. of this final rule, these compliance monitoring activities are an important and necessary part of the model test.

Therefore, we proposed to codify in § 512.130, that model participants and their downstream participants must comply with the requirements of 42 CFR 403.1110(b) (regarding the obligation of entities participating in the testing of a model under section 1115A of the Act to report information necessary to monitor and evaluate the model), and must otherwise cooperate with CMS' model evaluation and monitoring activities as may be necessary to enable CMS to evaluate the Innovation Center model in accordance with section 1115A(b)(4) of the Act. This participation in the evaluation may include, but is not limited to, responding to surveys and participating in focus groups. Additional details on the specific research questions that the Innovation Center model evaluation will consider for the RO Model and ETC Model can be found in in sections III.C.16. and IV.C.11. of this final rule, respectively. Further, we proposed to conduct monitoring activities according to proposed § 512.150, described later in this final rule, including producing such data as may be required by CMS to evaluate or monitor the Innovation Center model, which may include protected health information as defined in 45 CFR 160.103 and other individually identifiable data.

We solicited public comment on our proposal regarding cooperation with model monitoring and evaluation activities. We received no comments on these proposals and therefore are finalizing these proposals without modification in our regulation at § 512.130.

F. Audits and Record Retention

By virtue of their participation in an Innovation Center model, model participants and their downstream participants may receive model-specific payments, access to payment rule waivers, or some other model-specific flexibility. Therefore, as noted in the proposed rule, we believe that CMS's ability to audit, inspect, investigate, and evaluate records and other materials related to participation in Innovation Center models is necessary and appropriate. In addition, we proposed in § 512.120(b)(1) to require model participants and their downstream participants to continue to make medically necessary covered services available to beneficiaries to the extent required by law. Similarly, in order to expand a phase 1 model tested by the 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, as discussed in the proposed rule, there is a particular need for CMS to be able to audit, inspect, investigate, and evaluate records and materials related to participation in Innovation Center models to allow us to ensure that model participants are in no way denying or limiting the coverage or provision of benefits for beneficiaries as

part of their participation in the Innovation Center model. We proposed to define ''model-specific payment'' to mean a payment made by CMS only to model participants, or a payment adjustment made only to payments made to model participants, under the terms of the Innovation Center model that is not applicable to any other providers or suppliers; the term ''model-specific payment'' would include, unless otherwise specified, the terms ''home dialysis payment adjustment (HDPA),'' ''performance payment adjustment (PPA),'' ''participant-specific professional episode payment,'' or ''participant-specific technical episode payment.'' As noted in the proposed rule, we believe it is necessary in order to distinguish payments and payment adjustments applicable to model participants as part of their participation in an Innovation Center model, from payments and payment adjustments applicable to model participants as well as other providers and suppliers, as certain provisions of proposed part 512 would apply only to the former category of payments and payment adjustments.

We note here and in the proposed rule 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 of the Act (such as under 42 CFR 510.110 for the Innovation Center's Comprehensive Care for Joint Replacement Model). Building off those existing requirements, we proposed in § 512.135(a), that the Federal government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, would have a right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model. Additionally, in order to align with the policy of current models being tested by the Innovation Center, in § 512.135(b) and (c) we proposed that the model participant and its downstream participants must do the following:

• 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 Innovation Center model, including, without limitation, documents and other evidence regarding all of the following:

++ Compliance by the model participant and its downstream participants with the terms of the Innovation Center model, including proposed new subpart A of proposed part 512.

++ The accuracy of model-specific payments made under the Innovation Center model.

++ The model participant's payment of amounts owed to CMS under the Innovation Center model.

++ Quality measure information and the quality of services performed under the terms of the Innovation Center model, including proposed new subpart A of part 512.

++ Utilization of items and services furnished under the Innovation Center model.

++ The ability of the model participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

++ Patient safety.

++ Any other program integrity issues.

• Maintain the documents and other evidence for a period of 6 years from the last payment determination for the model participant under the Innovation Center 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 model participant at least 30 days before the normal disposition date; or

++ There has been a termination, dispute, or allegation of fraud or similar fault against the model participant in which case the records must be maintained for an additional six (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 model participant of a special need to retain a record or group of records at least 30 days before the normal disposition date, we proposed that the records must be maintained for such period of time determined by CMS. If CMS notifies the model participant of a special need to retain records or there has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants, the model participant must notify its downstream participants of the need to retain records for the additional period specified by CMS. As noted in the proposed rule, this provision will ensure that that the government has access to the records.

To avoid any confusion or disputes regarding the timelines outlined in these general provisions, we proposed to define the term ''days'' to mean calendar days.

We solicited public comment on these proposed provisions regarding audits and record retention.

Historically, the Innovation Center has required participants in section 1115A models to retain records for at least 10 years, which is consistent with the outer limit of the statute of limitations for the Federal False Claims Act and is consistent with the Shared Savings Program's policy outlined at 42 CFR 425.314(b)(2). For this reason, we also solicited public comments on whether we should require model participants and downstream participants to maintain records for longer than 6 years.

We summarize and respond in this section of this final rule to the public comments received on these proposals.

Comment: A few commenters applauded our proposed requirement for model participants and their downstream participants to maintain records for at least six (6) years from the last payment determination for the model participant under the Innovation Center model or from the date of completion of any audit, evaluation, inspection, or investigation.

Response: We thank the commenters for their support of this proposed policy.

Comment: A few commenters, while generally supporting our proposed record retention requirements, made alternative suggestions for how CMS should collect model-related records from model participants. Specifically, both commenters suggested that CMS expressly allow for e-transmission of model-related records when requested by CMS as this would allow additional flexibility for model participants and be less burdensome for model participants.

Response: We appreciate the commenters' support for our proposed record retention requirements. While we did not propose to prohibit e-transmission of records that are requested by CMS, we are not finalizing a provision that would permit the exclusive use of e-transmission for such records, as we believe that CMS should make case-by-case determinations regarding whether e-transmission is appropriate.

We received no comments on whether CMS should require model participants and downstream participants to maintain records for longer than 6 years. After considering public comments, we are finalizing our proposals on audits and record retention as proposed in our regulation at § 512.135. We received no comments on the proposed definitions for model-specific payments and days;

and therefore, are finalizing these definitions without modification in our regulation at § 512.110.

G. Rights in Data and Intellectual Property

To enable CMS to evaluate the Innovation Center models as required by section 1115A(b)(4) of the Act and to monitor the Innovation Center models pursuant to § 512.150, in § 512.140(a) we proposed to use any data obtained in accordance with §§ 512.130 and 512.135 to evaluate and monitor the Innovation Center models. We further proposed that, consistent with section 1115A(b)(4)(B) of the Act, that CMS would be allowed to disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. We proposed that the data to be disseminated would include, but would not be limited to, patient de-identified results of patient experience of care and quality of life surveys, as well as patient de-identified measure results calculated based upon claims, medical records, and other data sources.

In order to protect the intellectual property rights of model participants and downstream participants, in § 512.140(c) we proposed to require model participants and their downstream participants to label data they believe is proprietary that they believe should be protected from disclosure under the Trade Secrets Act. As we noted in the proposed rule, this approach is already in use in other models currently being tested by the Innovation Center, including the Next Generation Accountable Care Organization Model. Any such assertions would be subject to review and confirmation prior to CMS's acting upon such assertion.

We further proposed to protect such information from disclosure to the full extent permitted under applicable laws, including the Freedom of Information Act. Specifically, in § 512.140(b), we proposed that we would not release data that has been confirmed by CMS to be proprietary trade secret information and technology of the model participant or its downstream participants without the express written consent of the model participant or its downstream participant, unless such release is required by law.

We solicited public comment on these proposals. We received no comments on these proposals and therefore are finalizing these proposals without modification in our regulation at § 512.140.

H. Monitoring and Compliance

Given that model participants may receive model-specific payments, access to payment rule waivers, or some other model-specific flexibility while participating in an Innovation Center model, as noted in the proposed rule, we believe that enhanced compliance review and monitoring of model participants is necessary and appropriate to ensure the integrity of the Innovation Center model. In addition, as part of the Innovation Center's assessment of the impact of new Innovation Center models, 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 Innovation Center 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 Innovation Center, CMS or its designee monitors model participants to assess compliance with model terms and with other applicable program laws and policies. As noted in the proposed rule, 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 § 512.150(b)(1), we proposed to continue this standard practice of conducting monitoring activities for several reasons: (1) To ensure compliance by the model participant and each of its downstream participants with the terms of the Innovation Center model, including the requirements of proposed subpart A of proposed part 512; (2) to understand model participants' use of model-specific payments; and (3) to promote the safety of beneficiaries and the integrity of the Innovation Center model. Such monitoring activities would include, but not be limited to: (1) Documentation requests sent to the model participant and its downstream participants, including surveys and questionnaires; (2) audits of claims data, quality measures, medical records, and other data from the model participant and its downstream participants; (3) interviews with members of the staff and leadership of the model participant and its downstream participants; (4) interviews with beneficiaries and their caregivers; (5) site visits to the model participant and its downstream participants, which would be performed in a manner consistent with proposed § 512.150(c), described later in this rule; (6) monitoring quality outcomes and registry data; and (7) tracking patient complaints and appeals. We believe these specific monitoring activities, which align with those currently used in other models being tested by the Innovation Center, are necessary to ensure compliance with the terms and conditions of the Innovation Center model, including proposed subpart A of proposed part 512, and to protect beneficiaries from potential harms that may result from the activities of a model participant or its downstream participants, such as attempts to reduce access to or the provision of medically necessary covered services.

We proposed to codify in § 512.150(b)(2), that when we are conducting compliance monitoring and oversight activities, CMS or its designees would be authorized to use any relevant data or information, including without limitation Medicare claims submitted for items or services furnished to model beneficiaries. As noted in the proposed rule, we believe that it is necessary to have all relevant information available to us during our compliance monitoring and oversight activities, including any information already available to us through the Medicare program.

We proposed to require in § 512.150(c)(1) that model participants and their downstream participants cooperate in periodic site visits conducted by CMS or its designee in a manner consistent with § 512.130, described previously. Such site visits would be conducted to facilitate the model evaluation performed pursuant to section 1115A(b)(4) of the Act and to monitor compliance with the Innovation Center model terms (including proposed subpart A of proposed part 512).

In order to operationalize this proposal, in § 512.150(c)(2) we proposed that CMS or its designee would provide the model participant or its downstream participant with no less than 15 days advance notice of a site visit, to the extent practicable. Furthermore, to the extent practicable, we proposed that CMS would attempt to accommodate a request that a site visit be conducted on a particular date, but that the model participant or downstream participant would be prohibited from requesting a date that was more than 60 days after the date of the initial site visit notice from CMS. We believe the 60-day period would reasonably accommodate model participants' and downstream

participants' schedules while not interfering with the operation of the Innovation Center model. Further, in § 512.150(c)(3) we proposed to require the model participant and their downstream 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. As noted in the proposed rule, we believe this proposal is necessary to ensure an effective site visit and prevent the need for unnecessary follow-up site visits.

Also, in § 512.150(c)(4), we proposed that CMS or its designee could perform unannounced site visits to the offices of model participants and their downstream 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, in § 512.150(c)(5) we proposed that nothing in proposed part 512 would limit CMS from performing other site visits as allowed or required by applicable law. As noted in the proposed rule, 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 is necessary for us to monitor, and for model participants and their downstream 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 model results or their model-specific payments, including discrimination in the provision of services to at-risk beneficiaries (for example, due to eligibility for Medicaid based on disability).

Model participants that are enrolled in Medicare 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 Innovation Center model. Therefore, in § 512.150(a), we proposed to require that model participants and each of their downstream participants must comply with all applicable laws and regulations. We noted in the proposed rule that a law or regulation is not ''applicable'' to the extent that its requirements have been waived pursuant to section 1115A(d)(1) of the Act solely for purposes of testing the Innovation Center model in which the model participant is participating.

To protect the financial integrity of each Innovation Center model, in § 512.150(d) we proposed that if CMS discovers that it has made or received an incorrect model-specific payment under the terms of an Innovation Center model, CMS may make payment to, or demand payment from, the model participant. We did not propose a deadline for making or demanding such payments, but we stated that we were considering the imposition of some of the deadlines set forth in the Medicare reopening rules at 42 CFR 405.980. Specifically, we sought comment on whether CMS should be able to reopen an initial determination of a model-specific payment for any reason within 1 year of the model-specific payment, and within 4 years for good cause (as defined at 42 CFR 405.986). As noted in the proposed rule, we believe this may be necessary to ensure we have a means and a timeline to make redeterminations on incorrect model-specific payments that we have made or received in conjunction with the proposed Innovation Center models.

We proposed to codify at § 512.150(e) that nothing contained in the terms of the Innovation Center model or proposed part 512 would 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 model participant or its downstream participants for violations of any statutes, rules, or regulations administered by the Federal government. This provision simply reflects the limits of CMS authority.

We solicited comments on these proposals related to monitoring and compliance. In this section of this final rule, we summarize and respond to the public comments received on these proposals and comment solicitations.

Comment: A commenter expressed its support for our proposal to permit CMS to make corrections to model-specific payments. This commenter also suggested that RO participants be permitted to initiate requests to make corrections to model-specific payments in the RO Model.

Response: We thank this commenter for their support of the proposed policy. We would note that in section III.C.12. of this final rule, we have finalized the proposed process, with a modification to allow for 45 days instead of the proposed 30 days, for RO participants to notify CMS of suspected errors in the calculation of their reconciliation payment amount or repayment amount or aggregate quality score as reflected on an RO reconciliation report that has not been deemed final. In addition, in section IV.C.5.h. of this final rule, we have finalized the proposed process for ETC Participants to request a targeted review of the calculation of the Modality Performance Score (MPS).

We understand the commenter to be advocating that RO participants should have the right to request reopening of a model-specific payment determination. By way of background, a reopening is an administrative action taken to change a binding determination or decision that resulted in either an overpayment or underpayment, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record (see § 405.980(a)). Under the Medicare reopening rules, a party to an initial determination may request that the determination be reopened in a variety of circumstances, including within one year for any reason and within four years for good cause (as defined at § 405.986). The Medicare reopening rules also permit a CMS contractor to reopen an initial determination on its own motion for a variety reasons, including: (1) Within 1 year for any reason; (2) within 4 years for good cause (as defined at § 405.986); and (3) at any time if there is reliable evidence (as defined at § 405.902) that the initial determination was procured by fraud or similar fault (as defined at § 405.902). Under § 405.986, ''good cause'' may be established when there is new and material evidence that was not available or known at the time of the determination or decision and that may result in a different conclusion or when the evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision. Under the existing reopening rules, the decision whether to grant a request for reopening is within the sole discretion of CMS and is not reviewable (see § 405.980(a)(5)).

As noted previously in this final rule, we did not propose any temporal restrictions on when CMS could correct prior payments, but we stated in the proposed rule that we were considering the imposition of some of the deadlines set forth in the Medicare reopening rules at 42 CFR 405.980. We specifically sought comment regarding whether CMS should be able to reopen an initial determination of a model-specific payment for any reason within 1 year of the model-specific payment, and within

4 years for good cause (as defined at 42 CFR 405.986). After consideration of the public comments, we believe that model participants should have a limited opportunity to request the reopening of a model-specific payment determination. Specifically, we will permit the reopening of a model-specific payment determination, whether on CMS' own motion or at the request of a model participant, for good cause (as defined at § 405.986) within 4 years after the date of the determination. This reopening provision will help to ensure accurate payments under an Innovation Center model, while the temporal and ''good cause'' limitations will promote efficient use of administrative resources and the eventual finality of payment determinations. In addition, we are finalizing a policy that permits CMS to reopen a model-specific payment determination at any time if there exists reliable evidence (as defined at § 405.902) that the determination was procured by fraud or similar fault (as defined at § 405.902). The purpose of this provision is to remediate fraud and abuse that may not be discovered within four years of the initial payment determination.

Finally, consistent with the existing Medicare reopening rules, the decision to grant or deny a reopening request in an Innovation Center model with respect to a model-specific payment is solely at CMS discretion and not reviewable. For example, for purposes of an Innovation Center Model, CMS may exercise its discretion to reopen a model-specific payment determination to correct a clerical error that constitutes good cause for reopening under § 405.986(a)(2). We note that if CMS reopens a model-specific payment determination, the revised payment determination may be appealed in accordance with the applicable Innovation Center model regulations, including § 512.170 (limitations on review).

We do not believe, however, that it is necessary to permit the reopening of a model-specific payment determination for any reason within 1 year after the determination has been made. The reopening rule we are finalizing here adequately protects payment accuracy, especially in light of the review procedures set forth for the RO Model at § 512.290 and for the ETC Model at § 512.390. Moreover, as noted above, this final rule permits CMS to correct clerical errors that it determines constitute ''good cause'' for reopening. We are finalizing our reopening policy at § 512.150(d).

Comment: A commenter stated that on-site monitoring of RO participants should be conducted by personnel and contractors that can provide RO participants with certification, licensure, or other form of demonstrated knowledge in the specific field of radiation oncology.

Response: We disagree with the commenters' belief that site visits of RO participants must be conducted by personnel and contractors that have certification, licensure, or other form of demonstrated knowledge in the specific field of radiation oncology. We reiterate that the proposed site visits were intended to ensure compliance with the Innovation Center model terms, to facilitate the model evaluation, and to investigate concerns related to the health or safety of beneficiaries or other patients or other program integrity issues.

There are a variety of reasons for us to conduct site visits. While having a certain amount of knowledge of the field of radiation oncology may be necessary to conduct some site visits of RO participants, depending on the nature and purpose of the site visit, knowledge of the RO Model terms as well as general Medicare policies and procedures may be more important. As such, we are not accepting the commenters' suggestion to require the personnel and contractors conducting site visits to provide RO participants with certification, licensure, or other form of demonstrated knowledge in the specific field of radiation oncology.

After considering public comments, we are finalizing our proposals on monitoring and compliance in our regulation at § 512.150 with modification. Specifically, to align the regulatory text with the proposals discussed in the preamble to the proposed rule, we have modified the regulatory text at § 512.150(b)(1) to reference additional purposes for which CMS may conduct monitoring activities, namely to understand model participants' use of model-specific payments; and to promote the safety of beneficiaries and the integrity of the Innovation Center model. In addition, in response to public comment, we have modified paragraph (d) of § 512.150 to codify the reopening process. Specifically, paragraph (d) has been revised to state the following: (1) CMS may reopen a model-specific payment determination, either on its own motion or at the request of a model participant, within four years from the date of the determination for good cause (as defined at § 405.986); (2) CMS may reopen a model-specific payment determination at any time if there exists reliable evidence (as defined in § 405.902) that the determination was procured by fraud or similar fault (as defined in § 405.902); and (3) CMS's decision regarding whether to reopen a model-specific payment determination is binding and not subject to appeal. Finally, we have revised paragraph (e) for brevity, which now states that this final rule does not limit or restrict the authority of the OIG or any other Federal government authority to audit, evaluate, investigate, or inspect model participants or their downstream participants for violations of ''Federal statutes, rules, or regulations.''

I. Remedial Action

As stated in the proposed rule and earlier in this final rule, as part of the Innovation Center's monitoring and assessment of the impact of models tested under the authority of section 1115A of the Act, we have a special interest in ensuring that these model tests do not interfere with the program integrity interests of the Medicare program. For this reason, we monitor for compliance with model terms as well as other Medicare program rules. When we become aware of noncompliance with these requirements, it is necessary for CMS to have the ability to impose certain administrative remedial actions on a noncompliant model participant.

As we noted in the proposed rule, the terms of many models currently being tested by the Innovation Center permit CMS to impose one or more administrative remedial actions to address noncompliance by a model participant. We proposed that CMS would impose any of the remedial actions set forth in proposed § 512.160(b) if we determine that the model participant or a downstream participant—

- Has failed to comply with any of the terms of the Innovation Center model, including proposed subpart A of proposed part 512;
- Has failed to comply with any applicable Medicare program requirement, rule, or regulation;
- Has taken any action that threatens the health or safety of a beneficiary or other patient;
- Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Innovation Center model;
- Has undergone a change in control (as defined in section II.L. of this final rule) that presents a program integrity risk;
- Is subject to any sanctions of an accrediting organization or a Federal, state, or local government agency;
- Is subject to investigation or action by HHS (including the HHS–OIG and CMS) or the Department of Justice due

to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or 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; or

- Has failed to demonstrate improved performance following any remedial action imposed by CMS.

In § 512.160(b), we proposed to codify that CMS may take one or more of the following remedial actions if CMS determined that one or more of the grounds for remedial action described in § 512.160(a) had taken place—

- Notify the model participant and, if appropriate, require the model participant to notify its downstream participants of the violation;
- Require the model participant to provide additional information to CMS or its designees;
- Subject the model participant to additional monitoring, auditing, or both;
- Prohibit the model participant from distributing model-specific payments;
- Require the model participant to terminate, immediately or by a deadline specified by CMS, its agreement with a downstream participant with respect to the Innovation Center model;
- In the ETC Model only, terminate the ETC Participant from the ETC Model;
- Require the model participant to submit a corrective action plan in a form and manner and by a deadline specified by CMS;
- Discontinue the provision of data sharing and reports to the model participant;
- Recoup model-specific payments;
- Reduce or eliminate a model specific payment otherwise owed to the model participant, as applicable; or
- Such other action as may be permitted under the terms of proposed part 512.

As stated in the proposed rule, we noted that because the ETC Model is a mandatory model, we would not expect to use the provision that would allow CMS to terminate an ETC Participant's participation in the ETC Model, except in circumstances in which the ETC Participant has engaged, or is engaged in, egregious actions. We would note that we did not propose and are therefore not finalizing a provision authorizing CMS to terminate RO participants from the RO Model. The types of providers and suppliers selected for participation in the RO Model do not present the same risk of fraud and abuse that has historically been present in the dialysis industry, which includes ESRD facilities, one of the two types of participants in the ETC Model. We plan to monitor the RO Model for program integrity and fraud and abuse issues, and if necessary, we may add a termination provision for RO participants in future rulemaking.

We solicited public comment on these proposals regarding remedial action. We received no comments on these proposals and therefore are finalizing these proposals our regulation at § 512.160.

J. Innovation Center Model Termination by CMS

In the proposed rule, we proposed certain provisions that would allow CMS to terminate an Innovation Center model under certain circumstances. Section 1115A(b)(3)(B) of the Act requires the Innovation Center to terminate or modify the design and implementation of a model, after testing has begun and before completion of the testing, unless the Secretary determines, and the Chief Actuary certifies with respect to program spending, that the model is expected to: Improve the quality of care without increasing program spending; reduce program spending without reducing the quality of care; or improve the quality of care and reduce spending.

In § 512.165(a), we proposed that CMS could terminate an Innovation Center model for reasons including, but not limited to, the following circumstances:

- CMS determines that it no longer has the funds to support the Innovation Center model; or
- CMS terminates the Innovation Center model in accordance with section 1115A(b)(3)(B) of the Act.

As provided by section 1115A(d)(2)(E) of the Act and proposed § 512.170, we noted in the proposed rule that termination of the Innovation Center model in accordance with section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

To ensure model participants had appropriate notice in the case of the termination of the Innovation Center model by CMS, we also proposed to codify at § 512.165(b) that we would provide model participants with written notice of the model termination, which would specify the grounds for termination as well as the effective date of the termination.

We solicited public comment on these proposals regarding the termination of an Innovation Center model by CMS. We received no comments on these proposals; and therefore, are finalizing these proposals without modification in our regulation at § 512.165.

K. Limitations on Review

In § 512.170, we proposed to codify 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 any 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 proposed to interpret the preclusion from administrative and judicial review regarding the Innovation Center's selection of organizations, sites, or participants to test models selected to preclude from administrative and judicial review our selection of a model participant, as well as our decision to terminate a model participant, as these determinations are part of our selection of participants for Innovation Center model tests.

In addition, we proposed to interpret the preclusion from administrative 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 an Innovation Center model:

- The selection of quality performance standards for the Innovation Center model by CMS.
- The assessment by CMS of the quality of care furnished by the model participant.
- The attribution of model beneficiaries to the model participant by CMS, if applicable.

We solicited comments on these proposals regarding limitations on review. In this section of this final rule, we summarize and respond to the public comments received on these proposals.

Comment: A commenter suggested that model participants be afforded the

opportunity to challenge any adverse assessments relating to that model participant's quality of care through administrative or judicial review.

Response: We reiterate that the limitations on administrative and judicial review established in section 1115A(d)(2) of the Act include a preclusion from review for the elements, parameters, scope, and duration of such models for testing or dissemination. We proposed to interpret this provision as precluding from review the assessment by CMS of the quality of care furnished by the model participant. However, after reviewing this language in light of the concern flagged by the commenter, we realize that our proposed regulatory text was confusing. Our intent was to interpret the preclusion in section 1115A(d)(2)(C) of the Act related to the elements, parameters, scope, and duration of a model to apply to the methodology used to assess the quality of care furnished by a model participant, as this is an element of the design of an Innovation Center model. We did not intend to preclude from review a determination regarding how that methodology is applied to a particular model participant. We are therefore modifying the text of § 512.170(c)(2) to refer to the methodology used by CMS to assess of the quality of care furnished by the model participant. For the same reason, we are modifying the text of § 512.170(c)(3) to similarly refer to the methodology used by CMS to attribute model beneficiaries to the model participant, if applicable. We believe it is appropriate to codify the statutory limitations on judicial and administrative review in our regulations and that our interpretations thereof, with these clarifications, are consistent with the statute. We also agree with the commenter's assertion that model participants should be allowed to challenge adverse assessments that are not precluded, and have laid out a policy specifically allowing this for the RO Model (section III.C.12. of this final rule) and the ETC Model (section IV.C.5.h. of this final rule).

After considering public comments, we are finalizing our proposals on limitations on review in our regulation at § 512.170 with the modifications described previously in this final rule.

L. Miscellaneous Provisions on Bankruptcy and Other Notifications

Models currently being tested by the Innovation Center usually have a defined period of performance, but final payment under the model may occur long after the end of this performance period. In some cases, a model participant may owe money to CMS. As we noted in the proposed rule, we recognize that the legal entity that is the model participant may experience significant organizational or financial changes during and even after the period of performance for an Innovation Center model. To protect the integrity of the Innovation Center models and Medicare funds, we proposed a number of provisions to ensure that CMS is made aware of events that could affect a model participant's ability to perform its obligations under the Innovation Center model, including the payment of any monies owed to CMS.

First, in § 512.180(a), we proposed that a model participant must promptly notify CMS and the local U.S. Attorney Office if it files a bankruptcy petition, whether voluntary or involuntary. Because final payment may not take place until after the model participant ceases active participation in the Innovation Center model or any other model in which the model participant is participating or has participated (for example, because the period of performance for the model ends, or the model participant is no longer eligible to participate in the model), we further proposed that this requirement would apply until final payment has been made by either CMS or such model participant under the terms of each model in which the model participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved.

Specifically, we proposed that the notice of the bankruptcy must be sent by certified mail within 5 days after the bankruptcy petition has been filed and that the notice must contain a copy of the filed bankruptcy petition (including its docket number) and a list of all models tested under section 1115A of the Act in which the model participant is participating or has participated. To minimize the burden on model participants, while ensuring that CMS obtains the information necessary from model participants undergoing bankruptcy, we proposed that the list need not identify a model in which the model participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the model participant and CMS have been fully and finally resolved with respect to that model. We proposed that the notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3–01–24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified for purposes of receiving such notices on the CMS website.

As we noted in the proposed rule, by requiring the submission of the filed bankruptcy petition, CMS would obtain information necessary to protect its interests, including the date on which the bankruptcy petition was filed and the identity of the court in which the bankruptcy petition was filed. We recognize that such notices may already be required by existing law, but CMS often does not receive them in a timely fashion, and they may not specifically identify the models in which the individual or entity is participating or has participated. The failure to receive such notices on a timely basis can prevent CMS from asserting a claim in the bankruptcy case. We are particularly concerned that a model participant may not furnish notice of bankruptcy after it has completed its performance in a model, but before final payment has been made or administrative or judicial proceedings have been resolved. As we noted in the proposed rule, we believe our proposal is necessary to protect the financial integrity of the Innovation Center models and the Medicare Trust Funds. Because bankruptcies filed by individuals and entities that owe CMS money are generally handled by CMS regional offices, we stated that we were considering (and we solicited comment on) whether we should require model participants to furnish notice of bankruptcy to the local CMS regional office instead of, or in addition to, the Baltimore headquarters.

Second, in § 512.180(b), we proposed that the model participant, including model participants that are individuals, would have to provide written notice to CMS at least 60 days before any change in the model participant's legal name became effective. The notice of legal name change would have to be in a form and manner specified by CMS and include a copy of the legal document effecting the name change, which would have to be authenticated by the appropriate state official. As we stated in the proposed rule, the purpose of this notice requirement is to ensure the accuracy of our records regarding the identity of model participants and the entities to whom model-specific payments should be made or against whom payments should be demanded or recouped. We solicited comment on the typical procedure for effectuating a legal entity's name change and whether 60 days advance notice of such a change is feasible. Alternatively, we considered requiring notice to be furnished promptly (for example, within 30 days) after a change in legal name has become

effective. We solicited public comment on this alternative approach.

Third, in § 512.180(c), we proposed that the model participant would have to provide written notice to CMS at least 90 days before the effective date of any change in control. We proposed that the written notification must be furnished in a form and manner specified by CMS. For purposes of this notice obligation, we proposed that a ''change in control'' would mean any of the following: (1) The acquisition by any ''person'' (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the model participant representing more than 50 percent of the model participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the model participant by any individual or entity; (3) the sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the model participant; or (4) the approval and completion of a plan of liquidation of the model participant, or an agreement for the sale or liquidation of the model participant. We noted in the proposed rule that the proposed requirement and definition of change in control are the same requirements and definition used in certain models that are currently being tested under section 1115A authority. We further noted that we believe this notice requirement is necessary to ensure the accuracy of our records regarding the identity of model participants and to ensure that we pay and seek payment from the correct entity. For this reason, we proposed that if CMS determined in accordance with § 512.160(a)(5) that a model participant's change in control would present a program integrity risk, CMS could take remedial action against the model participant under § 512.160(b). In addition, to ensure payment of amounts owed to CMS, we proposed that CMS may require immediate reconciliation and payment of all monies owed to CMS by a model participant that is subject to a change in control.

We solicited comments on these proposals. Also, we solicited comment as to whether the requirement to provide notice regarding changes in legal name and changes in control are necessary, or are already covered by existing reporting requirements for Medicare-enrolled providers and suppliers. In this section of this final rule, we summarize and respond to the public comments received on the proposal to require model participants to notify CMS of a change in legal name.

Comment: A few commenters generally supported the proposed procedure for notifying CMS of a name change. However, the commenters noted that they would prefer that the model participant be required to notify CMS 30 days after a legal name change, instead of 60 days before, as they believe that would reduce the administrative burden of complying with the proposed requirement for model participants.

Response: We solicited comment on whether to require the model participant to provide CMS with written notice 30 days after a legal name change. We agree with the commenters' assertion that notifying CMS of a legal name change 30 days after the name change occurs would be less burdensome for model participants. We further believe that written notice received within 30 days after the name change occurs would provide CMS with sufficient notice to ensure the accuracy of our records.

We did not receive comments regarding our proposals to require the model participant to notify CMS regarding bankruptcy or a change in control. After considering public comments, we are finalizing our proposals on bankruptcy and other notifications in our regulation at § 512.180, with modification to § 512.180(b) to change the timeline under which a model participant must provide written notice to CMS regarding a legal name change from 60 days in advance of a legal name change to 30 days after the legal name change occurs. We have also made a non-substantive modification to our regulation text at § 512.110 to correct a drafting error in the final rule that removes the duplicative text from the definition of change in control.

III. Radiation Oncology Model

A. Introduction

As discussed in the proposed rule (84 FR 34478), we proposed to establish a mandatory Radiation Oncology Model (RO Model), referred to throughout section III. of this final rule as ''the Model'', to test whether prospective episode-based payments for radiotherapy (RT) services,[4] (also referred to as radiation therapy services) will reduce Medicare program expenditures and preserve or enhance quality of care for beneficiaries. As radiation oncology is highly technical and furnished in well-defined episodes, and because patient comorbidities generally do not influence treatment delivery decisions, as we stated in the proposed rule, we believe that radiation oncology is well-suited for testing a prospective episode payment model. Under the RO Model proposals, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee-for-service (FFS) beneficiaries diagnosed with certain cancer types. We proposed that the base payment amounts for RT services included in the Model would be the same for hospital outpatient departments (HOPDs) and freestanding radiation therapy centers. We proposed that the performance period for the RO Model would be 5 performance years (PYs), beginning in 2020, and ending December 31, 2024, with final data submission of clinical data elements and quality measures in 2025 to account for episodes ending in 2024 (84 FR 34493 through 34503).

We included the following proposals for the Model in the proposed rule: (1) The scope of the Model, including required participants and episodes under the Model test; (2) the pricing methodology under the Model and necessary Medicare program policy waivers to implement such methodology; (3) the quality measures selected for the Model for purposes of scoring a participant's quality performance; (4) the process for payment reconciliation; and (5) data collection and sharing. We solicited comments on these proposals.

B. Background

1. Overview

CMS is committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries while reducing costs. Accordingly, as part of that effort, we have in recent years undertaken a number of initiatives to improve cancer treatment, most notably with our Oncology Care Model (OCM). As we stated in the proposed rule (84 FR 34490), we believe that a model in radiation oncology will further these efforts to improve cancer care for

[4] *Radiotherapy (RT) services* (also referred to as radiation therapy services) are services associated with cancer treatment that use high doses of radiation to kill cancer cells and shrink tumors, and encompass treatment consultation, treatment planning, technical preparation and special services (simulation), treatment delivery, and treatment management.

Medicare beneficiaries and reduce Medicare expenditures.

RT is a common treatment for nearly two thirds of all patients undergoing cancer treatment [5] [6] and is typically furnished by a radiation oncologist. As we discussed in the proposed rule (84 FR 34490), we analyzed Medicare FFS claims between January 1, 2015, and December 31, 2017, to examine several aspects (including but not limited to modalities, number of fractions, length of episodes, Medicare payments and sites of service, as described in this section) of radiation services furnished to Medicare beneficiaries during that period. We used HOPD and Medicare Physician Fee Schedule (PFS) claims, accessed through CMS' Chronic Conditions Data Warehouse (CCW), to identify all FFS beneficiaries who received any radiation treatment delivery services within that 3-year period. These radiation treatment delivery services included various types of modalities.[7] Such modalities included external beam radiotherapy (such as 3-dimensional conformal radiotherapy (3DCRT)), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), and proton beam therapy (PBT); intraoperative radiotherapy (IORT); image-guided radiation therapy (IGRT); and brachytherapy. As discussed in the proposed rule (84 FR 34490), we conducted several analyses of radiation treatment patterns using that group of beneficiaries and their associated Medicare Part A and Medicare Part B claims.

Our analysis, as discussed in the proposed rule (84 FR 34490), showed that from January 1, 2015 through December 31, 2017, HOPDs furnished 64 percent of episodes nationally, while freestanding radiation therapy centers furnished the remaining 36 percent of episodes. In the proposed rule we stated that our intention was to make this data publically accessible in a summary-level, de-identified file titled the ''RO Episode File (2015–2017),'' on the RO Model's website, and we posted it for commenters' reference in conjunction with the publication of the proposed rule. In the proposed rule (84 FR 34490), we discussed that our analysis also showed that, on average, freestanding radiation therapy centers furnished (and billed for) a higher volume of RT services within such episodes than did HOPDs. Based on our analysis of Medicare FFS claims data from that time period, episodes of care in which RT was furnished at a freestanding radiation therapy center were, on average, paid approximately $1,800 (or 11 percent) more by Medicare than those episodes of care where RT was furnished at an HOPD. As we stated in the proposed rule (84 FR 34490), we are not aware of any clinical rationale that explains these differences, which persisted after controlling for diagnosis, patient case mix (to the extent possible using data available in claims), geography, and other factors. These differences also persisted even though Medicare payments are lower per unit in freestanding radiation therapy centers than in HOPDs. Upon further analysis, as we noted in the proposed rule (84 FR 34490), we observed that freestanding radiation therapy centers use more IMRT, a type of RT associated with higher Medicare payments, and perform more fractions (that is, more RT treatments) than HOPDs.

2. Site-Neutral Payments

Under Medicare FFS, RT services furnished in a freestanding radiation therapy center are paid under the Medicare PFS at the non-facility rate including payment for the professional and technical aspects of the services. For RT services furnished in an outpatient department of a hospital, the facility services are paid under the Hospital Outpatient Prospective Payment System (OPPS) and the professional component of the services are paid under the PFS. As we discussed in the proposed rule (84 FR 34490 through 34491), differences in the underlying rate-setting methodologies used in the OPPS and PFS to establish payment for RT services in the HOPD and in the freestanding radiation therapy centers respectively help to explain why the payment rate for the same RT service could be different depending on the setting in which it is furnished. This difference in payment rate, which is commonly referred to as the site-of-service payment differential, may incentivize Medicare providers and suppliers to deliver RT services in one setting over another, even though the actual treatment and care received by Medicare beneficiaries for a given modality is the same in both settings. We proposed to test a site-neutral payment in the RO Model rather than implementing a payment adjustment in the OPPS or PFS because—

- The Secretary of Health and Human Services has limited authority to adjust payments only within established payment methodologies such as under section 1848 of the Act governing the PFS;
- The Practice Expense (PE) component of the PFS is determined based on resource inputs (labor, equipment, and supplies) and input price estimates from entities paid under the PFS only, which means the PE calculation does not consider HOPD cost data that the RO Model proposed to use as the basis for national base rates;
- Further, the PE methodology itself calculates a PE amount for each service relative to all of the other services paid under the PFS in a budget neutral manner and consistent with estimates of appropriate division of PFS payments between PE, physician work, and malpractice resource costs; and
- Under the PFS and OPPS, the same payment rate applies for a service, irrespective of the diagnosis, whereas the proposed rule for the RO Model would establish different payments by cancer type.
- Neither the PFS nor OPPS payment systems would allow flexibility in testing new and comparable approaches to value-based payment outside of statutory quality reporting programs.

As we stated in the proposed rule (84 FR 34490 through 34491), we believe a site-neutral payment policy will address the site-of-service payment differential that exists under the OPPS and PFS by establishing a common payment amount to pay for the same services regardless of where they are furnished. In addition, we stated our belief that site-neutral payments would offer RT providers and RT suppliers more certainty regarding the pricing of RT services and remove incentives that promote the provision of RT services at one site of service over another. The RO Model is designed to test these assumptions regarding site-neutrality.

3. Aligning Payments to Quality and Value, Rather Than Volume

As discussed in the proposed rule (84 FR 34491), for some cancer types, stages, and characteristics, a shorter course of RT treatment with more radiation per fraction may be appropriate. For example, several randomized controlled trials have shown that shorter treatment schedules for low-risk breast cancer yield similar cancer control and cosmetic outcomes as longer treatment schedules.[8] [9] [10] [11] As

[5] Physician Characteristics and Distribution in the U.5., 2010 Edition, 2004 IMV Medical Information Division, 2003 SROA Benchmarking Survey.

[6] 2012/13 Radiation Therapy Benchmark Report, IMV Medical Information Division, Inc. (2013).

[7] Modality refers to various types of radiotherapy, which are commonly classified by the type of radiation particles used to deliver treatment.

[8] Whelan, T.J. et al. Long-term Results of Hypofractionated Radiation Therapy for Breast Cancer. N. Engl. J. Med. 2010 Feb. 11; 362(6):513–20. *https://www.ncbi.nlm.nih.gov/pubmed/20147717.*

another example, research has shown that radiation oncologists may split treatment for bone metastases into 5 to 10 fractions, even though research indicates that one fraction is often sufficient.[12] [13] [14] [15] In addition, recent clinical trials have demonstrated that, for some patients in clinical trials with low- and intermediate-risk prostate cancer, courses of RT lasting 4 to 6 weeks lead to similar cancer control and toxicity as longer courses of RT lasting 7 to 8 weeks.[16] [17]

Based on our review of claims data, we discussed our belief that the current Medicare FFS payment systems may incentivize selection of a treatment plan with a high volume of services over another medically appropriate treatment plan that requires fewer services. Each time a patient requires radiation, providers and suppliers can bill for RT services and an array of necessary planning services to make the treatment successful.[18] We discussed that this structure may incentivize providers and suppliers to furnish longer courses of RT because they are paid more for furnishing more services. Importantly, however, the latest clinical evidence suggests that shorter courses of RT for certain types of cancer would be equally effective and could improve the patient experience, potentially reduce cost for the Medicare program, and lead to reductions in beneficiary cost-sharing.

As discussed in the proposed rule (84 FR 34491), there is also some indication that the latest evidence-based guidelines are not incorporated into practices' treatment protocols in a timely manner.[19] For example, while breast cancer guidelines have since 2008 recommended that radiation oncologists use shorter courses of treatment for lower-risk breast cancer (3 weeks versus 5 weeks), an analysis found that, as of 2017, only half of commercially insured patients actually received the shorter course of treatment.[20]

4. CMS Coding and Payment Challenges

In the proposed rule (84 FR 34491 through 34492) we identified several coding and payment challenges for RT services. Under the PFS, payment is set for each service using resource-based relative value units (RVUs). The RVUs have three components: Clinician work (Work), practice expense (PE), and professional liability or malpractice insurance expense (MP). In setting the PE RVUs for services, we rely heavily on voluntary submission of pricing information for supplies and equipment, and we have limited means to validate the accuracy of the submitted information. As a result, it is difficult to establish the cost of expensive capital equipment, such as a linear accelerator, in order to determine PE RVUs for physicians' services that use such equipment.[21]

Further, as we discussed in the proposed rule (84 FR 34492), we examined RT services and their corresponding codes under our potentially misvalued codes initiative based on their high volume and increasing use of new technologies. Specifically, we reviewed codes for RT services for Calendar Years (CYs) 2009, 2012, 2013, and 2015 as potentially misvalued services. In general, when a code is identified as potentially misvalued, we use notice and comment rulemaking to propose and finalize the code as misvalued, and then review the Work and PE RVU inputs for the code. As a result of the review, we may engage in further rulemaking to adjust the Work or PE inputs either upward or downward. The criteria for identifying potentially misvalued codes are set forth in section 1848(c)(2)(K)(ii) of the Act.

As described in the proposed rule (84 FR 34492), through annual rulemaking for the PFS, we review and adjust values for potentially misvalued services, and also establish values for new and revised codes. We establish Work and PE RVU inputs for new, revised, and potentially misvalued codes based on a review of information that generally includes, but is not limited to, recommendations received from the American Medical Association's RVS Update Committee (AMA/RUC), Health Care Professional Advisory Committee (HCPAC), Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; a comparison of the work for other codes within the PFS; and consultation with other physicians and health care professionals within CMS and other federal government agencies. We also consider the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations.

Through the annual rulemaking process previously described, we have reviewed and finalized payment rates for several RT codes over the past few years. The American Medical Association identified radiation treatment codes for review because of site of service anomalies. We first identified these codes as potentially misvalued services during CY 2012 under a screen called ''Services with Stand-Alone PE Procedure Time.'' We observed significant discrepancies between the 60-minute procedure time assumptions for IMRT and public information which suggested that the procedure typically took between 5 and 30 minutes. In CY 2015, the American Medical Association CPT® Editorial Panel revised the entire code set that describes RT delivery. CMS proposed values for these services in the CY 2016 proposed rule but, due to challenges in revaluing the new code set, finalized the use of G-codes that we established to

[9] Bentzen, S.M. et al. The UK Standardisation of Breast Radiotherapy (START) Trial A of Radiotherapy Hypofractionation for Treatment of Early Breast Cancer: A Randomised Trial. Lancet Oncol. 2008 Apr.; 9(4):331–41. *https://www.ncbi.nlm.nih.gov/pubmed/18356109.*

[10] Bentzen, S.M. et al. The UK Standardisation of Breast Radiotherapy (START) Trial B of Radiotherapy Hypofractionation for Treatment of Early Breast Cancer: A Randomised Trial. Lancet Oncol. 2008 Mar. 29; 371(9618): 1098–107. *https://www.ncbi.nlm.nih.gov/pubmed/18355913.*

[11] Haviland, J.S. et al. The UK Standardisation of Breast Radiotherapy (START) Trials of Radiotherapy Hypofractionation for Treatment Of Early Breast Cancer: 10-Year Follow-Up Results of Two Randomised Controlled Trials. Lancet Oncol. 2013 Oct.; 14(11): 1086–94. *https://www.ncbi.nlm.nih.gov/pubmed/24055415.*

[12] Sze, W.M. et al. Palliation of Metastatic Bone Pain: Single Fraction Versus Multifraction Radiotherapy—A Systematic Review of The Randomised Trials. Cochrane Database Syst. Rev. 2004; (2):CD004721. *https://www.ncbi.nlm.nih.gov/pubmed/15106258.*

[13] Chow, E. et al. Update on the Systematic Review of Palliative Radiotherapy Trials for Bone Metastases. Clin. Oncol. (R. Coll. Radiol.). 2012 Mar; 24(2):112–24. *https://www.ncbi.nlm.nih.gov/pubmed/22130630.*

[14] Chow, Ronald et al. Efficacy of Multiple Fraction Conventional Radiation Therapy for Painful Uncomplicated Bone Metastases: A Systematic Review. Radiotherapy & Oncology: March 2017 Volume 122, Issue 3, Pages 323–331. *http://www.thegreenjournal.com/article/S0167-8140(16)34483-8/abstract.*

[15] Lutz, Stephen et al. Palliative Radiation Therapy for Bone Metastases: Update of an ASTRO Evidence-Based Guideline. Practical Radiation Oncology (2017) 7, 4–12. *http://www.practicalradonc.org/article/S1879-8500(16)30122-9/pdf.*

[16] D. Dearnaley, I. Syndikus, H. Mossop, et al. Conventional versus hypofractionated high-dose intensity-modulated radiotherapy for prostate cancer: 5-year outcomes of the randomised, non-inferiority, phase 3 CHHiP trial. Lancet Oncol, 17 (2016), pp. 1047–1060, *http://www.sciencedirect.com/science/article/pii/S1470204516301024.*

[17] W.R. Lee, J.J. Dignam, M.B. Amin, et al. Randomized phase III noninferiority study comparing two radiotherapy fractionation schedules in patients with low-risk prostate cancer. J Clin Oncol, 34 (2016), pp. 2325–2332, *http://ascopubs.org/doi/full/10.1200/JCO.2016.67.0448.*

[18] These planning and technical preparation services include dose planning, treatment aids, CT simulations, and other services.

[19] *http://www.npr.org/sections/health-shots/2017/10/21/558837836/many-breast-cancer-patients-receive-more-radiation-therapy-than-needed.*

[20] *https://www.practicalradonc.org/cms/10.1016/j.prro.2018.01.012/attachment/775de137-63cb-4c5d-a7f9-95556340d0f6/mmc1.pdf.*

[21] CY 2014 PFS final rule with comment period (78 FR 43296, 43286 through 43289, and 43302 through 43311).

largely mirror the previous radiation treatment coding structure.[22] The Patient Access and Medicare Protection Act (PAMPA) (Pub. L. 114–115), enacted on December 28, 2015, addressed payment for certain RT delivery and related imaging services under the PFS, and the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123) required the PFS to use the same service inputs for these codes as existed in 2016 for CY 2017, 2018, and 2019. (The PAMPA and BBA of 2018 are discussed in detail in this rule).

Despite the previously discussed challenges related to information used to establish payment rates for RT services, the proposed rule (84 FR 34492) noted that we have systematically attempted to improve the accuracy of payment for these codes under the PFS. While the potentially misvalued code review process is essential to the PFS, some stakeholders have expressed concern that changes in Work and PE RVUs have led to fluctuations in payment rates. Occasionally, changes in PE RVUs for one or more CPT® codes occur outside of the misvalued code review cycle if there are updates to the equipment and supply pricing. Any changes to CPT® code valuations, including supply and equipment pricing changes, are subject to public comment and review.

The proposed rule further explained that although the same code sets generally are used for purposes of the PFS and OPPS, there are differences between the codes used to describe RT services under the PFS and the OPPS, and those in commercial use more broadly (84 FR 34492). We continue to use some CMS-specific coding, or HCPCS codes, in billing and payment for RT services under the PFS, while we generally use CPT® codes under the OPPS. As a result of coding and other differences, these payment systems utilize different payment rates and reporting rules for the same services, which contribute to site-of-service payment differentials. These differences in payment systems can create confusion for RT providers and RT suppliers, particularly when they furnish services in both freestanding radiation therapy centers and HOPDs.

Finally, as noted in the proposed rule (84 FR 34492), there are coding and payment challenges specific to freestanding radiation therapy centers. Through the annual PFS rulemaking process, we receive comments from stakeholders representing freestanding radiation therapy centers and physicians who furnish services in freestanding radiation therapy centers. In recent years, these stakeholder comments have noted the differences and complexity in payment rates and policies for RT services between the PFS and OPPS; expressing particular concerns about differences in payment for RT services furnished in freestanding radiation therapy centers and HOPDs despite the fact that the fixed, capital costs associated with linear accelerators that are used to furnish these services do not differ across settings; and raising certain perceived deficiencies in the PFS rate-setting methodology as it applies to RT services delivered in freestanding radiation therapy centers.[23] It is also important to note that even if we were able to obtain better pricing information for inputs, PFS rates are developed to maintain relativity among other PFS office-based services, and generally without consideration of OPPS payment rates.

As previously noted, the PAMPA addressed payment for certain RT delivery and related imaging services under the PFS. Specifically, section 3 of the PAMPA directed CMS to maintain the 2016 code definitions, Work RVU inputs, and PE RVU inputs for 2017 and 2018 for certain RT delivery and related imaging services; prohibited those codes from being considered as potentially misvalued codes for 2017 and 2018; and directed the Secretary to submit a Report to Congress on development of an episodic alternative payment model (APM) for Medicare payment for radiation therapy services furnished in non-facility settings. Section 51009 of the BBA of 2018 extended these payment policies through 2019. In November 2017, we submitted the Report to Congress as required by section 3(b) of the PAMPA.[24] In the report, we discussed the current status of RT services and payment, and reviewed model design considerations for a potential APM for RT services.

In the proposed rule (84 FR 34493), we described how the Innovation Center, in preparing the Report to Congress, conducted an environmental scan of current evidence and held a public listening session followed by an opportunity for RT stakeholders to submit written comments about a potential APM. A review of the applicable evidence cited in the Report to Congress demonstrated that episode payment models can be a tool for improving quality of care and reducing expenditures. Episode payment models pay a fixed price based on the expected costs to deliver a bundle of services for a clinically defined episode of care. In the proposed rule, we stated our belief that radiation oncology is a promising area of health care for episode payments, in part, based on the findings in the Report to Congress. While the report discusses several options for an APM, in the proposed rule, we proposed what the Innovation Center has determined to be the best design for testing an episodic APM for RT services.

The following is a summary of comments we received on the proposed goals of the RO Model and the issues addressed in section III.B. of the proposed rule and our responses to these comments:

Comment: Many commenters supported most aspects of the proposed RO Model and expressed commitment to fully participating in a value-based care model. A commenter recommended that CMS finalize the RO Model as mandatory, site-neutral, and inclusive of all proposed modalities. Several commenters expressed their support and encouraged CMS to have value-based programs that allow health care providers, through shared decision-making with their patients, to determine appropriate and convenient delivery options. A few commenters noted appreciation for CMS' commitment to providing participants with stable rates. Some commenters expressed support for clinical episode-related payments and the removal of payment on a per fraction basis. A few of these commenters also expressed their support of the transition to value-based care solutions.

Response: We thank these commenters for their support of our efforts to move forward with the RO Model. We are finalizing the RO Model as mandatory (see section III.C.3.a. of this final rule) with the modification of a low volume opt-out (see section III.C.3.c. of this final rule), site-neutral (see section III.C.6.c. of this final rule), and inclusive of all proposed modalities except for IORT (see section III.C.5.d. of this final rule).

Comment: A commenter expressed concern that CMS has not provided enough evidence to indicate that RT services for cancer are over utilized and to support the application of a standard

[22] *See generally,* CY 2015 PFS final rule with comment period (79 FR 67547); CY 2016 PFS final rule with comment period (80 FR 70885); and CY 2016 PFS correcting amendment (81 FR 12024).

[23] *See generally,* CY 2018 PFS final rule with comment period, 82 FR 52976; CY 2015 PFS final rule with comment period, 79 FR 67547; CY 2014 PFS final rule with comment period, 78 FR 43296.

[24] United States Department of Health and Human Services Report to Congress: *Episodic Alternative Payment Model for Radiation Therapy Services.* (Nov. 2019). *https://innovation.cms.gov/resources/radiationapm-pubforum.html.*

set of RT services for cancer patients through a bundled payment program.

Response: We understand this commenter's concerns. However, we disagree with this commenter. We have performed extensive research, and we have received numerous stakeholders' requests to create an alternative payment model in the radiotherapy space. For more information on our research and rationale, please see sections III.B.3. and III.B.4. of this final rule, and 84 FR 34491 through 34493 of the proposed rule.

Comment: A commenter suggested that CMS allow RT providers and RT suppliers to select appropriate radiation modalities based on nationally recognized clinical guidelines to ensure that beneficiaries receive evidence-based care.

Response: The Model encourages the use of nationally recognized, evidence-based clinical treatment guidelines. We will monitor the use of guidelines during the Model.

Comment: A commenter requested that CMS take on more risk sharing, reduce the savings targets, reimburse administrative costs of participation, and have absolute scoring and setting or thresholds for payment linked to quality measures.

Response: We have addressed these comments throughout the applicable sections of this final rule, including in, but not limited to, sections III.C.6., C.6.f, and C.8. of this final rule.

Comment: A commenter expressed concern for overall payment stability because disruptions to payment may have unintended consequences such as the closure of radiotherapy centers which could result in a loss of access to care for Medicare beneficiaries.

Response: One of the objectives of this Model is to provide site-neutral, more predictable payments to RO participants. We believe that the payment methodology as finalized in section III.C.6. of this final rule accomplishes this goal of providing more predictable or foreseeable payments to RO participants. We further believe that having more predictable payments may mitigate closures of viable radiotherapy centers. Additionally, we will be monitoring for beneficiary access issues throughout the Model (see section III.C.14).

Comment: A few commenters raised concerns that the lack of telehealth discussion in this Model meant that such connected health technologies would not have a role in the RO Model. A commenter requested that CMS utilize every opportunity to remove barriers to the use of advanced technologies within a connected healthcare system.

Response: Although several Innovation Center models and programs include the use of telehealth services, at this time, there are no permanent Medicare telehealth codes included in the list of included RT services in section III.C.5.c. We note that HCPCS Code 77427 has been temporarily added to the list of Medicare telehealth codes for the public health emergency (PHE) for the COVID–19 pandemic. RT services can only be furnished via telehealth to the extent permitted under the Medicare telehealth coverage and payment rules. Participants can continue to furnish telehealth services in accordance with current coverage and payment guidelines. We are taking this comment into consideration for future rulemaking.

Comment: Some commenters expressed concerns with the episode-based payment concept and indicated that such programs may put patients' safety at risk (for example, increased radiation exposure to healthy tissues). One of these commenters requested that CMS prioritize total-cost-of-care models over other episode-based payment programs.

Response: We believe that the RO Model will best meet its objectives of delivering site-neutral payments for included radiation therapy modalities through episode-based payments rather than total-cost-of-care because radiation oncology is highly technical and furnished in well-defined episodes, and because patient comorbidities generally do not influence treatment delivery decisions. We also believe that providers and suppliers will not compromise their patients' safety or deviate from the standard practice of care in an attempt to ''game'' the system. We believe that the monitoring and compliance requirements will mitigate gaming by RO participants. In addition, we believe that there are sufficient safeguards in place to prevent providers and suppliers from engaging in acts that will harm their patients, including but not limited to the requirements to actively participate with an AHRQ-listed patient safety organization (PSO) and provide Peer Review (audit and feedback on treatment plans) (see section III.C.14).

Comment: Several commenters requested that the site neutral payment policy be abandoned. A few commenters stated that a site neutral payment approach assumes that care is equivalent in all settings. A commenter argued that the site neutral policy ignores the higher cost of providing services in an HOPD setting as compared to the physician office setting of freestanding radiation therapy centers as HOPDs provide wraparound services, such as translators and other social services that are not otherwise billable, and face requirements set by regulators and accreditors to which physician offices are not subject.

Response: As we documented in the proposed rule and in the November 2017 Report to Congress (see section III.B.4 of the proposed rule at 84 FR 34491 through 34493 and this final rule for background on the November 2017 Report to Congress), differences in the underlying methodologies used in the OPPS and PFS for rate setting often result in differences in the payment rate for the same RT service depending on whether the service is furnished in a freestanding radiation therapy center paid under the PFS, or an HOPD paid under the OPPS. We refer to this as the site-of-service payment differential, and we believe that such differentials between HOPDs and freestanding radiation therapy centers are unwarranted because the actual treatment and care received by patients for a given modality is the same in each setting. Therefore, we are using HOPD payment rates to create the RO Model national base rates. For a detailed discussion of this Model's Pricing Methodology see section III.C.6 of this final rule.

Comment: A commenter stated that CMS does not have authority to implement site-neutral payments and is using section 1115A to adopt a policy preference that CMS otherwise could not adopt.

Response: We disagree with this commenter, and believe that we are operating within our authority. Section 1115A of the Social Security Act authorizes the Secretary to test innovative payment and service delivery models expected to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries. Section 1115A(b) provides a non-exhaustive list of models to be tested. Under this authority, CMS has broad discretion to design its payment and service delivery models. For more discussion about CMS' statutory authority to conduct the RO Model under section 1115A of the Act, please reference section III.C.3.a of this final rule.

Comment: A few commenters requested that we abandon the proposal to have site-neutral payments because different sites of care have different operating costs.

Response: We believe that site-neutral payment is a necessary component of the RO Model test to avoid establishing an incentive for RO participants to deliver RT services in one setting over another, even though the actual treatment and care received by Medicare beneficiaries for a given modality is the same in both settings.

Comment: A commenter stated that the proposed RO Model's site-neutral payments do not go far enough and that these payments should be applied to all providers and suppliers, regardless of the Core-Based Statistical Areas (CBSAs) in which they furnish RT services. This commenter also does not believe that a 5-year test is necessary to conclude that payment rates for RT services under the OPPS and MPFS should be equalized.

Response: We agree that payment rates under the RO Model should be site-neutral, and are proceeding with the 5-year test of this Model, with CBSAs selected for participation to understand the impact of site-neutral payments on cost and quality of care. We believe that the Model performance period of 5 years, as opposed to a shorter duration, is necessary to obtain sufficient data to compute a reliable impact estimate and to analyze the data from the Model to determine next steps regarding potential expansion or extension of the Model. Further, we believe that a test period of 5 years is necessary to address and mitigate any potential implementation issues or unintended consequences. For a discussion of the Model performance period, please see section III.C.1. of this final rule.

Comment: A commenter requested clarification on how the RO Model will impact the budget neutrality requirements under the OPPS and PFS.

Response: With respect to the budget neutrality requirements under the Medicare Physician Fee Schedule (PFS) and Outpatient Prospective Payment System (OPPS), absent any further adjustment, we would expect the RO Model to pull utilization out of the traditional fee-for-service payment systems. The Center for Medicare will monitor this issue through the duration of the Model test and account for utilization for services included in the RO Model under the PFS and OPPS as appropriate. In essence, we believe that this Model will, in time, reduce program expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

Comment: A couple of commenters opposed paying for radiotherapy services based on the proposed prospective payment approach in the RO Model, and instead suggested that payment continue to be made on a fee-for-service basis, with a reduction in the reimbursement for fractions that are beyond the average for a particular diagnosis.

Response: The commenters' suggested approach, as we understand it, would require ongoing adjustments to fee-for-service payments based on changing averages for a particular diagnosis. We believe that the proposed prospective episode-based payment tested under this Model would be preferable as this approach will test whether a modality agnostic, bundled payment will lead to more appropriate courses of radiation treatment for certain cancer types.

Comment: A commenter urged CMS to establish policies that encourage participants' investment in care transformation to achieve the agency's long-term goal of improving quality of care while reducing costs.

Response: We believe that this Model embraces our goal of improving quality of care while reducing costs (see section III.C.14 of this final rule for the Model's monitoring and compliance requirements). We also believe that this Model, as finalized, will encourage RO participants to transform their care.

Comment: A commenter voiced concern that participants with fewer resources would attempt high dose hypofractionation without adequate equipment and that the proposed rule did not have a mechanism in place to test the ''fitness'' of the hypofractionation equipment.

Response: At this time, we are unable to perform such a test as we do not believe that testing equipment falls within the Innovation Center's authority to test payment and service delivery models. However, we will be using Peer Review and patient surveys, among other monitoring measures (see section III.C.14 of this final rule), to assess whether RO participants are engaging in such egregious behaviors.

Comment: A few commenters discussed concerns with hypofractionation. These commenters generally noted that data supporting fractionation is limited across cancer types. A commenter used prostate cancer as an example, concluding that the RO Model might make hypofractionated treatment the only economically viable option for treating men with low- and intermediate-risk prostate cancer. This commenter believed such a move would be premature, as the benefits of hypofractionation for prostate cancer are unclear.

Another commenter highlighted that testing whether hypofractionation lowers costs and improves quality will require providers and suppliers to upgrade their technology to provide lower and more precise fractions of RT. For this reason, the commenter recommended that CMS publish the science underlying its belief that hypofractionation would be appropriate for this range of cancer types.

A commenter shared specific recommendations and evidence for RT hypofractionation in breast cancer, prostate cancer, head and neck cancer, and Central Nervous System (CNS) cancers, as well as in bone and brain metastases.

A commenter emphasized that hypofractionated treatments may increase acute toxicity and that patients with pre-existing conditions like ulcerative colitis or collagen-vascular disorder are poor candidates for these types of hypofractionated treatments.

Response: We thank the commenters for this information. It was not CMS' intent to encourage hypofractionation specifically. It was our intent to use hypofractionation as an example of a treatment option often cited in nationally recognized, evidence-based guidelines. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. As finalized in section and III.C.14 and III.C.16, we will monitor for unintended consequences of the RO Model, and such monitoring could include utilization patterns regarding fractions.

Comment: A commenter expressed concern with the high cost of treating patients in a rural treatment facility.

Response: We believe that the policies as finalized in this final rule will help to address this commenter's concerns. In particular, we refer readers to section III.C.3.c of this final rule for the optional opt-out for low-volume RO participants, as well as section III.C.3.d that describes how CBSAs exclude extreme rural geographic areas, and section III.C.3.c that discusses the exclusion of critical access hospitals.

Comment: A commenter expressed the desire to maintain current valuations for Radiation Therapy G-codes under the PFS (HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017), and requested that these valuations be stable throughout the Model.

Response: The purpose of the RO Model is to test whether prospective episode payments in lieu of traditional FFS payments for RT services would reduce Medicare expenditures and preserve or enhance quality of care for beneficiaries. Additionally, the RO Model is designed to test a site-neutral

and modality agnostic approach to payment for RT services. Therefore, we do not believe that continuing to make payment based on the current valuations for certain G-codes under the PFS aligns with the intent of this Model test. Please refer to section III.C.5.c of this final rule for a discussion of our included RT services as well as section III.C.6 for details regarding the specific RO Model codes that will be used during this Model and how their value will be calculated in each performance year.

C. RO Model Regulations

In the proposed rule at 84 FR 34493, we discussed our policies for the RO Model, including model-specific definitions and the general framework for implementing the RO Model. We defined ''performance year'' (PY) as the 12-month period beginning on January 1 and ending on December 31 of each year during the Model performance period. We proposed to codify the term ''performance year'' at § 512.205 of our regulations.

In the proposed rule, we included our proposed policies for each of the following: (1) The scope of the RO Model, including the RO participants, beneficiary population, and episodes that would be included in the test; (2) the pricing methodology under the Model and the Medicare program policy waivers necessary to implement such methodology; (3) the measure selection for the Model, including performance scoring methodology and applying quality to payment; (4) the process for payment reconciliation; and (5) data collection and sharing.

In the proposed rule, we discussed codifying RO Model policies at 42 CFR part 512, subpart B (§§ 512.200 through 512.290). In addition, as we explained in section II. of the proposed rule, the general provisions codified at §§ 512.100 through 512.180 would apply to the RO Model.

1. Model Performance Period

We proposed to test the RO Model for five PYs. We proposed to define ''Model performance period'' to mean January 1, 2020, the date the Model begins, through December 31, 2024, the last date during which episodes under the Model must be completed (84 FR 34493). Alternatively, we also considered delaying implementation to April 1, 2020 to give RO participants and CMS additional time to prepare. As we discussed, an April 2020 start date would only affect the length of PY1 which would be 9 months. All other PYs would be 12 months. For all episodes to be completed by December 31, 2024, we proposed that no new episodes may begin after October 3, 2024. We solicited public comments on the Model performance period and potential participants' ability to be ready to implement the RO Model by January 1, 2020. We also solicited comments on delaying the start of the Model performance period to April 1, 2020. The following is a summary of comments received on these proposals and our responses:

Comment: Many commenters provided feedback related to the Model's start date for the RO Model. Almost all of the commenters were opposed to the RO Model beginning on January 1, 2020. Some commenters recommended that CMS consider delaying the implementation of the Model until the alternatively proposed date of April 1, 2020, but many still believed that this date would not allow sufficient time to prepare. Commenters believed the April 1, 2020 Model's start date fell short of providing adequate preparation time for RO participants and proposed alternative start dates of late spring or early summer of 2020; July 1, 2020; August 1, 2020; October 1, 2020; and January 1, 2021. Commenters recommended a delay from when the RO Model is finalized or when the CBSAs selected for participation are announced to when it would begin; a couple of commenters recommended a 6-month delay, some commenters requested a 9-month delay, and a few commenters recommended a 12-month delay.

Response: We appreciate these commenters' concerns. Regarding commenters' use of the term ''implementation date,'' we understand commenters are referring to the beginning of the Model performance period. After reviewing these concerns, we agree with commenters that both the January 1, 2020 and April 1, 2020 start dates would not provide RO participants with sufficient time to operationalize the RO Model requirements. We intended to start the RO Model on July 1, 2020, but as we were completing this final rule, the United States began responding to an outbreak of respiratory disease, referred to as ''Coronavirus disease 2019'', which created a serious public health threat greatly impacting the U.S. health care system. The Secretary of the Department of Health and Human Services, Alex M. Azar II, declared a Public Health Emergency (''PHE'') on January 31, 2020, retroactively effective from January 27, 2020, to aid the nation's healthcare community in responding to the Coronavirus disease 2019 pandemic. On July 23, 2020, Secretary Azar renewed, effective July 25, 2020, the determination that a PHE exists which he had previously renewed on April 21, 2020.

In light of this unprecedented PHE, which continues to strain health care resources, we are finalizing the RO Model's Model performance period to begin on January 1, 2021. We understand that RO participants may have limited capacity to meet the RO Model requirements in 2020. To ensure that participation in the RO Model does not further strain RO participants' capacity, potentially hindering the delivery of safe and efficient health care to beneficiaries receiving RT services, we are finalizing the RO Model's Model performance period to begin on January 1, 2021.

We also believe that finalizing the Model performance period to begin January 1, 2021 will give RO participants sufficient time to learn and understand the RO billing requirements, train staff on new procedures, prepare to report on quality measures and clinical data elements, evaluate and adjust their budgets to prepare for the RO Model, and to allow EHR vendors to begin to develop mechanisms to comply with the Model.

Therefore, we are finalizing our proposed Model performance period at § 512.205, with the modification that the Model performance period begin on January 1, 2021, where each PY will consist of a 12-month period beginning on January 1 and ending on December 31. For all episodes to be completed by December 31, 2025, we are finalizing that no new RO episodes may begin after October 3, 2025. The 5-year performance period will run from January 1, 2021, through December 31, 2025.

Comment: One commenter recommended that CMS issue an Interim Final Rule with comment period, identify the selected RO Model participants in the Interim Final Rule, and ensure selected participants have at least six months of advanced notice before the RO Model begins.

Response: An interim final rule with comment period (''IFC'') would be inappropriate for purposes of finalizing the RO Model, as the proposed rule for the RO Model was published July 18, 2019 (84 FR 34478). Further, we believe the selected RO participants will have sufficient time to prepare for a Model performance period that begins January 1, 2021. To ensure that RO participants have sufficient preparation time, we are publishing this final rule more than 60 days prior to the beginning of the Model performance period.

Comment: Many commenters stated that RO participants would face considerable administrative burden, and would not have the appropriate time to plan for implementation until the final rule was issued—noting that 60 days or fewer would be insufficient. These commenters identified many reasons for requesting more time, including that EHR vendors would need ample time to design, develop, build, test, validate, and implement the software to allow RO participants to fulfill the requirements of the RO Model in a streamlined manner through their EHR platforms. Some of these commenters specified that it could take 12 to 18 months for EHR vendors to complete software development cycles. A few commenters pointed out that successful implementation of the RO Model would require many RO participants as well as software vendors to change EHR configurations, organizational policies, and end user workflows. A commenter stated that radiation oncology departments utilize specific electronic medical record and record-and-verification systems that are linked to their linear accelerators, and the vendors that support those information systems would not be prepared for implementation in January 2020. A commenter also stated that hospitals and other participants need time to plan for budget requests and approvals relating to equipment upgrades and IT support. A few commenters expressed concern that EHR vendors would need to develop and implement complicated changes to collect information on clinical data elements in a short period of time because CMS has yet to publish the Model-specific clinical data elements.

Response: We agree with commenters' concerns that EHR vendors will need more time to design, develop, build, test, validate, and implement the software to allow RO participants to fulfill the requirements of the RO Model in a streamlined manner through their EHR platforms. We understand that successful implementation of the RO Model will require many RO participants as well as software vendors to change EHR configurations, organizational policies, and end user workflows. We also understand that some radiation oncology departments utilize specific electronic medical record and record-and-verification systems that are linked to their linear accelerators, and the vendors that support those information systems would not have been prepared for implementation in January 2020. We further understand that hospitals and other participants need time to plan for budget requests and approvals relating to equipment upgrades and IT support. Based on these concerns and the PHE, we are finalizing the Model performance period to begin on January 1, 2021. The Model requirements, including measure data collection and the use of certified EHR technology (CEHRT), will begin in PY1 (which begins on January 1, 2021). We believe that the period of time between publication of this final rule and the beginning of the Model performance period will provide EHR vendors with sufficient time to implement the software that RO participants may need to adhere to the RO Model requirements.

Comment: Many commenters stated that RO participants would need adequate time to prepare for the new reporting of quality measures and clinical data required by the RO Model. These commenters stated that they would need considerable time to develop and build a specific clinical infrastructure to meet the increased quality data collection and reporting requirements mandated by the RO Model. A commenter emphasized that such a delay would be particularly important for those RO participants treating Medicare beneficiaries with prostate, breast, or lung cancers as well as bone and brain metastases, given CMS' proposal to require those participants to collect and report clinical information not currently available in claims or captured in the proposed quality measures.

Response: We understand commenters' concerns that they will need considerable time to develop and build a specific clinical infrastructure to meet the increased quality data collection and reporting requirements mandated by the RO Model. We also understand that RO participants and Medicare contractors in the CBSAs selected for participation would need adequate time to prepare for the RO Model requirements, and to successfully modify operations. We believe that finalizing the Model performance period on January 1, 2021 provides sufficient time for selected RO participants to develop and build the necessary infrastructure to meet reporting requirements of the RO Model.

Comment: Many commenters requested that the RO Model be delayed so that RO participants and Medicare contractors in the CBSAs selected for participation would have adequate time to prepare for the RO Model requirements, and to successfully modify operations.

Response: We believe that finalizing the Model performance period to begin on January 1, 2021 will provide adequate time for RO participants to prepare for the RO Model and to modify their operations to meet the Model requirements. The Medicare Administrative Contractors in the CBSAs selected for participation will be prepared when the Model begins on January 1, 2021.

Comment: Many commenters requested more time to implement the RO Model, because RO participants would need adequate time to operationalize the RO Model's coding and billing requirements. Many commenters stated that they would need to hire additional staff, and to train and educate new and existing staff and clinicians on RO Model procedures, requirements, billing and other systems. A few commenters stated that they would need sufficient time to educate and engage clinical and operational staff about the RO billing practices and processes, and for these participants to learn and understand changes to coding, claims generation, claims processing, participant-specific modifiers and adjustments, withhold calculations, and payment programming. A couple of commenters expressed concern about the administrative burden of learning a new billing system under the RO Model while simultaneously maintaining a separate billing system for privately insured patients. One of these commenters stated that the billing staff would be burdened with the need to identify which patients are in the Model and which are not in order to appropriately bill claims because the billing would differ significantly for each patient and insurer. Many commenters stated that RO participants would need more time to make budgetary accommodations to offset the perceived additional expenses related to participation in the RO Model and to re-evaluate practice budgets to accommodate for changes in cash flow as a result of participation in the Model.

Response: We believe that finalizing the Model performance period to begin on January 1, 2021 will provide RO participants with sufficient time to prepare to meet the billing and coding requirements, to re-evaluate practice budgets to accommodate for changes in the Model, to hire new staff and educate existing staff, and to address concerns regarding the administrative burden of learning a new billing system under the RO Model. The Model requirements, codified at § 512.220, will start on January 1, 2021.

For concerns regarding changes in billing and coding requirements, we believe that the finalized billing process that will be easily implemented within

current systems because it is based on how FFS claims are currently submitted. Section III.C.7 of this final rule provides information on billing and coding changes under the RO Model. Additional guidance on billing and coding will be made available to RO participants before the beginning of the Model performance period through resources such as the Medicare Learning Network (MLN Matters) publications, Model-specific webinars, and/or the RO Model website.

Comment: A few commenters stated that they would need to operationalize the billing requirements of the RO Model in a shortened time frame, as they would not be notified of their selection until the publication of the final rule.

Response: We believe that finalizing the Model performance period to begin on January 1, 2021 will provide RO participants adequate time to operationalize the Model's billing requirements which are based on the current FFS claims systems.

Comment: A commenter stressed that it would take time to operationalize the beneficiary notification requirement.

Response: We will provide RO Model participants with a beneficiary notification letter template that RO participants may personalize with their contact information and logo. RO participants must provide this beneficiary notification letter to each beneficiary during the initial treatment planning session. We refer readers to section III.C.15 of this final rule for details regarding the beneficiary notification letter. We do not believe that the beneficiary notification letter, which will require minimal modification by the RO participant, will warrant significant additional time to operationalize.

Comment: A commenter requested additional time for participants to receive and review CMS data to better understand their current care processes and drive care transformation under the Model.

Response: We plan to allow RO participants, to the extent permitted by HIPAA and other applicable laws, to request claims data from CMS for purposes of care coordination and/or quality improvement work. Please see section III.C.13.d for more information. To request this data, RO participants will submit a Participant Data Request and Attestation (DRA) form, which will be available on the Radiation Oncology Administrative Portal (ROAP).

Comment: A few commenters suggested that CMS include a performance year 0 (PY0) for the RO Model. This PY0 could serve as a baseline measurement and preparation period that would allow RO participants to make practice transformations; change workflow; review, analyze, and act on data received from CMS; understand Model reporting requirements; and receive additional education from CMS on Model parameters and objectives. A couple of these commenters further suggested that RO participants could submit no-pay claims for the PY0 episodes while continuing their normal billing practices.

Response: We are finalizing the Model performance period that will include performance years (PYs) one through five (PY1–PY5), and it will not include a PY0. PY1 of the RO Model will begin on January 1, 2021. We believe that finalizing the Model performance period to begin on January 1, 2021 makes a PY0 unnecessary because RT providers and RT suppliers will have several months to prepare for the RO Model and its requirements.

Comment: A few commenters recommended reducing the number of performance years. A commenter requested that the duration of the Model be reduced to three years. This commenter stated that a reduction in both duration and number of episodes, coupled with voluntary participation, would provide sufficient information for CMS to assess the viability of the Model and to then scale the Model nationally if it had achieved its goals of improving care and reducing costs.

Response: We proposed that the performance period for the RO Model to be five performance years because at least five performance years are necessary to sufficiently test the proposed prospective payment approach, stimulate the development of new evidence-based knowledge, acquire additional knowledge relating to patterns of inefficient utilization of health care services, and to formulate methods to incentivize the improvement of high-quality delivery of RT services. Based upon our analyses we do not believe that three years will be sufficient to test the proposed payment approach. We believe that a Model performance period of five years is necessary to address implementation issues and for the evaluation to obtain sufficient data to compute a reliable impact estimate, and to determine next steps regarding potential expansion or extension of the Model. Notably, the evaluation will analyze data on the impact of the Model on an ongoing basis, so to the extent that evaluation results are definitive sooner than the end of the Model, we will consider next steps at that time rather than waiting until the Model ends. For these reasons, we believe that a Model performance period of five years is necessary, and we will not reduce the Model performance period to less than five years.

We also would like to clarify that we proposed that the RO Model would cover 40 percent of all eligible RO episodes in eligible CBSAs nationwide in order to have a nationally representative sample of RT providers and suppliers that is sufficiently large enough to confidently show the impacts of the Model within five years (84 FR34496). As discussed in section III.C.3.d, we are finalizing a policy that includes 30 percent of all eligible RO episodes in eligible CBSAs nationwide, and determined that we will still be able to maintain confidence in estimating the impacts of the RO Model. Finalizing a Model performance period to anything less than five years would not allow us to maintain that confidence necessary to show the impacts of the RO Model.

Regarding the commenters suggesting that the RO Model should be voluntary, please reference section III.C.3.a of this final rule for further discussion of why we believe a mandatory design is necessary for the testing of the RO Model.

After considering public comments, we are finalizing our proposal with modification to the Model performance period. Specifically, we are revising the regulations at § 512.205 to define the Model performance period to mean January 1, 2021, through December 31, 2025, the last date during which RO episodes must be completed, with no new RO episodes beginning after October 3, 2025, in order for all RO episodes to be completed by December 31, 2025. We are also codifying at § 512.205 that performance year (PY) means the 12-month period beginning on January 1 and ending on December 31 of each year during the Model performance period.

2. Definitions

In the proposed rule, we proposed to define certain terms for the RO Model at § 512.205. We described these proposed definitions in context throughout section III of the proposed rule. In the proposed rule, we solicited public comments on our proposed definitions. To the extent we have received comments relating to the definitions that we had proposed, we have responded to those comments in context throughout section III of this final rule.

3. Participants

In the proposed rule, we discussed how certain Medicare participating

HOPDs, physician group practices (PGPs), and freestanding radiation therapy centers that furnish RT services (RT providers or RT suppliers) in Core-Based Statistical Areas (CBSAs) randomly selected for participation, would be required to participate in the RO Model either as ''Professional participants,'' ''Technical participants,'' or ''Dual participants'' (as such terms are defined at 84 FR 34494). We defined ''RO participant'' at § 512.205 of the proposed rule as a PGP, freestanding radiation therapy center, or HOPD that participates in the RO Model pursuant to the criteria that we proposed to establish at § 512.210 (see section III.C.3.b in the proposed rule and in this final rule). In addition, we noted that the proposed definition of ''model participant,'' includes an RO participant. In the proposed rule, we discussed our proposals regarding mandatory participation, the types of entities that would be required to participate, and the geographic areas that would be subject to the RO Model test.

a. Required Participation

In the proposed rule (84 FR 34493 through 343494), we discussed how certain RT providers and RT suppliers that furnish RT services within CBSAs randomly selected for participation would be required to participate in the RO Model (as discussed in sections III.C.3.b and III.C.3.d of this final rule). To date, the Innovation Center has tested one voluntary prospective episode payment model, Bundled Payments for Care Improvement (BPCI) Model 4 that attracted only 23 participants, of which 78 percent withdrew from the initiative. In the proposed rule, we discussed our interest in testing and evaluating the impact of a prospective payment approach for RT services in a variety of circumstances. We stated our belief that by requiring the participation of RT providers and RT suppliers, we would have access to more complete evidence of the impact of the Model.

As discussed in the proposed rule, we believe a representative sample of RT providers and RT suppliers for the proposed Model would result in a robust data set for evaluation of this prospective payment approach, and would stimulate the rapid development of new evidence-based knowledge (84 FR 34493). Testing the Model in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for RT services. This learning could potentially inform future Medicare payment policy. Therefore, we proposed a broad representative sample of RT providers and RT suppliers in multiple geographic areas (see section III.C.3.d of both the proposed rule and this final rule for a discussion regarding the Geographic Unit of Selection). We proposed the best method for obtaining the necessary diverse, representative group of RT providers and RT suppliers would be random selection. This is because a randomly selected sample would provide analytic results that will be more generally applicable to all Medicare FFS RT providers and RT suppliers and would allow for a more robust evaluation of the Model.

In addition, in the proposed rule at 84 FR 34493 through 34494, we discussed actuarial analysis suggesting that the difference in estimated price updates for rates in the OPPS and PFS systems from 2019 through 2023, in which the OPPS rates are expected to increase substantially more than PFS rates, would result in few to no HOPDs electing to voluntarily participate in the Model. Further, those actuarial estimates suggested that freestanding radiation therapy centers with historically lower RT costs compared to the national average would most likely choose to participate, but those with historically higher costs would be less likely to voluntarily participate. We discussed how requiring participation in the RO Model would ensure sufficient proportional participation of both HOPDs and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers and RT suppliers and to help support a statistically robust test of the prospective episode payments made under the RO Model.

For these reasons, we believed that a mandatory model design would be the best way to improve our ability to detect and observe the impact of the prospective episode payments made under the RO Model. Therefore, we proposed that participation in the RO Model would be mandatory for all RT providers and RT suppliers furnishing RT services within the CBSAs randomly selected for participation (84 FR 34493 through 34494).

We solicited public comments on our proposal for mandatory participation. The following is a summary of comments received on this proposal and our responses to these comments:

Comment: CMS received many comments related to the proposed mandatory participation of the Model. One commenter agreed with CMS' decision to make participation in this Model mandatory for CBSAs randomly selected for participation.

Response: We appreciate the commenter's support. As explained in the proposed rule (84 FR 34493 through 34496) and in this final rule, mandatory participation eliminates selection bias, ensures participation from HOPDs, provides a representative sample of RT providers and RT suppliers, and facilitates a comparable evaluation comparison group. We maintain that the mandatory design for the RO Model is necessary to enable CMS to detect change reliably in a generalizable sample of RT providers and RT suppliers to support a potential model expansion.

Comment: A few commenters stated that the mandatory nature of the RO Model would force some RT providers and RT suppliers to participate in the Model that are not operationally ready while at the same time excluding others that are well prepared. This could create challenges for beneficiary access and could lead to operational issues for practices.

Response: Mandatory participation and random selection of participants are integral to the design and evaluation of this Model. However, we believe that finalizing the Model performance period to on January 1, 2021 will allow RT providers and RT suppliers sufficient time to prepare for the RO Model's requirements.

Comment: Some commenters stated that mandatory participation would have negative consequences on Medicare beneficiaries, such as depriving beneficiaries of their freedom to choose where they receive RT services, reducing access to care, and increasing financial and logistical burdens for beneficiaries that believe they need to travel outside of their CBSA to receive care from a non-RO participant.

Response: We would like to clarify that the RO Model will not interfere with the general guarantees and protections for all Medicare FFS beneficiaries. We support Medicare beneficiaries' rights to seek care wherever they choose, and we are codifying at § 512.120(a)(1) the requirement that RO participants not restrict a beneficiary's ability to choose his or her provider(s) and/or supplier(s). Further, we are using CBSAs as the unit of selection for the RO Model. We selected CBSAs, as opposed to larger geographic units of selection, in order to allow beneficiaries to travel to another area to receive RT services, if they so wished.

Comment: A couple of commenters stated that mandatory participation is a departure from the agency's previous approach to model participation, and

these commenters believed that CMS had previously indicated that mandatory models would only be used judiciously or when the agency could not guarantee enough participation or would have an adverse selection for voluntary models.

Response: We believe that the RO Model meets these circumstances. As discussed throughout this section and in Section III.C.3.d, we designed the RO Model to require participation by RT providers and RT suppliers in order to avoid selection bias. Further, as discussed earlier in this section, our actuarial analysis suggests that without mandatory participation in the RO Model, there will be limited to no participation from HOPDs.

Comment: Some commenters expressed concerns that the proposed mandatory participation would lack upside opportunity for high-performing participants and lead to hospitals and health systems bearing the expense of participation in a complicated program and the burden of generating all of the identified savings associated with the Model.

Response: We would like to note that the RO Model is an Advanced APM and a MIPS APM. As such, eligible clinicians who are Professional participants and Dual participants may potentially become Qualifying APM Participants (QPs) who earn an APM Incentive Payment and are excluded from the MIPS reporting requirements and payment adjustments. Under the current Quality Payment Program rules, those who are not excluded from MIPS as QPs or Partial QPs will receive a final score and payment adjustment under MIPS, unless otherwise excepted. We believe these aspects of the RO Model as an Advanced APM and a MIPS APM will provide eligible participants with an example of the upside opportunity for high-performing participants under the Model stated by the commenters. The RO Model also affords all RO participants the opportunity to actively participate in the effort of moving toward and incentivizing value-based RT care, offering to make certain data available that RO participants can request for use in care coordination and quality improvement, which would potentially increase beneficiary satisfaction.

Comment: Many commenters suggested that other unintended consequences could result from mandatory participation in the RO Model. These commenters listed the following potential consequences: A competitive disadvantage for participants who are subject to new and uncertain pricing; unfair financial hardship for participating practices; a disproportionate effect on cancer centers with a predominantly Medicare patient base; Medicare patients being exposed to unnecessary excess radiation; stifled innovation; and a decrease in overall quality of care.

Response: We will conduct ongoing monitoring and evaluation analyses to watch for any unintended consequences of the Model, as finalized in section III.C.16. Please also refer to sections III.C.3.d. and III.C.14 of this final rule for more discussion about how we will monitor for unintended consequences under the RO Model.

Specifically regarding the comment about Medicare patients being exposed to unnecessary excess radiation, we rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. As for concerns regarding stifled innovation under the RO Model, we believe these concerns will be mitigated by the fact that new technologies, upon receiving an assigned HCPCS code, would be paid FFS until such time that they could be proposed for the RO Model through future rulemaking. We also believe these concerns about stifled innovation under the RO Model will be mitigated by the trend factor, which will reflect updates to input prices as reflected in updated PFS and OPPS rates. Please refer to section III.C.6 of this final rule for further discussion about this.

We do not believe that RO participants will be at a competitive disadvantage, or subject to uncertain pricing, because the RO Model pricing methodology employs a trend factor, which is applied to an established national base rate, that is based on updated PFS and OPPS rates and ensures that spending under the RO Model will not diverge too far from spending under the FFS that non-participants will receive for the underlying bundle of services had they been in the Model. See section III.C.6.d for more information.

Regarding the comment that the Model would have a disproportionate effect on cancer centers with a predominantly Medicare patient base, we disagree. Episode payments will be largely determined by what an RO participant was historically paid. As described in section III.C.6, the pricing methodology as finalized will blend together the national base rate with an RO participant's unique historical experience. If the RO participant is historically less efficient than the national average, the blend in PY1 will be 90 percent of the RO participant's historical payments and 10 percent of the national base rate. This means that prior to applying the discount factor and withholds, payments under the Model will be between 90 and 100 percent of the RO participant's historical payments. For historically inefficient RO participants, the blend shifts over time to a 70/30 blend in PY5. For historically efficient RO participants, the blend for the Model performance period is fixed at 90/10 blend.

Regarding the comment that the mandatory nature of the RO Model will result in a decrease in overall quality of care, we disagree. We specifically designed the Model to preserve or enhance quality of care, and we are putting in place measures, like the collection of quality measures and clinical data elements, to help us to quantify the impact of the RO Model on quality of care. See section III.C.8 of this final rule for more information regarding our finalized provisions for the quality measures and clinical data elements that will be collected for the RO Model.

Comment: Many commenters suggested that participation in the Model be voluntary, or that participants have the option to opt-in or opt-out of the Model. Many commenters provided operational suggestions should the Model be voluntary, including that participants could choose to participate for the entirety of the Model performance period. Many commenters referenced other voluntary models, namely the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model and the Oncology Care Model (OCM), and suggested that these models have significant health care provider interest and participation, and have demonstrated that the RO Model could be successful and garner sufficient participation as a voluntary model. The commenters suggested that a voluntary model would provide an opportunity to mitigate unintended consequences prior to expanding to a mandatory model. Many commenters stated that making the RO Model voluntary would reduce the potential risk, disruption, and financial hardships to RO participants.

As an alternate recommendation, many commenters suggested that the RO Model have a ''phase in'' period for participants such that the Model would begin as voluntary and transition to mandatory participation in subsequent years. One of these commenters recommended voluntary participation for the initial two of five performance years, and then phase in mandatory participation over the remaining 3-year period. Another commenter recommended voluntary participation for the first performance year (PY) with

a transition to limited mandatory participation in the subsequent performance years. Another commenter recommended voluntary participation with a gradual phase in of additional participants through expansion of the Model by 10 percent each year.

Another commenter suggested that providers and suppliers in the selected geographic areas be allowed to opt out of participation in the first year of the Model, and that CMS remove downside risk for those that do participate. Then, in the remaining four years of the Model, all providers and suppliers in the selected geographic areas would be required to participate with two-sided risk. A few commenters recommended that CMS initiate the Model on a voluntary basis with little to no risk, and then transition to a risk-based Model with opt-in and opt-out provisions to take place over a period of time. These commenters compared this suggested risk approach to those implemented in both the Comprehensive Care for Joint Replacement (CJR) Model and OCM. A few commenters recommended that CMS consider a voluntary Model for the first four years with incentives for participants, and then subsequently transition to a limited mandatory Model. Another commenter suggested that the RO Model be voluntary for the initial three years, and then move to mandatory in PY4 and PY5.

Many commenters recommended that the Model have voluntary participation throughout the Model performance period. A commenter recommended testing multiple small-scale voluntary models with differing payment methodologies simultaneously to determine which approach would have the greatest impact with the fewest unintended consequences. This commenter recommended that these tests be conducted with interested RT providers and RT suppliers before CMS scaled it to the size proposed in the NPRM. Another commenter suggested implementing the Model nationally as a voluntary model and utilizing the approach of evaluating the impact through an interrupted time series approach rather than a control group. A commenter recommended voluntary participation with a 10 percent reimbursement lift to allow participants to ramp up for the program and have the internal administrative and clinical operations necessary to support and succeed in the Model.

These commenters provided a variety of reasons for their recommendations of a voluntary, phase in approach to the RO Model. A commenter believed this approach would promote an equitable opportunity for success and ensure accurate and useful results from the Model. Another commenter believed this process would allow practices to transition to the coding and billing requirements and allow time to build infrastructures to collect data. A couple of commenters stated that this approach would support CMS' objectives, as well as allow CMS to build the infrastructure to administer this program effectively and to then scale it as additional participants joined. A few commenters suggested that this approach would be more consistent with the processes that previous CMS models have followed. One of these commenters stated that this approach would provide participants with more feasible pathways to value-based payment by allowing for flexibility and time to adjust practice patterns to best meet the Model's requirements. Another commenter stated that this process would be fairer to providers and suppliers that are currently unprepared to participate, and would avoid penalties on participants that are unequipped to provide value-based care and require additional time to prepare a plan for a successful transformation.

Response: We appreciate commenters' suggested alternatives to mandatory participation for the RO Model. However, as explained in the proposed rule (84 FR 34493 through 34496) and in this final rule, we believe that if the Model is voluntary for all RT providers and RT suppliers or allow for a phased-in approach, then we will face complications in our ability to accurately evaluate the RO Model.

Regarding the comment about voluntary participation with a 10 percent reimbursement lift to allow participants to ramp up for the program and have the internal administrative and clinical operations necessary to support and succeed in the Model, we believe, although we are not sure as more detail was not provided by the commenter, that the commenter is suggesting that payments be increased for participants by 10 percent. We would like to note that we would not be able to maintain or reduce costs under this type of design.

Regarding the comment suggesting that we implement the Model nationally as a voluntary model and utilize the approach of evaluating the impact through an interrupted time series approach rather than a control group, as discussed throughout this section of the final rule, we maintain that the mandatory design for the RO Model is necessary. We have decided not to use an interrupted time series design for the RO Model because the use of a comparison group not exposed to the intervention improves our ability to make causal inferences. A time series analysis is only necessary in circumstances when a comparison group does not exist, and under the RO Model, a control group of nonparticipants will exist.

While we will not allow for voluntary participation for the Model, after considering the concerns raised by the commenters, including potential financial hardship for practices under the RO Model, we are modifying the proposed policy to include an opt-out option for RT providers and RT suppliers that are low volume (see section III.C.3.c of this final rule for additional information). While we appreciate the commenters' suggestions to employ a phase in process for the RO Model, we believe that allowing a phase in process for participants would create a selection bias in the early years of the Model that would hinder robust evaluation. As we stated in the proposed rule and in this final rule, actuarial analysis suggests that the difference in estimated price updates for rates in the OPPS and PFS systems from 2019 through 2023, in which the OPPS rates are expected to increase substantially more than PFS rates, would result in few to no HOPDs electing to voluntarily participate in the Model. These actuarial estimates also suggest that freestanding radiation therapy centers with historically lower RT costs compared to the national average would most likely choose to participate, but those with historically higher costs would be less likely to volunteer to participate. Therefore, we believe that requiring participation in the RO Model, without a voluntary phase in option, is necessary to ensure sufficient proportional participation of both HOPDs and freestanding radiation therapy centers, and obtain a diverse, representative sample of RT providers and RT suppliers that will allow a statistically robust test of the prospective episode payments made under the RO Model.

Comment: Some commenters questioned CMS' statutory authority to implement the RO Model using section 1115A of the Act. A few of these commenters stated that the proposal requiring mandatory participation of approximately 40 percent of radiation oncology episodes represents a major policy change, and not a test of payment and service delivery models, which is what CMS is authorized to do in section 1115A of the Act. A few commenters stated that Innovation Center models should be implemented on a voluntary basis as the statute does not authorize

CMS to mandate participation in any Innovation Center model, and any agency interpretation that the statute permits mandatory models raises issues of impermissible delegation of lawmaking authority where none was intended and is inconsistent with the expressed mandate of section 1115A. A commenter stated that making the Model a mandatory requirement could be found potentially unlawful and is unprecedented. A commenter surmised that the RO Model was not developed by the Innovation Center, that the Secretary does not have the authority to waive Medicare provisions or any requirements of the Medicare statute under the RO Model, and that the RO Model violates section 3601 of the Patient Protection and Affordable Care Act (''the ACA'').

Response: We disagree with these commenters. The Innovation Center designed and developed the RO Model, and we will be testing the RO Model, consistent with section 1115A of the Act. We believe that we have the legal authority to test the RO Model and to require the participation of all RT providers and RT suppliers in the CBSAs selected for participation, and that this does not constitute an impermissible delegation of lawmaking authority that is inconsistent with section 1115A of the Act. First, we note that the RO Model will not be the first Innovation Center model that requires participation under the authority of section 1115A of the Act; we refer readers to the Comprehensive Care for Joint Replacement (CJR) Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services Final Rules, and the Home Health Prospective Payment System (HHPPS) Final Rules implementing the Home Health Value-Based Purchasing (HHVBP) Model. Hospitals in selected Metropolitan Statistical Area (MSAs) were required to participate in the CJR Model beginning in April 2016, and home health agencies in selected states were required to participate in the HHVBP Model beginning in January 2016.

We believe that both section 1115A of the Act and the Secretary's existing authority to operate the Medicare program authorize us to finalize mandatory participation in the RO Model as we have proposed. Section 1115A of the Act authorizes the Secretary to test payment and service delivery models intended to reduce Medicare costs while preserving quality of care. The statute does not require that models be voluntary, but rather gives the Secretary broad discretion to design and test models that meet certain requirements as to spending and quality. Although section 1115A(b) of the Act describes a number of payment and service delivery models that the Secretary may choose to test, the Secretary is not limited to those models. Rather, as specified in section 1115A(b)(1) of the Act, models to be tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. Here, the RO Model addresses a defined population (FFS Medicare beneficiaries who receive included RT services) for which there are potentially avoidable expenditures (arising from the lack of site neutrality for payments, incentives that encourage volume of services over the value of services, and coding and payment challenges in the PFS). We designed the RO Model to require participation by RT providers and RT suppliers in order to avoid the selection bias inherent to any model in which providers and suppliers may choose whether or not to participate. Such a design will ensure sufficient proportional participation of both HOPDs and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers and RT suppliers that will allow a statistically robust test of the prospective episode payments made under the RO Model. We believe this is the most prudent approach for the following reasons. Under the mandatory RO Model, we will test and evaluate a Model across a wide range of RT providers and RT suppliers, representing varying degrees of experience with episode payment. The information gained from testing the mandatory RO Model will allow CMS to comprehensively assess whether RO episode payments are appropriate for a potential expansion in duration or scope, including on a nationwide basis. Thus, the RO Model meets the criteria required for Phase I model tests.

Moreover, the Secretary has the authority to establish regulations to carry out the administration of Medicare. Specifically, the Secretary has authority under sections 1102 and 1871 of the Act to implement regulations as necessary to administer Medicare, including testing this Medicare payment and service delivery model. We note that the RO Model is not a permanent feature of the Medicare program; the Model will test different methods for delivering and paying for services covered under the Medicare program, which the Secretary has clear legal authority to regulate. The proposed rule went into detail about the provisions of the proposed RO Model, enabling the public to understand how the proposed Model was designed and could apply to affected RT providers and RT suppliers. As permitted by section 1115A of the Act, we are testing the RO Model within specified limited geographic areas. The fact that the Model will require the participation of certain RT providers and RT suppliers does not mean it is not a Phase I Model test. If the Model test meets the statutory requirements for expansion, and the Secretary determines that expansion is appropriate, we would undertake rulemaking to implement the expansion of the scope or duration of the Model to additional geographic areas or for additional time periods, as required by section 1115A(c) of the Act.

Furthermore, we wholeheartedly disagree that the RO Model is in violation of section 3601 of the ACA. Section 3601 of the ACA requires that nothing in the provisions of or amendments to the ACA, including models being designed and tested by the Innovation Center, may result in a reduction of guaranteed Medicare benefits. The RO Model is designed not to result in a reduction of guaranteed Medicare benefits, and in fact as finalized in section II.D.2 and codified at § 512.120(b)(1), we are specifically requiring RO participants to continue to make medically necessary covered services available to beneficiaries to the extent required by law. Further, we will monitor compliance with the Model requirements through monitoring activities that may include documentation requests sent to RO participants and individual practitioners on the individual practitioner list; audits of claims data, quality measures, medical records, and other data from RO participants and clinicians on the individual practitioner list; interviews with members of the staff and leadership of the RO participants and clinicians on the individual practitioner list; interviews with beneficiaries and their caregivers; site visits; monitoring quality outcomes and clinical data, if applicable; and tracking patient complaints and appeals. Please see section III.C.14 of this final rule for further discussion on monitoring activities.

After considering public comments, we are finalizing our proposal for mandatory participation with modification. Specifically, we are codifying at § 512.210(a) that any Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD, unless otherwise specified at § 512.210(b) or (c), that furnishes included RT services in a 5-digit ZIP

Code linked to a CBSA selected for participation to an RO beneficiary for an RO episode that begins on or after January 1, 2021, and ends on or before December 31, 2025, must participate in the RO Model.

Further, after considering the concerns raised by the commenters regarding the mandatory nature of the RO Model, we are finalizing required participation for all RT providers and RT suppliers located within the CBSAs selected for participation, with the modification that the Model size will be reduced to approximately 30 percent of eligible episodes in eligible CBSAs (see section III.C.5 of this final rule), and with an inclusion of a low volume opt-out for any PGP, freestanding radiation therapy center, or HOPD that furnishes fewer than 20 episodes in one or more of the CBSAs randomly selected for participation in the most recent year with claims data available (see section III.C.3.c of this final rule). We believe that these modifications address some of the commenters' concerns regarding the mandatory nature of the RO Model, including those relating to potential financial hardship as well as the size and scope of the Model (see section III.C.3.d of this final rule for more information).

As stated in the proposed rule and in this final rule, we believe that by requiring the participation of RT providers and RT suppliers, we would have access to more complete evidence of the impact of the Model. We also believe that a representative sample of RT providers and RT suppliers would result in a robust data set for evaluation of this prospective payment approach, and would stimulate the development of new evidence-based knowledge. Testing the Model in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for RT services. This learning could potentially inform future Medicare payment policy. Therefore, we are finalizing as proposed the selection of a broad, representative sample of RT providers and RT suppliers in multiple geographic areas (see 84 FR 34495 through 34496, and section III.C.3.d. of this final rule for a discussion regarding the Geographic Unit of Selection) for RO Model participation. However, in response to comments, we are reducing the scale of the RO Model from the proposed approximately 40 percent of episodes to approximately 30 percent of eligible episodes (please reference section III.C.3.d. of this final rule for more information).

We have determined that the best method for obtaining the necessary diverse, representative group of RT providers and RT suppliers is random selection. This is because a randomly selected sample would provide analytic results that will be more generally applicable to all Medicare FFS RT providers and RT suppliers and will allow for a more robust evaluation of the Model. As we explained in the proposed rule and in this final rule, because actuarial analysis suggests that the difference in estimated price updates for rates in the OPPS and PFS systems from 2019 through 2023, in which the OPPS rates are expected to increase substantially more than PFS rates, would result in few to no HOPDs electing to voluntarily participate in the Model and that freestanding radiation therapy centers with historically lower RT costs compared to the national average would most likely choose to participate, but those with historically higher costs would be less likely to voluntarily participate, we believe that requiring participation in the RO Model will ensure sufficient proportional participation of both HOPDs and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers and RT suppliers that will allow a statistically robust test of the prospective episode payments made under the RO Model.

For the previously identified reasons, we believe that a mandatory model design would be the best way to improve our ability to detect and observe the impact of the prospective episode payments made under the RO Model. We therefore are finalizing our proposal with modification that participation in the RO Model will be mandatory.

b. RO Model Participants

An RO participant, a term that we defined in the proposed rule at § 512.205, would be a Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that is required to participate in the RO Model pursuant to § 512.210 of the proposed rule. As discussed in the proposed rule at 84 FR 34494 through 34495, an RO participant would participate in the Model as a Professional participant, Technical participant, or Dual participant.

In the proposed rule, we proposed to define the term ''Professional participant'' as an RO participant that is a Medicare-enrolled physician group practice (PGP), identified by a single Taxpayer Identification Number (TIN) that furnishes only the professional component of RT services at either a freestanding radiation therapy center or an HOPD. We proposed at 84 FR 34494 that Professional participants would be required annually to attest to the accuracy of an individual practitioner list provided by CMS, of all of the eligible clinicians who furnish care under the Professional participant's TIN, as discussed in section III.C.9 of this final rule. We proposed to define the term ''individual practitioner'' to mean a Medicare-enrolled physician (identified by an NPI) who furnishes RT services to Medicare FFS beneficiaries, and have reassigned his/her billing rights to the TIN of an RO participant (84 FR 34494). We further proposed that an individual practitioner under the RO Model would be considered a downstream participant, as discussed in section II.B. of the proposed rule and this final rule.

We proposed at 84 FR 34494 to define the term ''Technical participant'' to mean an RO participant that is a Medicare-enrolled HOPD or freestanding radiation therapy center, identified by a single CMS Certification Number (CCN) or TIN, which furnishes only the technical component of RT services. Finally, we proposed at 84 FR 34494 to define ''Dual participant'' to mean an RO participant that furnishes both the professional component and technical component of an episode for RT services through a freestanding radiation therapy center, identified by a single TIN. We proposed to codify the terms ''Professional participant,'' ''Technical participant,'' ''Dual participant'' and ''individual practitioner'' at § 512.205.

We also explained in the proposed rule at 84 FR 34494 that an RO participant would furnish at least one component of an episode, which would have two components: A professional component and a technical component. We proposed to define the term ''professional component (PC)'' to mean the included RT services that may only be furnished by a physician. We proposed to define the term ''technical component (TC)'' to mean the included RT services that are not furnished by a physician, including the provision of equipment, supplies, personnel, and costs related to RT services. (See section III.C.5.c of the proposed rule at 84 FR 34494 through for a discussion regarding our proposed included RT services.) We proposed to codify the terms ''professional component (PC)'' and ''technical component (TC)'' at § 512.205 of the proposed rule.

In the proposed rule, we proposed that an episode of RT under the RO Model would be furnished by either: (1) Two separate RO participants, that is, a

Professional participant that furnishes only the PC of an episode, and a Technical participant that furnishes only the TC of an episode; or (2) a Dual participant that furnishes both the PC and TC of an episode. For example, if a PGP furnishes only the PC of an episode at an HOPD that furnishes the TC of an episode, then the PGP would be a Professional participant and the HOPD would be a Technical participant. In other words, the PGP and HOPD would furnish separate components of the same episode and would be separate participants under the Model.

The following is a summary of the public comments received on these proposed definitions related to RO participants and our responses to those comments:

Comment: A commenter supported these key participant distinctions, appreciated that CMS recognized that RT services can be delivered at different sites of service, and stated that this participant construct lends itself well to the establishment of separate professional and technical payment components.

Response: We appreciate this commenter's support on our proposed definitions for the Professional, Technical, and Dual participants in the RO Model.

Comment: A commenter requested clarification on how RO participants will be defined if there are multiple sites of service during an episode. This commenter provided an example where a physician delivers EBRT in a freestanding setting and then chooses to deliver brachytherapy in the hospital outpatient department (HOPD) setting. This commenter asked whether the physician in this example would be considered a Dual participant such that there would be no technical component payment issued to the HOPD. This commenter suggested that CMS should provide clarification regarding how these types of situations will be handled and reimbursed within the Model.

Response: As stated in the proposed rule at 84 FR 34494, a Professional participant is an RO participant that is a Medicare-enrolled physician group practice (PGP), identified by a single Taxpayer Identification Number (TIN) that furnishes only the professional component of RT services at either a freestanding radiation therapy center or an HOPD. A Technical participant is an RO participant that is a Medicare-enrolled HOPD or freestanding radiation therapy center, identified by a single CMS Certification Number (CCN) or TIN, which furnishes only the technical component of RT services. A Dual participant is an RO participant that furnishes both the professional component and technical component of an RO episode for RT services through a freestanding radiation therapy center, identified by a single TIN. Professional participant, Technical participant and Dual participant are similar to the proposed definitions, RT provider and RT supplier. In the proposed rule, an RT provider is defined as a Medicare-enrolled HOPD that furnished RT service in a 5-digit ZIP Code linked to a CBSA selected to participate, and an RT supplier is defined as a Medicare –enrolled PGP or freestanding radiation therapy center that furnishes RT services in a 5-digit ZIP Code linked to a CBSA selected to participate. These definitions taken together with other proposed definitions, RO participant, Professional participant, Technical participant and Dual participant, are duplicative. For clarification, we are finalizing proposed definitions for the Professional, Technical, and Dual participants in the RO Model without modification, and finalizing the proposed definitions for RT provider and RT supplier with modification. RT provider will mean any Medicare-enrolled HOPD that furnishes RT services and RT supplier will mean any Medicare-enrolled PGP or freestanding radiation therapy center that furnishes RT services.

As for the specific example the commenter presented, the freestanding radiation therapy center would be considered a Dual Participant for delivery of EBRT, and the HOPD delivering brachytherapy would bill traditional Medicare fee-for-service as described in section III.C.7. In the example described, FFS payments made to the HOPD would be considered duplicate payments during reconciliation as described in section III.C.11.

Comment: Some commenters were concerned with the possibility that health systems could have some of their practices participating in the RO Model and their remaining practices operating outside of the Model. These commenters stated that it is common for large health systems to have a single TIN covering multiple locations, and that the proposed RO Model design could allow practices within the same health system to fall into different CBSAs. This may cause challenges for both RT providers and RT suppliers and patients as well as cause avoidable complexity in rare situations where patients shift between care locations. These commenters, therefore, recommended that CMS make accommodations for health systems with multiple sites, where practices that span multiple CBSA's with a single TIN can request to opt-in or opt-out of the Model.

Response: We recognize that this scenario could occur where practices under the same TIN could fall into different CBSAs whereas some are either in the Model and others are out of the Model. As stated in the proposed rule in section III.C.3.d (84 FR 34495 through 34496), we are using CBSAs as the geographic unit of selection for the RO Model for various reasons, including that CBSAs are large enough to reduce the number of RO participants in close proximity to other RT providers and RT suppliers that would not be required to participate in the Model. As we have chosen the method of using randomly selected stratified CBSAs in the RO Model, it is unavoidable that some practices within the same TIN may fall into different CBSAs, though we anticipate that the numbers will be limited. As noted in the commenters' letters, situations where a beneficiary changes treatment locations is rare in radiation oncology, and we believe that our billing policies would allow sufficient flexibility to accommodate these uncommon instances, where the first treatment provider or supplier would be paid through the Model and a subsequent provider or supplier would bill FFS. We appreciate the commenters' concerns on this matter, and we will monitor this situation for any issues or complications that may arise from this policy.

After considering public comments, we are finalizing our proposed provisions on the RO Model participant definitions without change. Specifically, we will codify at § 512.205 to define an RO participant as a Medicare-enrolled physician group practice (PGP), freestanding radiation therapy center, or HOPD that is required to participate in the RO Model pursuant to § 512.210. We are further finalizing our proposal to define the term ''Professional participant'' at § 512.205 as an RO participant that is a Medicare-enrolled PGP identified by a single Taxpayer Identification Number (TIN) that furnishes only the professional component of an RO episode. We are also finalizing our proposal define the term ''Technical participant'' at § 512.205 to mean an RO participant that is a Medicare-enrolled HOPD or freestanding radiation therapy center, identified by a single CMS Certification Number (CCN) or TIN, which furnishes only the technical component of an episode. Finally, we are finalizing our proposal to define ''Dual participant'' at § 512.205 to mean an RO participant that furnishes both the professional component and technical component of

an RO episode through a freestanding radiation therapy center, identified by a single TIN.

c. RO Model Participant Exclusions

In the proposed rule at 84 FR 34493 through 34494, we proposed to exclude from RO Model participation any PGP, freestanding radiation therapy center, or HOPD that—

- Furnishes RT only in Maryland;
- Furnishes RT only in Vermont;
- Furnishes RT only in U.S. Territories;
- Is classified as an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or
- Participates in or is identified as eligible to participate in the Pennsylvania Rural Health Model.

The proposed rule specified that these exclusion criteria would apply during the entire Model performance period. If an RO participant undergoes changes such that one or more of the exclusion criteria becomes applicable to the RO participant during the Model performance period, then that RO participant would be excluded from the RO Model (that is, it would no longer be an RO participant subject to inclusion criteria). For example, if an RO participant moves its only service location [25] from a CBSA randomly selected for participation in Virginia to Maryland, it would be excluded from the RO Model from the date of its location change. Conversely, if a PGP, freestanding radiation therapy center, or HOPD satisfies the exclusion criteria when the Model begins, and subsequently experiences a change such that the exclusion criteria no longer apply and the PGP, freestanding radiation therapy center, or HOPD is located in one of the CBSAs selected for participation, then participation in the RO Model would be required. For example, if an HOPD is no longer classified as a PPS-exempt hospital and the HOPD is located in one of the CBSAs selected for participation, then the HOPD would become an RO participant from the date that the HOPD became no longer classified as a PPS-exempt hospital.

We proposed that in the case of Professional participants and Dual participants, any episodes in which the initial RT treatment planning service is furnished to an RO beneficiary on or after the day of this change would be included in the Model. In the case of Technical participants, any episodes where the RT service is furnished within 28 days of a RT treatment planning service for an RO beneficiary and the RT service is furnished on or after the day of this change would be included in the Model.

We proposed to exclude RT providers and RT suppliers in Maryland due to the unique statewide payment model being tested there (the Maryland Total Cost of Care Model), in which Maryland hospitals receive a global budget. We noted in the proposed rule that this global budget includes payment for RT services and as such would overlap with the RO Model payment. Thus, we proposed to exclude Maryland HOPDs to avoid double payment for the same services. We proposed to extend the exclusion to all RT providers and RT suppliers in Maryland to avoid creating a gaming opportunity where certain beneficiaries could be shifted away from PGPs and freestanding centers to HOPDs.

In the proposed rule, we proposed to exclude RT providers and RT suppliers in Vermont due to the Vermont All-Payer ACO Model, which is a statewide model in which all-inclusive population-based payments (AIPBPs) are currently made to the participating ACO for Medicare FFS services furnished by all participating HOPDs and an increasing number of participating PGPs. Given the scope of this model as statewide and inclusive of all significant payers, we explained in the proposed rule that we believe excluding RT providers and RT suppliers in Vermont from the RO Model is appropriate to avoid any potential interference with the testing of the Vermont All-Payer ACO Model.

We also proposed to exclude HOPDs that are participating in or eligible to participate in the Pennsylvania Rural Health Model from the RO Model. Hospitals and CAHs that are participating in the Pennsylvania Rural Health Model receive a global budget, much like hospitals participating in the Maryland Total Cost of Care Model. Further, we proposed to extend the exclusion to HOPDs that are eligible to participate in the Pennsylvania Rural Health Model because additional hospitals and CAHs may join that model in the future or may be included in the evaluation comparison group for that model. We stated in the proposed rule that we would identify the hospitals and CAHs that are participating in or are eligible to participate in the Pennsylvania Rural Health Model on a list to be updated quarterly and made available on the Pennsylvania Rural Health Model's website at *https://innovation.cms.gov/initiatives/pa-rural-health-model/.*

We designed the proposed RO Model to test whether prospective episode payments in lieu of traditional FFS payments for RT services would reduce Medicare expenditures by providing savings for Medicare while preserving or enhancing quality. In the proposed rule, we discussed our belief that it would be inappropriate to include these entities for the reasons previously described. Also, we proposed to exclude ASCs and RT providers and RT suppliers located in the U.S. Territories, at § 512.210, due to the low volume of RT services that they provide. In addition, we proposed to exclude CAHs and PPS-exempt cancer hospitals due to the differences in how they are paid by Medicare.

As a result, we proposed that RT services furnished by these RT providers and RT suppliers would be excluded from the RO Model. We also stated that if in the future we determine that providers and suppliers in these categories should be included in the RO Model, we would revise our inclusion criteria through rulemaking.

We proposed to codify these policies at § 512.210 of our regulations. We solicited comments on the proposals related to RO participant exclusions. The following is a summary of the comments received on these proposals and our responses to those comments:

Comment: A commenter supported CMS' decision to exclude from the Model providers and suppliers that furnish RT services only in Maryland, Vermont, or U.S. Territories; that are participating in or eligible to participate in the Pennsylvania Rural Health Model; or that are classified as an ambulatory surgery center, CAH, or PPS-exempt cancer hospital.

Response: We thank this commenter for the support on our proposed exclusions from the RO Model; we are finalizing these exclusions without modification.

We would like to clarify that we recognize HOPDs are not standalone institutions and, as such, may not, independent of a hospital or CAH, participate in or be eligible for participation in the Pennsylvania Rural Health Model. We will use the list on the Pennsylvania Rural Health Model's website at *https://innovation.cms.gov/initiatives/pa-rural-health-model/,* which is updated quarterly, to identify the hospitals and CAHs eligible to participate in the Pennsylvania Rural Health Model, and therefore identify the specific HOPDs that are excluded from participation in the RO Model. We would also like to clarify that this

[25] Service location means the site of service in which an RO Participant or any RT provider or RT supplier furnishes RT services.

exclusion of HOPDs associated with hospitals and CAHs eligible to participate in the Pennsylvania Rural Health Model from the RO Model will apply only during the period of such eligibility. If the Pennsylvania Rural Health Model is terminated or if the HOPD is no longer eligible to participate in the Pennsylvania Rural Health Model as part of an eligible hospital or CAH, and the HOPD otherwise meets the definition of an RO participant, then the HOPD will be required to participate in the RO Model.

Comment: A commenter supported CMS' decision to exclude CAHs from the RO Model, and stated that they appreciated CMS' recognition of the potential negative impact the Model could have on CAHs. This commenter also requested that CMS clarify whether a clinician who provides cancer treatment services at a CAH would be considered a Professional participant under the RO Model. This commenter also suggested that CMS ensure that the technical and professional services are aligned, and further recommended that if a treatment center is excluded from the Model, then the clinicians providing services at that treatment center should also be excluded.

A few commenters requested clarification on CMS' proposed policy regarding an exclusion for PPS-exempt cancer hospitals (PCHs) in the Model. A commenter requested clarification on whether radiation oncology physicians who work for a PCH but bill under a practice TIN, would be considered a Professional or Dual participant.

Another commenter requested clarification on how the professional reimbursement will be handled for physicians practicing in a PCH, but not employed by that legal entity. The commenter asked for clarification on whether the physicians would also be exempt. This commenter further stated that the same physicians may also practice at other non-PCH, and it is not uncommon for radiation oncologists to rotate through multiple facilities in a given week, depending on the size of the physician practice and the number of facilities where they practice.

Response: To clarify, a physician who provides cancer treatment services at a CAH, PCH, or ASC, and also provides services in a freestanding radiation therapy center or HOPD that is located in a CBSA selected for participation, in addition to their services at a CAH, PCH, or ASC, will be considered either a Dual participant or Professional participant, respectively, under the RO Model. We also want to clarify that a physician who provides RT services at a PCH, regardless of their employment status at the PCH, and also provides only the professional component of an RO episode for RT services in a freestanding radiation therapy center or HOPD that is located in a CBSA selected for participation will be considered a Professional participant under the RO Model. Similarly, a physician who provides RT services at a PCH, and also furnishes both the professional component and technical component of an RO episode for RT services through a freestanding radiation therapy center, identified by a single TIN, will be considered a Dual participant under the RO Model. In contrast, a physician who provides RT services only at an exempt facility (PCH, CAH, or ASC) will not be an RO participant. RT services that are furnished at an exempt facility (PCH, CAH, or ASC) will be paid through FFS, while RO episodes that are furnished at a PGP, freestanding radiation therapy center, or HOPD that is in a CBSA selected for participation will be paid under the RO Model payment methodology.

Comment: A few commenters agreed with CMS' proposal to exclude from the Model PCHs, which some commenters also referred to as DRG-exempt cancer hospitals. A commenter agreed that PCHs should be excluded from the Model, and further requested that all of the physicians practicing in these PCHs be exempted from the RO Model because these physicians practice in the PCHs as well as eligible community practices and they all bill under the same TIN. The commenter indicated that this would complicate data submission and analysis as well as billing practices. A couple of commenters suggested that CMS expand the exclusion list to include all National Cancer Institute (NCI) Designated Comprehensive Cancer Centers. One of these commenters stated that this policy would align with CMS' proposal to exempt PCHs. Another commenter stated that NCI-designated centers deliver innovative cancer treatments to patients in communities across the United States, and dedicate significant resources toward developing multidisciplinary programs and facilities that lead to better and innovative approaches to cancer prevention, diagnosis, and treatment. This commenter stated that introducing an APM based on complex calculations and historical rates would represent a significant burden that would negatively impact the innovation and discovery missions of NCI-designated centers.

Response: We appreciate these commenters' support of our proposal to exclude PCHs from the RO Model. With regard to the comment requesting that all physicians practicing in a PCH be exempted from the RO Model because these physicians practice in the PCHs as well as eligible community practices and they all bill under the same TIN, we would like to clarify that the physicians will be exempted from the RO Model if they only provide RT services at a PCH. However, if the physician also provides RT services at any other freestanding radiation therapy center and/or HOPD that is included in a CBSA selected for participation, they will be considered a Dual participant and/or Professional participant under the RO Model. We disagree with commenters' requests to expand the PCH exclusion list to include all National Cancer Institute (NCI) Designated Comprehensive Cancer Centers as PCHs are reimbursed on a ''reasonable cost'' basis instead of the OPPS FFS methodology, and we are excluding entities that are paid via reasonable cost or cost-reporting, and including all HOPDs that are currently paid through the OPPS/FFS methodology. Thus, we will be finalizing our policy as proposed and without modification to exclude from the RO Model any PGP, freestanding radiation therapy center, or HOPD that is classified as a PCH. However, the RO Model will include PGPs, freestanding radiation therapy centers and HOPDs that are paid under FFS.

Comment: Conversely, some commenters disagreed with the proposal to exclude PCHs from the Model. Of those who disagreed, a couple of commenters stated that PCHs should be incentivized to reduce costs, and pointed to a Government Accountability Office (GAO) report that advised that the payment method for PCHs should be revised to promote efficiency and reduce costs to Medicare. Another commenter inquired why PCHs are exempted when they are among the best resourced institutions and are considered high cost centers due to emerging technologies. Another commenter sought clarification on why CMS decided to exclude a set of RT providers and RT suppliers that specifically treat the targeted conditions in the RO Model, and stated that the largest cancer treatment centers should not be excluded from a model that seeks to address utilization for cancer services. Another commenter stated that it is difficult to understand why PCHs would be excluded from the RO Model on the basis of payment methodology when payment methodology is the primary basis of the Model. Another commenter stated the 11 PCH have large amounts of grant money, have many staff, and receive significant Medicare

payments, and accordingly should be included in the Model. A commenter stated that the 11 PCHs should not be excluded from Model because these hospitals have developed financial relationships with many community hospitals that give those hospitals both a financial and a marketing advantage. This commenter stated that if a CBSA is selected for participation and has one of these exempt hospitals, that facility will have a significant advantage over the other sites of service in that area, and this would allow that facility to more heavily market and to purchase upgraded equipment, which would threaten the viability of other programs and decrease access and choice for Medicare beneficiaries needing RT services.

Response: The RO Model is designed to test whether prospective episode payments in lieu of traditional FFS payments for RT services would reduce Medicare expenditures by providing savings for Medicare while preserving or enhancing quality of care. We proposed to exclude PCHs because of the differences in how these hospitals are paid by Medicare. That is, they are not paid through traditional FFS payments (see, generally, the Social Security Amendments of 1983 (Pub. L. 98–21), the Balanced Budget Act of 1997 (Pub. L. 105–33), and the Omnibus Reconciliation Act of 1989 (Pub. L. 101–239)), and the RO Model is designed to test and evaluate the change from traditional FFS payments to prospective episode based payments. Regarding the commenter's concern about PCHs and their community hospital partners potentially having a financial and marketing advantage, we will monitor the Model for the occurrence of any such advantages, by monitoring for changes in referral patterns. Based on this monitoring, if we determine to modify the excluded categories of RT providers and RT suppliers, including PCHs, we would revise the RO Model inclusion criteria through future notice-and-comment rulemaking. Therefore, we are finalizing our policy as proposed without modification to exclude from RO Model participation any PGP, freestanding radiation therapy center or HOPD that is classified as a PPS-exempt cancer hospital.

Comment: A commenter suggested that CMS should exclude sole community hospitals (SCH) and Medicare dependent hospitals (MDH). These hospitals are generally rural, small, and highly dependent on Medicare and/or Medicaid funding. This commenter does not believe it would be appropriate to include these hospitals in the RO Model as it could significantly impact the financial viability of these hospitals or lead to a reduction in available services for the community.

Response: We did not propose to exclude MDH or SCH entities from the RO Model because, unlike CAHs, these entities are full service hospitals. If MDH and SCH entities believe they qualify for the RO Model's low volume opt-out option, please reference the discussion on the low volume opt-out option in this section of the final rule for more information. We will monitor the extent to which these hospitals are selected for participation in the Model, and we will monitor the impact the RO Model may have on these types of entities.

Comment: A commenter requested an exemption to the RO Model for practices that serve socioeconomically disadvantaged populations. This commenter stated that these practices tend to have higher costs of care because patients present with advanced stages of disease often due to the lack of access to preventative services, and these practices should not be penalized due to circumstances that are out of their control.

Response: We did not propose to exclude practices that serve socioeconomically disadvantaged populations, and we will not be creating an exemption of this nature at this time. While we understand the commenter's concern, we believe that the RO Model pricing methodology, through the historical experience and case mix adjustments, will account for differences in RO participants' historical care patterns and the demographic characteristics of their patient populations. We will monitor the effect that the RO Model may have on RO participants that serve these populations.

Comment: Many commenters stated that a mandatory RO Model will present operational, administrative, and financial challenges for many RT providers and RT suppliers, and therefore requested a low-volume or hardship exemption to allow participants to opt out of the RO Model. Many commenters disagreed with CMS' decision to not include a model participation hardship exemption for any providers or suppliers, and requested an exemption from Model participation specifically for low-volume providers and suppliers. These commenters argued that failure to include a low-volume exemption could result in unintended consequences, such as smaller providers and suppliers incurring significant financial losses and potentially ending their programs due to lower payment through the RO Model. Additionally, some of these commenters suggested that that the RO Model should be limited to large groups (30 physicians or more), and that the Model should be limited to large hospitals with employed physicians.

A couple of commenters stated that a low-volume exemption is critical in a shared risk-based model of care, and should therefore be included in the RO Model. Another commenter supported CMS' proposal to exclude ASCs and RT providers and suppliers located in the U.S. Territories due to the low volume of RT services that they provide because of the commenter's belief that such providers and suppliers lack the infrastructure and support to achieve efficiencies. However, the commenter requested that CMS fully exclude from the Model providers and suppliers who furnished fewer than 60 attributed episodes during the 2015–2017 period, rather than just making adjustments to their episode payments. This commenter further stated that its analysis found that there is considerable variation in episode spending relative to payment amounts for providers and suppliers that perform a very low volume of RT, and the commenter maintained that this analysis suggests that episode pricing for these providers and suppliers would be highly random and, therefore, very difficult to manage. The commenter finally concluded that excluding these and other low-volume providers and suppliers would have a minimal impact on the RO Model test, but doing so would prevent these providers and suppliers from being inappropriately penalized by being required to participate in the Model.

Response: We appreciate the commenters' comments and feedback regarding low-volume entities under the RO Model. We understand the commenters' concerns regarding administrative, financial, and infrastructural challenges for low-volume providers and suppliers under the RO Model. In response to stakeholder comments, we are finalizing our mandatory participation proposal, with a modification for an opt-out option for low-volume entities, which we are codifying at § 512.210(c). This option allows any PGP, freestanding radiation therapy center, or HOPD to opt-out of the RO Model, if in the most recent calendar year with episode data available, the entity furnishes fewer than 20 episodes in one or more of the CBSAs randomly selected for participation. Please reference the end of this section for more information on the low volume opt-out option.

Regarding the commenters suggested that that the RO Model should be limited to large groups (30 physicians or more), we would like to note that most RT providers and suppliers have fewer than 30 oncologists, so this number would not provide a feasible threshold for the RO Model.

We agree in part with the commenter who suggested that we add an exclusion of entities with fewer than 60 episodes over the full baseline period of three years. We are focusing on entities with fewer than 20 episodes in the most recent year with available claims data, and we believe this corresponds with this commenter's suggestion. However, instead of excluding such entities, we believe that allowing entities with fewer than 20 episodes to opt-out achieves the right balance of allowing very small entities to opt-out if they believe the burden from participation in the Model would outweigh the possibility of benefits from model participation (for example, potential for care improvements or increased payments), while also maintaining a variety of participant types in the RO Model to promote generalizability (to the extent possible) of any impact results. Further, as discussed in section III.C.6.e(4), we do not apply adjustments to RO participant episode payments for participants that have less than 60 episodes in the last three years of data. Thus, the opt-out option for entities with fewer than 20 episodes aligns with the threshold set for the historical experience and case mix adjustments. The low volume opt-out option is intended to allow RO participants furnishing a small volume of RT services in the CBSAs selected for participation in the Model to opt out if they so choose given the investment required to implement the Model versus the benefit of participating in the Model for a limited frequency of RT services.

Comment: Some commenters suggested that CMS apply the MIPS low-volume threshold or the CJR Model low-volume exemption as low-volume participation thresholds for mandatory RO Model participation.

Response: For the 2020 MIPS performance period, the MIPS low-volume threshold excludes from the definition of a MIPS eligible clinician an individual eligible clinician, group, or APM Entity group that, during the MIPS determination period (consisting of two 12-month segments during 10/1/18–9/30/19 and 10/1/19–9/30/20), has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B–enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B–enrolled individuals. RT providers and RT suppliers tend to see smaller numbers of patients but at a higher price per patient than the average MIPS eligible clinician. Therefore, we estimate that using the MIPS low-volume threshold as a threshold for mandatory participation in the RO Model would result in a nearly 50 percent reduction in the number of RO participants. As stated in section III.C.3.d of this final rule, the number of RO participants must remain above a certain level in order to maintain statistical power for Model evaluation, and to generate sufficient savings. We are finalizing our mandatory participation proposal, with a modification for an opt-out option for low-volume entities as described in this final rule. Similar to the CJR Model's policy, this option would allow any PGP, freestanding radiation therapy center, or HOPD that furnishes fewer than 20 episodes in the most recent year with available claims data within one or more of the CBSAs randomly selected for participation to opt-out of the RO Model, if they so choose. For more information on this final policy please see this section of this rule. There are notable differences between the CJR and RO Models' low volume opt-out options. The CJR Model's low-volume policy was a one-time opt-in option for participants, while the RO Model will make the low volume opt-out option available to eligible participants annually, prior to each year of the Model.

After considering public comments, we are finalizing, with one modification, our proposed provisions on RO Model participant exclusions. As proposed, we are finalizing our policy, and codifying at § 512.210(b), to exclude from RO Model participation any PGP, freestanding radiation therapy center, or HOPD that furnishes RT services only in Maryland; furnishes RT services only in Vermont; furnishes RT services only in U.S. Territories; is classified as an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or participates in or is identified by CMS as eligible to participate in the Pennsylvania Rural Health Model.

In response to public comments, we are finalizing with one modification our proposal regarding mandatory participation in the Model. A PGP, freestanding radiation therapy center, or HOPD which would otherwise be required to participate in the RO Model under § 512.210(a) may choose to opt-out of the RO Model on an annual basis if the PGP, freestanding radiation therapy center, or HOPD furnishes fewer than 20 episodes across all CBSAs selected for participation in the most recent calendar year with available claims data. We are codifying this modified policy at § 512.210(c) of the final rule.

Each RO participant's episode volume will be assessed at the TIN and CCN level across all CBSAs randomly selected for participation, not according to how many episodes an RO participant furnishes in a single CBSA. For example, if an RO participant furnished 30 episodes in two different CBSAs and both CBSAs are selected for participation in the Model, then the RO participant would not be eligible for the low volume opt-out option, even if the RO participant furnished fewer than 20 episodes in each of those CBSAs. If, however, an RO participant only furnished 15 episodes in only one CBSA selected to participate in the Model, then this RO participant would be eligible for the low volume opt-out option.

RO participants that qualify for the low volume opt-out may still choose to participate in the Model, as our data show that many of these RT providers and RT suppliers may see increased payments (compared to historical payments) and improvements in quality of care under the RO Model despite having a low volume of episodes. Thus, we believe it is important to allow them the option of participating in the RO Model if they so choose.

Prior to the start of each RO Model PY, we will identify which RO participants would be eligible to opt out of the Model (including the RO Model payments and participation requirements) based on the most recently available claims data. For PY1 (January 1, 2021, through December 31, 2021), we will use 2019 episode data, for PY2 (January 1, 2022 through December 31, 2022), we will use 2020 episode data, and so on. The most current episode data is two years removed from the period to which it applies for two reasons. First, as described in the pricing methodology section in section C.III.6, if an RO episode straddles calendar years, the RO episode and its claims are counted in the calendar year for which the initial treatment planning service is furnished. This means that an RO episode could carry 89 days into the next performance year. Second, we will allow for at least one month of claims run-out after all RO episodes have been completed. A longer claims run-out is not necessary since the low volume opt-out is based on a count

of complete episodes and not on volume of services during those RO episodes. For these reasons, the most current episode data is two years removed from the period to which it applies. Broadening the assessment period to multiple years would even further remove the opt-out option from current practice patterns.

We will use only the most recent year with available claims data rather than a 3-year baseline to identify low-volume RO participants. This policy would allow us to better recognize low-volume RO participants over time and avoid creating a permanent opt out for new entities. At the same time, we want to minimize the possibility that RT providers and RT suppliers would have an incentive to create a new billing identifier each year to get out of the Model. Thus, we would monitor for this scenario by examining whether new TINs/CCNs in the Model geographic area have the same address as a previous TIN/CCN to ensure that our policy is serving its intent.

Eligibility for the opt-out option will be assessed annually. A participant may qualify for the opt-out option in one performance year, but not in another. At least 30 days prior to the start of each PY, we will notify participants eligible for the opt-out option as it concerns that upcoming PY. Those RO participants eligible to opt-out of the RO Model must attest to the intention of opting out of the Model prior to the start of the applicable PY (that is, on or before December 31 of the prior PY in which the opt-out would occur). We will provide further instructions on submitting this attestation through subregulatory channels of communication, such as model-specific webinars, and the RO Model website. This process would be repeated prior to each performance year of the Model. This could result in some RO participants being eligible for the opt-out option in some years and not others, that is, an RO participant could be able to opt out in one year and then be required to participate in the subsequent year. We will notify participants to remind them to verify their eligibility for the opt-out option prior to each performance year.

d. Geographic Unit of Selection

We proposed at 84 FR 34495 through 34496 that the geographic unit of selection for the RO Model would be OMB's Core-Based Statistical Areas (CBSAs). Due to geographic data limitations on Medicare claim submissions, we proposed to link RT providers and RT suppliers to a CBSA by using the five-digit ZIP Code of the location where RT services are furnished. This will permit us to identify RO participants (see section III.C.3.c of the proposed rule and this final rule for a discussion of RO Model participant exclusions for the RT providers and RT suppliers we proposed to exclude from this Model) while still using CBSA as a geographic unit of selection. We proposed to codify the term ''Core-Based Statistical Area (CBSA)'' at § 512.205 of our regulations.

The proposed rule explained that CBSAs are delineated by the Office of Management and Budget and published on *Census.gov.*[26] A CBSA is a statistical geographic area with a population of at least 10,000, which consists of a county or counties anchored by at least one core (urbanized area or urban cluster), plus adjacent counties having a high degree of social and economic integration with the core (as measured through commuting ties with the counties containing the core). CBSAs are ideal for use in statistical analyses because they are sufficiently numerous to allow for a robust evaluation and are also large enough to reduce the number of RO participants in close proximity to other RT providers and RT suppliers that would not be required to participate in the Model. CBSAs do not include the extreme rural regions, but there are very few RT providers and RT suppliers in these areas such that, if included, the areas would likely not generate enough episodes to be included in the statistical analysis; further, CBSAs do contain rural RT providers and RT suppliers as designated by CMS and Health Resources and Services Administration (HRSA). Therefore, CBSAs would capture the diversity of RT providers and RT suppliers who may be affected by the RO Model, and, consequently, we did not propose to include non-CBSA geographies in the RO Model test.

However, as noted in the proposed rule, most RT providers and RT suppliers may not know in what CBSA they furnish RT services. In order to simplify the notification process to inform RT providers and RT suppliers whether or not they furnish RT services in a CBSA selected for participation, we proposed to use an RT provider's or RT supplier's service location five-digit ZIP Code found on the RT provider's or RT supplier's claim submissions to CMS to link them to CBSAs selected for participation and CBSAs selected for comparison under the Model.

As explained in the proposed rule, not all five-digit ZIP Codes fall entirely within OMB delineated CBSA boundaries, resulting in some five-digit ZIP Codes assigned to two different CBSAs. Approximately 15 percent (15%) of five-digit ZIP Codes have portions of their addresses located in more than one CBSA. If each ZIP Code was assigned only to the CBSA with the largest portion of delivery locations in it, about 5 percent of all delivery locations in ZIP Codes would be assigned to a different CBSA. Rather than increase health care provider burden by requiring submission of more detailed geographic data by RT providers and RT suppliers, we proposed to assign the entire five-digit ZIP Code to the CBSA where the ZIP code has the greatest portion of total addresses (business, residence, and other addresses) such that each five-digit ZIP Code is clearly linked to a unique CBSA or non-CBSA geography. In the event that the portion of total addresses within the five-digit ZIP Code is equal across CBSAs and cannot be used to make the link, we proposed that the greater portion of business addresses would take precedence to link the five-digit ZIP Code to the CBSA.

We proposed to use a five-digit ZIP Code to CBSA crosswalk found in the Housing and Urban Development (HUD) ZIP to CBSA Crosswalk file[27] to link each five-digit ZIP Code to a single CBSA. The HUD ZIP to CBSA Crosswalk file lists the ZIP Codes (which come from the United States Postal Service) that correspond with the CBSAs (which are Census Bureau geographies) in which those ZIP Codes exist, allowing these two methods of geographic identification to be linked.

We indicated in the proposed rule that we believed that linking a five-digit ZIP Code to a single CBSA would not substantially impact statistical estimates for the RO Model. In addition, we believed that using a service location's five-digit ZIP Code to determine whether an RT provider or RT supplier must participate in the Model will avoid potential RT provider or RT supplier burden by avoiding an additional requirement that they submit claims using more detailed geographic information. We proposed to provide a look-up tool that includes all five-digit ZIP Codes linked to CBSAs selected for participation in accordance with our

[26] See OMB Bulletin No. 18–04 entitled ''Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas,'' *https://www.census.gov/programs-surveys/metro-micro/about/omb-bulletins.html.*

[27] Datasets and documentation for HUD USPS Zip Code Crosswalk Files (which includes the previously mentioned HUD ZIP–CBSA crosswalk file) can be found here: *https://www.huduser.gov/portal/datasets/usps_crosswalk.html.*

selection policy described in this final rule. This tool will be located on the RO Model website, as proposed.

In the proposed rule, we discussed how using CBSAs to identify RO participants would enable CMS to analyze groups of RT providers and RT suppliers in areas selected to participate in the Model and compare them to groups of RT providers and RT suppliers not participating in the Model (84 FR 34496). To the extent that CBSAs act like or represent markets, these group analyses would allow CMS to observe potential group level, market-like effects. We have found group level effects important as context for understanding the results of other models tested under section 1115A of the Act. For example, stakeholders questioned whether a model changed the overall volume of services related to the specific model in a given area. As noted in the proposed rule, we will not be able to address this issue for the RO Model without using a geographic area as the unit of analysis.

With respect to selecting CBSAs for participation and comparators under the Model, we proposed to use a stratified sample design based on the observed ranges of episode counts in CBSAs using claims data from calendar years 2015–2017. We proposed to then randomize the CBSAs within each stratum into participant and comparison groups until the targeted number of RO episodes within each group of CBSAs needed for a robust [28] test of the Model is reached. We noted that the primary purpose of the evaluation is to estimate the impact of the Model across all participating organizations. Larger sample sizes decrease the chances that the evaluation will produce mistakes, that is, show 'no effect' when an effect is actually present (for example, when a smoke detector fails to sound an alarm even though smoke is actually present) or show 'an effect' when no effect is actually present (for example, when a smoke detector is sounding an alarm that suggests smoke is detected when actually no smoke is present). Given that we proposed to sample approximately 40 percent of all eligible RO episodes in eligible CBSAs nationwide (as discussed in section III.C.5 of the proposed rule and this final rule), we believe we should be sufficiently powered (that is, the sample size and the expected size of the effect of the Model are both large enough at a given significance level) to confidently show the impact of the Model. The comparison group would consist of RT providers and RT suppliers from randomized CBSAs within the same strata as the selected RO participants from the participant group, resulting in a comparison group of an approximately equal number of CBSAs and episodes as in the participant group that would allow for the effects of the RO Model to be evaluated. We proposed that strata would be divided into five quintiles based on the total number of episodes within a given CBSA. The stratification would improve the balance between the CBSAs selected for participation and the CBSAs selected for comparison by limiting uneven numbers of RT provider and RT supplier and episodes within the CBSAs selected for participation and of CBSAs selected for comparison that could result from a simple random sample. We proposed that if a CBSA were randomly selected to the participant group, then the RT providers and RT suppliers who furnish RT services in that CBSA selected for participation would be RO participants. If the CBSA were randomly assigned to the comparison group, then the providers and suppliers who furnish RT services in that CBSA selected for comparison would not be RO participants, but the claims they generate and the episodes constructed from those claims would be used as part of the RO Model's evaluation.

As discussed in the proposed rule, after determining the sampling framework, we conducted the necessary power calculations (statistical tests to determine the minimum sample size of the participant and comparison groups in the Model, designed in order to produce robust and reliable results) using Medicare FFS claims from January 1, 2015 through December 31, 2017, to construct episodes and then identify a sufficient sample size so that results would be precise and reliable. We stated in the proposed rule that we determined that approximately 40 percent of eligible episodes (as discussed in section III.C.5 of the proposed rule and this final rule) in eligible CBSAs nationally would allow for a rigorous test of the RO Model that would produce evaluation results that we can be confident are accurately reflecting what actually occurred in the Model test. We also stated that this size would limit the number of episodes expected in the participant group to no more than is needed for a robust statistical test of the projected impacts of the Model.

The proposed rule explained that using randomly selected stratified CBSAs would ensure that the CBSAs selected for participation and CBSAs selected for comparison each contain approximately 40 percent of all eligible episodes nationally. We proposed that the CBSAs selected for comparison would be used to evaluate the impact of the RO Model on spending, quality, and utilization. Further, we proposed that CBSAs would be randomly selected and the ZIP Codes linked to those CBSAs selected for participation would be published on the RO Model website once the final rule is displayed.

The following is a summary of comments we received related to the proposed geographic unit of selection and our responses to those comments:

Comment: A couple of commenters believed that approximately 40 percent of episodes constituted more than a test and a few requested a reduction in the scale of the proposed Model. CMS received many comments related to the proposed size of the RO Model, where CMS proposed to include approximately 40 percent of episodes in the Model. All of the commenters who submitted feedback on this issue were opposed to the size of the Model, and many commenters suggested that the size of the Model should be decreased from approximately 40 percent of all eligible episodes annually. These commenters suggested many alternatives to CMS' proposal to include approximately 40 percent of all eligible episodes, most of which suggested a range of 7 percent to 25 percent of episodes to be included in the Model; some suggested a gradual phase in of additional RO participants over the course of the Model.

Response: Incorporating some public commenters' request for a reduced size of the Model while ensuring sufficient sample for a robust evaluation, we have determined that a reduced scale from approximately 40 percent of eligible episodes to approximately 30 percent of eligible episodes, is sufficient to produce robust evaluation results for the finalized Model. By requiring approximately 30 percent of eligible episodes to be included in the Model, we expect to be able to detect a savings of 3.75 percent or greater at a significance level of 0.05 and with a power of 0.8.

Based on the comments received, we are finalizing the proposed scope of the Model at § 512.210(d) with modification to reflect a reduced scale to approximately 30 percent of the eligible episodes. We note that this decision is supported by additional power calculations incorporating updated episode data from 2016–2018 FFS claims data that was not available for reliable analysis at the time of the proposed rule but became available during the fall of 2019 in order to

[28] 'Robust' in statistical terminology means that we can have high confidence in the test results under a broad range of conditions, for example, lower quality data, a shortened test period, or other unexpected complications.

confirm the appropriateness of the minimal sample size that would incorporate the finalized design of the RO Model.

Comment: Many commenters were opposed to mandatory participation of RT providers and RT suppliers located in a random sample of core-based statistical areas (CBSAs). A commenter was concerned that random selection of participants did not account for vulnerable beneficiary populations or vulnerable providers and suppliers. Another commenter expressed concern on the potential of certain RT provider and RT supplier sites being selected in the Model and the potential payment reductions they may face due to the Model, which would prevent them from subsidizing more rural locations which currently do not cover the costs of care.

Response: As we explained in the proposed rule and this final rule, due to concerns about a voluntary model being subject to: (1) Selection bias from limited to no participation from HOPDs; (2) an even larger geographic scope requirement for a model with optional participation to account for the projected bias and lower participation rates; (3) the ability of such a model with optional participation to achieve savings; and (4) a reduced likelihood of reliably detecting change to support Model expansion, we proposed to require participation of RT providers and RT suppliers located in a random sample of core-based statistical areas (CBSAs). Mandatory participation among randomly selected providers and suppliers ensures that the evaluation results about the RO Model will be robust (both reliable, in that the effects in savings we would see are not due to chance and not biased due to selection of participants that are not representative of all RT providers and RT suppliers), so that these results can provide for the Chief Actuary of CMS to certify that expansion of the Model would reduce (or would not result in any increase in) net program spending in the future if the Department chooses to pursue expansion under 1115A(c) of the Act. Therefore, we will not be modifying our proposal to randomly select CBSAs to identify RT providers and RT suppliers that are required to participate in the Model through a stratified sample design.

The well-being of potentially vulnerable patients is always of primary concern to CMS. As such, we will examine and monitor vulnerable populations and providers and suppliers for any unintended consequences of the random selection of RO participants in the Model. CMS expects that the payments to providers and suppliers under the RO Model will appropriately cover the costs of standard operations and profits for RT providers and suppliers. We appreciate the possibility of instances where RT providers and suppliers are cross-subsidizing finances from high-earning locations to lower-earning locations, but this is not directly under CMS control—these are external financing practices which CMS does not have authority over. HHS has additional programs which provide help with financing for potentially vulnerable populations and providers and suppliers (such as HRSA programs for the vulnerable and underserved). Additionally, for certain low volume RT providers and RT suppliers, we are providing a low volume opt-out option, as discussed in section III.C.3.c of this final rule.

Comment: Some commenters expressed concern that the use of Core-Based Statistical Areas (CBSAs) to identify RO participants could result in unintended consequences, such as picking 'winners and losers' in markets. These comments largely focused on 'patient overlap' and the potential incentive for patients to travel, depending on the patient's preference, in order to see a RT provider or RT supplier who either is an RO participant or a RT provider or RT supplier not selected to participate in the Model. Comments appeared to suggest that all RT providers and RT suppliers in a particular market be selected to be RO participants or not. A commenter stated that patients could be negatively impacted by the Model as beneficiaries seeking RT services in included ZIP Codes must also participate in the Model or travel to a geographic area not included in the Model for care (regardless of their ability to do so). A commenter was worried about the potential differences between CBSAs selected for participation and CBSAs selected for comparison with respect to treating prostate cancer if there was an uneven incidence of prostate cancer cases between RO participants and comparators—the comment cited the 'greater levels of technology', such as IMRT (intensity-modulated radiation therapy) that is often used to treat prostate cancer. The commenter was similarly concerned with the potential for lower-risk patients to be used as a benchmark in comparison CBSAs while higher-risk patients would be in the CBSAs selected for participation, particularly with regards to race.

One commenter fully agreed with proposed geography-based randomization process, stating that the proposed process was fair and unbiased. A commenter suggested that site-neutral payments be applied to all RT providers and RT suppliers and not restrict this payment change to the proposed approximately 40 percent of CBSAs selected for participation.

Response: In designing the Model, a driving principle for us was patients being able to continue to access high-quality care. As we stated in the proposed rule and in this final rule, there are tradeoffs to consider in the design of a Model with respect to the unit of selection. The mixture of concern and support for the proposed design as expressed through the comments described here is further evidence of those tradeoffs.

We do not have data that definitively delineates markets for RT services. However, we believe by adopting CBSAs as proxies for those markets that we will achieve a reasonable balance among the tradeoffs raised by commenters and discussed in the proposed rule. To the extent that CBSAs act like or represent markets, these group analyses would allow CMS to observe potential group level, market-like effects. We have found group level effects important as context for understanding the results of other models tested under section 1115A of the Act. Please see section III.C.3.d for a discussion of CBSAs as markets due to their high degree of social and economic integration. Because CBSAs can yield market-like effects, CMS believes that CBSAs are the best available option for selection of RT participation.

We shared the concerns with commenters that selection of some CBSAs may create specific situations, such as a health system having practices in multiple locations and/or those located near the border of a CBSA. We understand the concern that the Model could potentially result in health systems having both RO participants and non-participants, as this could produce additional burden for these systems in terms of billing and the ability to manage patients. This issue is one such tradeoff in the design of the Model. We determined that some systems would have locations providing RT services that experience the Model conditions as an RO participant and other locations providing RT services that are not RO participants. We chose CBSAs to attempt to minimize the number of such occurrences. We would also like to note that episodes are assigned to a single CBSA by way of the ZIP Code of the RT supplier that furnished the planning service that triggered the RO episode.

We believe that using stratified randomization will minimize potential

selection problems and unintended consequences, including other potential imbalances in cancer type (and corresponding modality) or patient risk. We can identify and account for observed imbalances that may result from randomized selection in the evaluation. The Model (and its exclusions) were designed to minimize the potential consequences. We are finalizing the adoption of CBSAs as the geographic unit of selection in the RO Model.

We seek to support Medicare patients' rights to seek care wherever they choose. We do not believe that the changes in health care provider payments in the RO model would justify or lead to beneficiaries travelling to entirely different CBSAs to seek RO care, which involves frequent treatments over a short period. We designed the model with CBSAs to prevent RO participants from shifting patients who require more expensive care to a site of service which would not be included in the RO Model. The CBSAs selected for participation will be in distinctive locations, and we believe the potential effects on patient costs would not substantial. Based on these facts and the frequency needed for radiation therapy treatments, we do not believe that the RO Model would create an incentive for beneficiaries to avoid RO participants. In other words, we do not believe that the RO Model would create a situation where beneficiaries systematically choose to receive RT services from an RT provider or supplier that they would not otherwise seek care from in absence of the model. We believe the compensation we are providing under this Model is fair and this should not affect where beneficiaries seek RT services.

The RO Model's inclusion of approximately 30 percent (or a greater percent) of all RT providers and suppliers for a finite period of time does not constitute a program change but a model test. In order to test the effect of payments in the RO Model to determine whether they reduce cost while maintaining and/or improving quality of care and patient outcomes, we believe using both a case (participant) and control (non-participant) will provide the most meaningful comparison. We have designed the Model to include a limited sample size (that is, approximately 30 percent of eligible episodes nationwide), while ensuring both sufficient sample size and power to produce robust data that can provide evidence to certify the Model in the future if the Department chooses.

Comment: A few commenters encouraged us to allow public comment on the particular CBSAs selected for participation in the RO Model.

Response: We appreciate the commenters' concerns regarding an opportunity to comment on particular CBSAs selected for participation, but these comments fall outside the scope of our proposed policy. We would like to clarify that we will use the most recently available HUD USPS ZIP Code Crosswalk Files (*https://www.huduser.gov/portal/datasets/usps_crosswalk.html#data*) to link a new five-digit ZIP Code to a CBSA in the manner as described in section III.C.3.d. Currently, the HUD USPS ZIP Code Crosswalk Files are updated quarterly. If the most recently available HUD USPS ZIP Code Crosswalk File links any additional five-digit ZIP Codes to the CBSAs selected for participation, we will add those ZIP Codes to the ZIP Codes included under the Model. The look-up tool that includes all of the five-digit ZIP Codes linked to CBSAs selected for participation will be updated with the additional ZIP Codes. Once a five-digit ZIP Code is assigned to a CBSA selected for participation under the Model, it will not be removed from the list of included ZIP Codes.

Comment: A couple of commenters were concerned that the Model design had the potential not to include a sufficient number of proton beam therapy (PBT) centers to be able adequately detect the impact of the Model on proton centers in isolation.

Response: The evaluation of the RO Model will be primarily interested in the impacts of the Model on the overall spending and quality of care across all included RT services at the population level, and not the effects on one RT modality compared to another. While some future evaluation analyses may include differences in costs and quality by modality, we will make no impact estimates on cost nor quality where we do not have suitable sample size of practices or episodes among the participants and non-participant comparators, understanding that any differences we may observe will be observational and not causative.

Comment: A commenter requested that CMS should publish online an explicit list of excluded RT providers and RT suppliers, including their names, addresses, and NPIs to ensure there's no confusion about excluded providers and suppliers. This commenter further stated that it is important for Professional participants to have a CMS-approved list that clearly indicates which RT providers and RT suppliers are excluded despite the fact that they are located within a ZIP Code selected for the RO Model.

Response: We appreciate the commenter's suggestion. A look-up tool that includes all of the five-digit ZIP Codes linked to CBSAs selected for participation in accordance with our finalized selection policy described in this final rule is located on the RO Model website (*https://innovation.cms.gov/initiatives/radiation-oncology-model/*). This tool will allow included entities that furnish RT services to identify if they are included or excluded from the RO Model based on their site of service. We will refrain from including personal identification information of specific physicians in the release of the RT providers and suppliers selected to participate. We believe that relevant entities within selected participating ZIP Codes will already be aware if they meet the exclusion criteria for the Model (for example, if they whether they are PPS-exempt cancer hospitals, critical access hospitals (CAHs), or are located within certain exclude states (Maryland, Vermont, U.S. Territories) or are participating in or eligible to participate in the Pennsylvania Rural Health Model as codified at § 512.210. However, any entity who may want to confirm their exclusion will be free to contact the RO Model help desk (*RadiationTherapy@cms.hhs.gov*).

Comment: A commenter has requested that we select patients randomly to be included in the Model.

Response: The Model design is such that RO participants will be selected through randomized CBSAs: Those CBSAs selected for participation and CBSAs selected for comparison. The Model is not designed to randomly select patients from within selected RO participants. CMS chose not to design the RO Model to randomly select patients as this would have created a much greater burden, administratively and operationally, for RT providers and suppliers who see both participating and non-participating beneficiaries within a single site of care who would then need to operationalize 2 different billing systems (one for participating beneficiaries, one for non-participating beneficiaries) within that one site. Additionally, if the sample size (approximately 30 percent of episodes) were calculated at the beneficiary level (rather than RT provider and supplier level), a substantially greater number of RT providers and suppliers would be included as RO participants to reach the necessary approximately 30 percent sample size. We are finalizing as proposed that patients will be RO beneficiaries if they receive included RT services from an RO participant. The Model will be finalized using the

proposed random selection of CBSAs as the method of determining an RT provider's or RT supplier's participation (or not) in the model.

After considering public comments, we are finalizing with modification our proposed provisions on the RO Model's geographic unit of selection. Specifically, we are codifying at § 512.210(d) that we will randomly select CBSAs to identify RT providers and RT suppliers to participate in the Model through a stratified sample design. However, instead of allowing for participant and comparison groups to contain approximately 40 percent of all eligible episodes in eligible geographic areas as we had proposed, we are modifying this provision in the final rule allowing for participant and comparison groups to contain approximately 30 percent of all eligible episodes in eligible geographic areas (that is, CBSAs). The sample size was calculated incorporating the final parameters of the model, and we are using a sample size that we believe is necessary to detect the anticipated impact of the model. Therefore, we are finalizing that approximately 30 percent of eligible episodes will be randomly selected for this Model. For the final rule, we used Medicare FFS claims from January 1, 2016 through December 31, 2018 for constructing episodes, determining sufficient sample size, and for the eventual selection of participants and comparators for the RO Model, as this was the timeliest data available at the time of this final rule's release.

4. Beneficiary Population

In the proposed rule at 84 FR 34496, we proposed that a Medicare FFS beneficiary would be included in the RO Model if the beneficiary:

- Receives included RT services in a five-digit ZIP Code, linked to a CBSA selected for participation, from an RO participant during the Model performance period for a cancer type that meets the criteria for inclusion in the RO Model; and
- At the time that the initial treatment planning service of the episode is furnished by an RO participant, the beneficiary:

++ Is eligible for Medicare Part A and enrolled in Medicare Part B; and

++ Has traditional Medicare FFS as his or her primary payer.

In addition, we proposed to exclude from the RO Model any beneficiary who, at the time that the initial treatment planning service of the episode is furnished by an RO participant:

- Is Enrolled in any Medicare managed care organization, including but not limited to Medicare Advantage plans;
- Is Enrolled in a PACE plan;
- Is in a Medicare hospice benefit period; [29] or
- Is covered under United Mine Workers.

We explained in the proposed rule that the RO Model will evaluate RT services furnished to beneficiaries who have been diagnosed with one of the cancer types identified as satisfying our criteria for inclusion in the Model, as discussed in section III.C.5.a of the rule (84 FR 34496 through 34497). Thus, we stated that we believed it would be necessary to include only beneficiaries who have at least one of the identified cancer types and who also receive RT services from RO participants. We also stated that a key objective of the RO Model is to evaluate if and/or how RT service delivery changes, in either the HOPD or freestanding radiation therapy center setting, as a result of a change in payment systems from FFS to prospectively determined bundled rates for an episode. We proposed these criteria in order to limit RT provider and RT supplier participation in the RO Model to beneficiaries whose RT providers and RT suppliers would otherwise be paid by way of traditional FFS payments for the identified cancer types. We discussed our belief that these eligibility criteria for RO beneficiaries are necessary in order to properly evaluate this change with minimal intervening effects in the proposed rule.

We proposed to define a beneficiary who meets all of these criteria, and who does not trigger any of the beneficiary exclusion criteria, a ''RO beneficiary''. We proposed to codify the terms ''RO beneficiary,'' ''RT provider,'' and ''RT supplier'' at § 512.205.

In addition, we proposed to include in the RO Model any beneficiary participating in a clinical trial for RT services for which Medicare pays routine costs, provided that such beneficiary meets all of the beneficiary inclusion criteria. The proposed rule provides that we would consider routine costs of a clinical trial to be all items and services that are otherwise generally available to Medicare beneficiaries (that is, there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial.[30] Medicare pays routine costs by way of FFS payments, making it appropriate to include RT services furnished for RO episodes in this case under the RO Model.

We stated that the RO Model's design would not allow RO beneficiaries to ''opt out'' of the Model's pricing methodology. A beneficiary who is included in the RO Model pursuant to the proposed criteria would have his or her RT services paid for under the Model's pricing methodology and would be responsible for the coinsurance amount as discussed in section III.C.6.i of this final rule. Beneficiaries do have the right to choose to receive RT services in a geographic area not included in the RO Model.

We explained in the proposed rule, at 84 FR 34497, that if an RO beneficiary stops meeting any of the eligibility criteria or triggers any of the exclusion criteria before the TC of an episode initiates, then the episode would be an incomplete episode as discussed in section III.C.6.a of the proposed rule (84 FR 34503 through 34504) and this final rule. Payments to RO participants would be retrospectively adjusted to account for incomplete episodes during the annual reconciliation process, as described in section III.C.11 of the proposed rule and this final rule. We proposed that if traditional Medicare stops being an RO beneficiary's primary payer after the TC of the episode has been initiated, then regardless of whether the beneficiary's course of RT treatment was completed, the 90-day period would be considered an incomplete episode, and the RO participant would receive only the first installment of the episode payment. In the event that a beneficiary dies or enters hospice during an episode, then the RO participant would receive both installments of the episode payment, regardless of whether the RO beneficiary's course of RT has ended (see section III.C.7 of the proposed rule and this final rule).

We proposed these beneficiary eligibility criteria for purposes of determining beneficiary inclusion in and exclusion from the Model. The following is a summary of comments received related to our proposal on the RO Model's beneficiary population and our responses to those comments:

Comment: A few commenters requested that all patients enrolled in clinical trials should be excluded from

[29] Please note that this was incorrectly stated in the section III.C.4 of the preamble to the Notice of Proposed Rulemaking, as ''Is not in a Medicare hospice benefit period'' (at 84 FR 34496), but was correctly stated in the proposed regulatory text at 84 FR 34585. It has been corrected in the preamble to this Final Rule to ''Is in a Medicare hospice benefit period.''

[30] The current Medicare policy on routine cost in clinical trials is described in Routine Costs in Clinical Trials 100–3 section 310.1.

the RO Model. One of these commenters also stated that some Medicare contractors provide exceptions to providers and suppliers with a history of evidence development and they suggested that the Innovation Center consider this as a basis for exclusion as well.

Response: We thank the commenters for their suggestions. Medicare pays routine costs by way of FFS payments for Medicare beneficiaries participating in clinical trials when there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision, making it appropriate to include these beneficiaries in the RO Model provided that such beneficiary meets all of the proposed beneficiary inclusion criteria. It is important that the RO Model include clinical trials because the goal of the Model is to test whether prospective episode payments for RT services, in lieu of traditional FFS payments, would reduce Medicare expenditures. Therefore, not including clinical trials that are paid through FFS could skew the Model results. With regard to the commenter who suggested that the Innovation Center provide exceptions to providers and suppliers with a history of evidence development, we appreciate the suggestion, however, we believe that less experienced RO participants will benefit from this type of experience through peer-to-peer learning activities and performance reports that will allow for comparison between participants. We also believe that including providers and suppliers with all levels of experience would result in a more robust data set for evaluation of the RO Model's prospective payment approach. We will continue to monitor the Model for a need of this exception in the future.

Comment: A commenter suggested that CMS should open the RO Model to voluntary participation by Medicare Advantage plans and other payers. This commenter stated that limiting the RO Model to Medicare fee-for service would miss an opportunity to allow as many health care providers and payers as possible to explore and assess innovative approaches to delivering care under a bundled payment model.

Response: At this time, we are finalizing as proposed that the RO Model will include only Medicare fee-for-service beneficiaries receiving RT services by RO Participants. This Model was designed to test an alternative payment approach instead of FFS, and is therefore limited to only Medicare FFS beneficiaries and does not include other payers like Medicare Advantage. As we discussed in the NPRM, a key objective of the RO Model would be to evaluate if and/or how RT service delivery changes in either the HOPD or freestanding radiation therapy center setting as a result of a change in payment systems from that of FFS under OPPS or PFS, respectively, to that of prospectively determined bundled rates for an episode as described in section III.C.6.c. We proposed these beneficiary criteria in order to limit participation in the RO Model to beneficiaries whose RT providers and/or RT suppliers would otherwise be paid by way of traditional FFS payments for the identified cancer types. We believe that these eligibility criteria for RO beneficiaries are necessary in order to properly evaluate this change with minimal intervening effects; therefore, we are not including additional payers such as Medicare Advantage to the RO Model in this final rule. We recognize that other payers may be conducting similar alternative payment models. Other payers who are interested in testing an alternative payment system to FFS are welcome to align with our RO Model methodologies. However, we are not soliciting formal partnerships with other payers at this time.

Comment: Another commenter requested clarification on what will happen if a patient joins a Medicare Advantage plan during the fall open enrollment period while in an RO episode. This commenter expressed concern that both systems will assume the other will pay.

Response: In this scenario, if Medicare FFS stops being the primary payer during the 90-day episode, this would be considered an incomplete episode. Please refer to section III.C.6.a of the proposed rule (84 FR 34503 through 34504) and this final rule for an overview of our incomplete episode policy.

Comment: A commenter stated that patients should always have a choice in their care, and therefore a patient opt-out provision is warranted just as it is in the OCM.

Response: As we stated in the proposed rule, the RO Model's design will not allow RO beneficiaries to ''opt out'' of the Model's pricing methodology as described in section III.C.6 of the proposed rule, as well as this final rule. Of note, this policy is the same as in OCM, where beneficiaries who receive care from an OCM participant have the same Medicare rights and protections, including the right to choose which health care provider they see, and they may choose a health care provider who does not participate in the OCM. However, just as in OCM, this Model protects beneficiary choice because beneficiaries have the right to choose to receive RT services from a RT provider and/or RT supplier not included in the RO Model.

Comment: A commenter supported the participant criteria with the exception of excluding those in a Medicare hospice benefit (MHB) period. This commenter stated that such patients may benefit from RT services as a palliative measure and so should be allowed to participate in this Model if so. They further stated that while they agreed this is a reimbursement issue for hospices, palliative radiation is by its nature not curative and so should be covered under the MHB, at least for those people with cancer participating in this Model.

Response: We thank the commenter for their recommendation. Medicare beneficiaries will be excluded from the RO Model if they are in a MHB period at the start of their receipt of RT services, because the MHB is not paid FFS. As we previously stated, the goal of the RO Model is to test whether prospective episode payments in lieu of traditional FFS payments for RT services would reduce Medicare expenditures; therefore, it is important that non-FFS beneficiaries be excluded in order to properly evaluate the results of the Model. Traditionally, if a beneficiary receives RT services during a MHB period, the cost of the treatment would be covered under the Medicare hospice per diem. The RO Model allows for RO Model payments to continue (in addition to the Medicare hospice per diem) if a beneficiary selects MHB during an RO episode so as not to dissuade RO participants from making a hospice referral when needed. The Medicare hospice agency will not be responsible for the cost of RT services in this case. This RO Model policy does not intend to imply that the MHB should pay for curative treatment. While we understand the commenter's concern, we will not be creating an exemption of this nature at this time.

Comment: A commenter requested clarification on the definition of an RO beneficiary, specifically they would like clarification on what happens if a patient starts an episode with inpatient treatment and then changes to an outpatient setting, and if a patient changes ZIP Codes during the course of treatment.

Response: To the commenter's question regarding moving from inpatient treatment to outpatient treatment, if a beneficiary starts inpatient treatment and then changes to an outpatient setting, this situation would not be considered an RO episode,

and treatment would be billed under traditional fee-for-service.

For the commenter's question about a patient changing ZIP Codes during the course of treatment, we note that the ZIP Codes are relevant only to the location of the RO participant, not the residence of the beneficiary. If the beneficiary with an included cancer type receives included professional and technical services from one or more RO participants located in one or more ZIP Codes linked to CBSAs selected for participation, then the beneficiary will be an RO beneficiary. If the beneficiary receives professional RT services from an RO participant in a ZIP Code linked to CBSAs selected for participation, but receives technical RT services from non-participants (or vice versa), the beneficiary will not be in the Model, and this will be an incomplete episode as defined at § 512.205 and as further described in section III.C.6.a of this final rule. Payments to RO participants will be retrospectively adjusted to account for incomplete episodes during the annual reconciliation process, as described in section III.C.11 of this final rule.

Comment: A commenter did not support our proposal regarding the beneficiaries that will be included and excluded from the RO Model. This commenter stated that linking beneficiaries by ZIP Code could create adverse selection and skew the results of the Model. This commenter requested clarity on whether inclusion and exclusion is linked to the beneficiary's address being in the ZIP Code or the address of the RO participant. This commenter also requested clarification about whether the RO participant is responsible for the entire ZIP Code even if the beneficiary goes out-of-area.

Response: We are clarifying that a beneficiary's address does not determine his or her inclusion in the RO Model, rather it is determined by the address where the RO participant furnished the included RT services. Nor did we propose to link beneficiaries by ZIP Code. Regarding the requested clarification about whether the RO participant is responsible for the entire ZIP Code even if the beneficiary goes ''out-of-area'', we take the commenter's reference to a beneficiary going ''out-of-area'' to mean that the beneficiary has switched providers and stopped receiving RT services from the RO participant that initiated the RO episode. This would be considered an incomplete episode. We also note that in the case of incomplete episodes, RO participants are owed beneficiary coinsurance payment of 20 percent of the FFS amounts that would have been paid in the absence of the RO Model, except when the RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer at any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and EOE modifier. In that case, the RO participant would be owed beneficiary coinsurance payment would equal 20 percent of the first installment of the episode payment amount. See III.C.6.a of the proposed rule (84 FR 34503 through 34504) and this final rule for an overview of our incomplete episode policy. Payments to RO participants will be retrospectively adjusted to account for incomplete episodes during the annual reconciliation process, as described in section III.C.11. of this proposed rule.

Comment: A commenter requested clarification about what will occur if a beneficiary refuses to participate in the Model by notifying CMS in writing after treatment is started and the start of episode (SOE) HCPCS is submitted to CMS.

Response: We would like to clarify that under this Model, RO beneficiaries will not provide direct notification to CMS when they do not wish to participate in the Model. If a beneficiary does not wish to ''participate'' in the Model, (s)he can seek treatment from a non-participant. The notification that we believe this commenter is referring to is in cases where beneficiaries do not wish to have their claims data shared with the RO participant for care coordination and quality improvement purposes under the Model. In such cases, the RO participant must notify CMS in writing within 30 days of when the RO beneficiary notifies the RO participant (see section III.C.15 of the proposed rule and this final rule for more details on this policy).

Comment: A commenter was concerned with the potential for adverse health outcomes for certain vulnerable populations defined by race, income, and the presence of prostate cancer under the Model.

Response: The evaluation of the RO Model will be taking into account, to the extent feasible, any potential adverse health outcomes, and any underlying differences in patient characteristics, severity, and the related differences in technology in the monitoring and evaluation of this Model.

After considering public comments, we are finalizing our proposal on the beneficiary population with modification. We have made additional non-substantive changes to the proposed provisions at § 512.215 in this final rule to improve readability. Specifically, we are finalizing, with modification, the RO Model beneficiary inclusion criteria as codified at § 512.215(a) and illustrated in Figure A. We have made additional non-substantive changes to the proposed provisions at § 512.215 in this final rule to improve readability. We are also finalizing with modification at § 512.215(a) that an individual is an RO beneficiary if the individual receives included RT services from an RO participant that billed the SOE modifier for the PC or TC of an RO episode during the Model performance period for an included cancer type. An individual is an RO beneficiary if, at the time that the initial treatment planning service of an RO episode is furnished by an RO participant, the individual is eligible for Medicare Part A and enrolled in Medicare Part B, the individual has traditional FFS Medicare as his or her primary payer (for example, is not enrolled in a PACE plan, Medicare Advantage or another managed care plan, or United Mine Workers insurance), and if the individual is not in a MHB period. We are further finalizing with modification at § 512.215(b) that any individual enrolled in a clinical trial for RT services for which Medicare pays routine costs will be an RO Beneficiary if the individual satisfies all of the beneficiary inclusion criteria codified at § 512.215(a).

Additionally, we are finalizing as proposed to codify the terms ''RT provider,'' and ''RT supplier'' at § 512.205. We are finalizing, with modification, to codify the term ''RO beneficiary'' at § 512.205 to mean a Medicare beneficiary who meets all of the beneficiary inclusion criteria at § 512.215(a) and whose RO episode meets all of the criteria defined at § 512.245. As explained in the proposed rule and in this final rule, the RO Model's design would not allow RO beneficiaries to ''opt out'' of the Model's pricing methodology.

FIGURE A—FINALIZED RO BENEFICIARY INCLUSION CRITERIA

The individual receives included RT services:
- From an RO participant that billed the SOE modifier for the PC or TC of an RO episode during the Model performance period for an included cancer type.

At the time that the initial treatment planning service of the RO episode is furnished by an RO participant, the individual:
- Is eligible for Medicare Part A and enrolled in Medicare Part B.
- Has traditional Medicare FFS as his or her primary payer (for example, is not enrolled in a PACE plan, Medicare Advantage or another managed care plan, or United Mine Workers insurance).
- Is not in a Medicare hospice benefit period.

5. RO Model Episodes

We proposed that under the RO Model, Medicare would pay RO participants a site-neutral, episode-based payment amount for all specified RT services furnished to an RO beneficiary during a 90-day episode (84 FR 34497). In section III.C.5 of the proposed rule, we first explained our proposal to include criteria to add or remove cancer types under the Model and their relevant diagnoses codes in the Model as well as the RT services and modalities that would be covered and not covered in an episode payment for treatment of those cancer types. We then explained our proposal for testing a 90-day episode and proposed the conditions that must be met to trigger an episode.

a. Included Cancer Types

We proposed the following criteria for purposes of including cancer types under the RO Model. The cancer type—

- Is commonly treated with radiation; and
- Has associated current ICD–10 codes that have demonstrated pricing stability.

We proposed to codify these criteria for included cancer types at § 512.230(a) of our regulation.

We proposed the following criteria for purposes of removing cancer types under the RO Model.

- RT is no longer appropriate to treat a cancer type per nationally recognized, evidence-based clinical treatment guidelines;
- CMS discovers a ≥10 percent (≥10%) error in established national base rates; or
- The Secretary determines a cancer type not to be suitable for inclusion in the Model.

We proposed to codify these criteria for removing cancer types at § 512.230(b) of our regulation.

We identified 17 cancer types in Table 1—Identified Cancer Types and Corresponding ICD–9 and ICD–10 Codes of the proposed rule that met our proposed criteria. We explained in the proposed rule that these 17 cancer types are commonly treated with RT and Medicare claims data was sufficiently reliable to calculate prices for prospective episode payments that accurately reflect the average resource utilization for an episode. These cancer types are made up of specific ICD–9 and ICD–10 diagnosis codes. For example, as shown in Table 1 of the proposed rule, there are cancer types for ''breast cancer'' and ''prostate cancer,'' which are categorical terms that represent a grouping of ICD–9 and ICD–10 codes affiliated with those conditions. To identify these cancer types and their relevant diagnosis codes to include in the Model, we identified cancers that are treated with RT.

As described in the proposed rule, we used the list of cancer types and relevant diagnosis codes, to analyze the interquartile ranges of the episode prices across diagnosis codes within each cancer type to determine pricing stability. We chose to exclude benign neoplasms and those cancers that are rarely treated with radiation because there were not enough episodes for reliable pricing and they were too variable to pool.

We stated in the proposed rule that during our review of skin cancer episodes, we discovered that Current Procedural Terminology® (CPT®) code 0182T (electronic brachytherapy treatment), which was being used mainly by dermatologists to report treatment for non-melanoma skin cancers, was deleted and replaced with two new codes (CPT® code 0394T to report high dose rate (HDR) electronic skin brachytherapy and 0395T to report HDR electronic interstitial or intracavitary treatments) in 2016. Local coverage determinations (LCDs) that provide information about whether or not a particular item or service is covered were created and subsequently changed during this time period. Our analysis suggested that the volume and pricing of these services dropped significantly between 2015 and 2016, with pricing decreasing more than 50 percent. As a result, we did not believe that we could price episodes for skin cancers that accurately reflect the average resource utilization for an episode. Thus, skin cancer was excluded in the proposed rule.

The proposed RO Model's included cancer types are commonly treated with RT and can be accurately priced for prospective episode payments. As proposed, an up-to-date list of cancer types, upon any subsequent revisions, will be kept on the RO Model website.

We proposed to define the term ''included cancer types'' to mean the cancer types determined by the proposed criteria set forth in § 512.230, which are included in the RO Model test.

We proposed to maintain the list of ICD–10 codes for included cancer types under the RO Model on the RO Model website. We indicated in the proposed rule that any addition or removal of these codes would be communicated via the RO Model website and written correspondence to RO participants. We proposed to notify RO participants of any changes to the diagnosis codes for the included cancer types per the CMS standard process for announcing coding changes and update the list on the RO Model website no later than 30 days prior to each PY.

We solicited comments on the proposed cancer types included in the RO Model. The following is a summary of the public comments received on this proposal and our responses to those comments:

Comment: A couple of commenters expressed support for the inclusion of all 17 cancer types named in the proposed rule, emphasizing that it expands the benefit to the broadest population of patients. A few of these commenters stated that including all 17 cancer types would reduce the overall administrative burden on RO participants, as this scale decreases the burden associated with operationalizing a model for a few key cancer sites and not others. Other commenters emphasized that, since these 17 cancer types are commonly treated with RT services, they can be accurately priced.

Response: We thank the commenters for their support.

Comment: A commenter described how inaccurate coding could lead to

misvalued episode payments and included renal cell carcinoma in one of the examples.

Response: Based on further clinical review, kidney cancer is not commonly treated with radiotherapy and as such it does not meeting the criteria for inclusion. Kidney cancer may have been included as an artifact of inaccurate coding and we are therefore excluding it from the RO Model.

Comment: Many commenters expressed concern over the inclusion of cervical cancer. A commenter suggested separate payment for each physician involved in treating cervical cancer. A few commenters recommended using the OPPS Ambulatory Payment Classification (APC) payment rates without the comprehensive APC (C–APC) methodology for the technical component of the national base rate for cervical cancer, because they believe that the C–APC OPPS methodology undervalues the brachytherapy reimbursement. Another commenter called into question the data used to determine the national base rates for cervical cancer, stating that the payment methodology is not well-suited for cancers commonly treated with multiple modalities. This commenter also believed that the RO Episode File misattributed episodes to cervical cancer that ought to have fallen under a different cancer type. This commenter noted episodes that are inconsistent with clinical medicine and could be only partially captured episodes, incorrectly captured delivery codes, or misattributed episodes. Regarding misattribution, the commenter stated that approximately 2 percent of cervical cancer episodes include SRS, yet since SRS is a single fraction of radiation to the brain, these episodes are likely treating a metastatic site rather than treating the primary site of cervical cancer. Regarding partially captured episodes, the commenter asserted that there are 75 episodes from the RO Episode File where fewer fractions were provided than is the established clinical approach.

Response: We believe that the national base rates represent the average of all RT services provided to beneficiaries with a given cancer type, including cervical cancer, and it is probable that there will be individual episodes where there is deviation from the standard treatment given the clinical profile of an individual patient. Our data shows that in addition to episodes with lower numbers of fractions, there are other episodes with higher numbers of fractions than is typically recommended. Over the past few years, we have repeatedly examined the C–APC methodology with regard to brachytherapy and cervical cancer and determined that it provides appropriate reimbursement. For examples, please see the CY 2020 OPPS/ASC final rule with comment period (84 FR 61163) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58843). As such, we believe that the C–APC methodology is appropriate to use in the base rate calculations for the RO Model. We will continue to examine these concerns. Please refer to the pricing methodology in section III.C.6 for further explanation of these points, including rationale related to APCs and C–APCs. We rely on Medicare providers and suppliers to furnish appropriate care to beneficiaries.

Comment: A commenter suggested adding a specific category for an isolated lymph node treated with radiation, emphasizing that this is a common clinical situation.

Response: We thank the commenter for their suggestion. However, we believe that the treatment of an isolated lymph node would likely be part of a treatment plan for an included cancer type. If it is not part of a treatment plan for an included cancer type, the treatment would be paid FFS.

Comment: A few commenters recommended that CMS remove liver cancer from the RO Model. These commenters argued that the treatments for liver cancer are not well-suited for the RO Model as treatment can involve multiple physicians. A few commenters stated that liver cancer sometimes involves radioembolization treatment using Yttrium-90, and that this therapy frequently involves both a radiation oncologist and an interventional oncologist, most likely in the HOPD. These commenters believed that including this therapy could trigger incomplete episodes, as one physician is typically involved in planning and a second in delivery. These commenters also believed that, when the radiation oncologist triggers the episode, there would be a separate FFS payment to the interventional radiologist for their work, ultimately resulting in a higher payment from the patient.

Other commenters believed that liver cancer should be excluded from the Model, as it is uncommon for a patient to receive more than one session of brachytherapy for liver cancer, thus there is no opportunity to improve efficiency or reduce spending. A couple of commenters added that liver cancer treated with brachytherapy accounts for only 0.29 percent of all episodes included in the Model, and, therefore, any cost savings would be trivial. Another commenter suggested that this low percentage indicated that liver cancer treated with brachytherapy should fall under the ''certain brachytherapy surgical services'' excluded by the proposed rule due to low volume.

Response: As noted in section III.C.5.c of this final rule, we are removing Yttrium-90 from the RT services included on the list referred to as ''RO Model Bundled HCPCS'' (Table 2; as such, it may be billed FFS. Liver cancer meets the criteria for inclusion as a cancer type under the RO Model as codified at § 512.230(a). The RO Model is designed to be disease-specific and agnostic to treatment and modality type. Liver cancer is commonly treated with radiation and has associated current ICD–10 codes that demonstrate pricing stability. It is important to note, that when just one treatment is clinically appropriate and furnished, the RO participant will be paid more than they would have under FFS. CMS recognizes that there is no efficiency or savings to be earned in these instances, but by including liver cancer in the RO Model we will be able to test whether prospective payments for RT services, as opposed to traditional FFS payments, would reduce Medicare expenditures while preserving or enhancing quality of care. Thus, we are finalizing our proposal to include liver cancer in the RO Model.

Comment: Some commenters recommended that CMS implement the Model with fewer cancer types. A commenter suggested that CMS limit the number of cancer types to those for which treatment protocols are the most standardized across patient cohorts and with low propensity for outlier cases. A couple of these commenters expressed concerns that the administrative burden imposed by the sheer number of included cancer types would be too much for RO participants and CMS to manage effectively. A commenter noted the variation in treatment pathways and requested that CMS consider excluding treatments that are extensive or serve as outliers. These commenters indicated that focusing on fewer cancer types would allow providers and suppliers to focus efforts on specific areas of medicine, causing less disruption to RO participants.

A few of these commenters had specific recommendations for which subset of cancer types should be included. A couple of commenters suggested targeting the most prevalent cancer types: Breast, colon, lung, and prostate, as treatments for these cancers are often more homogenous and their costs are more predictable. A few other commenters recommended including

only cancer types that had sufficient clinical data to support hypofractionation as clinically appropriate care. A few commenters recommended excluding complex cancer types with variable costs, such as cancers of the brain and of the head and neck. Specifically, commenters emphasized that these cancer types frequently require more complicated workup, planning, and technology than others, and must be adjusted as the tumor shrinks or the patient loses weight. A commenter underscored that, even within these three cancer types, patients may receive treatments that vary widely in cost based on clinical indicators.

A couple of commenters suggested phasing in the 17 cancer types over time, beginning with one or two cancer types and then expanding to the full set of 17 over the Model performance period. A couple commenters suggested reducing the number of cancer types included and analyzing performance data before including all 17 cancer types from the outset of the Model.

Response: The 16 cancer types that we are finalizing for inclusion in the RO Model are cancers commonly treated with RT. The Innovation Center excluded those cancers that are rarely treated with radiation. Once an initial list of cancer types and relevant diagnosis codes were identified, the Innovation Center reviewed them for pricing stability. For example, the Innovation Center analyzed the interquartile ranges of the episode prices across diagnosis codes within cancer types. There will likely be individual episodes where there is deviation from the standard treatment given the clinical profile of an individual patient. Our data shows that, in addition to episodes with lower numbers of fractions, there are other episodes with higher numbers of fractions than is typically recommended, including but not limited to as cancers of the brain and of the head and neck. The final list includes those cancer types that are commonly treated with RT and have demonstrated pricing stability, which allows them to be accurately priced. The diagnoses selected to be included in the RO Model account for over 90 percent of episodes during the time period that was analyzed (2016–2018, as discussed in section III.C.6.d). CMS believes that phasing in the included cancer types would prevent a robust evaluation because doing so would reduce the amount of available data for any cancer types phased in at a later time. As previously stated, we believe that a Model performance period of at least 5 years is sufficient to obtain data to compute a reliable impact estimate. Please refer to section III.C.1 of the rule for more information on the Model performance period.

Additionally, CMS believes that limiting or phasing in the number of included cancer types would be more burdensome for most RO participants. As previously noted, the included diagnoses accounted for over 90 percent of episodes from 2016 through 2018. Thus, for most RO participants, limiting or phasing in cancer types would mean that the RO Model requirements and billing guidance would apply to a subset of their RT services rather than to than to the majority of their RT services for a significant portion of the Model performance period (or if cancer types were further limited, for the entire Model performance period).

As explained earlier in this section of the final rule, we are modifying the list of included cancer types to exclude kidney cancer. We believe that including the 16 cancer types (Anal Cancer, Bladder Cancer, Bone Metastases, Brain Metastases, Breast Cancer, Cervical Cancer, CNS Tumors, Colorectal Cancer, Head and Neck Cancer, Liver Cancer, Lung Cancer, Lymphoma, Pancreatic Cancer, Prostate Cancer, Upper GI Cancer, and Uterine Cancer) that are commonly treated with RT and that can be accurately priced for prospective episode payments, is the best design for testing an episodic APM for RT services. The list of ICD–10 codes for the included cancer types under the RO Model, upon any subsequent revisions, can be located on the RO Model website.

After considering public comments, we are finalizing, without change, our proposed criteria for included cancer types and for removing cancer types at § 512.230(a) and (b) of our regulations. Additionally, we are finalizing without change at § 512.230(c) our proposal to notify RO participants of any changes to the diagnosis codes for the included cancer types by displaying them on the RO Model website no later than 30 days prior to each performance year.

TABLE 1: IDENTIFIED CANCER TYPES AND CORRESPONDING ICD-10 CODES

Cancer Type	ICD-10 Codes
Anal Cancer	C21.xx
Bladder Cancer	C67.xx
Bone Metastases	C79.5x
Brain Metastases	C79.3x
Breast Cancer	C50.xx, D05.xx
Cervical Cancer	C53.xx
CNS Tumors	C70.xx, C71.xx, C72.xx
Colorectal Cancer	C18.xx, C19.xx, C20.xx
Head and Neck Cancer	C00.xx, C01.xx, C02.xx, C03.xx, C04.xx, C05.xx, C06.xx, C07.xx, C08.xx, C09.xx, C10.xx, C11.xx, C12.xx, C13.xx, C14.xx, C30.xx, C31.xx, C32.xx, C76.0x
Liver Cancer	C22.xx, C23.xx, C24.xx
Lung Cancer	C33.xx, C34.xx, C39.xx, C45.xx
Lymphoma	C81.xx, C82.xx, C83.xx, C84.xx, C85.xx, C86.xx,

Cancer Type	ICD-10 Codes
	C88.xx, C91.4x
Pancreatic Cancer	C25.xx
Prostate Cancer	C61.xx
Upper GI Cancer	C15.xx, C16.xx, C17.xx
Uterine Cancer	C54.xx, C55.xx

b. Episode Length and Trigger

(1) Episode Length

We proposed to define the length of an episode under the RO Model as 90 days (84 FR 34498). Based on the analysis of Medicare claims data between January 1, 2014 and December 30, 2015, approximately 99 percent of beneficiaries receiving RT completed their course of radiation within 90 days of their initial treatment planning service. We proposed that Day 1 would be the date of service that a Professional participant or Dual participant furnishes the initial treatment planning service (included in the PC), provided that a Technical participant or Dual participant furnishes an RT delivery service (included in the TC) within 28 days of the treatment planning service. In other words, the relevant 90-day period would be considered an episode only if a Technical participant or Dual participant furnishes the TC to an RO beneficiary within 28 days of when a Professional participant or Dual participant furnishes the PC to such RO beneficiary. As we explained in the proposed rule, when those circumstances occur, the ''start'' of the episode would be the date of service that the initial treatment planning service was rendered. If, however, a Technical participant or Dual participant does not furnish the TC to an RO beneficiary within the 28-day period, then no episode would have occurred and any payment will be made to the RO participant in accordance with our incomplete episode policy. (See 84 FR 34498 through 34499.) We refer readers to sections III.C.5.b and III.C.6 of the proposed rule and this final rule for an overview of our episode trigger and incomplete episode policies, respectively.

As discussed in the proposed rule (84 FR 3499), to better understand the standard length of a course of RT, we analyzed Medicare claims for beneficiaries who received any RT services between January 1, 2014 and December 30, 2015. Preliminary analysis showed that average Medicare spending for radiation treatment tends to drop significantly 9 to 11 weeks following the initial RT service for most diagnoses, including prostate, breast, lung, and head and neck cancers. Furthermore, based on this data, approximately 99 percent of beneficiaries receiving RT completed their course of radiation within 90 days of their initial treatment planning service. As we stated in the proposed rule, we made a summary-level, de-identified file titled ''RT Expenditures by Time'' available on the RO Model's website (*https://innovation.cms.gov/initiatives/radiation-oncology-model/*) that supports our findings in this preliminary analysis.

Based on our proposed rule analysis, for the purpose of establishing the national base rates for the PC and TC of each episode for each cancer type, episodes were triggered by the occurrence of a treatment planning service followed by a radiation treatment delivery service within 28 days of the treatment planning service (HCPCS codes 77261–77263). In addition, for the purpose of establishing the national base rates in section III.C.6.c, the episodes lasted for 89 days starting from the day after the initial treatment planning service in order to create a full 90-day episode. Based on these analyses, we proposed a 90-day episode duration.

(2) Episode Trigger

Because we only want to include episodes in which beneficiaries actually receive RT services, we proposed that an episode would be triggered only if both of the following conditions are met: (1) There is an initial treatment planning service (that is, submission of treatment planning HCPCS codes 77261–77263, all of which would be included in the PC) furnished by a Professional participant or a Dual participant; and (2) at least one radiation treatment delivery service (as listed in the proposed rule at Table 2) is furnished by a Technical participant or a Dual participant within the following 28 days. The PC is attributed to the RT supplier of the initial radiation treatment planning service. The TC is attributed to the RT provider or RT supplier of the initial radiation treatment delivery service. As we explained in the proposed rule, an episode that is triggered will end 89 days after the date of the initial treatment planning service, creating a 90-day episode. If, however, a beneficiary receives an initial treatment planning service but does not receive RT treatment from a Technical participant or Dual participant within 28 days, then the requirements for triggering an episode would not be met, and no RO episode will have occurred, and the proposed incomplete episode policy would take effect.

In those instances where the TC of an episode is not furnished by a Dual participant (that is, when the same RO participant does not furnish both the PC and the TC of an episode), we proposed that the Professional participant would provide the Technical participant with a signed radiation prescription and the final treatment plan, all of which is usually done electronically. This will inform the Technical participant of the episode start date.

(3) Policy for Multiple Episodes and the Clean Period

Given our proposed rule findings that 99 percent of Medicare FFS beneficiaries complete treatment within

90 days of the initial treatment planning service, and to minimize any potential incentive for an RO participant to extend a treatment course beyond the 90-day episode in order to trigger a new episode, we proposed that another episode may not be triggered until at least 28 days after the previous episode has ended (84 FR 34499). This is because, while a missed week of treatment is not uncommon, a break from RT services for more than four weeks (or 28 days) generally signals the start of a new course of treatment.[31] As we explained in the proposed rule, we refer to the 28-day period after an episode has ended as the ''clean period,'' and during this time an RO participant would bill for RT services furnished to an RO beneficiary as FFS. We proposed to codify the term ''clean period'' at § 512.205 of our regulations.

We proposed that if clinically appropriate, an RO participant may initiate another episode for the same beneficiary after the 28-day clean period has ended. During the clean period, an RO participant would be required to bill for RT services for the beneficiary in accordance with FFS billing rules. We proposed that the Innovation Center would monitor the extent to which services are furnished outside of 90-day episodes, including during clean periods, and for the number of RO beneficiaries who receive RT in multiple episodes.

We solicited public comment on our proposal regarding episode length and trigger. The following is a summary of the public comments received on this proposal and our responses to those comments:

Comment: Some commenters noted their concern that the 90-day episode period would inappropriately incentivize providers and suppliers to reduce the number of fractions into the shortest possible course of treatment. A commenter believed this would have negative effects on research, as encouraging providers and suppliers to opt for the shortest length of treatment possible would make it more difficult to study the optimal length of treatment for different types of patients. Another commenter suggested that this structure would disincentivize adoption of ground-breaking treatment paradigms. A few commenters requested that CMS consider the negative impact of the 90-day episode on services with higher upfront investment but longer term value. A couple of these commenters suggested that the 90-day episode period is unduly focused on short-term gains, failing to capture the medium- and long-term benefits and savings from treatment modalities like PBT. A few commenters also suggested that the financial disincentives created by the RO Model would lead to long-term adverse clinical consequences and additional spending. A commenter believed that short term savings would be outweighed by longer term costs.

Response: We appreciate commenters' concerns. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. We expect Medicare providers and suppliers to select the clinically appropriate treatment modality that will confer the greatest short-, medium-, or long-term benefit on the beneficiary. And, we believe our payment methodology, with its blend of national rates with participant-specific case mix and historical experience, will provide appropriate payment to incentivize high-value care, including the appropriate treatment modality and number of fractions. Thus, we do not believe that the Model will lead to long-term adverse clinical consequences or additional spending. We will be monitoring to ensure there are no unintended consequences.

Comment: A commenter requested clarification on whether an episode of care includes any course of treatment within 90 days or if an episode is limited to a specific diagnosis. Another commenter requested clarification regarding billing practices for patients who, within a 90-day episode, are found to have new cancer sites with different HCPCS codes.

Response: We thank the commenter for their question. An RO episode includes all included RT services (See Table 2) furnished to an RO beneficiary with an included cancer type during the 90-day episode as codified at §§ 512.205 and 512.245. RT services furnished to an RO beneficiary for any additional diagnosis not specified on the list of included cancer types, the RT provider and/or RT supplier would bill FFS for those services.

Comment: Many commenters believed the 90-day episode period is not sufficiently responsive to patients whose cancer might recur, metastasize, require multiple treatment modalities, or otherwise require additional treatments within the 90-day period. A couple of commenters believed that the 90-day episode structure would incentivize participants to delay care or shift patients to other treatment, waiting to capture payment for those services in the clean period or a subsequent episode. A commenter believed this might limit patient access to life-extending treatment protocols.

Response: We believe that the RO Model pricing methodology, with its reliance on historical experience and case mix adjustments, accounts for the range of patient scenarios and provides appropriate compensation to participants. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. As finalized in section III.C.14, we will monitor for unintended consequences of the RO Model including but not limited to stinting on care.

Comment: Some commenters recommended that CMS reconsider its methodology in bundling multiple treatments into a single episode, factoring in the complexity of multiple eligible sites requiring treatment within a 90-day period. Some commenters specifically suggested that participants should be eligible for multiple bundles if they treat distinct disease sites or diagnoses within a 90-day episode of care to accurately capture the costs of multiple treatments. A commenter suggested that FFS payment should be permitted for treatment of metastases within the 90-day episode as long as it is for a new site. A commenter recommended eliminating the 90-day episode to reimburse providers and suppliers for separate courses of radiation therapy within this period. Another commenter requested more information about what happens to a course of treatment for a specific diagnosis that lasts longer than 90 days.

Response: We believe that the RO Model pricing methodology, through the historical experience and case mix adjustments, will account for differences in RO participants' historical care patterns and the demographic characteristics of their patient populations and addresses the cost of treating multiple diagnoses or the cost of multiple treatments. It is important to note that, if treatment goes beyond the end of 90 days, after the RO participant bills the modifier indicating the end of an RO episode (EOE) the additional RT services furnished will be billed and paid FFS—this does not create an incomplete episode.

Comment: A couple commenters recommended that CMS tailor episode length to the likely pattern and timing of RT treatment for each cancer type.

Response: We believe that the RO Model pricing methodology will adequately reimburse participants for the patterns and timing of RT services during a uniform 90-day episode period. As previously stated, 99 percent of beneficiaries complete their RT course within 90 days. Although some cancer

[31] CMS was advised by radiation oncologists consulting on the design of the Model that four weeks signals the start of a new course of treatment.

types might typically complete treatment in a period of time shorter than 90 days, our data shows that while significant expenditures occur through week 10 of an episode, additional expenditures occur throughout the remainder of the episode for all of the included cancer types. (See RT Expenditures by Time on the RO Model website.) As explained in section III.C.7, we have modified the billing requirements to allow the EOE claim to be submitted and paid at the completion of a planned course of treatment, even when that course of treatment is shorter than 90 days. We believe that participants will be reimbursed for their services in an appropriate and timely manner under this structure.

Comment: A few commenters voiced concern about potential delays or breaks in therapy caused by adverse patient response or concurrent patient illness. A commenter believed that providers and suppliers could lose reimbursement for delivered services if a patient cannot tolerate treatment. A couple such commenters expressed that the breaks in treatment could extend the therapy beyond the 90-day end point, preventing timely EOE submission and resulting in an incomplete episode. This commenter recommended adjusting the EOE to the completion of the episode.

Response: Such breaks in therapy will not cause an incomplete episode. It is important to note that if treatment goes beyond the end of 90 days, the RO participant can bill the EOE and the additional RT services furnished will be billed and paid FFS.

Comment: A commenter noted that each clinical scenario is different and that physicians may have good reasons for ordering more treatment sessions with lower intensity. This commenter believed that CMS should evaluate the specifics of a clinical scenario that falls outside the expected parameters as part of the agency's data analysis.

Response: We appreciate this commenter's concerns. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. And, we believe that our cancer-specific bundles strike the right balance of capturing a range of clinical scenarios with little variability in pricing to prohibit setting a base rate. As described in section III.C.16, we will monitor for unintended consequences of the RO Model.

Comment: A commenter emphasized that the episode length could reduce the availability of palliative radiotherapy for pain control, as some evidence suggests that shorter courses of treatment lead to increased need for additional treatment and shortened pain control. Another commenter, believing that the episodes do not match standard medically accepted episodes of care, recommended that CMS create a separate category for palliative cases.

Response: Based on the analysis of Medicare claims data between January 1, 2014 and December 30, 2015, approximately 99 percent of beneficiaries receiving RT completed their course of radiation within 90 days of their initial treatment planning service. The Model does include Brain Metastasis and Bone Metastasis as included cancer types. For the other cancer types, our data shows that palliative treatment is included when RT services are being furnished to treat the primary cancer type and secondary malignancies and metastases. Thus, we will not be creating a separate category for palliative cases or altering the length of the episode.

Comment: A couple commenters expressed support of the 28-day window between the treatment planning code and the first treatment delivery service, finding this structure reasonable.

Response: We thank the commenters for their support.

Comment: A commenter requested clarification on how the planning and simulation of treatment are designated within an episode. In the event a patient receives multiple planning services prior to the commencement of treatment, this commenter wished to know which planning service would be considered the trigger and how multiple planning sessions are represented in the national base rates. A commenter expressed concern about claims processing for multiple planning services furnished within a 90-day episode for metastases identified during the episode. This commenter emphasized that the resources expended for subsequent planning sessions are equivalent to those expended in the initial planning session.

Response: The treatment planning service identified as the ''first'' treatment planning service is the trigger for an episode and its corresponding date of service marks the episode's start date. Subsequent planning sessions occurring within a previously defined episode are indeed included in the national base rates. Each treatment planning service furnished should be included on the no-pay claims described in section III.C.7 and codified at § 512.260(d). We will monitor utilization of services via these no-pay claims.

Comment: A few commenters expressed concern about the 28-day episode trigger window between the treatment planning code and the first treatment delivery service in particular scenarios. For example, a commenter stated that some cases of multi-radiation modalities, like EBRT followed by brachytherapy, require coordination with other specialties that might make it difficult to begin delivering treatment within a 28-day episode trigger window. Another commenter recommended that CMS remove the 28-day episode trigger window and instead trigger the first episode payment at the completion of treatment planning and commencement of treatment delivery without any required timeline.

Response: Our data show that treatment almost always occurs within this time period. And, if it does not, this would constitute an incomplete episode. We are finalizing that an episode will be triggered only if both of the following conditions are met: (1) There is an initial treatment planning service (HCPCS codes 77261–77263) furnished by a Professional participant or a Dual participant; and (2) at least one radiation treatment delivery service (See Table 2) is furnished by a Technical participant or a Dual participant within the following 28 days.

Comment: A commenter expressed concern about incomplete episodes resulting from planning services provided by an RO participant and treatment provided in an ASC outside of the Model, whether or not treatment is furnished within the 28-day episode trigger window.

A couple of commenters requested clarification on how PC and TC claims will be paid if treatment is not delivered within the 28-day episode trigger window. One such commenter advised that cash flow problems would result if providers and suppliers are required to wait until the reconciliation periods and true-up periods to receive payment for these incomplete episodes. For this reason, this commenter recommended that CMS pay all CPT/HCPCS codes that are billed outside this 28-day episode trigger window as FFS.

Response: We thank the commenters for their inquiry. RT services furnished in an ASC are not included in the RO Model. Thus, if the planning service was provided by a Professional participant (in an HOPD or a freestanding radiation therapy center) and the treatment delivery was furnished in an ASC, an episode could be triggered but rendered incomplete, thus the planning services should be billed FFS. If the TC is not rendered by a participant within 28 days, an episode will be considered incomplete and those services should be billed FFS. As noted

in section III.C.7 of the proposed rule (84 FR 34512 through 34513) and this final rule, we expect to provide RO participants with additional instructions for billing, particularly as billing pertains to incomplete episodes, through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A couple of commenters supported FFS payments for treatments that exceed the 90-day episode period.

Response: We thank the commenters for their support. We will be finalizing as proposed in § 512.260 that an RO participant shall bill for any medically necessary RT services furnished to an RO beneficiary during a clean period pursuant to existing FFS billing processes in the OPPS and PFS.

Comment: A commenter supported the 28-day clean period between episodes for all but one included cancer type, metastatic bone disease. Because metastatic bone disease often requires ongoing treatment, this commenter suggested that RO participants have the ability to initiate subsequent episodes immediately after the prior episode ends, eliminating the clean period.

Response: We appreciate the suggestion, but we do not want to provide a financial incentive for RO participants to prolong or delay treatment for bone metastasis or any other clinical condition to initiate an additional episode.

Comment: A commenter recommended that the clean period be extended to 60 days to allow for treatment of secondary cancers.

Response: We appreciate the comment, but CMS was advised by radiation oncologists consulting on the design of the Model that four weeks typically signals the start of a new course of treatment. Therefore, we will not be extending the clean period in this final rule.

Comment: A commenter requested clarification on billing practices for patients who complete one 90-day episode and then return with a new diagnosis under their existing diagnosis code within the clean period.

Response: As stated in sections III.C.5.b(3) and III.C.7 of this final rule, any services provided during the 28-day clean period would be paid FFS.

After considering public comments received, we are finalizing at § 512.205 the definition of RO episode. Specifically, we are defining that an RO episode means the 90-day period that begins on the date of service that a Professional participant or a Dual participant furnishes an initial RT treatment planning service to an RO beneficiary, provided that a Technical participant or the same Dual participant furnishes a technical component RT service to the RO beneficiary within 28 days of such RT treatment planning service, with a modification to clarify that the initial RT treatment planning service to the RO beneficiary be furnished in a freestanding radiation therapy center or an HOPD. We are finalizing as proposed that the circumstance in which an episode does not occur because a Technical participant or a Dual participant does not furnish a technical component to an RO beneficiary within 28 days following a Professional participant or the Dual participant furnishing an initial treatment planning service to that RO beneficiary qualifies as an incomplete episode. In addition, we are finalizing as proposed at § 512.245(c) that an episode must not be initiated for the same RO beneficiary during a clean period.

c. Included RT Services

We proposed at 84 FR 34499 that the RO Model would include most RT services furnished in HOPDs and freestanding radiation therapy centers. Services furnished within an episode of RT usually follow a standard, clearly defined process of care and generally include a treatment consultation, treatment planning, technical preparation and special services (simulation), treatment delivery, and treatment management, which are also categorical terms used to generally describe RT services. As outlined in the proposed rule, the subcomponents of RT services have been described in the following manner: [32]

Consultation: A consultation is an evaluation and management (E/M) service, which typically consists of a medical exam, obtaining a problem-focused medical history, and decision making about the patient's condition/care.

Treatment planning: Treatment planning tasks include determining a patient's disease-bearing areas, identifying the type and method of radiation treatment delivery, specifying areas to be treated, and selecting radiation therapy treatment techniques. Treatment planning often includes simulation (the process of defining relevant normal and abnormal target anatomy and obtaining the images and data needed to develop the optimal radiation treatment process). Treatment planning may involve marking the area to be treated on the patient's skin, aligning the patient with localization lasers, and/or designing immobilization devices for precise patient positioning.

Technical preparation and special services: Technical preparation and special services include radiation dose planning, medical radiation physics, dosimetry, treatment devices, and special services. More specifically, these services also involve building treatment devices to refine treatment delivery and mathematically determining the dose and duration of radiation therapy. Radiation oncologists frequently work with dosimetrists and medical physicists to perform these services.

Radiation treatment delivery services: Radiation treatment is usually furnished via a form of external beam radiation therapy or brachytherapy, and includes multiple modalities. Although treatment generally occurs daily, the care team and patient determine the specific timing and amount of treatment. The treating physician must verify and document the accuracy of treatment delivery as related to the initial treatment planning and setup procedure.

Treatment management: Radiation treatment management typically includes review of port films, review and changes to dosimetry, dose delivery, treatment parameters, review of patient's setup, patient examination, and follow-up care.

As discussed in the proposed rule (84 FR 34500), our claims analysis revealed that beneficiaries received a varying number of consultations from different physicians prior to the treatment planning visit, which determines the prescribed course of radiation therapy, including modality and number of treatments to be delivered. We proposed to include treatment planning, technical preparation and special services, treatment delivery, and treatment management as the RT services in an episode paid for by CMS, and we proposed to codify this at § 512.235. E/M services are furnished by a wide range of physician specialists (for example, primary care, general oncology, others) whereas the other radiation services are typically only furnished by radiation oncologists and their team. This is reflected in the HCPCS code set used to bill for these services. In our review of claims data for the proposed rule, many different types of specialists furnish E/M services. It is common for multiple entities to bill for treatment consultations (E/M services) for the same beneficiary, whereas typically only a single entity bills for RT services for a beneficiary when we limited the services considered to treatment planning, technical

[32] American Society for Radiation Oncology (ASTRO). Basics of RO Coding. *https://www.astro.org/Basics-of-Coding.aspx.*

preparation and special services, treatment delivery, and treatment management. When consultations and visits were included for an analysis of professional RT services during 2014–2016, only 18 percent of episodes involved billing by a single entity (TIN or CCN) as opposed to 94 percent of episodes when consultations and visits were excluded. When consultations and visits were included for an analysis of technical RT services during 2014–2016, 78 percent of episodes involved billing by a single entity (TIN or CCN) as opposed to 94 percent of episodes when consultations and visits were excluded. The difference in percentages is due to the fact that patients see a wide variety of doctors during the course of cancer treatment, which will often involve visits and consultations.

In the proposed rule we noted that we were not proposing to include E/M services as part of the episode payment. RO participants would continue to bill E/M services under Medicare FFS.

Given that physicians sometimes contract with others to supply and administer brachytherapy radioactive sources (or radioisotopes), we explained in the proposed rule that we considered omitting these services from the episode payment. After considering either including or excluding brachytherapy radioelements from the RO Model, we proposed to include brachytherapy radioactive elements, rather than omit these services, from the episodes because they are generally furnished in HOPDs and the hospitals are usually the purchasers of the brachytherapy radioactive elements. When not furnished in HOPDs, these services are furnished in ASCs, which we noted were proposed to be excluded from the Model.

We also proposed to exclude low volume RT services from the RO Model. These include certain brachytherapy surgical procedures, neutron beam therapy, hyperthermia treatment, and radiopharmaceuticals. We proposed to exclude these services from the Model because they are not offered in sufficient amounts for purposes of evaluation.

We proposed that the RO Model payments would replace current FFS payments only for the included RT services furnished during an episode. For the included modalities, discussed in section III.C.5.d of the proposed rule (84 FR 34502 through 34503), we proposed that the RO Model episode include HCPCS codes related to radiation oncology treatment. Please see section III.C.7 for a discussion of our billing guidelines. We have compiled a list of HCPCS codes that represent treatment planning, technical preparation and special services, treatment delivery, and treatment management for the included modalities. As discussed in the proposed rule, RT services included on this list are referred to as ''RO Model Bundled HCPCS'' when they are provided during an RO Model episode since payment for these services is bundled into the RO episode payment. Thus, we proposed to codify at § 512.270 that these RT services would not be paid separately during an episode. In the proposed rule, we indicated that we may add, remove, or revise any of the bundled HCPCS codes included in the RO Model. We proposed to notify participants of any changes to the HCPCS codes per the CMS annual Level 2 HCPCS code file. We proposed to maintain a list of the HCPCS codes included in the RO Model on the RO Model website.

We solicited public comment on our proposal. The following is a summary of the public comments received on this proposal and our responses:

Comment: A commenter recommended that CMS exclude consultation services from the Model, as these services are often provided to patients seeking second opinions. If CMS includes consultation services, this commenter suggested classifying these services as incomplete episodes when the patient does not pursue treatment post-consultation.

Response: Consultations, which are billed as E/M services, were not included in the RO Model's proposed pricing methodology and are not RT services, and they are not included in the final rule.

Comment: A couple of commenters expressed support for the exclusion of E/M services from the Model.

Response: We thank these commenters for their support.

Comment: A few commenters expressed concern over the bundling of IMRT planning code 77301 in that it no longer allows payment for advanced imaging used in data sets for dose planning and simulations when charged with IMRT treatments. The commenter believed this was inappropriate as it places a burden on providers and suppliers that cannot afford to upgrade their CT, MR or PET equipment used in planning. The commenters expressed concern that these costs are not reflected appropriately in the national base rates.

Response: The episode payment amounts reflect payments made under the PFS and OPPS for RT services furnished during the baseline period. As such, when determining payment rates, we look at RT services in the baseline period that were allowed by Medicare (such as claims with HCPCS 77301 with payment amounts allowed), but we do not assign payment rates to other claims with other HCPCS codes from the baseline period that were denied (for example, in this example because they were in the range of HCPCS codes not allowed to be reported in addition to 77301 because they are part of the valuation of 77301). The RO Model is not intended to change Medicare policy on coverage.

Comment: A few commenters recommended excluding proton beam therapy (PBT) as a low-volume service. A couple commenters suggested specifically excluding neutron beam therapy, hyperthermia, and brachytherapy radioactive elements as low-volume services.

Some commenters requested clarification on how ''low-volume'' and ''commonly used'' will be defined in the Model. A couple of commenters suggested that the test for low-volume services should be conducted on a total and per cancer type basis.

Response: We used ''low-volume'' and ''commonly used'' in several different places in the proposed rule. We proposed to exclude certain RT services as low volume, including certain brachytherapy surgical procedures, neutron beam therapy, hyperthermia treatment, and radiopharmaceuticals. All of these RT services are rarely furnished to Medicare beneficiaries. In contrast, we proposed to include the ''most commonly used'' RT modalities, including PBT, in the RO Model as they represent standard approaches to treatments that are cited in guidelines for the included cancer types. While we did not propose a definition for a commonly used RT modality or RT service, we used those terms to describe what is standard practice for radiation oncology and the included cancer types. Though we appreciate the suggestion to look at low-volume RT services on a per cancer type basis, as described in the proposed rule, we plan to test the impact of the RO Model on RT as a whole, rather than specific RT services for specific cancer types. Further, we believe that including certain RT services for some cancer types but not others would be burdensome for RO participants, specifically regarding the tracking and management of which beneficiaries are in or out of the Model. We note that we are finalizing a low volume opt-out option for RO participants with fewer than 20 episodes in one or more of the CBSAs randomly selected for participation in the most recent calendar year with available claims data, as described in

section III.C.3.c. Any PBT providers and suppliers who believe they qualify for such an exemption should refer to this section.

Comment: A couple of commenters requested clarification on the Model's treatment of radiopharmaceuticals. These commenters emphasized that, in the case of Radium, treatment often occurs monthly for six months, far longer than the 90-day episode. Many commenters requested the removal of C2616 for Yttrium 90 or Y90 as it is a radiopharmaceutical.

Response: We thank these commenters for this point. As indicated in the NPRM, radiopharmaceuticals are excluded from the RO Model, thus C2616 has been removed from the list of RO Model Bundled HCPCS.

Comment: Many commenters recommended that CMS exclude the radioactive sources from the Model. These commenters emphasized that individual patients often require unique brachytherapy sources, expressing concern that the Model would not appropriately compensate for differences in isotopes and radioactive intensity. A few believed that the Model would undermine access to the optimal isotope. A commenter believed that brachytherapy sources were more appropriately considered medical devices rather than RT procedures. Some of these commenters recommended that CMS exclude specific brachytherapy sources, primarily the HCPCS A-codes, C-codes, and Q-codes from the Model. Many commenters emphasized that brachytherapy sources alone are frequently more expensive than the proposed bundled payments—particularly for high dose rate brachytherapy—in the proposed Model and that hospitals have little control over these costs. A couple commenters recommended excluding high dose rate brachytherapy from the Model.

Response: We thank the commenters for their suggestion. We package many expensive and more expensive services in value-based bundled payment; there is no reason to treat brachytherapy sources any differently than other necessary items and services such as linear accelerators. We believe that once the national base rates are adjusted for the RO participant's case mix and historical experience, they will see that final payments will be reflective of the inclusion of radioelements. As discussed in section III.C.14 and III.C.16 of this final rule, we will monitor for unintended consequences of the RO Model.

Comment: Several commenters stated that including medical physics services in the RO Model will lead to a loss of direct financial accountability for providing adequate technical supervision that is provided to each patient and could significantly reduce medical physics resources around the country. A commenter stated that medical physicists would move to an area not participating in the Model in order to maintain their salary.

Response: It is our understanding that medical physics is a state licensure requirement and is an integral to the delivery of RT services. We do not anticipate that the Model will have a detrimental impact on medical physics resources, as participants would continue to need these health care providers for many functions, including output calibrations and, where clinically appropriate, hypo fractionation. As discussed in section III.C.14 and III.C.16 of this final rule, we will monitor for unintended consequences of the RO Model.

Comment: A commenter has requested that any changes made to the HCPCS code bundles be made through notice and comment rulemaking rather than through a list on the RO Model website.

Response: We believe that our proposal allows us to update the list in an expeditious manner if we detect an error to facilitate prompt and accurate payments. Thus, we are finalizing our policies as proposed, without modification, to add, remove, or revise any of the bundled HCPCS codes included in the RO Model; notify participants of any changes to the HCPCS codes per the CMS annual Level 2 HCPCS code file or quarterly update; and maintain a list of the HCPCS codes included in the RO Model on the RO Model website. If CMS intends to add any new HCPCS codes to the RO Model, we would go through rulemaking to add those new codes to the list of RO Model Bundled HCPCS.

Comment: Several commenters expressed concern that the proposed payment methodology was insufficient for codes 77387 and G6017, as these commenters believed that there is not currently sufficient payment under the PFS for these codes for surface guided radiation therapy (SGRT). These commenters believed that by including these two codes as RT services in the RO Model, payment under the Model would not accurately reflect the cost of all care in an episode. Specifically, a commenter noted that CMS has not assigned a relative value unit (RVU) for HCPCS 77387 or G6017 in the PFS. The commenter believed that inclusion of these two codes as RT services in the RO Model would extend the payment challenges associated with SGRT services into the Model. Another commenter stated that CMS has not established PFS payment for the G6017 code, which has been in existence since 2015, and recommended CMS pay for SGRT separately from the Model.

Response: Although CPT® code 77387 was active in the PFS or OPPS in some year prior to the updated baseline period with spillover (2015–2019), it is not paid separately. As proposed, the Model was only to include codes paid separately. This code was mistakenly included on the list of include RT services but not in the pricing methodology. We would also like to clarify that the code G6017 is contractor-priced under the PFS. This means that CMS has not established nationally applicable RVUs for the service. Instead, individual Medicare Administrative Contractors (MACs) determine the payment rate for the service and apply that rate in their jurisdiction(s). Payment rates across MAC jurisdictions can vary. Due to the potential differences across jurisdictions, we calculated the average paid amounts for each year in the baseline period for contractor-priced RT services to determine their average paid amount to be included in the calculation of the national base rates. We will use the most recent calendar year with claims data available to determine the average paid amounts for these contractor-priced RT services that will be included in the calculation of the trend factors for the PC and TC of each cancer type. For instance, for the 2021 trend factor, we will calculate the average paid amounts for these contractor-priced RT services using their allowed charges listed on the 2019 claims.

Comment: A commenter stated that inserting a hydrogel spacer between the prostate and rectum has become a standard of care at many practices to reduce the toxicity of radiotherapy, by decreasing rectal dose exposure. Many practices have also implanted fiducial markers into the prostate to improve the accuracy of targeting. These items, particularly the hydrogel spacer, have a significant cost and added physician work component. The commenter suggested that payment include a provision to account for this added labor and cost.

Response: We believe the commenter is referring to HCPCS 55784. This is not an included RT service. Thus, the RO participant may continue to receive FFS payment upon furnishing this service.

Comment: Many commenters expressed concern about the lack of consideration for emerging or new

technologies in the Model, and that the pricing methodology of the RO Model generally does not provide an incentive for participants to invest in new technologies and equipment. A commenter explained that the incentive is removed, because 2D, 3D, IMRT, and HDR treatment courses will be billed at the same rate, and the latest IGRT technologies will not be pursued. Another commenter noted that the RO Model does not include any approach to recognize new technology such as the MRI–LINAC.

Commenters defined emerging and new technologies differently. A commenter suggested defining new technology as any service that has been granted a new technology APC or pass-through payment. Another commenter suggested that devices be granted an innovative designation if a new technology and as a result qualify for additional reimbursement. This commenter suggested that the innovative designation would need approval by the FDA under a Premarket Approval Process and not be ''substantially equivalent'' to an existing device. Another commenter suggested that new technology could be signaled through a CPT® code transitions from a Category III code to a Category I code. This commenter also suggested that new technology could include the use of existing CPT®/HCPCS codes used in different combination or in more fractions than what has historically been used. A few commenters called attention to the need to reimburse HCPCS codes bundled in the RO Model that come to be used differently than historical patterns indicate, whether in frequency or in combination with other modalities, and this in itself was a new form of technology.

One commenter recommended adding a payment adjustment for new technology in the same way OCM has a novel therapies adjustment. Another commenter suggested that CMS consider modalities with the 510(k) clearances as innovations that should be paid separately outside of the RO Model.

A few commenters requested clarification as to whether new technologies would be paid FFS. A couple of commenters requested clarification concerning CPT® and HCPCS codes established after the publication of the Final Rule specifically, and if those code would be paid FFS.

Response: To the extent that new technologies and new equipment are billed under new HCPCS codes, we would go through rulemaking to add those new codes to the list of RO Model Bundled HCPCS list. We believe that any increased utilization of established codes that are included RT services over time will be accounted for with the trend factor described in section III.C.6.d. Until new technologies with corresponding HCPCS codes are added the list of included services for the RO Model, they will be paid FFS.

Comment: Many commenters recommended excluding HCPCS codes that refer to either brachytherapy services commonly provided in a surgical setting or that refer to brachytherapy sources. These commenters emphasized that surgical codes for other modalities were excluded from the Model and questioned why surgical codes 57155, 57156, 55920, and 53846 were included for brachytherapy. These commenters emphasized that the surgical procedures often involve sub-specialized physicians, equipment, and other costs. By including the surgical component in the Model, these commenters worried that it would undermine patient access to care. As relatively low-volume services, these commenters believe excluding them from the Model would not have a large impact on savings. A few commenters requested clarification on the inclusion of brachytherapy insertion codes.

Response: We have confirmed with clinical experts that these services are commonly furnished by radiation oncologists and thus will be included in the RO Model. We have not included brachytherapy surgical codes that are only provided by other types of physicians.

Comment: A few commenters agreed with the inclusion of RT services as proposed.

Response: We thank these commenters for their support. See Table 2 for the finalized list of included RT services.

TABLE 2: LIST OF RO MODEL BUNDLED HCPCS

HCPCS	HCPCS Description	Category
55920	Placement Pelvic Needles/Catheters, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
57155	Placement Tandem and Opioids, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
57156	Placement Vaginal Cylinder, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
58346	Placement Heyman Capsules, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
77014	Computed tomography guidance for placement of	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77021	Magnetic resonance guidance for needle placement	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77261	Radiation therapy planning	Treatment Planning
77262	Radiation therapy planning	Treatment Planning
77263	Radiation therapy planning	Treatment Planning
77280	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77285	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77290	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77293	Respirator motion mgmt simul	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77295	3-d radiotherapy plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77299	Radiation therapy planning	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77300	Radiation therapy dose plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77301	Radiotherapy dose plan imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77306	Telethx isodose plan simple	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77307	Telethx isodose plan cplx	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77316	Brachytx isodose plan simple	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77317	Brachytx isodose intermed	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77318	Brachytx isodose complex	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77321	Special teletx port plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services

HCPCS	HCPCS Description	Category
77331	Special radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77332	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77333	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77334	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77336	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77338	Design mlc device for imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77370	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77371	Srs multisource	Radiation Treatment Delivery
77372	Srs linear based	Radiation Treatment Delivery
77373	Sbrt delivery	Radiation Treatment Delivery
77385	Ntsty modul rad tx dlvr smpl	Radiation Treatment Delivery
77386	Ntsty modul rad tx dlvr cplx	Radiation Treatment Delivery
77399	External radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77402	Radiation treatment delivery	Radiation Treatment Delivery
77407	Radiation treatment delivery	Radiation Treatment Delivery
77412	Radiation treatment delivery	Radiation Treatment Delivery
77417	Radiology port images(s)	Radiation Treatment Delivery (Guidance)
77427	Radiation tx management x5	Treatment Management
77431	Radiation therapy management	Treatment Management
77432	Stereotactic radiation trmt	Treatment Management
77435	Sbrt management	Treatment Management
77470	Special radiation treatment	Treatment Management
77499	Radiation therapy management	Treatment Management
77520	Proton trmt simple w/o comp	Radiation Treatment Delivery
77522	Proton trmt simple w/comp	Radiation Treatment Delivery
77523	Proton trmt intermediate	Radiation Treatment Delivery
77525	Proton treatment complex	Radiation Treatment Delivery
77761	Apply intrcav radiat simple	Radiation Treatment Delivery
77762	Apply intrcav radiat interm	Radiation Treatment Delivery
77763	Apply intrcav radiat compl	Radiation Treatment Delivery
77767	Hdr rdncl skn surf brachytx	Radiation Treatment Delivery
77768	Hdr rdncl skn surf brachytx	Radiation Treatment Delivery
77770	Hdr rdncl ntrstl/icav brchtx	Radiation Treatment Delivery
77771	Hdr rdncl ntrstl/icav brchtx	Radiation Treatment Delivery
77772	Hdr rdncl ntrstl/icav brchtx	Radiation Treatment Delivery
77778	Apply interstit radiat compl	Radiation Treatment Delivery

HCPCS	HCPCS Description	Category
77789	Apply surf ldr radionuclide	Radiation Treatment Delivery
77790	Radiation handling	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77799	Radium/radioisotope therapy	Radiation Treatment Delivery
A9527	Iodine i-125 sodium iodide	Radiation Treatment Delivery (Brachytherapy Materials)
C1716	Brachytx, non-str, gold-198	Radiation Treatment Delivery (Brachytherapy Materials)
C1717	Brachytx, non-str,hdr ir-192	Radiation Treatment Delivery (Brachytherapy Materials)
C1719	Brachytx, ns, non-hdrir-192	Radiation Treatment Delivery (Brachytherapy Materials)
C2634	Brachytx, non-str, ha, i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2635	Brachytx, non-str, ha, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2636	Brachy linear, non-str,p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2638	Brachytx, stranded, i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2639	Brachytx, non-stranded,i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2640	Brachytx, stranded, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2641	Brachytx, non-stranded,p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2642	Brachytx, stranded, c-131	Radiation Treatment Delivery (Brachytherapy Materials)
C2643	Brachytx, non-stranded,c-131	Radiation Treatment Delivery (Brachytherapy Materials)
C2644	Brachytx cesium-131 chloride	Radiation Treatment Delivery (Brachytherapy Materials)
C2645	Brachytx planar, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2698	Brachytx, stranded, nos	Radiation Treatment Delivery (Brachytherapy Materials)
C2699	Brachytx, non-stranded, nos	Radiation Treatment Delivery (Brachytherapy Materials)
G0339	Robot lin-radsurg com, first	Radiation Treatment Delivery
G0340	Robt lin-radsurg fractx 2-5	Radiation Treatment Delivery
G6001	Echo guidance radiotherapy	Radiation Treatment Delivery (Guidance)
G6002	Stereoscopic x-ray guidance	Radiation Treatment Delivery (Guidance)
G6003	Radiation treatment delivery	Radiation Treatment Delivery
G6004	Radiation treatment delivery	Radiation Treatment Delivery

HCPCS	HCPCS Description	Category
G6005	Radiation treatment delivery	Radiation Treatment Delivery
G6006	Radiation treatment delivery	Radiation Treatment Delivery
G6007	Radiation treatment delivery	Radiation Treatment Delivery
G6008	Radiation treatment delivery	Radiation Treatment Delivery
G6009	Radiation treatment delivery	Radiation Treatment Delivery
G6010	Radiation treatment delivery	Radiation Treatment Delivery
G6011	Radiation treatment delivery	Radiation Treatment Delivery
G6012	Radiation treatment delivery	Radiation Treatment Delivery
G6013	Radiation treatment delivery	Radiation Treatment Delivery
G6014	Radiation treatment delivery	Radiation Treatment Delivery
G6015	Radiation tx delivery imrt	Radiation Treatment Delivery
G6016	Delivery comp imrt	Radiation Treatment Delivery
G6017	Intrafraction track motion	Radiation Treatment Delivery (Guidance)
Q3001	Brachytherapy radioelements	Radiation Treatment Delivery (Brachytherapy Materials)

After considering public comments, we are modifying our proposed list of included RT services to the corresponding HCPCS codes in Table 2 of this final rule. We are not adding any HCPCS codes to those identified in the proposed rule, but are removing HCPCS codes 77387, 77424, 77425, C1715, C1728, C2616, and 77469 from the Model. We are codifying at § 512.235 that only the following RT services furnished using an included modality identified at § 512.240 for an included cancer type are included RT services that are paid for by CMS under § 512.265: (1) Treatment planning; (2) technical preparation and special services; (3) treatment delivery; and, (4) treatment management; and at § 512.270 that these RT services would not be paid separately during an episode. All other RT services furnished by an RO participant during the Model performance period will be subject to Medicare FFS payment rules.

d. Included Modalities

We proposed at 84 FR 34502 through 34503 to include the following RT modalities in the Model: Various types of external beam RT, including 3-dimensional conformal radiotherapy (3DCRT), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), and proton beam therapy (PBT); intraoperative radiotherapy (IORT); image-guided radiation therapy (IGRT); and brachytherapy. We proposed to include all of these modalities because they are the most commonly used to treat the 17 proposed cancer types and including these modalities would allow us to determine whether the RO Model is able to impact RT holistically rather than testing a limited subset of services.

As discussed in the proposed rule, because the OPPS and PFS are resource-based payment systems, higher payment rates are typically assigned to services that use more expensive equipment. Additionally, newer treatments have traditionally been assigned higher payment. Researchers have indicated that resource-based payments may encourage health care providers to purchase higher priced equipment and furnish higher-cost services, if they have a sufficient volume of patients to cover their fixed costs.[33] Higher payment rates for services involving certain treatment modalities may encourage use of those modalities over others.[34]

In the proposed rule, we explained that Medicare expenditures for RT have increased substantially. From 2000 to 2010, for example, the volume of physician billing for radiation treatment increased 8.2 percent, while Medicare Part B spending on RT increased 216 percent.[35] Most of the increase in the 2000 to 2010 time period was due to the adoption and uptake of IMRT. From 2010 to 2016, spending and volume for PBT in FFS Medicare grew rapidly,[36] driven by a sharp increase in the number of proton beam centers and Medicare's relatively broad coverage of this treatment. While we cannot assess through claims data what caused this increase in PBT, we can monitor changes in the utilization of treatment modalities during the course of the Model. The previously stated increase in PBT volume may depend on a variety of factors.

As stated in the proposed rule, the RO Model's episode payment was designed, in part, to give RT providers and RT suppliers greater predictability in payment and greater opportunity to clinically manage the episode, rather than being driven by FFS payment incentives. The design of the payment model grouped together different modalities for specific cancer types, often with variable costs, into a single payment that reflects average treatment costs. As explained in the proposed rule, the Model would include a historical experience adjustment, which would account for an RO participant's historical care patterns, including an RO participant's historical use of more expensive modalities, and certain factors that are beyond a health care provider's control. We stated in the proposed rule that we believe that applying the same payment for the most commonly used RT modalities would allow physicians to pick the highest-value modalities.

[33] Falit, B.P., Chernew, M.E., & Mantz, C.A. (2014). Design and implementation of bundled payment systems for cancer care and RT. International Journal of Radiation Oncology• Biology• Physics, 89(5), 950–953.

[34] Ibid.

[35] Shen, X., Showalter, T.N., Mishra, M.V., Barth, S., Rao, V., Levin, D., & Parker, L. (2014). Radiation oncology services in the modern era: Evolving patterns of usage and payments in the office setting for Medicare patients from 2000 to 2010. Journal of Oncology Practice, 10(4), e201–e207.

[36] Spending in PBT rose from $47 million to $115 million, and the number of treatment sessions for PBT rose from 47,420 to 108,960, during that period.

We stated in the proposed rule that given the goals of the RO Model as well as the payment design, we believe that it is important to treat all modalities equally.

With respect to PBT, we noted in the proposed rule that there has been debate regarding the benefits of proton beam relative to other, less expensive modalities. The Institute for Clinical and Economic Review (ICER) evaluated the evidence of the overall net health benefit (which takes into account clinical effectiveness and potential harms) of proton beam therapy in comparison with its major treatment alternatives for various types of cancer.[37] ICER concluded that PBT has superior net health benefit for ocular tumors and incremental net health benefit for adult brain and spinal tumors and pediatric cancers. ICER judged that proton beam therapy is comparable with alternative treatments for prostate, lung, and liver cancer, although the strength of evidence was low for these conditions. In a June 2018 report to Congress, MedPAC discussed Medicare coverage policy and use of low-value care and examined services, including PBT, which lack evidence of comparative clinical effectiveness and are therefore potentially low value.[38] They concluded that there are many policy tools, including new payment models, that CMS could consider adopting to reduce the use of low-value services. Given the continued debate around the benefits of PBT, and understanding that the PBT is more costly, we discussed in the proposed rule that we believe that it would be appropriate to include in the RO Model's test, which is designed to evaluate, in part, site neutral payments for RT services. We solicited public comment on our proposal to include PBT in the RO Model.

As discussed in the proposed rule, we considered excluding PBT from the included modalities in instances where an RO beneficiary is participating in a federally-funded, multi-institution, randomized control clinical trial for PBT so that further clinical evidence assessing its health benefit comparable to other modalities can be gathered. We also solicited public comment on whether or not the RO Model should include RO beneficiaries participating in federally-funded, multi-institution, randomized control clinical trials for PBT. The following is a summary of the public comments received on these proposals and our responses:

Comment: Some commenters recommended including PBT in the final rule. A couple of commenters believed that including PBT in the episode payment would create an incentive to use lower-cost, comparable modalities. A commenter believed including PBT would allow the Model to test whether financial incentives are driving clinical decision-making. Another commenter believed the historical experience adjustment would compensate RO participants who use more expensive modalities. A couple of commenters believed that the evidence supporting PBT in certain common types of cancer, such as prostate and lung, is questionable.

Response: We thank the commenters for their support and note that we are finalizing as proposed the inclusion of PBT in the RO Model with the exception of when PBT is furnished to an RO beneficiary participating in a federally-funded, multi-institution, randomized control clinical trial for PBT so that further clinical evidence assessing its health benefit comparable to other modalities can be gathered. See § 512.240 for the finalized list of included modalities.

Comment: Many commenters believed that PBT is of high value and an effective, evidence-based treatment for many clinical indications. Some commenters suggested that CMS should not use questions about PBT's clinical value or high, upfront investment as the basis for inclusion in the RO Model. Some of these commenters believed that PBT was distinct from other forms of RT and should not be treated as equivalent to other modalities by the Model. A couple of commenters also recommended exemptions for high-cost services like PBT when its use is supported by evidence.

Some of these commenters believed that the 2014 reports from the Institute for Clinical and Economic Review (ICER) and Medicare Patient Advisory Commission (MedPAC), which suggested PBT was of lower value than other modalities, were outdated. A few commenters specified that PBT is indicated for numerous forms of cancer, and can be particularly useful for patients who undergo re-irradiation.

Many these commenters stressed that patients often have better experiences with PBT than other forms of radiation, with improved survival, fewer side effects, fewer hospitalizations, and better quality of life.

Some commenters emphasized that, while PBT is more expensive up-front, it has significant long-term benefits and savings that may not be captured within the 90-day episode. A couple of commenters emphasized that PBT improves outcomes and reduces the total cost of care over 12 months. These commenters pointed to savings from lower health care consumption to treat side effects and lower rates of secondary malignancies due to more precise radiation delivery. A couple of commenters emphasized that PBT's precision makes it the safest way to hypofractionate treatment to sensitive parts of the body. A commenter emphasized that PBT is frequently used to hypofractionate regimens when proven to be effective, using prostate cancer as an example.

Response: We appreciate the commenters' concerns. The most recent ICER report focuses primarily on a pediatric population, whose outcomes may not be comparable to the Medicare population. The 2018 MedPAC report emphasized that the use of PBT has expanded in recent years from pediatric and rare adult cancers to include more common types of cancer, such as prostate and lung cancer, despite a lack of evidence that PBT offers a clinical advantage over alternative treatments for these types of cancers. The 2019 Washington State Health Care Authority PBT re-review examined the comparative effectiveness of PBT over other forms of RT. For adult tumors, the report stated that the evidence was insufficient to evaluate the comparative effectiveness of PBT for bladder, bone, and pancreatic cancers; unclear for brain, spinal, and breast cancers; and comparable for head and neck, lung, and prostate cancers. The report did find that PBT may pose a benefit for liver and certain ocular cancers under specific conditions, but concluded that the strength of evidence for these benefits was low. As such, we are including PBT in the RO Model with the clinical trial exception, which we believe provides sufficient opportunity for more conclusive evidence to be generated around PBT in the Medicare population. We believe that continuing to gather such evidence in the excepted clinical trials will allow CMS to better address the commenters' beliefs about PBT's long term benefits. We will continue to review new evidence generated about PBT's effectiveness in the Medicare population as it becomes available.

Comment: Many commenters recommended that CMS exclude PBT

[37] Ollendorf, D.A., J.A. Colby, and S.D. Pearson. 2014. Proton beam therapy. Report prepared by the Institute for Clinical and Economic Review for the Health Technology Assessment Program, Washington State Health Care Authority. Olympia, WA: Washington State Health Care Authority. *https://icer-review.org/wp-content/uploads/2014/07/pbt_final_report_040114.pdf.*

[38] *http://medpac.gov/docs/default-source/reports/jun18_ch10_medpacreport_sec.pdf.*

from the RO Model. Many commenters emphasized that the reimbursement for PBT under the Model would be too low. These commenters emphasized the high operational cost of PBT, which commenters generally believed would not be covered by the current Model's proposed approach to setting episode payments. These commenters indicated that the Model would disproportionately reduce reimbursement for PBT as compared to other modalities. Some commenters believed that the RO Model would result in a nearly 50 percent reduction in payment for PBT, while reimbursement across all other modalities would decrease by 4 percent. A few commenters believed that low reimbursement under the Model would further reduce PBT payments outside of the Model, as commercial insurers and Medicaid programs would follow suit.

Some commenters believed that the national base rate did not include a meaningful volume of proton therapy episodes, leading to payment rates that do not reflect the costs of providing PBT. A couple of these commenters emphasized that restricting the national base rate-setting methodology to only HOPD episodes excludes about 65 percent of PBT episodes. A commenter recommended that CMS reconsider the establishment of the national base rate based only on HOPD episodes due to its detrimental impact on proton beam therapy centers. Another commenter emphasized that PBT services do not follow the pattern for other RT services in HOPD and freestanding facilities: Freestanding RT centers are paid less than their HOPD counterparts and PBT has a higher ratio of freestanding to HOPD providers than other modalities. This commenter also highlighted that a significant number of PBT centers have opened since 2015, meaning that the CMS data on which the base rates are founded does not represent the current state of PBT.

Many commenters believed the bundled price would either reduce investment in PBT therapies or cause existing PBT facilities to close. A couple of commenters stated their belief that many PBT facilities operate on thin margins and believed the Model would place them in tenuous financial positions. A commenter emphasized that such closures would result in the loss of jobs. A few of commenters emphasized the uneven geographic distribution of existing PBT facilities—a commenter stated that only 35 percent of the U.S. population has access to PBT today, and believed that this percentage would shrink under the Model. These commenters suggested that PBT center closures would force patients to travel significant distances to access PBT or forgo treatment.

Many commenters believed that the bundled price would reduce patient access to PBT. Some believed patient access would be reduced if PBT facilities closed due to financial hardship caused by the RO Model. Other commenters suggested that patient access would be reduced by providers and suppliers prescribing alternative modalities when PBT would be more appropriate. A couple commenters suggested that providers and suppliers might refer patients to PBT facilities in CBSAs selected for comparison. A commenter expressed that patients should have access to the treatment modality that affords them a chance to achieve the best possible outcome. Other commenters generally emphasized the value of PBT in delivering lower and more precise radiation doses. These commenters voiced their concern that, in incentivizing RO participants to utilize modalities other than PBT, patients would be exposed to more radiation and a greater risk of additional, costly cancers in the future. A couple of commenters stated that other countries will have greater access to PBT than the U.S. by 2024. These commenters generally believed that excluding PBT from the Model and continuing to reimburse it as FFS would prevent these reductions in patient access.

Some commenters believed that the impact of any PBT center closures would have an impact beyond the Medicare population. These commenters generally referenced the value of PBT to certain pediatric cancers, as well as head and neck cancer, brain tumors, and thoracic lymphoma, and feared that PBT center closures would jeopardize access for these patient groups. A couple of commenters believed the Model will deepen cancer disparities by targeting freestanding radiation therapy centers. One such commenter believed that if the Model forced freestanding PBT facilities to close, the impact would disproportionately impact low-income and minority groups. A commenter emphasized that the IPPS and OPPS provide stratifications of cost to avoid similar reductions in access to technology.

Some commenters expressed concern that including PBT in the Model would reduce the ability of providers and suppliers to generate evidence about PBT and stifle innovation in this field. A couple such commenters emphasized that slowing innovation could deprive Medicare of potentially significant long-term cost savings. A commenter recommended excluding PBT to allow the industry to further demonstrate the value of PBT. A few commenters emphasized that the cost of PBT has fallen over the years and believed that it would continue to fall if excluded from this rule.

Response: We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. We believe that the clinical trial exception will continue to enable providers and suppliers to generate evidence about PBT, allowing innovation in this field to continue. Further, our approach to the calculation of participant-specific episode payment amounts places great weight on an individual entity's historical experience. This approach accounts for an entity's high cost relative to the national average and includes a glide path over time. Furthermore, as described in section III.C.6.b, to address the concerns regarding the Model's national base rate, the base rates that were calculated for purposes of this final rule were shifted forward to 2016–2018, capturing more recent data from a greater number of PBT centers compared with the data used in the proposed rule. As described in section III.C.6.c, we believe that the use of HOPD episodes for calculating the national base rates provides a stronger empirical foundation. Blending together the national base rates, which are derived from HOPD episodes, with the RO participant's own historical experience (whether HOPD or freestanding radiation therapy center) will allow the RO participant's unique care patterns to be recognized in the participant-specific episode payment amounts.

We do not believe that the RO Model, which as finalized will be tested in approximately 30 percent of episodes nationally and which will include a gradual shift in payments toward the national average, will affect access to PBT. We plan to carefully monitor the RO Model for unintended consequences as finalized in section III.C.14 and III.C.16. If our monitoring reveals that the Model reduces patient access to PBT, we would consider making changes to the Model via future rulemaking. Further, our evaluation will consider longer-term impacts on health outcomes associated with the Model.

Comment: If included in the Model, many commenters had suggestions for how to structure PBT payments. A couple of these commenters recommended creating a separate bundled price for PBT that is a percentage of the current medically accepted case rate instead of the

proposed APM bundled prices. A commenter suggested that CMS consider a step wise reduction in payments, which would account for the fact that adoption of this technology is still in the nascent stages. A couple other commenters recommended creating a separate Model for PBT. A few commenters recommended creating a separate base rate for PBT. Another commenter suggested that PBT should be reconsidered for inclusion at the end of the five-year pilot phase. Another commenter recommended exempting PBT facilities that have yet to be constructed. MedPAC expressed support for the inclusion of PBT in the RO Model because Medicare's payment rates for PBT are substantially higher than for other types of external beam radiation therapy. In addition, MedPAC noted that the use of PBT has expanded in recent years from pediatric and rare adult cancers to include more common types of cancer, such as prostate and lung cancer, despite a lack of evidence that it offers a clinical advantage over alternative treatments for these types of cancer. Therefore, including PBT in the episode payment would create an incentive to use lower-cost, comparable modalities.

Response: We thank the commenters for their feedback. We believe that our approach to blending the national base rates with the RO participant's historical experience, with the blend shifting more to the national base rates over time for those with historical payments above the national base rates, provides a stepwise reduction in payment over the Model, regardless of modality. We do not believe a separate model for PBT is necessary because we have created an exemption where PBT is not an included modality when furnished to an RO beneficiary participating in a federally-funded, multi-institution, randomized control clinical trial for PBT so that further clinical evidence assessing its health benefit comparable to other modalities can be gathered. If we were to exclude all PBT from the RO Model or to create a separate base rate, it would undermine the RO Model test, which is testing an episode-based payment that does not vary based on where the services are provided or how many or which type of RT services are provided during the episode. Further, doing either of these recommended approaches could create an incentive for RO participants to provide PBT as a way to avoid being in the Model. In addition, we do not believe that an exemption is necessary for PBT facilities that have not yet been constructed since the geographic areas selected to participate in the Model and the national base rates will be publicly available; new PBT facilities in a selected geographic area will have their episode payment amounts adjusted for case mix once data are available. We are finalizing the inclusion of PBT in the RO Model's pricing methodology (see section III.C.6) to maintain our modality agnostic approach. See § 512.240 for the finalized list of included modalities.

Comment: A commenter believed that a randomly selected sample for the RO Model has a high likelihood of not selecting an adequate number of centers that provide PBT. The commenter believed this would reduce the ability to statistically validate the impact of proton therapy in the bundle. This commenter further believed that the geographic dispersion of centers means that only a few centers could contribute the majority of episodes, leading to results inconsistent with the industry.

Response: As discussed in section III.C.16, the evaluation's focus will be on the impact of the Model as a whole rather than on comparing the impact of the Model on individual modalities, though subanalyses will be conducted where feasible.

Comment: Many commenters recommended that CMS exclude PBT as a low-volume modality. These commenters generally believed that PBT is not commonly used and that there is insufficient data supporting its inclusion in the Model. Some commenters emphasized that PBT only accounted for 0.7 percent of all episodes in 2017, while others specified that PBT episodes would represent more than 1 percent of total episodes for only six of the 17 cancer types and less than 0.5 percent of the episodes for the remaining 11. A commenter expressed concern that including a low-volume service like PBT would decrease the rigor of any evaluation, rendering results unreliable or misleading. A commenter suggested both limiting low-volume modalities like PBT to a smaller percentage of episodes and making participation voluntary.

Response: We appreciate these commenters' suggestions. Per many commenters as well as claims data, PBT is one of the standard approaches to providing radiotherapy for the included cancer types, and as such, it is appropriate and important to include PBT as a modality in the Model. Although PBT is currently used less frequently than the other included modalities, we believe that its exclusion would undermine our ability to test whether the Model incentivizes the use of high-value, appropriate care for RO beneficiaries. Notably, as discussed in section III.C.16, the evaluation's focus will be on the impact of the Model as a whole rather than on comparing the impact of the Model on individual modalities, though subanalyses will be conducted where feasible.

Comment: Some commenters supported the proposed exclusion of cases where an RO beneficiary is participating in a federally-funded, multi-institution, randomized control clinical trial for PBT. These commenters generally believed that the exclusion, as proposed, would permit the generation of further clinical evidence comparing PBT to other modalities, while allowing the Model to include some beneficiaries who receive PBT. MedPAC added that if CMS decides to exclude PBT from the Model when it is part of a research study, CMS should only do so if the study is a federally-funded, multi-institution, randomized control trial. This requirement would help ensure that studies of PBT produce robust information on how it compares with other modalities. In addition, limiting this exclusion would allow the Model to include at least some beneficiaries who receive PBT.

Many commenters recommended that CMS expand the proposed exclusion of cases where an RO beneficiary is participating in a federally-funded, multi-institution, randomized control trial. These commenters generally believed that the proposed exclusion might restrict opportunities that would benefit Medicare FFS beneficiaries.

One commenter believed that CMS should expand the proposed exclusion of cases because no existing clinical trials would meet the proposed criteria. Some commenters suggested that CMS use Medicare evidence development precedent—via a registry structured in compliance with CMS or AHRQ guidance or a clinical trial registered on *clinicaltrials.gov*—to structure this exemption. A commenter emphasized that this approach would be consistent with existing Local Coverage Decisions for some proton beam therapy providers and suppliers. Other commenters suggested that RT providers or RT suppliers with a history of evidence development should be exempt from the Model.

Some commenters, emphasizing the extensive evidence generated by recent PBT studies, recommended expanding the exclusion to cover all clinical trials, regardless of whether such trials are federally funded or randomized controlled trials. A couple of commenters emphasized that randomized clinical trials are challenging and not always practical in radiation oncology. These commenters

also believed that registry data could generate clinical evidence. Other commenters believed that much ongoing research takes place in academic institutions without federal funding. These commenters generally believed that a broadened exemption would incentivize the collection of additional clinical data to determine PBT's clinical value, particularly in comparison to other modalities such as IMRT and brachytherapy.

An additional commenter suggested excluding beneficiaries who are enrolled in an IRB-approved clinical trial. A commenter recommended using this regulation to address the scope and caliber needed for a clinical trial to become exempt.

A couple of commenters recommended that the proposed clinical trial exclusion not be modified. A commenter recommended that the exclusion only cover participants in randomized clinical trials, suggesting that the payment could be readjusted if these studies demonstrate a defined clinical benefit.

A couple of commenters suggested that CMS decline to expand this exemption to include registry trials. A commenter emphasized that in sites such as breast, head and neck, esophagus, and prostate cancer, a registry trial adds only a single arm or retrospective data that does little to compare proton to photon therapy in these sites. Another commenter believed that an exemption for registry trials would lead every patient at every proton center to be put on a registry trial, adding only to an existing body of literature on single arm series of proton therapy. This commenter did not believe registry trials add sufficient evidence to change the standard of care.

One commenter emphasized that proton therapy for primary treatment of prostate cancer should be performed within the context of a prospective clinical trial or registry.

A few commenters recommended that CMS exempt all care—not just PBT—provided under a clinical trial protocol from the Model. A commenter specifically recommended that CMS exclude patients enrolled in clinical trials in which the focus is radiation oncology treatment or technology, emphasizing that the costs of these cases are unique and may influence adjustment factors or future Model data.

Response: We appreciate these comments and suggestions. We agree with commenters that the use of registry trials is insufficient, as the single-arm design of registry trials makes them unlikely to result in published studies evaluating the comparative effectiveness of PBT to other RT modalities. We agree that these registry trials are unlikely to generate the type of evidence needed to change the standard of care. We also note that data collected through registry trials is often not analyzed or published. We believe that the inclusion of federally-funded, multi-institution, randomized control clinical trial for PBT is important to include so that further clinical evidence assessing its health benefit comparable to other modalities can be gathered. There are established procedures that exist in the Medicare claims systems for identifying and paying for services furnished during participation in clinical trials. A recent study concluded that prospective trials are warranted to validate studies related to the use of proton and photon beam therapies.[39]

Comment: Some commenters supported the inclusion of brachytherapy in the Model, while many comments opposed its inclusion. For those that supported the inclusion of brachytherapy, they argued that its inclusion in the Model along with the other modalities would incentivize the provision of the most efficacious and cost-effective treatments and improve access to brachytherapy as a treatment option. A couple of commenters opposed brachytherapy's inclusion in the Model, worrying the Model might disincentivize its use, particularly among vulnerable cancer populations, such as women with cervical cancer. A couple of commenters recommended excluding brachytherapy on the premise that it is a low-volume modality.

Many commenters expressed concerns with the inclusion of brachytherapy as proposed. Some of these commenters emphasized brachytherapy's unique nature as it is a standalone treatment and is also used in combination with external beam radiotherapy (EBRT). These commenters were concerned that the RO Model would not provide adequate payment for all situations in which brachytherapy is indicated, particularly when a single episode involves multiple treatment modalities, multiple RT providers or RT suppliers, multiple disease sites, or multiple treatment settings.

Some commenters focused on cases involving multiple modalities. These commenters emphasized that the brachytherapy ''boost'' when accompanying other modalities is an important, clinical guideline-driven treatment for certain patients. These multimodality cases are particularly common for treating cervical cancer, breast cancer, and prostate cancer, and they require more work than cases involving a single modality, as each modality requires unique treatment planning and delivery services. A commenter emphasized that patients are often sent to regional hub facilities for these boosts, reducing unnecessary duplication of expensive equipment and staff. A couple of these commenters expressed concern that should the Model not provide adequate compensation for multiple modalities furnished within a single episode, particularly those involving brachytherapy, providers and suppliers might be incentivized to delay treatment or to depart from clinical guidelines. These commenters emphasized that these perverse incentives could reduce patient access to medically necessary care. Moreover, a couple of commenters believed that there were problems with the underlying data and pricing methodology. A commenter believed that errors in the claims data stemming from incorrect attribution of CPT®/HCPCS codes to certain modalities underrepresented the true cost of delivering a combination of modalities like EBRT and brachytherapy.

A few commenters emphasized that brachytherapy services are often provided by physicians other than radiation oncologists, such as gynecological oncologists, urologists, interventional radiologists, and surgical oncologists, and that these physicians could operate under the same or different RT provider or RT supplier when brachytherapy is provided in conjunction with another modality. Some commenters expressed concern that the current RO Model does not adequately account for the various combinations of physicians and treatment settings in which brachytherapy is furnished. A few commenters explained that CMS should not consider multiple modality cases delivered by two physicians as duplicate RT services, as these physicians are working in tandem on a treatment plan rather than duplicating one another's efforts.

A few commenters recommended that brachytherapy trigger a second RO Model bundle, with a separate PC and TC payment, when delivered within a single 90-day episode that also includes EBRT. Some commenters suggested that brachytherapy be reimbursed as FFS when delivered during an episode

[39] Baumann, B.C., Mitra, N., Harton, J.G., Xiao, Y., Wojciezynski, A.P., Gabriel, P.E., Zhong, H., Geng, H., Doucette, A., Wei, J., O'Dwyer, P.J., Bekelman, J.E., & Metz, J.M. (2019). Comparative effectiveness of proton vs proton therapy as part of concurrent chemoradiotherapy for locally advanced cancer. JAMA Oncology, doi:*https://doi.org/10.1001/jamaoncol.2019.4889.*

including EBRT. To implement this change, a commenter suggested adding a modifier to episodes in which both brachytherapy and EBRT are provided. This modifier would trigger the second bundled or FFS payment and prevent the episode from going to reconciliation. These commenters believed that these solutions would adequately address the various combinations of modalities, RT providers and RT suppliers, and settings that might arise during brachytherapy treatment. A commenter further emphasized that this structure would alleviate possible negative incentives in the Model, ensure that patients continue to receive high-quality care, and have minimal impact on overall CMS expenditures.

Response: We thank commenters for their support of including brachytherapy as well as those commenters expressing their concerns and their suggestions.

An episode-based payment covers all included RT services furnished to an RO beneficiary during a 90-day episode. Bundled episode payment rates are premised on the notion of averages. The cases including a combination of EBRT and brachytherapy described by the commenters are part of the set of historical episodes included in the averages that determine the national base rates and contribute to how payment amounts are valued, and, therefore, an adjustment for multiple modalities that include brachytherapy is not warranted at this time. Also, the case mix and historical experience adjustments help account for the costlier beneficiary populations in the participant-specific episode payment amounts. We will be monitoring for change in treatment patterns throughout the Model performance period and will consider modifications to the pricing methodology in future years of the Model should it be warranted.

We believe that including brachytherapy in the Model supports this modality as high value, and also that including it preserves the goal of the Model in establishing a true bundled approach to radiotherapy that is also site neutral and modality agnostic. And, we believe that the proposed and finalized pricing methodology and subsequent national base rates for each cancer type accounts for the cost of brachytherapy as a primary modality and if furnished in conjunction with EBRT. We recognize the billing complexity when separate RT providers and RT suppliers furnish the brachytherapy and EBRT and will address this in billing guidance provided to RO participants. We will monitor for any unintended consequences of the Model on multi-modality treatment that includes both external beam and brachytherapy.

As for the concern that errors in the claims data (specifically those that commenters believe stem from incorrect attribution of CPT®/HCPCS codes to certain modalities) underrepresented the true cost of delivering a combination of modalities like EBRT and brachytherapy, we rely on the data submitted on claims by providers and suppliers to be accurate per Medicare rules and regulations. We are finalizing the provision to include brachytherapy in the RO Model.

Comment: A commenter specifically requested that the Model include electronic brachytherapy (EB).

Response: EB radiation is generated and delivered in a markedly different way than traditional brachytherapy, and its dosing and clinical implications are still being studied. Until EB is more commonly used, CMS will continue to pay FFS for this RT service.

Comment: A few commenters suggested excluding more modalities from the Model due to their infrequent use. A commenter recommended including only the most common modalities and excluding brachytherapy, SRS, SBRT, and PBT. A commenter recommended excluding IORT since it is used so rarely. A commenter was concerned that the proposed payment structure will promote the use of short course, less costly forms of treatment such as IORT in cases where traditional external beam radiation would have been preferred.

Response: We thank these commenters for these suggestions. We agree with the commenter that it would be appropriate to exclude IORT from the RO Model because it is not a standard approach to treatment, and we believe that including IORT may incentivize misuse of this treatment. See § 512.240 for the finalized list of included modalities.

Comment: A commenter requested clarity on the codes used to define stereotactic radiosurgery and also expressed concern that the RO Episode File (2015–2017) has SRS attributed to episodes that are classified as brain metastasis or CNS. SRS as defined in the HCPCS should be a single treatment delivery and directed at an intracranial brain lesion. It is likely that CMS is incorrectly including SBRT into the SRS count, since SRS is typically used for brain metastases, and SBRT is typically used for early primary lung cancers or metastatic disease to various locations in the body. In addition to misattribution of the SRS episodes, this commenter stated that episodes of brachytherapy, SRS, and 1–10 3D EBRT occur in clinically unlikely episodes in the RO Episode File.

Response: We appreciate this question. We are confirming that SRS and SBRT are both included in the RO Episode File (2015–2017) under the classification of SRS. We understand the difference between and SRS and SBRT but erroneously labeled the column in the file as COUNT_SRS without explaining in the Data Dictionary posted on the RO Model website that COUNT_SRS includes both SRS and SBRT. This clerical error did not impact our calculations of the proposed base rates.

Comment: Some commenters expressed concern that the bundled payment structure might lead providers and suppliers to substitute older, less expensive modalities for newer, more expensive modalities. One of these commenters emphasized their concern for patient access to the most effective care from the RT provider or RT supplier, noting that the clinician is best suited to determine appropriate treatment for the patient. Another commenter emphasized that, while an individual RO participant might save costs by selecting the cheapest treatment during the 90-day episode, longer-term Medicare costs could rise due to later complications or secondary tumors. A different commenter stated this Model incentivizes the use of the cheapest forms of radiation therapy, which also deliver the greatest amount of radiation to healthy tissue.

Response: We appreciate commenters' concerns. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. As finalized in section III.C.14, we will monitor for unintended consequences of the RO Model including but not limited to stinting on care.

Comment: A commenter requested that CMS provide additional comparative effectiveness data between included and excluded modalities. This commenter expressed concern that more effective, and potentially more expensive modalities, were not included because they are not accessible to many Medicare beneficiaries. This commenter emphasized that racial and gender disparities in cancer outcomes may be due to disparities in treatment options, and requested that CMS justify how the inclusion of these modalities addresses disparities.

Response: We appreciate this commenter's concerns. We did not use comparative effectiveness data to determine whether modalities were included/excluded but rather focused on the most commonly utilized approaches to radiotherapy for the

included cancer types. We believe that the RO Model pricing methodology, through the historical experience and case mix adjustments, will account for differences in RO participants' historical care patterns and the demographic characteristics of their patient populations. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. This includes prescribing the most appropriate modality. If a modality is not included in the RO Model, it will continue to be paid FFS. As finalized in section III.C.14 and III.C.16, we will monitor for unintended consequences of the RO Model.

Comment: A couple of commenters expressed concern about the impact of the Model not only on Medicare beneficiaries, but also about the continued viability of offering PBT to patients. These commenters stated that unsustainable payment rates from Medicare would put centers' viability at risk, both operational centers as well as centers currently under development. They stated that Medicare is a material payor for the majority of members, representing the majority of their payor mix, and reducing their payment rates by up to 50 percent below cost will not be sustainable. They also stated that while the RO Model is focused on Medicare fee-for-service, it has implications for other payors, as many private payors often use the Medicare rates as a proxy, which could impact a center's broader payor mix. Further, these commenters stated that viability impacts not only Medicare beneficiaries but indirectly affects a broader set of patients including pediatric cancer patients who will lose access to a treatment that is now the standard of care.

Response: We appreciate these commenters' concerns. We disagree with the commenters on the expected magnitude of reduction in RO participants' payments for PBT compared to what they currently receive. As described in section III.C.6, the pricing methodology as finalized will blend together the national base rate with an RO participant's unique historical experience. If the RO participant is historically more costly than the national average, the blend in PY1 will be 90 percent of the RO participant's historical payments and 10 percent of the national base rate. This means that, prior to applying the discount factor and withholds that payments under the Model will be between 90 and 100 percent of the RO participant's historical payments. For historically inefficient RO participants, the blend shifts over time to a 70/30 blend in PY5. This means that in PY5, prior to applying the discount factor and withholds that payments under the model will be more than 70 percent of the RO participant's historical payments. We believe that the pricing methodology tested under the Model represents an opportunity to provide high-value episode-based payments to RO participants for Medicare FFS beneficiaries; other payors determine their own payment approaches for RT services.

Comment: A commenter recommended applying savings proportionately to all modalities, particularly if CMS has a savings target under the Patient Access and Medicare Protection Act.

Response: While the RO Model is projected to be expenditure neutral or achieve Medicare savings, we did not have any specific predefined targets in mind, and we believe our pricing methodology has a graduated approach to setting participant-specific payments that is heavily weighted to the participant's historical experience.

After considering public comments, we are finalizing our proposed list of included modalities in the RO Model at § 512.240, with the modifications of removing intraoperative radiotherapy (IORT) from the list of included modalities in the RO Model.

6. Pricing Methodology

a. Overview

The proposed pricing methodology in the proposed rule described the data and process used to determine the amounts for participant-specific professional episode payments and participant-specific technical episode payments for each included cancer type (84 FR 34503). In the proposed rule, we proposed to define the term ''participant-specific professional episode payment'' as a payment made by CMS to a Professional participant or Dual participant for the provision of the professional component of RT services furnished to an RO beneficiary during an episode, which is calculated as set forth in § 512.255. We further proposed to codify this term, ''participant-specific professional episode payment,'' at § 512.205 of our regulations.

We proposed to define the term ''participant-specific technical episode payment'' as a payment made by CMS to a Technical participant or Dual participant for the provision of the technical component of RT services to an RO beneficiary during an episode, which we proposed to calculate as set forth in § 512.255 of the proposed rule. Further, we proposed to codify this term, ''participant-specific technical episode payment,'' at § 512.205 of our regulations.

In the proposed rule, we proposed eight primary steps to the pricing methodology (84 FR 34503 through 34504). In the first step, we proposed to create a set of national base rates for the PC and TC of the included cancer types, yielding 34 different national base rates. Each of the national base rates represents the historical average cost for an episode of care for each of the included cancer types. We proposed that the calculation of these rates will be based on Medicare FFS claims paid during the CYs 2015–2017 that are included under an episode where the initial treatment planning service occurred during the CYs 2015–2017 as described in section III.C.6.b of the proposed rule (84 FR 34504 through 34505) and this final rule. If an episode straddles calendar years, the episode and its claims are counted in the calendar year for which the initial treatment planning service is furnished. We proposed to exclude those episodes that do not meet the criteria described in section III.C.5 of the proposed rule and this final rule. From the remaining episodes (that is, not including the excluded episodes), we proposed to then calculate the amount CMS paid on average to providers and suppliers for the PC and TC for each of the included cancer types in the HOPD setting, creating the Model's national base rates. Unless a broad rebasing is done after a later PY in the Model, these national base rates will be fixed throughout the Model performance period.

In the second step, we proposed to apply a trend factor to the 34 different national base rates to update those amounts to reflect current trends in payment for RT services and the volume of those services outside of the Model under the OPPS and PFS. We proposed to define the term ''trend factor'' to mean an adjustment applied to the national base rates that updates those rates to reflect current trends in the OPPS and PFS rates for RT services. We proposed to codify the term ''trend factor'' at § 512.205 of our regulations. In this step, we would calculate separate trend factors for the PC and TC of each cancer type using data from HOPDs and freestanding radiation therapy centers not participating in the Model. More specifically, as noted in the proposed rule, the calculations would update the national base rates using the most recently available claims data of those non-participating providers and suppliers and the volume at which they billed for RT services as well as their corresponding payment rates. Adjusting

the national base rates with a trend factor will help ensure payments made under the Model appropriately reflect changes in treatment patterns and payment rates that have occurred under OPPS and PFS.

In the third step, we proposed to adjust the 34 now-trended national base rates to account for each Participant's historical experience and case mix history. The historical experience and case mix adjustments account for RO participants' historical care patterns and certain factors that are beyond an RO participant's control, which vary systematically among RO participants so as to warrant adjustment in payment. We proposed that there would be one professional and/or one technical case mix adjustment per RO participant depending on the type of component the RO participant furnished during the 2015–2017 period, just as there would be one professional and/or one technical historical experience adjustment per RO participant, depending on the type of component the RO Participant furnished during the 2015–2017 period. We proposed to generate each RO participant's case mix adjustments using an ordinary least squares (OLS) regression model that predicts payment based on a set of beneficiary characteristics found to be strongly correlated to cost. In contrast, we proposed to generate each RO participant's historical experience adjustments based on Winsorized payment amounts for episodes attributed to the RO participant during the calendar years 2015–2017. The historical experience adjustments for each RO participant would be further weighted by an efficiency factor.[40] The blend measures if an RO participant's episodes (from the retrospectively constructed episodes from 2015–2017 claims data) have historically been more or less costly than the national base rates, and this determines the weight at which each RO participant's historical experience adjustments are applied to the trended national base rates.

In the fourth step, we proposed to further adjust payment by applying a discount factor. The discount factor is the set percentage by which CMS reduces payment of the PC and TC. The reduction on payment occurs after the trend factor and adjustments have been applied, but before standard CMS adjustments including the geographic practice cost index (GPCI), sequestration, and beneficiary coinsurance. The discount factor will reserve savings for Medicare and reduce beneficiary cost-sharing. We proposed to codify the term ''discount factor'' at § 512.205.

In the fifth step, we proposed to further adjust payment by applying an incorrect payment withhold, and either a quality withhold or a patient experience withhold, depending on the type of component the RO participant furnished under the Model. The incorrect payment withhold would reserve money for purposes of reconciling duplicate RT services and incomplete episodes during the reconciliation process, as discussed in section III.C.11 of the proposed rule and this final rule. We proposed to define the term ''duplicate RT service'' to mean any included RT service (as identified at § 512.235 of the proposed rule) that is furnished to a single RO beneficiary by a RT provider or RT supplier or both that did not initiate the PC or TC of that RO beneficiary during the episode. We proposed to codify ''duplicate RT service'' at § 512.205 of the proposed rule. We proposed that an incomplete episode means the circumstances in which an episode does not occur because: (1) A Technical participant or a Dual participant does not furnish a technical component to an RO beneficiary within 28 days following a Professional participant or the Dual participant furnishing the initial RT treatment planning service to that RO beneficiary; (2) traditional Medicare stops being the primary payer at any point during the relevant 90-day period for the RO beneficiary; or (3) an RO beneficiary stops meeting the beneficiary population criteria under § 512.215(a) or triggers the beneficiary exclusion criteria under § 512.215(b) before the technical component of an episode initiates.

We also proposed to adjust for a quality withhold for the professional component of the episode. This withhold would allow the Model to include quality measure results as a factor when determining payment to participants under the terms of the APM, which is one of the criteria for an APM to qualify as an Advanced APM as specified in 42 CFR 414.1415(b)(1). We proposed to adjust for a patient experience withhold for the technical component of the episode starting in PY3 to account for patient experience in the Model. We would then apply all of these adjustments, as appropriate to each RO participant's trended national base rates.

In the sixth step, we proposed to apply geographic adjustments to payments. In the seventh and final eighth step, we proposed to apply beneficiary coinsurance and a 2 percent adjustment for sequestration to the trended national base rates that have been adjusted as described in steps three through six, yielding participant-specific episode payment amounts for the provision of the PC and TC of each included cancer type in the Model. We proposed to calculate a total of 34 participant-specific professional and technical episode payment amounts for Dual participants, whereas we would only calculate 17 participant-specific professional episode payment amounts or 17 participant-specific technical episode payment amounts for Professional participants and Technical participants, since they furnish only the PC or TC, respectively.

Following this description of the data and process used to determine the amounts for participant-specific professional episode payments and participant-specific technical episode payments for each included cancer type, the proposed rule provided a pricing example for an episode of lung cancer (at 84 FR 34511). We provided this example to show how each pricing component (that is, national base rates, trend factors, case mix and historical experience adjustments, withholds, discount factors, geographic adjustment, beneficiary coinsurance, and sequestration) figures into these amounts. We also provided a summary-level, de-identified file titled the ''RO Episode File (2015–2017),'' on the RO Model's website to further facilitate understanding of the RO Model's pricing methodology. The following is a summary of the public comments received on this proposal, specifically those comments related not to particular pricing components, but rather comments related to the Model's pricing methodology in its general approach, potential impact, and structure as well as information provided to thoroughly review the methodology on these points and our response:

Comment: Many commenters requested additional information and data be provided in order to ascertain the degree of impact that the Model's pricing methodology will have on participant payment relative to what participants have historically been paid under FFS. Some commenters argued that additional information is needed in order to justify the RO Model's pricing and policies in general. Several other commenters made requests for information related to specific pricing components. Several commenters stated that the case mix adjustment is not adequately defined and that more detail is needed concerning the regression models used to construct the case mix

[40] Please note that in the final rule we are renaming the efficiency factor the ''blend,'' as discussed in section III.C.6.e(2) of this final rule.

adjustments. A few commenters requested additional information regarding the historical experience adjustments, specifically the number and type of providers and suppliers that are classified as efficient versus inefficient.

Response: Based on a full review of comments and the detailed analyses contained within some of them, we believe that commenters have had sufficient detail to fully comment on the proposed RO Model. We prioritize, however, these comments and along with the finalized parameters of the Model, provide additional resources to include detailed illustrations, examples, and data, particularly concerning the case mix and historical experience adjustments. We refer readers to sections III.C.6.e.(1) and III.C.6.e.(2) of the case mix and historical adjustments, respectively, for that additional detail and to section III.C.6.j which closes the pricing methodology section. Here we list additional data we are able to provide at request of the commenters.

Comment: Many commenters expressed support for a prospective payment model in radiation oncology. A few commenters took issue with the prospective nature of the Model's payment rates, because they were not adjusted for factors occurring in the current performance year. A commenter suggested that the RO Model change to a retrospective payment model in that this would allow for payment rates to be adjusted for the patient population of the performance period for which payment was being allotted. A commenter opposed the Model generally, explaining that the RO Model is an experiment focusing on short-term effects and costs, and ignores medium- and long-term complications and the resulting cost of care, such as costly side effects and secondary malignancies.

Response: We thank the commenters for sharing their support and concerns regarding a prospective payment model in radiation oncology. It is not the intent of the Model for payment based on 90-day episodes to incorporate the long-term health outcomes of a patient or associated costs, though the RO Model evaluation will analyze health outcomes that occur after RO episodes end to the extent feasible. The Model is designed to predict payment based on the historical characteristics of a participant's population based on the most recent claims data available. In particular, we refer readers to section III.C.6.e.(1) concerning the case mix adjustments. We update the case mix adjustment for each RO participant every year to account for the most recent set of episodes for which claims data is available. Also, it is important to note that in analyzing 2015–2017 episode data, we found that participants' case mix is relatively stable over time for most providers and suppliers.

We believe that this prospective episode-based payment structure for RT services is the best design for testing an episodic APM for RT services. The payment rates for RO episodes of care are unambiguous and known to RO participants prior to furnishing RT services. We are testing an approach where prospective episode-based payments will not be reconciled based on how many or which individual RT services are provided by the RO participant during the RO episode, with the exception of incomplete episodes and duplicate RT services. This allows us to test the impact of episode-based payments that do not have today's FFS incentives.

Comment: Many commenters expressed concern over the participant-specific professional episode payment and technical episode payment amounts related to what non-participants in the Model will receive under FFS. Commenters believed that the proposed pricing methodology as constructed with the national base rates based on HOPD claims data alone along with the proposed adjustments, discounts, and withholds, RO participants will be unable to receive sufficient payment under the Model or reasonably achieve savings. A commenter estimated that RO participants would receive up to 50 percent less in payments under the Model than non-participants who continue to be compensated under FFS. Many commenters stated that the proposed pricing methodology does not adequately pay RO participants for labor and resources required to care for the most complex patients and that the Model underestimates the costs and administrative burden of adjusting to and complying with the Model. A few commenters explained that payment under the Model would represent significant cuts to what RT providers and RT suppliers have been historically paid, particularly because the TC is not associated with an APM Incentive Payment. A commenter expressed concern that there could be a great degree of variation in episode spending outside the control of HOPDs, particularly those with little experience with episode-based payments.

Several commenters recommended that CMS limit the downside risk for RO participants, because as proposed, the Model provides no safeguard for excessive financial downside risk. A few commenters recommended restructuring the Model altogether to permit two-sided risk that would allow providers and suppliers to enter into risk at a self-determined pace. A few commenters suggested that the RO Model take a ''shared savings'' approach with RO participants sharing risk for gains and losses. Another commenter suggested a graduated glide path to risk for the RO Model, similar to the approach adopted in the Medicare Shared Savings Program (Shared Savings Program) Pathways to Success final rule. Another commenter suggested that payment be set by optimal actual costs of well-managed sites of service that furnish radiation with a margin to allow for innovation and upgrades. A commenter requested clarification as to whether RO participants could reinsure or get stop-loss insurance to mitigate risk, since RO participants are at risk for all costs over the bundled payment amounts.

Response: We thank these commenters on their feedback and suggestions related to Model payments relative to those received under FFS. We disagree that episode payment amounts would be reduced by 50 percent as compared to non-participants. We designed the pricing methodology so that participant-specific professional and technical episode payment amounts are largely based on what each participant has been paid historically under FFS and trended forward based on latest payment rates under FFS. Moreover, we adjust for those beneficiary characteristics that have a large impact on cost in the case mix adjustment.

We note, however, that RO participants that have fewer than 60 episodes in the baseline period do not have sufficient historical volume to calculate a reliable historical experience adjustment. Since these RO participants will not qualify to receive a historical experience adjustment and may see greater increases or reductions as compared to what they were historically paid under FFS as a result of not receiving the adjustment, we believe that it is appropriate to adopt a stop-loss limit of 20 percent for RO participants that have fewer than 60 episodes in the baseline period and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of this final rule (see section III.C.6.e(4) of this final rule). We are adding a definition at § 512.205 for ''stop-loss limit,'' which means the set percentage at which loss is limited under the Model used to calculate the stop-loss reconciliation amount. We are also adding at § 512.205 a definition for ''stop-loss reconciliation amount'' which means the amount owed to RO

participants that have fewer than 60 episodes during 2016–2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of this final rule for the loss incurred under the Model as described in § 512.285(f).

Thus, we disagree with the premise that the proposed pricing methodology does not adequately pay RO participants for labor and resources required to care for the most complex patients. In particular, we refer readers to section III.C.6.e.(2) of this final rule for more information regarding the blend used to determine how much participant-specific historical payments and national base rates figure into payment. The blend provides a glide path toward the national average for each cancer type. Moreover, this is not a total cost of care model in that each RO episode covers only RT services. We limited the Model in this way, because we believe that these RT services are in control of the RT provider and RT supplier. For these reasons, reconfiguring the RO Model to incorporate either a ''shared savings'' element or gradual risk at a pace determined by RO participants is not necessary.

To ease any burden of adjusting to and complying with the Model, we are finalizing policies that reduce the discount factor by 0.25 percent for both the PC and TC, so that the discount rates are 3.75 percent and 4.75 percent for the PC and TC, respectively (see sections III.C.6.a and III.C.6.f). See section § 512.205 for the modification to the proposed discount factors. Also, we are finalizing policies that reduce the incorrect payment withhold to 1 percent. See section III.C.6.g(1) for the modification to the proposed incorrect payment withhold. These reductions, as detailed in the pricing methodology component sections to which they apply, should further minimize any cost differential that a participant may experience under the Model as opposed to what the participant historically received in payment under FFS.

Comment: Many commenters suggested that the payment structure be adjusted to account for patients receiving treatment for multiple tumor sites. A commenter stated that a diagnosis of primary lung cancer and prophylactic whole brain treatment would not both be covered by the national base rate for lung cancer. A commenter suggested monitoring the frequency and cost of care associated with multiple treatment sites in order to determine if the pricing methodology should be modified in future years on this point.

Response: We thank these commenters for their feedback regarding patients receiving treatment for multiple tumor sites. An episode-based payment covers all included RT services furnished to an RO beneficiary during a 90-day RO episode as codified at § 512.205 and § 512.245. Episodes are constructed using all Medicare FFS claims for radiation therapy services included in the Model. All RT services included on a paid claim line during the 90-day episode were multiplied by the OPPS or PFS national payment rate for that service and were included in the payment amounts for the PC and TC of that episode regardless of whether the service is aimed at treating the attributed primary disease site or not. As such, the national base rates incorporate payments for treatment of multiple tumor sites to the extent that more than one site was the focus of RT services during episodes of care in the historical period. Bundled episode payment rates are premised on the notion of averages. These cases described by the commenters are part of the set of historical episodes included in the averages that determine the national base rates and contribute to how payment amounts are valued, and, therefore, an adjustment for multiple tumor sites is not warranted at this time. Yet, we will be monitoring for change in treatment patterns related to patients being treated for multiple tumor sites throughout the Model performance period and will consider modifications to the pricing methodology in future years of the Model should it be warranted. Any changes to the pricing methodology will be made via notice and comment rulemaking.

Comment: Several commenters noted that the national base rates for prostate cancer and for gynecological cancers are not reflective of the increased costs of combined modality care, but rather these rates are driven by large volumes of patients who receive external beam radiation only. As a consequence, these commenters argued that RO participants would not be sufficiently compensated for these beneficiaries.

Response: As noted in the previous comment, an episode-based payment covers all included RT services furnished to an RO beneficiary during a 90-day episode as codified at § 512.205 and § 512.245. All RT services included on a paid claim line during the 90-day episode are multiplied by the OPPS or PFS national payment rate for that service and are included in the payment amounts for the PC and TC of that episode regardless of the type of modality used to treat the beneficiary. As such, the national base rates incorporate payments for treatment from multiple modalities to the extent that more than one modality was furnished during episodes of care in the historical period. These cases described by the commenters are part of the set of historical episodes included in the averages that determine the national base rates and contribute to how payment amounts are valued, and, therefore, an adjustment for multiple modalities is not warranted at this time. Yet, we will be monitoring for change in treatment patterns related to patients being treated with multiple modalities throughout the Model performance period and will consider modifications to the pricing methodology in future years of the Model should it be warranted. Any changes to the pricing methodology will be made via notice and comment rulemaking.

Comment: A few commenters requested clarity on whether episode payment amounts covered all RT services furnished during a 90-day period, even in instances where multiple courses of treatment were furnished. Several commenters expressed concern that no adjustment would be made if multiple courses of treatment were furnished within that 90-day period.

Response: An RO episode includes all included RT services (See Table 2) furnished to an RO beneficiary with an included cancer type during the 90-day episode as codified at § 512.205 and § 512.245. These cases described by the commenters are part of the set of historical episodes included in the averages that determine the national base rates and contribute to how payment amounts are valued and, therefore, an adjustment for multiple courses of treatment is not warranted at this time.

Comment: Many commenters suggested that the payment structure be adjusted to account for patients receiving treatment for secondary malignancies.

Response: An RO episode includes all included RT services (See Table 2) furnished to an RO beneficiary with an included cancer type during the 90-day episode. If an RO episode includes RT services for different included cancer types (for example, there may be claims for RT services included in the pricing for that episode that indicate more than one cancer type according to the ICD–10 diagnosis codes listed on the various claims), those RT services and their costs are all included in the calculation of the payment rate for that episode.

We would like to clarify how cancer type is assigned to an episode for calculation of the national base rates. It

is important to note that episodes are first assigned a cancer type when the episode is created, whether the cancer type is included in the Model or not, and then if that cancer type is not included in the Model, that episode is excluded subsequently from Model pricing. For instance, episodes first assigned with a secondary malignancy for cancer type during the episode construction phase are then excluded when pricing calculations are conducted. Our process for assigning a cancer type to an episode is as follows:

First, ICD–10 diagnosis codes during an episode were identified from:

(1) E&M services with an included cancer diagnosis code from Medicare PFS claim lines with a date of service during the 30 days before the episode start date, on the episode start date, or during the 29 days after the episode start date.

(2) Treatment planning and delivery services (See Table 2) with an included cancer diagnosis code from Medicare PFS claim lines, or treatment delivery services from Medicare OPPS claim lines with an included cancer diagnosis code on the claim header, with a date of service on the episode start date or during the 29 days after the episode start date. Note that the cancer diagnosis code from OPPS claims must be the principal diagnosis to count toward cancer type assignment; and that treatment delivery services that concern image guidance do not count toward cancer type assignment as we determined that image guidance was not an important indicator of cancer type.

Then, these ICD–10 diagnosis codes are summarized and counted across the claim lines to determine the episode's cancer type assignment according to the algorithm described in (a) through (c):

(a) If two or more claim lines fall within brain metastases or bone metastases or secondary malignancies (per the mapping of ICD–10 diagnosis code to cancer type described in Table 1 of Identified Cancer Types and Corresponding ICD–10 Codes), we set the episode cancer type to the type (either brain metastases or bone metastases) with the highest count. If the count is tied, we assign the episode in the following order of precedence: Brain metastases; bone metastases; other secondary malignancies.

(b) If there are fewer than two claim lines for brain metastases, bone metastases and other secondary malignancies, we assign the episode the cancer type with the highest claim line count among all other cancer types. We exclude the episode if the cancer type with the highest claims line count among other cancer types is not an included cancer type.

(c) If there are no claim lines with a cancer diagnosis meeting the previously discussed criteria, then no cancer type is assigned to that episode and therefore, that episode is excluded from the national base rate calculations.

Comment: A commenter recommended that a payment adjustment be made for the increased use of Magnetic Resonance simulation that was not present during the baseline period of 2015–2017 in order to monitor patient safety and treatment efficacy.

Response: We will be monitoring for changes in treatment patterns throughout the Model's performance period with particular attention to the increased use of MR simulation. We will consider proposing modifications to the pricing methodology in future years of the Model should it be warranted.

Comment: Many commenters expressed concern that the pricing methodology fails to account for complex clinical scenarios and treatment costs. Many commenters recommended that only standard medically accepted case rates should be used to determine payment.

Response: At this time, we have only claims data available to design and operationalize the RO Model. The claims data do not include clinical data. We are finalizing our proposal to collect clinical data from RO participants so that we can assess the potential utility of additional clinical data for monitoring and calculating episode payment amounts (see section III.C.8.e of this final rule). Further, we believe that the case mix adjustment appropriately accounts for the complexity of an RO participant's patient population, and the historical experience adjustment captures additional unmeasured factors that may make one RO participant's patient population more complex, and thus more costly, than another's. We also believe that the national base rates would be lower if we were to use a standard treatment course to set payments, since there are situations in which greater volume is used than would be prescribed by a standard course of treatment.

Comment: A commenter suggested assigning an episode of care initiator, who would be responsible for total spending for the PC and TC, similar to the BPCI Advanced Model.

Response: Similar to the BPCI Advanced Model, the RO participants initiate (or trigger) RO episodes of care with an initial service, which is the treatment planning service in the RO Model. In both the RO Model and BPCI Advanced Model, the model participant is responsible for Medicare fee-for-service (FFS) expenditures for all items and services included in an episode of care starting with the episode trigger. However, in the RO Model, we have limited financial risk to RT services whereas the BPCI Advanced Model participants are responsible for the total amount of Medicare spending for non-excluded items and services in the episode of care. As described in section III.C.5.c, we believe that it is appropriate to limit risk in the RO Model just to RT services, which are managed by the radiation oncologist.

Comment: A commenter expressed support for the proposed policies related to the definition of incomplete episodes. A few commenters requested that CMS provide an example calculation for how an incomplete episode would be paid. Another commenter requested clarification on the situation of a beneficiary switching RT providers and/or RT suppliers and how each would be paid if both RT providers and/or RT suppliers were participants in the Model.

Response: We thank these commenters for their support and requests. As noted in the proposed rule and in this final rule, we expect to provide RO participants with additional instructions for billing, particularly as billing pertains to incomplete episodes and duplicate RT services, through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website. For a subset of incomplete episodes in which (1) the TC is not initiated within 28 days following the PC; (2) the RO beneficiary ceases to have traditional FFS Medicare prior to the date upon which a TC is initiated, even if that date is within 28 days following the PC; or (3) the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished the RO participant is owed only what it would have received under FFS for the RT services furnished to that RO beneficiary, CMS will reconcile the episode payment for the PC and TC that was paid to the RO participant with what the FFS payments would have been for those RT services using no-pay claims. When an RO beneficiary switches RT provider or RT supplier, he or she is no longer under the care of the RO participant that initiated the PC and/or TC of the RO episode.

In the case that traditional Medicare ceases to be the primary payer for an RO beneficiary after the TC of the RO episode has been initiated but before all included RT services in the RO episode have been furnished, then each RO

participant will be paid only the first installment of the episode payment. The RO participant will not be paid the EOE PC or TC for these RO episodes as CMS cannot process claims for a beneficiary with dates of service on or after the date that traditional Medicare is no longer the primary payer. If the SOE for the PC is paid and the RO beneficiary ceases to have traditional Medicare FFS, for example by switching to a Medicare Advantage plan, before the TC is initiated, then during reconciliation, CMS will calculate what the RO participant would have received under FFS for the RT services included in the PC furnished to that beneficiary prior to the beneficiary switching from traditional Medicare to another payer.

We account for duplicate RT services differently. In the proposed rule, a duplicate RT service means any included RT service that is furnished to a single RO beneficiary by a RT provider or RT supplier or both that did not initiate the PC or TC for that RO beneficiary during the RO episode. We are finalizing this proposed definition of duplicate RT service with modification. Duplicate RT service means any included RT service identified at § 512.235 that is furnished to an RO beneficiary by an RT provider or RT supplier that is not excluded from participation in the RO Model at § 512.210(b), and that did not initiate the PC or TC of the RO beneficiary's RO episode. Such services are furnished in addition to the RT services furnished by the RO participant that initiated the PC or TC and continues to furnish care to the RO beneficiary during the RO episode. This modification also clarifies that RT services furnished by a RT provider or supplier excluded from participation in the Model (for example, an ambulatory surgery center, see section III.C.3.c for exclusion criteria) are not considered a duplicate RT service. If the EOE PC and TC payments have been made to the RO participant that initiated the PC or TC of that RO episode, and claims are submitted on behalf of that same beneficiary for RT services furnished by another RT provider or RT supplier during that RO episode, then during reconciliation, payments for those duplicate RT services will be reconciled against the incorrect payment withhold for the RO participant that received full payment for the RO episode. The other RT provider or RT supplier that furnished RT services to that beneficiary, whether an RO participant or not, will be paid FFS for those RT services.

For any RO episode that involves one or more duplicate RT services, the payment for the RO participant that initiated the PC or TC will be reconciled by reducing the RO participant's episode payment by the FFS amount of the duplicate RT services furnished by the RT provider or RT supplier that did not initiate the PC or TC. The FFS amount to be subtracted from the RO participant's bundled payment, however, cannot exceed the amount that the RO participant would receive under FFS for the RT services they furnished during the RO episode. We note that a duplicate RT service is distinct from the situation where an RO beneficiary switches to a different RT provider or RT supplier. As explained above, when an RO beneficiary switches to a new RT provider or RT supplier, and is no longer under the care of the RO participant that initiated the PC and/or TC, the RO episode is an incomplete episode. The RO participant is owed what it would have received under FFS for the RT services furnished to that RO beneficiary, and CMS will use no-pay claims to reconcile the episode payment with what the FFS payments would have been for the RT services. For further details, see section III.C.11(b) of this final rule.

In sum, all claims for RT services for an RO beneficiary with dates of service during the 90-day RO episode will be reviewed during annual reconciliation, to determine if that RO episode qualifies as complete as stipulated in section III.C.11 and codified at § 512.285 and if duplicate RT services occurred as defined in section III.C.6a and codified at § 512.205. As a consequence of this process, CMS will determine how all of these claims impact the annual reconciliation amount on an episode-by-episode basis. The sum of payments for duplicate RT services and the sum of payments for RT services during the incomplete episode represent the impact of those duplicate RT services and incomplete episodes across all RO episodes attributed to the RO participant for the PY considered in that annual reconciliation. See section III.C.11 for further details on this process. Table 14 in that section is an example of the annual reconciliation calculation. For more information on billing under the RO Model, see section III.C.7; for more information on reconciliation during the RO Model, see section III.C.11.

In our proposed eight primary steps to the pricing methodology, we are making one technical change to apply the geographic adjustment to the trended national base rates prior to the case mix and historical experience adjustments and prior to the discount factor and withholds. We proposed to apply the OPPS Pricer as it is automatically applied under OPPS outside of the Model at 84 FR 34510 of the proposed rule, and see section III.C.6.h. of this final rule. We also proposed to use RO Model-specific RVU shares to apply PFS RVU components (Work, PE, and MP) to the new RO Model payment amounts in the same way they are used to adjust payments for PFS services in section III.C.6.h. In order to use RO Model-specific RVU shares to apply PFS RVU components to the new RO Model payment amounts in the same way they are used to adjust payments for PFS services, the geographic adjustment must be applied to the trended national base rates prior to the case mix and historical experience adjustments and prior to the discount factor and withholds. We note that, although modifying the sequence of the pricing methodology in this way slightly changes the amount of dollars attributed to the discount factor and to each withhold, the participant-specific professional episode payment amounts and the participant-specific technical episode payment amounts do not change as a result of this modification. We list all modifications to the pricing methodology at the end of the pricing methodology section, section III.C.6 of this final rule.

b. Construction of Episodes Using Medicare FFS Claims and Calculation of Episode Payment

For the purpose of calculating the national base rates, case mixes, and historical experience adjustments, we proposed to construct episodes based on dates of service for Medicare FFS claims paid during the CYs 2015–2017 as well as claims that are included under an episode where the initial treatment planning service occurred during the CYs 2015–2017 as discussed in section III.C.3.d of the proposed rule and this final rule. We proposed to exclude those episodes that do not meet the criteria discussed in section III.C.5 of this final rule. Each episode and its corresponding payment amounts, one for the PC and one for the TC, would represent the sum totals of calculated payment amounts for the professional services and the technical services of the radiation treatment furnished over a defined 90-day period as discussed in section III.C.5.b of this final rule. We proposed to calculate the payment amounts for the PC and TC of each episode as the product of: (a) The OPPS or PFS national payment rates for each of the RT services included in the Model multiplied by (b) the volume of each professional or technical RT service included on a paid claim line during each episode. We proposed to

neither Winsorize nor cap payment amounts nor adjust for outliers in this step.

So that all payment amounts are in 2017 dollars, we proposed to convert 2015 payment amounts to 2017 by multiplying: (a) The 2015 payment amounts by the ratio of (b) average payment amounts for episodes that initiated in 2017 to (c) average payment amounts for episodes that initiated in 2015. We proposed to apply this same process for episodes starting in 2016. To weigh the most recent observations more heavily than those that occurred in earlier years, we would weight episodes that initiated in 2015 at 20 percent, episodes that initiated in 2016 at 30 percent, and episodes that initiated in 2017 at 50 percent.

We proposed that conversion of 2015 and 2016 payment amounts to 2017 dollars would be done differently, depending on which step of the pricing methodology was being calculated. For instance, episode payments for episodes used to calculate national base rates and case mix regression models would only be furnished in the HOPD setting, and consequently, for purposes of calculating the national base rates and case mix regression models, the conversion of episode payment amounts to 2017 dollars would be based on average payments of episodes from only the HOPD setting. On the other hand, episode payments for episodes used to calculate the historical experience adjustments would be furnished in both the HOPD and freestanding radiation therapy center settings (that is, all episodes nationally), and consequently, for purposes of calculating the historical experience adjustments, the conversion of episode payment amounts to 2017 dollars would be based on average payments of all episodes nationally from both the HOPD and freestanding radiation therapy center settings.

Comment: A few commenters disagreed with weighting the most recent episodes more heavily than those that occurred in earlier years, specifically weighting episodes that initiated in 2015 at 20 percent, episodes that initiated in 2016 at 30 percent, and episodes that initiated in 2017 at 50 percent. A couple of commenters stated that the 2017 rates were the lowest rates of all three years in the baseline, yet accounts for 50 percent of the national base rates. A commenter stated that the average reduction in rates from 2015 to 2017 was 11 percent for all included modalities except Conformal External Beam (CEB), which saw an 8 percent increase. Another commenter stated that the lower 2017 rates would increase the net loss that participants are likely to experience under the Model.

Response: We proposed to weight the most recent year in the baseline more heavily because this gives more weight to the most recent episode data available, including the most recent treatment patterns, not because they are the ''lowest'' rates. Furthermore, since we are moving the dates of service for the construction of episodes up a year from CYs 2015–2017 to CYs 2016–2018, episodes initiated in 2017 will be weighted at 30 percent not 50 percent. We are finalizing this provision with modification to construct episodes based on dates of service for Medicare FFS claims paid during the CYs 2016–2018 as well as claims that are included under an episode where the initial treatment planning service occurred during the CYs 2016–2018 as discussed in section C.III.6 of the proposed rule and this final rule. To weigh the most recent observations more heavily than those that occurred in earlier years as proposed, we will weight episodes that initiated in 2016 at 20 percent, episodes that initiated in 2017 at 30 percent, and episodes that initiated in 2018 at 50 percent.

c. National Base Rates

We proposed to define the term ''national base rate'' to mean the total payment amount for the relevant component of each episode before application of the trend factor, discount factor, adjustments, and applicable withholds for each of the included cancer types. We further proposed to codify this term at § 512.205 of our regulations.

The proposed rule would exclude the following episodes from calculations to determine the national base rates:

- Episodes with any services furnished by a CAH;
- Episodes without positive (>$0) total payment amounts for professional services or technical services;
- Episodes assigned a cancer type not identified as cancer types that meet our criteria for inclusion in the Model, as discussed in section III.C.5.a of the proposed rule (84 FR 34497 through 34498) and this final rule;
- Episodes that are not assigned a cancer type;
- Episodes with RT services furnished in Maryland, Vermont, or a U.S. Territory;
- Episodes in which a PPS-exempt cancer hospital furnishes the technical component (is the attributed technical provider);
- Episodes in which a Medicare beneficiary does not meet the eligibility criteria discussed in section III.C.4 of this final rule.

We proposed to exclude episodes without positive (>$0) total payment amounts for professional services or technical services, since we would only use episodes where the RT services were not denied and Medicare made payment for those RT services. We proposed to exclude episodes that are not assigned a cancer type and episodes assigned a cancer type not on the list of Included Cancer Types, since the RO Model evaluates the furnishing of RT services to beneficiaries who have been diagnosed with one of the included cancer types. The remaining proposals listed in section III.C.6.c of the proposed rule excluded episodes that are not in accordance with section III.C.5 of the proposed rule.

(1) National Base Rate Calculation Methodology

When calculating the national base rates, we proposed to only use episodes that meet the following criteria: (1) Episodes initiated in 2015–2017; (2) episodes attributed to an HOPD; and (3) during an episode, the majority of technical services were provided in an HOPD (that is, more technical services were provided in an HOPD than in a freestanding radiation therapy center). We explained in the proposed rule that OPPS payments have been more stable over time and have a stronger empirical foundation than those under the PFS. The OPPS coding and payments for radiation oncology have varied less year over year than those in the PFS for the applicable time period. In addition, generally speaking, the OPPS payment amounts are derived from information from hospital cost reports, which are based on a stronger empirical foundation than the PFS payment amounts for services involving capital equipment.

CMS proposed to publish the national base rates and provide each RO participant its participant-specific professional episode payment amounts and/or its participant-specific technical episode payment amounts for each cancer type no later than 30 days before the start of the PY in which payments in such amounts will be made.

Our proposed national base rates for the Model performance period based on the criteria set forth for cancer type inclusion were summarized in Table 3 of the proposed rule.

Comment: Many commenters disagreed with the proposal for calculating the national base rates based on average payment of episodes from only the HOPD setting. These commenters stated that utilizing only

HOPD episodes does not reflect the actual payment experience for freestanding radiation therapy centers, and that it is inappropriate to base a site neutral test on HOPD episodes alone. Some commenters questioned CMS' rationale for excluding freestanding radiation therapy center data from the calculation of the national base rates. The commenters claim that CMS' rationale (that is, that HOPDs furnished a lower volume of services and used less costly modalities within such episodes than did freestanding radiation therapy centers even though HOPDs provided more episodes nationally from 2015 through 2017) is not sufficient to warrant the exclusion of freestanding radiation therapy centers from the calculation of the national base rates. Another commenter stated that the analysis conducted by CMS provides no basis to suggest that higher utilization, particularly of IMRT in freestanding radiation therapy centers, is not medically necessary. Another commenter stated that particularly with respect to treatment of prostate cancer, the number of fractions for a course of treatment have held constant for nearly a decade, regardless of site of service. A few commenters questioned the veracity of the claim that the vast majority of increased utilization is occurring in the freestanding radiation therapy centers and requested that CMS share the details of its calculation that freestanding radiation therapy centers received 11 percent higher reimbursement per episode than HOPDs. MedPAC argued that using HOPD rates would increase payments to freestanding radiation therapy centers and reduce savings for Medicare. Finally, a few commenters took issues with the premise that OPPS rates have been more stable than the PFS rates, since PFS payments for radiation therapy codes have been frozen since 2015. Using one or more of the previously discussed arguments, many commenters recommended calculating the national base rates using a blend of PFS and OPPS rates rather than basing the rates on OPPS rates alone. These commenters argued that this blend would better account for different care patterns across the different sites of service. Additionally, several commenters recommended CMS use more recent data than 2015–2017, if available.

Response: We refer readers to the November 2017 Report to Congress that discusses FFS incentives and the site-of-service payment differential between HOPDs and freestanding radiation therapy centers in detail. It is true that the PFS rates have been fixed since 2015 and added stability temporarily, but these rates were fixed at the behest of professional organizations in radiation oncology in large part because of their concerns that those rates were unstable and under review as being potentially misvalued. The OPPS rates are constructed from hospital cost data. This cost data provides empirical support for the OPPS rates. The PFS rates do not have the same empirical cost data backing, as we explained in the proposed rule and in the November 2017 Report to Congress. We would also like to clarify that, although the national base rates in the RO Model are calculated based on episodes occurring in the HOPD setting, these episodes include payments made to physicians under the PFS for the PC and payments to freestanding radiation therapy centers for the TC in episodes where beneficiaries sought treatment from both HOPDs and freestanding radiation therapy centers.

We disagree that a blend of PFS and OPPS rates would better account for different care patterns across the different settings of HOPDs and freestanding radiation therapy centers. We believe the argument that the number of fractions has held constant for nearly a decade for a course of treatment for prostate cancer, regardless of site of service, supports the Model's move toward site neutrality, in that the settings are comparable, and no matter which site of service is used as the basis for payment, it should make no difference to treatment outcomes. We have found no evidence supporting different utilization rates based on setting. For clarity, we have found no evidence to suggest that, on average, higher utilization rates are warranted for RT services furnished in freestanding radiation therapy centers than for RT services furnished in the HOPD setting. We proposed to adopt both case mix and historical experience adjustments to account for the different care patterns of each RO participant specifically, not the different care patterns of HOPDs and freestanding radiation therapy centers in general. Furthermore, as patterns of care change over time, we will apply a trend factor to the 32 different national base rates to account for current trends in payment for RT services and the volume of those services outside of the Model in both HOPDs and freestanding radiation therapy centers. For clarity, we will use the volume and payment for RT services experienced in both settings to determine the trend factor.

As for hypofractionation, the RO Model is not intended to make hypofractionation the standard of care in radiation oncology unless it is clinically appropriate to do so. We refer readers to section III.B.3, aligning payments to quality and value, rather than volume, where the issue of hypofractionation is discussed in detail.

We agree with the comment that using HOPD rates would increase payments to freestanding radiation therapy centers, but only if we are considering payment on a per service basis, not when services are bundled under an episode of care and paid for accordingly, as will be done under the RO Model.

Finally, we agree with the commenters about using more recent baseline data, and therefore, we are finalizing the calculation of national base rates based on HOPD data as proposed with modification to change the baseline from 2015–2017 to 2016–2018.

Comment: Several commenters raised concerns regarding the OPPS comprehensive APC (C–APC) methodology. CMS applies this policy to certain RT services under the OPPS and commenters explained that radiation oncology is better suited for component coding to account for several steps in the process of care. The commenters also noted that the OPPS C–APC methodology does not account for the several steps in the process of care and fails to capture appropriately coded claims. A few commenters stated that the amount a hospital charges for a service does not have a direct or consistent relationship to what the service actually costs, and hospitals often use monthly or repetitive service claims. The commenters suggested that CMS monitor the impact of the OPPS methodology on payment rates under the RO Model and consider using the OPPS APC without the C–APC methodology for the technical component of the national base rate for cervical cancer, in particular.

Response: We thank the commenters for expressing their concerns regarding the OPPS C–APC policy that is used to pay for certain HOPD-furnished RT services. We also appreciate their recommendations regarding monitoring the impact of these policies on the episode payment amounts under the Model. We refer readers to section III.C.5.a, where we discuss the inclusion of cervical cancer as it relates to the C–APC methodology.

The purpose of the RO Model is to test a site-neutral and modality-agnostic approach to payment for RT services. We determined it was necessary to include certain RT services (for example, Stereotactic Radio Surgery) which are subject to the packaging policy under the OPPS in the RO Model

to help ensure site neutrality and a modality-agnostic approach. For clarity, we would have likely had to exclude certain commonly provided RT services if we wanted to avoid those codes that are subject to the OPPS C–APC policy. In addition, the RO Model will calculate a single episode payment rate for all of the included RT services for a 90-day period. As a result, the impact of any one code on the overall episode payment amount is minimal. We will monitor the impact of the C–APCs on the episode payment rates.

Comment: Many commenters expressed concerns regarding the calculation of the national base rates in that they believe the rates inappropriately include palliative care cases and distort the true cost of cancer care. A few commenters expressed concern about the lung cancer national base rates, in particular, and stated that 47 percent of the cases were palliative in nature. These commenters argued that the intent of treatment should determine pricing in these cases. CMS should determine whether these cases are palliative or curative in nature, and from this, develop separate rates within this cancer type.

Many commenters suggested that removing palliative cases would more accurately account for the cost of delivering standard of care in radiation oncology, but commenters differed on which cases would constitute care that is palliative in nature. A commenter suggested removing conformal radiation therapy treatment with ten or fewer fractions and then creating a separate ''Cancer symptom palliation, not otherwise specified'' episode, asserting that pulling these cases out would more accurately account for the cost of care. A few commenters suggested removing all episodes of 1–10 fractions with 2D or 3D management and removing non-SBRT episodes. Another commenter noted that even treatment courses of 11–20 fractions have high probability of being palliative episodes.

Response: In assigning cancer types, we created the Model to be as sensitive as possible in identifying palliative cases, including bone and brain metastasis cases. We believe the methodology we use to assign cancer types, which preferences assignment of bone and brain metastasis cases, appropriately captures those clinical circumstances where a beneficiary was treated not for cancer at the original site but for metastasis to the bone or brain, respectively. Other palliative cases described by the commenters are part of the set of historical episodes for other cancer types and are included in their national base rates. We refer readers to the comment responses in the overview of the pricing methodology in section III.C.6.a, where we detail how cancer type is assigned to an episode. Removing episodes determined to be palliative based solely on a low number of treatments would remove cases where a curative treatment included a low number of fractions. We cannot definitively determine if a treatment was palliative in nature based on count of fractions, and we do not intend to tie episode payment to fraction count, which would keep in place the FFS-incentive structure the RO Model intends to change. We will be monitoring to ensure that episodes of bone and brain metastasis are appropriately billed under the Model. We will not remove cases that are perceived to be palliative in nature based on the number of fractions furnished during the episode.

Comment: Many commenters called into question the integrity of data used to generate the national base rates. Many commenters stated that the national base rate calculations inappropriately include incomplete episodes of care. A commenter stated that 14 percent of HOPD cases look like incomplete episodes, because they had technical charges that were less than $5,000. A commenter estimated that if these incomplete episodes of care were to be excluded, this would increase the national base rates by approximately 16 percent.

Another commenter expressed concern about the payment differential between the average freestanding radiation therapy center rate and the average HOPD rate with regard to prostate cancer. The commenter attributed the payment differential, whereby the freestanding radiation therapy center rate was 7.5 percent higher than the average HOPD rate, to the additional $4,000 per episode for brachytherapy.

A commenter stated that a few providers and suppliers account for a large percentage of the total amount of episodes and that these providers and suppliers could have a disproportionate impact on the setting of the national base rates, homogenizing the data used to set those rates, and therefore, the method of calculating the national base rates should be reconsidered. Several commenters stated that non-standard treatment episodes are included in the calculation of the national base rates, and as a consequence, artificially depress actual cost. In a similar vein, a commenter added that artificially low payments caused by coding errors and billing infrequency in the HOPD setting may cause CMS to qualify otherwise efficient practices as inefficient participants. As an example, the commenter explained that many episodes had more than 10 brachytherapy treatment delivery services, while other episodes had brachytherapy counts 1–10 or 11–20 and also 11–20 or 21–30 IMRT/CEB counts. This signals an inconsistency in the way codes were used in COUNT_BRACHY. The commenter requested that the code set used for each code count be provided in the data dictionary that accompanies the episode file on the RO Model website.

Several commenters suggested CMS establish tiered base rates rather than a single base rate per cancer type. A commenter suggested developing different base rates based on resource levels and clinical complexity analogous to OPPS ambulatory payment classification levels. Similarly, a few commenters recommended the national base rates be stratified based on the clinical characteristics of beneficiaries as this significantly affects the number and type of treatment received, not just by the broad category of cancer they have. A commenter suggested that cancer stage and intensity of treatment be considered in payment. A commenter suggested that CMS use fewer than 34 different national base rates, because so many different rates would cause confusion for RO participants that treat multiple types of cancers.

Response: We thank these commenters for expressing these concerns and for their suggestions. We disagree that incomplete episodes were inappropriately included in the national base rates. We used the same criteria to identify episodes in the baseline as we will use in the Model. Only episodes that meet certain criteria, codified at § 512.250, would be included in the national base rate calculation and in the calculation of the trend factor, case mix and historical experience adjustments. We are finalizing episode exclusion criteria with a few clarifications. We are clarifying that we exclude episodes in the baseline which are not attributed to an RT provider or RT supplier, an exceedingly rare case (less than 15 episodes out of more than 518,000 episodes in the baseline period) where the only RT delivery services in the episode are classified as professional services (because there are a few brachytherapy surgery services that are categorized as professional services). We are also clarifying that episodes are excluded if either the PC or TC is attributed to an RT provider or RT supplier with a U.S. Territory service location or to a PPS-exempt entity. However, services within an episode

provided in a US Territory or provided by a PPS-exempt entity are included in the episode pricing. Thus, for the constructed episodes used to determine the baseline, we will include the costs of any services provided by such an RT provider or RT supplier, as long as the RT provider or RT supplier does not provide the majority of either the professional or technical services, in which case the PC or TC would be attributed to the entity and the episode would be excluded. We are also clarifying that episodes are excluded if they include any RT service furnished by a CAH. Further, we are clarifying that we exclude all Maryland and Vermont claims before episodes are constructed and attributed to an RT provider or RT supplier. For this reason, there are not episodes in which either the PC or TC is attributed to an RT provider or RT supplier with a Maryland or Vermont service location. We similarly exclude inpatient and ASC claims from episode construction and attribution.

Episodes are not excluded based on any clinical standards of care or based on the size of HOPD that furnished the episode. We also do not use the size of RT providers or RT suppliers, that is, the number of episodes that a given RT provider or RT supplier furnishes, as a measure of exclusion. We disagree that the national base rate calculation should account for size of the RT provider or RT supplier, as we do not believe that large RT providers and RT suppliers make up a disproportionate share of the episodes in the calculation of the national base rates. As long as HOPD episodes meet inclusion criteria as stated in section III.C.6.c, they will be included in the calculation of the national base rates, regardless of the size of the RT provider or RT supplier where the episode was furnished. It is important to note that the cost of RT services vary by modality and cancer type, and although payment differentials may exist across episodes due to the use of multiple modalities as a commenter stated, we believe that using a blend to determine payment (that is, a blending of participant-specific historical payments with national base rates to determine payment) allows us to balance the national context (as represented by the spectrum of HOPDs nationally) with participant experience.

Furthermore, we have only claims data available to design and operationalize the RO Model. These claims data do not include clinical data, which is why we are finalizing our proposal to collect clinical data from RO participants to assess the potential utility of additional data for monitoring and calculating episode payment amounts (see section III.C.8.e). We do not have the clinical or resource level data to design tiered base rates as several commenters suggested. Further, we believe that the case mix adjustment appropriately accounts for the complexity of an RO participant's patient population, and the historical experience adjustment captures additional unmeasured factors that may make one RO participant's patient population more complex, and thus more costly, than another's. Similarly, no resource databases are available that have the kind of data necessary to determine national base rates for a generalizable sample of Medicare FFS beneficiaries. We believe the best way to calculate prospective payment rates is to look to what we have historically paid for those episodes based on treatment patterns in claims and historical payment rates, and then trend these amounts forward. We believe that treatment patterns as reflected in the episode file represent the variation in care patterns currently delivered nationally. We can only account for codes that have been submitted in claims. We cannot account for coding or submission errors made on the part of RT providers or RT suppliers, unless they have been corrected appropriately in claims. Furthermore, using fewer than 32 different national base rates would not appropriately compensate RO participants for the cancer type they are treating and the component they are furnishing, whether professional or technical. Based on a full review of comments and the detailed analyses contained within some of them, we believe that commenters have had sufficient detail to fully comment on the proposed RO Model.

Comment: Many commenters also expressed concern about the way in which primary and secondary malignancies are coded, suggesting that improper coding could skew the national base rates. These commenters suggested that the presence of low cost episodes in the episode file posted on the RO Model website are likely misattributed to a primary disease site and should have been attributed to a palliative care site and should not have been included in the calculation of the base rate of the attributed primary disease site.

Response: The pricing methodology does not attempt to assign cancer types using clinical logic of primary and secondary cancers, but rather follows a plurality rule based on E&M services, treatment planning services, and treatment delivery services. We rely on the data submitted on claims by providers and suppliers to be accurate per Medicare rules and regulations. We refer readers to the comment responses in the overview of pricing methodology in section III.C.6.a, where we detail how cancer type is assigned to each episode. We believe this approach appropriately captures episodes for the treatment of metastases by prioritizing assignment to those cancer types.

Comment: Several commenters stated that data integrity is challenged by the ICD–9 and ICD–10 diagnosis coding. Many commenters requested more detail on how diagnosis codes are assigned. A few commenters stated that the episode file on the RO Model website had each episode classified by disease site but not by ICD–9 or ICD–10 and requested that ICD–9 and ICD–10 codes be made available in the episode file for review along with a guide on how these codes are mapped to the corresponding disease site. A few commenters noted concern about the transition from ICD–9 to ICD–10 coding systems and called into question providers' and suppliers' coding accuracy when using the new ICD–10 code set alongside the 1-year grace period that was granted for using the ICD–9 code set. A commenters requested specifically that the algorithm for metastatic brain and breast ICD codes be made public.

Response: We rely on the data submitted on claims by providers and suppliers to be accurate per Medicare rules and regulations. The mapping of ICD–10 diagnosis codes to cancer type is described in Table 1. We believe sufficient information was provided in the episode file available on RO Model website to allow comment. We are finalizing the calculation of national base rates based on HOPD data as proposed with modification to change the baseline from 2015–2017 to 2016–2018. This modification reduces the risk of coding errors that could result from the transition from ICD–9 to ICD–10 codes.

Comment: Many commenters disagreed with the proposal to include proton beam therapy in the calculation of the national base rates. MedPAC, however, expressed support of CMS' proposal to include PBT in the Model. MedPAC explained that Medicare's payment rates for PBT are substantially higher than for other types of external beam radiation therapy. Additionally, the use of PBT has expanded in recent years from pediatric and rare adult cancers to include more common types of cancer, such as prostate and lung cancer, despite a lack of evidence that it offers a clinical advantage over alternative treatments for these types of

cancer. Some commenters believe that including PBT in the episode payment would create an incentive to use lower-cost, comparable modalities.

Many commenters stated that the national base rates do not include a meaningful volume of PBT episodes in the calculation and, therefore, the payment rates are not reflective of the cost of providing PBT, and, if finalized, would lead to significant cuts. Several commenters called attention to the national base rate for head and neck cancer in that PBT does not statistically contribute to that rate, only accounting for 0.8 percent of all modalities used, 18 of which were boost treatments. Therefore, a large cohort of patients incurs costs below the cost of the standard episode of care for head and neck cancer. Many commenters recommended that PBT-specific national base rates be developed to reflect the high value resources and patient complexity that is unique to patients that require PBT.

Response: We thank these commenters for expressing their concerns and for their suggestions. RO Model payments are designed to be disease specific and agnostic to treatment and modality type. We believe that using a blend to determine payment (that is, a blending of participant-specific historical payments with national base rates to determine payment), whereby a large share of the payment calculation is determined by historical payments will appropriately account for the difference in payment for PBT. We refer readers to section III.C.5.d for discussion of PBT.

Comment: A couple of commenters noted that the episode file contained episodes where the professional pay and technical pay categories had a $0 value and requested clarity on how this data would be included in the analysis.

Response: Some payment variables on the episode file that was made available under the NPRM had missing values by design. For example, the RADONC_PRO_PAY, RADONC_TECH_PAY, RADONC_PRO_PAY_WINSORIZED_OPD, and RADONC_TECH_PAY_WINSORIZED_OPD variables have values set to ''missing'' for episodes in the free-standing facility setting because they are not used for payment-related purposes under the Model. The variables RADONC_PRO_PAY_WINSORIZED_ALL and RADONC_TECH_PAY_WINSORIZED_ALL are fully populated because they are used in creating historical experience adjustments. These values are all greater than $0.

Comment: Several commenters disagreed with the proposal to provide each RO participant its participant-specific professional episode payment and/or its participant-specific technical episode payment for each cancer type no later than 30 days before the start of the PY in which payments in such amounts would be made, explaining that 30-day notice is insufficient. A few commenters proposed 60-day notice and a commenter proposed 90-day notice similar to the notice given to participants of the CJR Model.

Response: Because the RO payment amounts incorporate the PFS and OPPS payment rates in the trend factor, the participant-specific professional and technical episode payment amounts are dependent upon publication of the PFS and OPPS final payment rules for the upcoming calendar year. These payment regulations are statutorily required to be 60 days in advance of the start of a calendar year. CMS then subsequently performs calculations to determine the RO Model trend factor and then creates the participant-specific professional and technical episode payment amounts. We may notify RO participants of these adjustments prior to the 30-day notice deadline to the extent possible. As noted in the proposed rule, even though the Model will establish a common payment amount for the same RT services regardless of where they are furnished, payment will still be processed through the current claims systems, with geographic adjustments as discussed in section III.C.7 of the proposed and this final rule, for OPPS and PFS.

We are noting one technical change. CMS will provide each RO participant its case mix and historical experience adjustments for both the PC and TC in advance of the PY, rather than their participant-specific professional and technical episode payment amounts, because exact figures for the participant-specific professional and technical episode payment amounts cannot be known prior to claims processing for several reasons.

First, we are only able to provide estimates for geographic adjustment based on the payment area(s) in which an RO participant furnishes included RT services. The exact geographic adjustment will vary based on the location billed by the RO participant, so the actual payments calculated by CMS' payment contractors may be different from preliminary estimates. Second, any differences of rounding at one step versus another during payment processing between a preliminary estimate and what actually occurs during claims processing could create some small discrepancies. Third, any estimate of the participant-specific professional episode payment amounts would not include any payment adjustments due under MIPS. Fourth, the participant-specific technical payment amounts would not include possible additional payments that Medicare would make in the event that the beneficiary coinsurance is capped at the inpatient deductible limit under OPPS. These issues taken together will leave a discrepancy (and the size of the discrepancy will vary among RO participants) between what CMS could estimate the participant-specific professional and technical episode payment amounts to be before the PY begins and what RO participants actually receive. Therefore, CMS will provide each RO participant its case mix and historical experience adjustments for both the professional and technical components, rather than their participant-specific professional and technical episode payment amounts, at least thirty (30) days prior to the start of the PY to which those adjustments apply.

After considering public comments on the proposed national base rates, we are finalizing as proposed the determination of national base rate as codified at § 512.250. We are finalizing our proposal with one technical change. We are modifying the regulatory text at § 512.255 to specify that 30 days before the start of each performance year, CMS will provide each RO participant its case mix and historical experience adjustments for both the professional and technical components. We are also finalizing the calculation of national base rates with a modification from the proposed rule that changes the baseline from 2015–2017 to 2016–2018 and a modification to exclude episodes from the baseline in which either the PC or TC is attributed to a provider with a Maryland, Vermont, or US Territory service location, rather than exclude episodes with RT services furnished in Maryland, Vermont, or a U.S. Territory as proposed. Our 32 national base rates for the Model performance period based on the criteria set forth for cancer type inclusion are summarized in Table 3 (noting the removal of kidney cancer from the list of included cancer types discussed in section III.C.5.c).

TABLE 3 –NATIONAL BASE RATES BY CANCER TYPE (in 2018 DOLLARS)

RO Model-Specific Placeholder Codes[41]	Professional or Technical	Cancer Type	Base Rate
MXXXX	Professional	Anal Cancer	$3,001.19
MXXXX	Technical	Anal Cancer	$16,543.53
MXXXX	Professional	Bladder Cancer	$2,688.35
MXXXX	Technical	Bladder Cancer	$13,291.62
MXXXX	Professional	Bone Metastases	$1,398.14
MXXXX	Technical	Bone Metastases	$5,971.73
MXXXX	Professional	Brain Metastases	$1,601.70
MXXXX	Technical	Brain Metastases	$9,648.92
MXXXX	Professional	Breast Cancer	$2,081.47
MXXXX	Technical	Breast Cancer	$10,128.61
MXXXX	Professional	Cervical Cancer	$3,829.34
MXXXX	Technical	Cervical Cancer	$17,581.18
MXXXX	Professional	CNS Tumor	$2,510.55
MXXXX	Technical	CNS Tumor	$14,711.14
MXXXX	Professional	Colorectal Cancer	$2,449.38
MXXXX	Technical	Colorectal Cancer	$12,039.84
MXXXX	Professional	Head and Neck Cancer	$3,019.00
MXXXX	Technical	Head and Neck Cancer	$17,485.19
MXXXX	Professional	Liver Cancer	$2,082.23
MXXXX	Technical	Liver Cancer	$11,976.09
MXXXX	Professional	Lung Cancer	$2,181.23
MXXXX	Technical	Lung Cancer	$11,993.83
MXXXX	Professional	Lymphoma	$1,690.41
MXXXX	Technical	Lymphoma	$7,854.53
MXXXX	Professional	Pancreatic Cancer	$2,394.14
MXXXX	Technical	Pancreatic Cancer	$13,384.14
MXXXX	Professional	Prostate Cancer	$3,260.97
MXXXX	Technical	Prostate Cancer	$20,248.82
MXXXX	Professional	Upper GI Cancer	$2,585.57
MXXXX	Technical	Upper GI Cancer	$13,530.21
MXXXX	Professional	Uterine Cancer	$2,435.59
MXXXX	Technical	Uterine Cancer	$11,869.29

d. Proposal To Apply Trend Factors to National Base Rates

We proposed to next apply a trend factor to the 34 different national base rates in Table 3 of the proposed rule. For each PY, we would calculate separate trend factors for the PC and TC of each cancer type using data from HOPDs and freestanding radiation therapy centers not participating in the Model. The 34 separate trend factors would be updated and applied to the national base rates prior to the start of each PY (for which they would apply) so as to account for trends in payment rates and volume for RT services outside of the Model under OPPS and PFS.

For the PC of each included cancer type and the TC of each included cancer type, we proposed to calculate a ratio of: (a) Volume-weighted FFS payment rates for RT services included in that component for that cancer type in the upcoming PY (that is, numerator) to (b) volume-weighted FFS payment rates for RT services included in that component for that cancer type in the most recent baseline year (that is, the denominator), which will be FFS rates from 2017.

To calculate the numerator, we proposed to multiply: (a) The average

[41] The final HCPCS codes specific to the RO Model would be published in an upcoming quarterly update of the CY2020 Level 2 HCPCS code file.

number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished for the most recent calendar year with complete data [42] by (b) the corresponding FFS payment rate (as paid under OPPS or PFS) for the upcoming performance year.

To calculate the denominator, we proposed to multiply: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished in 2017 (the most recent year used to calculate the national base rates) by (b) the corresponding FFS payment rate in 2017. The volume of HCPCS codes determining the numerator and denominator would be derived from non-participant episodes that would be otherwise eligible for Model pricing. For example, for PY1, we would calculate the trend factor as:

2020 Trend factor = (2017 volume * 2020 corresponding FFS rates as paid under OPPS or PFS)/(2017 volume * 2017 corresponding FFS rates as paid under OPPS or PFS)

We proposed to then multiply: (a) The trend factor for each national base rate by (b) the corresponding national base rate for the PC and TC of each cancer type from Step 1, yielding a PC and a TC trended national base rate for each included cancer type. The trended national base rates for 2020 would be made available on the RO Model's website once CMS issues the CY 2020 OPPS and PFS final rules that establish payment rates for the year.

To the extent that CMS introduces new HCPCS codes that CMS determines should be included in the Model, we proposed to cross-walk the volume based on the existing set of codes to any new set of codes as we do in the PFS rate-setting process.[43]

We proposed to use this trend factor methodology as part of the RO Model's pricing methodology.

The following is a summary of the public comments received on the proposal to apply trend factors to national base rates and our responses to those comments:

Comment: A few commenters expressed support for the proposal to update the trend factor using the most recent, complete calendar year of data available. Several commenters, however, opposed the application of the trend factor as proposed for various reasons. Several commenters stated that the trend factor will reflect macro changes to reimbursement and utilization, not practice-specific technology acquisition and, therefore, the trend factor will not provide an adequate safeguard for innovation before technology has a significant foothold in the marketplace. Many commenters stated that the trend factor is not nuanced enough and will disadvantage providers and suppliers who care for higher risk patients. Many commenters expressed concern with the delay between any increase in episode cost occurring outside of the Model among non-participants and the time it would take to be reflected in the trend factor. A commenter opposed the trend factor as proposed if it would result in lower base rates.

Many commenters suggested modifications to the proposed trend factor. Several commenters suggested that CMS trend payment amounts based on changes in the cost of technologies and the mix of treatments that evidence indicates is appropriate. In a similar vein, several commenters suggested that in addition to the trend factor, CMS adopt a rate review mechanism whereby RO participants could make the case for participant-specific rate modifications based on added service lines. Similarly, a few commenters suggested carve out payments for new service lines. For the RO participants that introduced a new radiation oncology service line in a given period of time, for example, they would be eligible for a carve-out payment for part of the Model's performance period.

One commenter suggested using only OPPS data to determine the trend factors for the TC of the national base rates. Another commenter suggested including RO participant data in the calculation of the trend factor. Another commenter suggested recalculating the trend factor denominator based on a more recent year rather than 2017.

Several commenters requested clarification as to how the trend factor is calculated. A few commenters requested clarity specifically as to which fee schedules CMS will use to calculate the trend factors.

Response: We will calculate unique trend factors for the PC and TC separately for each cancer type, since the number and types of RT services within episodes vary across the PC and TC of each cancer type, and there is sufficient national data to develop separate trend factors for the PC and TC of each cancer type just as there were for development of the national base rates. For the PC of each included cancer type and the TC of each included cancer type, we will calculate as proposed a ratio of: (a) Volume-weighted FFS payment rates for RT services included in that component for that cancer type in the upcoming PY (that is, numerator) to (b) volume-weighted FFS payment rates for RT services included in that component for that cancer type in the most recent baseline year (that is, the denominator), which will be FFS rates from 2018 rather than 2017 as was proposed.

We would like to clarify how RT services that are contractor-priced under MPFS are incorporated into Model pricing. Instead of relying on the CMS-determined resource-based relative value units (RVUs) to establish the payment rate under the MPFS, Medicare Administrative Contractors (MACs) determine the payment rate for contractor-priced services. This rate is used by the MAC in their respective jurisdiction. Payment rates across MAC jurisdictions can vary. Due to the potential differences across jurisdictions, we will calculate the average paid amounts for each year in the baseline period for each of these RT services to determine their average paid amount that will be used in the calculation of the national base rates. We will use the most recent calendar year with claims data available to determine the average paid amounts for these contractor-priced RT services that will be used in the calculation of the trend factors for the PC and TC of each cancer type. For instance, for the 2021 trend factor, we will calculate the average paid amounts for these contractor-priced RT services using the allowed charges listed on 2018 claims. For the 2022 trend factor, we will calculate the average paid amounts for these contractor-priced RT services using the allowed charges listed on the 2019 claims, and so forth.

We will calculate the numerator as proposed and multiply: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished for the most recent calendar year with complete data by (b) the corresponding FFS payment rate (as paid under OPPS or PFS) for the upcoming PY. It is important to note that for PY1 (2021), the most recent year with complete episode data will be 2018, not 2017, as proposed. This mirrors the final policy to change the baseline from 2015–2017 to 2016–2018 with respect to the calculation of the national base rates.

[42] For 2020 (PY1), the most recent year with complete episode data would be 2017; for 2021 (PY2), the most recent year with complete episode data would be 2018.

[43] The process of cross-walking the volume from a previous set of codes to the new set of codes in rate-setting for the PFS was most recently explained in the CY 2013 PFS Final Rule, 77 FR 68891, 68996–68997.

We would like to clarify that volume-weighted FFS payment rate means a weighted average of all of the included RT services' FFS payment rates, where the frequency of each RT service determines its relative contribution to the calculation.

We will calculate the denominator as proposed and multiply: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applying) was furnished in 2018 (and not 2017 as proposed), since this is the most recent year used to calculate the national base rates by (b) the corresponding FFS payment rate in 2018 (and not 2017 as proposed). The volume of HCPCS codes, which determines the numerator and denominator of the trend factors, will be derived as proposed from non-participant episodes that would be otherwise eligible for Model pricing. For example, for PY1, we will calculate the trend factor as:

2021 (PY1) Trend factor = (2018 volume * 2021 corresponding FFS rates as paid under OPPS or PFS)/(2018 volume * 2018 corresponding FFS rates as paid under OPPS or PFS)

It is important to note that the trend factors will be based on service volumes from episodes attributed to both HOPDs and freestanding radiation therapy centers, and both PFS and OPPS fee schedules will be used to create the annual trend factors. The use of trend factors based on updated PFS and OPPS rates ensures that spending under the RO Model does not diverge too far from spending under the FFS that non-participants will receive for the underlying bundle of services had they been in the Model. The trend factors will only generate significant swings if there are large swings in payment rates for RT services that are frequently used during episodes, which is unlikely to be the case. If there are big swings upward, that is, OPPS or PFS rates or service volumes increase, then RO participants would receive the corresponding increases. Conversely, if there were big swings downward, spending under the RO Model would become unsustainably high comparable to the FFS alternative if we did not apply a negative trend factor, so RO participants would receive the corresponding decreases.

As for considerations of innovation and added service lines, the trend factor will reflect updates to input prices as reflected in updated PFS and OPPS rates. Prospective payments in general, including episode-based payment rates of the RO Model, are not designed to reflect specific investment decisions of individual providers and suppliers, such as practice-specific technology acquisition. Furthermore, we do not want to incorporate RO participants' episodes (RO episodes) in the trend factor calculation, because we do not want to penalize RO participants for any efficiencies gained during the Model. A rate-review mechanism is not practical at this time. We will monitor the adequacy of payments over time, including the trend factor and consider re-baselining in the later PY if analysis indicates it is necessary.

We are finalizing policies in this section as proposed with a modification to the years used in the trend factor's numerator and denominator calculation. For the trend factor's numerator calculation, the most recent calendar year with complete data used to determine the average number of times each HCPCS code was furnished will be 2018 for PY1, 2019 for PY2, and so forth. We note that the corresponding FFS payment rate (as paid under the OPPS and PFS) included in the numerator calculation is still that of the upcoming PY (2021 payment rates for PY1, 2022 payment rates for PY2, and so forth). The trend factor's denominator calculation will use data from 2018 to determine: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applying) was furnished; and (b) the corresponding FFS payment rate. As described in the proposed rule, the denominator does not change over the Model's performance period unless we propose to rebaseline, which we would propose through future rulemaking.

e. Adjustment for Case Mix and Historical Experience

In the proposed rule, we proposed that after applying the trend factor in section III.C.6.d of the proposed rule (84 FR 34506 through 34507), we would adjust the 34 trended national base rates to account for each RO participant's historical experience and case mix history.

(1) Case Mix Adjustments

As explained in the proposed rule, the cost of care can vary according to many factors that are beyond a health care provider's control, and the presence of certain factors, otherwise referred to here as case mix variables, may vary systematically among providers and suppliers and warrant adjustment in payment. For this reason, we proposed to apply an RO participant-specific case mix adjustment for the PC and the TC that would be applied to the trended national base rates.

In developing the proposed rule, we consulted clinical experts in radiation oncology concerning potential case mix variables believed to be predictive of cost. We then tested and evaluated these potential case mix variables and found several variables (cancer type; age; sex; presence of a major procedure; death during the first 30 days, second 30 days, or last 30 days of the episode; and presence of chemotherapy) to be strongly and reliably predictive of cost under the FFS payment system.

Based on the results of this testing, we proposed to develop a case mix adjustment, measuring the occurrence of the case mix variables among the beneficiary population that each RO participant has treated historically (that is, among beneficiaries whose episodes have been attributed to the RO participant during 2015–2017) compared to the occurrence of these variables in the national beneficiary profile. The national beneficiary profile was developed from the same episodes used to determine the Model's national base rates, that is 2015–2017 episodes attributed to all HOPDs nationally. We would first Winsorize, or cap, the episode payments in the national beneficiary profile at the 99th and 1st percentiles, with the percentiles being identified separately by cancer type. We proposed to use OLS regression models, one for the PC and one for the TC, to identify the relationship between episode payments and the case mix variables. The regression models would measure how much of the variation in episode payments can be attributed to variation in the case mix variables.

The regression models generate coefficients, which are values that describe how change in episode payment corresponds to the unit change of the case mix variables. From the coefficients, we proposed to determine an RO participant's predicted payments, or the payments predicted under the FFS payment system for an episode of care as a function of the characteristics of the RO participant's beneficiary population. As proposed, for PY1, these predicted payments would be based on episode data from 2015 to 2017. These predicted payments would be summed across all episodes attributed to the RO participant to determine a single predicted payment for the PC or the TC. This process would be carried out separately for the PC and the TC.

We proposed to then determine an RO participant's expected payments or the payments expected when a participant's case mix (other than cancer type) is not considered in the calculation. To do this, we would use the average Winsorized episode payment made for

each cancer type in the national beneficiary profile. These average Winsorized episode payments by cancer type would be applied to all episodes attributed to the RO participant to determine the expected payments. These expected payments would be summed across all episodes attributed to an RO participant to determine a single expected payment for the PC or the TC. The difference between an RO participant's predicted payment and an RO participant's expected payment, divided by the expected payment, would constitute either the PC or the TC case mix adjustment for that RO participant. In the proposed rule, we explained that mathematically this would be expressed this as follows:

Case mix adjustment = (Predicted payment − Expected payment)/Expected payment

The proposed rule noted that neither the national beneficiary profile nor the regression model's coefficients would change over the course of the Model's performance period. The coefficients would be applied to a rolling 3-year set of episodes attributed to the RO participant so that an RO participant's case mix adjustments take into account more recent changes in the case mix of their beneficiary population. For example, we proposed to use data from 2015–2017 for PY1, data from 2016–2018 for PY2, data from 2017–2019 for PY3, etc.

(2) Historical Experience Adjustments and Blend (Efficiency Factor in Proposed Rule)

To determine historical experience adjustments for an RO participant we proposed to use episodes attributed to the RO participant that initiated during 2015–2017. We proposed to calculate a historical experience adjustment for the PC (that is, a professional historical experience adjustment) and the TC (that is, a technical historical experience adjustment) based on attributed episodes. For purposes of determining historical experience adjustments, we proposed to use episodes as discussed in section III.C.6.b of this final rule (that is, all episodes nationally), except we proposed to Winsorize, or cap, episode payments attributed to the RO participant at the 99th and 1st percentiles. These Winsorization thresholds would be the same Winsorization thresholds used in the case mix adjustment calculation. We would then sum these payments separately for the PC and TC. As with the case mix adjustments, the historical experience adjustments will not vary by cancer type.

As discussed in the proposed rule, the historical experience adjustment for the PC would be calculated as the difference between: The sum of (a) Winsorized payments for episodes attributed to the RO participant during 2015–2017 and (b) the summed predicted payments from the case mix adjustment calculation, which will then be divided by (c) the summed expected payments used in the case mix adjustment calculations. We proposed to repeat these same calculations for the historical experience adjustment for the TC. In the proposed rule, we explained that mathematically, for episodes attributed to the RO participant, this would be expressed as:

Historical experience adjustment = (Winsorized payments − Predicted payments)/Expected payments

Based on our calculation, if an RO participant's Winsorized episode payments (determined from the retrospectively constructed episodes from 2015–2017 claims data) are equal to or less than the predicted payments used to determine the case mix adjustments, then it would have historical experience adjustments with a value equal to or less than 0.0, and be categorized as historically efficient compared to the payments predicted under the FFS payment system for an episode of care as a function of the characteristics of the RO participant's beneficiary population. Conversely, if an RO participant's episode payments are greater than the predicted payments used to determine the case mix adjustments, then it would have historical experience adjustments with a value greater than 0.0 and be categorized as historically inefficient compared to the payments predicted under the FFS payment system for an episode of care as a function of the characteristics of the RO participant's beneficiary population. The historical experience adjustments would be weighted differently and therefore, applied to payment (that is the trended national base rates after the participant-specific case mix adjustments have been applied) differently, depending on these categories. To do this, we proposed to use an efficiency factor. Efficiency factor means the weight that an RO participant's historical experience adjustments are given over the course of the Model's performance period, depending on whether the RO participant's historical experience adjustments fall into the historically efficient or historically inefficient category.

For RO participants with historical experience adjustments with a value greater than 0.0, the efficiency factor would decrease over time to reduce the impact of historical practice patterns on payment over the Model's performance period. More specifically, for RO participants with a PC or TC historical experience adjustment with a value greater than 0.0, we proposed that the efficiency factor would be 0.90 in PY1, 0.85 in PY2, 0.80 in PY3, 0.75 in PY4 and 0.70 in PY5. For those RO participants with a PC or TC historical experience adjustment with a value equal to or less than 0.0, the efficiency factor would be fixed at 0.90 over the Model's performance period. The following is a summary of the public comments received on the proposed case mix adjustment and historical experience adjustments, and our responses to those comments.

Comment: Several commenters expressed support for the proposal to have case mix and historical experience adjustments. These commenters stated that these adjustments would account for RO participants' varied historical uses of more or less expensive modalities and treatment decisions that may be impacted by patient demographics.

Response: We thank these commenters for their support of these adjustments.

Comment: A couple of commenters expressed concern that the Model does not address equipment replacement or upgrades. A few commenters suggested that CMS adopt a rate review mechanism for new service lines and upgrades. Another commenter used the example of providers and suppliers who add PBT centers and therefore lack evidence of historical pricing in their claims data—in such cases, this commenter recommends exempting these new service line modalities for three years until the modality and higher payment is accurately accounted for in the practice's historical claims data.

Response: We appreciate the commenters' recommendations. In section III.C.6.d of this final rule, we respond to comments related to added service lines. We note that prospective payments in general, including episode-based payment rates of the RO Model, are not designed to reflect specific investment decisions of individual providers and suppliers, such as practice-specific technology acquisition. We did not propose to re-baseline participants during the model to avoid a possible reduction in payment due to participants becoming more efficient during the model, but we would consider balancing this consideration against the issue of new service lines as

the model is implemented. We will monitor for this occurrence and if necessary propose a method to support this in future rulemaking.

Comment: Several commenters recommended that CMS design the case mix and historical experience adjustments to be cancer-specific rather than participant-specific as it is currently proposed.

Response: There are not enough episodes to design a separate case mix adjustment approach for each cancer type, so we have chosen to create a single case mix adjustment approach across all cancer types. The case mix model incorporates cancer type and so the RO participant-specific case mix adjustment for the PC and the TC reflects the case mix of the participant's population including variation in the cancer types treated. The same is true for the approach taken for the historical experience adjustment.

Comment: A commenter suggested that aside from the case mix and historical experience adjustments, CMS should adjust payments to account for the higher cost of delivering RT services in rural communities than in urban settings.

Response: Generally, CBSAs do not include the extreme rural regions. In cases where RO participants are furnishing RT services in rural communities, the historical experience adjustment will account for those RO participants' historical care patterns and their relative cost.

Comment: Many commenters expressed concern over the case mix adjustments. A few commenters suggested that rather than deriving the case mix adjustments from a rolling three-year average, CMS should implement a static baseline, while other commenters suggested that the coefficients of the case mix adjustment formula should change annually. A commenter suggested that a health care provider's case mix adjustment should reflect the beneficiaries they treated in the current performance year rather than a beneficiary cohort for a few years earlier. A few commenters stated that the time lag between the years on which the adjustment data is based and its application to payment was especially problematic for the use of mortality rate as a case mix variable. These commenters explained that death during an episode and the timing of when a patient died has the largest impact on a health care provider's case mix adjustment. A commenter estimated that if a beneficiary dies in the first 30 days of an episode, the TC payment for that episode would be nearly $6,000 less than if the patient had survived. A commenter argued that the case mix adjustment disregards the differences between the case mix of freestanding radiation therapy centers and HOPDs.

Many commenters suggested that the case mix adjustment be based on beneficiary characteristics that affect the appropriate type and amount of evidence-based treatment that is reflected in clinical data. These commenters suggested a variety of clinical factors should be accounted for in the case mix adjustment. Commenters stated such factors as disease stage, line of treatment, comorbidities, treatment intent, and change in patient acuity over the course of the episode. A couple of commenters recommended that social determinants of health be incorporated into the calculation of the case mix adjustment. A commenter requested that CMS derive each beneficiary's HCC score or NCI comorbidity index, test that variable in the regression models, and disclose the results. Another commenter suggested differing payments based on a participant's patient risk levels.

Several commenters requested clarity on the ordinary least squares regression model that derives the case mix adjustments. Several commenters asked why cancer type is included in the case mix adjustment. A few commenters requested that CMS clarify the weight of each variable used to calculate the case mix adjustment. A few commenters requested examples regarding the calculation of predicted payments and expected payments that determine the case mix and historical adjustments. A commenter specifically requested how chemotherapy and major procedures are defined under the RO Model and suggested that the definitions align with the OCM to promote alignment between the two models.

Response: We thank these commenters for expressing their concerns and suggestions regarding the case mix adjustment. The case mix adjustment is designed to adjust payment rates for demographic characteristics, presence of chemotherapy, presence of major procedures, and death rates. We call these the case mix variables. With respect to chemotherapy, we define chemotherapy using the same definitions and coding lists as OCM. With respect to major procedures, the list of major procedure codes for radiation oncology goes beyond the list of cancer-related surgeries used in OCM's risk adjustment to include a comprehensive set of major procedures not necessarily related to cancer. As noted in the proposed rule, we adopted this approach after consulting with clinical experts in radiation oncology. These experts advised that utilization and expenditures are influenced by the presence of any major procedure, and not just cancer-related procedures. Cancer type is included in the case mix adjustment to capture the proportionate share of each cancer type in an RO participant's beneficiary population and assess the resulting effects of the particular mix of cancer types treated by that RO participant on cost.

As noted in response to comments concerning the national base rates, we have only claims data available to design and operationalize the RO Model. The claims data do not include clinical data. We are finalizing our proposal to collect clinical data from RO participants so that we can assess the potential utility of additional clinical data for monitoring and calculating episode payment amounts (see section III.C.8.e).

The case mix approach we adopt in the Model has the goal of reflecting the net impact of the case mix variables after controlling for cancer type, which is already accounted for in the national base rates. We believe that the case mix adjustment will provide a consistent adjustment approach to the case mix of episodes furnished by RO participants in both the HOPD and freestanding radiation therapy center settings. It is true that we have designed the pricing methodology around HOPD episode utilization and expenditure patterns, and that the case mix adjustment is designed to measure the occurrence of the case mix variables among the beneficiary population that each RO participant has treated historically in the most recent 3-year set of data with complete episodes available (that is, among beneficiaries whose episodes have been attributed to the RO participant during 2016–2018 in PY1 and 2017–2019 in PY2, etc.) relative to the occurrence of these variables in the national beneficiary profile. The RO Model, a prospective episode-based payment model, requires a time lag between the years on which the adjustment data is based and the year it is applied to payment, precisely because it is prospective in nature. Since the national base rate calculations are premised on HOPD episodes nationally, so too is the case mix model and the case mix coefficients built upon these episodes, so differences in characteristics between that HOPD-based national beneficiary population and the beneficiary population the RO participant has historically treated is appropriately captured. Recall that the national beneficiary profile is developed from the same episodes used to determine the Model's national base

rates, that is the updated 2016–2018 episodes attributed to all HOPDs nationally. The 2016–2018 episodes attributed to all HOPDs nationally are the reference point used for comparison to measure how much an RO participant's case mix should affect their respective episode payment amounts, precisely because the national base rates are derived from those same episodes.

We will develop a regression model as proposed that predicts Winsorized episode payment amounts based on cancer type and demographic characteristics, presence of chemotherapy, presence of major procedures, and death rates, and we will also finalize our approach to calculating the case mix adjustment as the difference between predicted and expected payment, which is then divided by expected payment. To provide more clarification and simplify the process for calculating the expected payment for each RO participant, rather than using average Winsorized episode payments for each cancer type as proposed, we will develop a second regression model that calculates expected payment amounts based on cancer type alone. This will align the use of regression models in the numerator and denominator of the case mix calculation. For a given RO participant, the difference between predicted episode payment amounts from the first regression model and expected payment amounts from the second regression model, which is then divided by the expected payment amounts, represents the net impact of demographics, presence of chemotherapy, presence of major procedures, and death rates on episode payment amounts for that RO participant.

The case mix adjustment will be updated for each RO participant annually, based on a three-year rolling period of episodes attributed to the RO participant that will be input into the case mix regression model. We cannot use the case mix of episodes during the current PY, because this would prevent us from making a prospective payment. As for the suggestion that rather than deriving the case mix adjustments from a rolling three-year average, CMS should implement a static baseline, we note that we use the same set of episodes to create the case mix coefficients as we did to generate the national base rates, so that the case mix adjustment properly connects to the starting point of the national base rates. We will include examples on the RO Model website that demonstrate how the case mix and historical experience adjustments are calculated.

Comment: Many commenters expressed concern over the historical experience adjustments. A commenter recommended that the historical experience adjustment be removed entirely as the national base rates are disproportionately determined by the Winsorized historical payment, preventing the adoption of a truly site neutral policy for radiation oncology. A few commenters also recommended removing the historical experience adjustment, and adjusting the national base rates instead through a blend of a participant's historical experience with the national historical experience and corresponding regional historical experience.

One commenter requested that CMS provide the number and type of providers and suppliers that are identified as historically efficient and historically inefficient and how the adjusted episode rates compare to the amount providers and suppliers would receive absent the Model.

Response: Our analyses show that variation across regions of the country is low, so we believe that a regional historical experience adjustment is not necessary. We identify what proportion of CCNs and TINs are historically efficient and what proportion are historically inefficient based on the updated 2016–2018 episode data, as shown in Table 4. We do not want to remove the historical experience adjustments as this would cause an abrupt transition in payment determined largely or entirely by national base rate amounts. We are finalizing the case mix and historical experience adjustments as proposed with modification to a component part of their calculation, the expected payments as previously discussed in this section, and with modification to derive calculations based on episodes from the same period, 2016–2018, used to derive the national base rates, as appropriate.

TABLE 4. PERCENT OF RO PARTICIPANTS (PGPS, HOPDS, AND FREESTANDING RADIATION THERAPY CENTERS RANDOMIZED INTO THE MODEL) THAT ARE HISTORICALLY EFFICIENT, HISTORICALLY INEFFICIENT OR NEITHER

	Professional	Technical
Efficient (historical experience adjustment < 0.0)	25.6%	36.2%
Inefficient (historical experience adjustment > 0.0)	49.9%	27.6%
Neither (historical experience adjustment = 0.0)*	24.5%	36.2%

* RO participants with fewer than 60 attributed episodes in the baseline period are assigned historical experience adjustments of 0.0.

Comment: A few commenters supported the proposed efficiency factor, stating that this will help practices as they transition into the Model. Many commenters recommended that the efficiency factor be removed for efficient practices. Several commenters including MedPAC stated that the historical experience adjustment as applied under the efficiency factor would reward historically inefficient providers and suppliers and penalize historically efficient providers and suppliers, paying them more and less than the base rate, respectively. A commenter added that the efficiency factor does not protect efficient participants from experiencing

payment cuts under the Model. Several commenters disagreed with the efficiency factor proposal on the grounds that it would financially penalize participants that appropriately treat beneficiaries who require more expensive or more frequent treatments.

A few commenters suggested that CMS should determine annually whether a participant is efficient or not based on more recent data, so that participants that become efficient over the course of the Model are rewarded with an efficiency factor fixed at 0.90 over the Model performance period.

Response: We thank these commenters for expressing both their support and their concerns as well as suggestions for the proposed efficiency factor. We believe that renaming the efficiency factor as the ''blend,'' will help clarify what it represents and call attention to its purpose of setting the precise level of impact that the RO participant's specific historical experience has on the episode payment amounts. We calculate episode-based payments under the RO Model based on the average spend for each episode in all HOPDs nationally. If RO participants spent less historically (on average) than the average spend of all HOPDs nationally, then their payment amount is 90 percent of what they would have been paid historically for the PC and/or TC of the respective cancer type furnished and 10 percent of the corresponding national base rate. This will result in the historically efficient RO participant seeing an increase in payment compared to historical amounts prior to the discount and withholds being applied; for some of these participants, the payment amounts will be an increase under the Model even with the discount and withholds being applied. If we remove the efficiency factor for efficient providers and suppliers, this would prevent the Model from maintaining costs or achieving savings. For instance, see Table 5 for an example of an efficient RO participant in this section of this final rule.

TABLE 5: RO PARTICIPANT WITH HISTORICAL EXPERIENCE

ADJUSTMENT EQUAL TO OR BELOW 0.0 (EFFICIENT)

National Base Rate	$15,000
RO Participant 1 Average	$14,000
90/10 (PY1-PY5)	$14,100

Similarly, if RO participants spent more historically (on average) than the average spend of all HOPDs nationally, then their payment amount begins at 95 percent of what would have been paid historically for the PC and/or TC of the respective cancer type furnished and 5 percent of the corresponding national base rate. This will result in the historically inefficient RO participant seeing a decrease in payment compared to historical amounts, but the difference would be gradual over time to allow the RO participant to gradually adjust to the new model payments. An RO participant that is categorized as historically inefficient, but becomes more efficient over time, is rewarded under this Model design, specifically as the blend is designed. These RO participants are privy to the sliding-scale blend factor where payment each PY is determined more and more by the national base rates. If a historically inefficient RO participant becomes more efficient than the national average, payment would be higher than what they would receive under FFS because the payment would be based on the blend of the RO participant's historical payments and the national base rate, both of which would be higher than what they would receive under FFS during the model for less costly care. See Table 6 for examples of inefficient RO participants in this section of this final rule.

TABLE 6: RO PARTICIPANTS WITH HISTORICAL EXPERIENCE

ADJUSTMENT ABOVE 0.0 (INEFFICIENT)

National Base Rate	$15,000
RO Participant 2 Average	$30,000
90/10 (PY1)	$28,500
85/15 (PY2)	$27,750
80/20 (PY3)	$27,000
75/25 (PY3)	$26,250
70/30 (PY5)	$25,500

National Base Rate	$15,000
RO Participant 3 Average	$20,000
90/10 (PY1)	$19,500
85/15 (PY2)	$19,250
80/20 (PY3)	$19,000
75/25 (PY3)	$18,750
70/30 (PY5)	$18,500

We believe that historical payment is the proper basis for comparison, and to this effect, historically efficient RO participants will experience an increase in payment. In contrast, historically inefficient RO participants will experience an incremental decrease in payment over the Model's performance period as the national base rates come to account for incrementally more of the payment outcomes. The RO Model is not designed to create equal rates for all RO participants as the only way to do this without significantly decreasing some RO participants' payments compared to their historical would be to pay all RO participants at the highest levels of any in the historical period. If we were to do so, the RO Model would result in much higher spending during its performance period than would occur absent the Model. Rather, the RO Model is designed to create participant-specific professional and technical episode payment amounts that draw RO participants as a group toward an average payment over time. In order to soften the transition from a FFS payment system to an episode-based one for RO participants, we designed a pricing methodology that hews closely to historical payment amounts. Finally, we believe the case mix and historical experience adjustments account for beneficiaries who require more expensive or more frequent treatments.

After considering the comments received, we will finalize the case mix adjustment with modification. The formula that constitutes either the PC or the TC case mix adjustment for an RO participant, that is the difference between an RO participant's predicted payment and an RO participant's expected payment, divided by the expected payment, will not be modified. We modified the way in which we will calculate the expected payments. For calculating the expected payment for each RO participant, rather than using average Winsorized episode payments for each cancer type as proposed, we will use a second regression model that calculates expected payment amounts based on cancer type alone.

After considering the comments received, we will finalize the historical experience adjustment as proposed, and we will finalize the efficiency factor, henceforth called the ''blend,'' with modification. We refer readers to our regulation at § 512.255(d). For RO participants with a PC or TC historical experience adjustment with a value greater than zero (that is, historically inefficient), the blend will be 90/10 in PY1 where 90 percent of payment is determined by the historical experience of the RO participant and 10 percent of payment is determined by the national base rates. The blend will be finalized as proposed to be 90/10 in PY1, 85/15 in PY2, 80/20 in PY3, 75/25 in PY4 and 70/30 in PY5. For those RO participants with a PC or TC historical experience adjustment with a value equal to or less than zero (that is, historically efficient), the blend will be finalized as proposed to be fixed at 90/10 over the Model's performance period (PY1–PY5).

(3) Proposal To Apply the Adjustments

To apply the case mix adjustment, the historical experience adjustment, and the efficiency factor (now referred to as the blend) as discussed in section III.C.6.e of the proposed rule (84 FR 34507 through 34509) and this final rule to the trended national base rates detailed in Step 2, for the PC we proposed to multiply: (a) The corresponding historical experience adjustment by (b) the corresponding efficiency factor, and then add (c) the corresponding case mix adjustment and (d) the value of one. This formula creates a combined adjustment that can be multiplied with the national base rates. In the proposed rule, we expressed this mathematically as:

Combined Adjustment = (Historical experience adjustment * Efficiency factor) + Case mix adjustment + 1.0

The combined adjustment would then be multiplied by the corresponding trended national base rate from Step 2 for each cancer type. We proposed to repeat these calculations for the corresponding case mix adjustment, historical experience adjustment, and blend for the TC, yielding a total of 34 RO participant-specific episode payments for Dual participants and a total of 17 RO participant-specific episode payments for Professional participants and Technical participants (now 32 RO participant-specific episode payments for Dual participants and a total of 16 RO participant-specific episode payments for Professional participants and Technical participants with the removal of kidney cancer).

We proposed to use these case mix adjustments, historical experience adjustments, and efficiency factors to calculate the adjustments under the RO Model's pricing methodology.

We received no comments on this proposal and, therefore, are finalizing this provision with only the modification that reflects the removal of kidney cancer. We are finalizing this provision with modification in that calculations for the corresponding case mix adjustment, historical experience adjustment, and blend for the PC and TC, yielding a total of 32 (not 34) RO participant-specific episode payments for Dual participants and a total of 16 (not 17) RO participant-specific episode payments for Professional participants and Technical participants.

(4) Proposal for HOPD or Freestanding Radiation Therapy Center With Fewer Than Sixty Episodes During 2015–2017 Period

In the proposed rule (84 FR 34508), we proposed that if an HOPD or freestanding radiation therapy center (identified by a CCN or TIN) furnished RT services during the Model performance period within a CBSA selected for participation and was required to participate in the Model because it meets eligibility requirements, but had fewer than 60 episodes attributed to it during the 2015–2017 period, then the RO participant's participant-specific professional episode payment and technical episode payment amounts would equal the trended national base rates in PY1. In PY2, if an RO participant with fewer than 60 episodes attributed to it during the 2015–2017 period continued to have fewer than 60 episodes attributed to it during the 2016–2018 period, then we proposed that the RO participant's participant-specific professional episode payment and technical episode payment amounts would continue to equal the trended national base rates in PY2. However, if the RO participant had 60 or more attributed episodes during the 2016–2018 period, then we proposed that the RO participant's participant-specific professional episode payment and technical episode payment amounts for PY2 would equal the trended national base rates with the case mix adjustment added. In PY3–PY5, we proposed to reevaluate those same RO participants as we did in PY2 to determine the number of episodes in the rolling three-year period used in the case mix adjustment for that performance year (for example, PY3 will be 2017–2019). RO participants that continue to have fewer than 60 attributed episodes in the rolling three year period used in the case mix adjustment for that performance year would continue to have participant-specific professional episode payment and technical episode payment amounts that equal the trended national base rates, whereas those that have 60 or more attributed episodes would have participant-specific professional episode payment and technical episode payment amounts that equal the trended national base rates with the case mix adjustment added. The following is a summary of the public comments we received on the proposal related to RO participants with fewer than 60 episodes during the 2015–2017 period, and our responses to those comments.

Comment: A few commenters expressed support for the proposal that if an RO participant had fewer than 60 episodes during the 2015–2017 period, then that RO participant's participant-specific professional episode payment and technical episode payment amounts would equal the trended national base rates. These commenters supported this gradual approach to establishing payment rates for low volume participants that are typically small or new practices that are likely to gradually ramp up services over the life of the Model.

Several commenters recommended CMS exclude providers and suppliers with fewer than 60 episodes during the 2015–2017 period, rather than just making adjustments to their episode payments. Another commenter noted that for participants without historical experience, the reduction in payment, particularly for those delivering PBT, would be immediate and could be as high as 50 percent. Several commenters proposed that a stop-loss policy be added to protect those participants at risk for significant loss. A few of those commenters suggested that CMS pay participants amounts that correspond to the no-pay HCPCS codes in the amount participants would have been paid absent the RO Model if it exceeds episode payments by a certain percentage and referenced CMS APMs such as the BPCI Advanced Model, the CJR Model, Medicare Shared Savings Program (MSSP), and OCM, which all cap downside risk.

Response: We thank these commenters for their support and suggestions. We refer readers to the low volume opt-out option in section III.C.3.c, which applies to those providers and suppliers that furnish fewer than 20 episodes during the most recent calendar year with claims data in the CBSAs randomly selected for participation. We agree with commenters that if an RO participant has fewer than 60 episodes during the 2016–2018 period (rather than 2015–2017 period), then the RO participant will not have a historical experience adjustment unless we find the need to rebaseline, which would require future rulemaking. Furthermore, if an RO participant has fewer than 60 episodes during the 2016–2018 period, then the RO participant will not receive a case mix adjustment for PY1. Therefore, we are finalizing our policy at § 512.255(c)(7) with the modification that if an RO participant continues to have fewer than 60 episodes attributed to it during the 2017–2019 period, then the RO participant will not have a case mix adjustment for PY2. However, if the RO participant has 60 or more attributed episodes during the 2017–2019 period that had fewer than 60 episodes in both the 2016–2018 period, then the RO participant will have a case mix adjustment for PY2 and the remaining PYs of the Model. In PY3–PY5, we will reevaluate those same RO participants that did not receive a case mix adjustment the previous PY to determine the number of episodes in the rolling three-year period used in the case mix adjustment for that performance year (for example, PY3 will be 2018–2020). Please see Table 10 that summarizes data sources and time periods used to determine the values of key pricing components.

We also agree with commenters regarding their concerns for RO participants without historical experiences and the payment reduction that would result in the absence of a historical experience. In response to comments, we are including a stop-loss limit of 20 percent for the RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services in the CBSAs selected for participation at

the time of the effective date of this final rule.

Using no-pay claims to determine what these RO participants would have been paid under FFS as compared to the payments they received under the Model, CMS will pay these RO participants retrospectively for losses in excess of 20 percent of what they would have been paid under FFS. Payments under the stop-loss policy are determined at the time of reconciliation.

We are finalizing this stop-loss policy at § 512.255(b)(7).

(5) Apply Adjustments for HOPD or Freestanding Radiation Therapy Center With a Merger, Acquisition, or Other New Clinical or Business Relationship, With or Without a CCN or TIN Change

We proposed that a new TIN or CCN that results from a merger, acquisition, or other new clinical or business relationship that occurs prior to October 3, 2024, meets the Model's proposed eligibility requirements discussed in section III.C.3 of the proposed rule and this final rule. If the new TIN or CCN begins to furnish RT services within a CBSA selected for participation, then it must participate in the Model. We proposed this policy in order to prevent HOPDs and freestanding radiation therapy centers from engaging in mergers, acquisitions, or other new clinical or business relationships so as to avoid participating in the Model.

We proposed for the RO Model to require advanced notification so that the appropriate adjustments are made to the new or existing RO participant's participant-specific professional episode payment and participant-specific technical episode payment amounts. This requirement for the RO Model is the same requirement as at § 512.180(c) of the proposed rule, except that under the RO Model, RO participants must also provide a notification regarding a new clinical relationship that may or may not constitute a change in control. If there is sufficient historical data from the entities merged, absorbed, or otherwise changed as a result of this new clinical or business relationship, then this data would be used to determine adjustments for the new or existing TIN or CCN. For our policy regarding change in legal name and change in control provisions, we refer readers to discussion at 84 FR 34489 of the proposed rule and in section II.L this final rule and our regulations at § 512.180(b) and (c).

We received no comments on this proposal. We are finalizing our proposal at § 512.255(b)(5), with modification to align with the finalized Model performance period so that this provision would apply to a new TIN or CCN that results from a merger, acquisition, or other new clinical or business relationship that occurs prior to October 3, 2025 (changed from October 3, 2024).

f. Applying a Discount Factor

After applying participant-specific adjustments under section III.C.6.e of the proposed rule to the trended national base rates, we proposed, at 84 FR 34509, to next deduct a percentage discount from those amounts for each performance year. The discount factor would not vary by cancer type. We proposed that the discount factor for the PC be 4 percent and the discount factor for the TC be 5 percent. We proposed to use the 4 and 5 percent discounts based on discounts in other models tested under section 1115A and private payer models. We believed these figures for the discount factor, 4 and 5 percent for the PC and TC, respectively, struck an appropriate balance in creating savings for Medicare while not creating substantial financial burden on RO participants with respect to reduction in payment.

We proposed to apply these discount factors to the RO participant-adjusted and trended payment amounts for each of the RO Model's performance years. The following is a summary of the public comments received on this proposal to apply a discount factor and our responses to those comments:

Comment: Many commenters suggested reducing the discount factors for both the PC and TC down within the 1 and 3 percent range or phasing in the percentage of the discount factor over several PYs. These commenters cited the BPCI Advanced Model, the CJR Model, and the proposed Episode Payment Model along with the downside track of the OCM, all of which had lower discount factors than what is currently proposed for the RO Model.

Many commenters expressed particular concern about the discount factor related to the TC. A few suggested that RO participants should receive a 5 percent incentive payment based on both the PC and TC as part of their APM Incentive Payment. Alternatively, if there is no opportunity to include the TC payments in calculating the 5 percent APM Incentive Payment, then the commenters recommended that there should be no discount factor for the TC. These commenters explained that RO participants rely on technical payments to invest in technologies, which can increase the value of care and decrease the long-term toxicity of RT services.

Several commenters stated that the discount factors create an un-level playing field between RO participants and non-participants. A commenter questioned the validity of using private payer models as a guide to setting discount factor amounts in a Medicare model, given the meaningful differences in rate structures. A few commenters requested that a rationale be given as to why the discount factor for the TC is higher than that of the PC.

Response: We thank these commenters for expressing their concerns and for their suggestions. We designed the RO Model to test whether prospective episode payments in lieu of traditional FFS payments for RT services would reduce Medicare expenditures while preserving or enhancing quality. We believe that reducing the discount factors to 3.75 percent and 4.75 percent for the PC and TC, respectively, balances the need for the Model to achieve savings while also reducing the impact on payment to RO participants as initially proposed. The level of discounts is based on actuarial projections for how the Model as a whole will impact Medicare payments; the level of discounts is not based on the percentage rate of the APM Incentive Payments. We believe that RO participants will benefit from their participation in this alternative payment model, and we disagree that the Model will create an un-level playing field between RO participants and non-participants. Also, given that the 2 percent quality withhold applies to the PC whereas the TC will have a 1 percent patient experience withhold beginning in PY3 (see section III.C.6.g), we believe that the PC should have a lower discount factor than the TC.

We are finalizing this provision with modification in section III.C.6.f in that the discount factors for the PC and TC will each be reduced by 0.25 percent. The discount factor for the PC will be 3.75 percent. The discount factor for the TC will be 4.75 percent. Additionally, we are modifying the regulatory text at § 512.205 to specify the Discount factor means the set percentage by which CMS reduces payment of the PC and TC. The reduction on payment occurs after the trend factor and model-specific adjustments have been applied but before beneficiary cost-sharing and standard CMS adjustments, including the geographic practice cost index (GPCI) and sequestration, have been applied.

g. Applying Withholds

We proposed to withhold a percentage of the total episode payments, that is the payment amounts

after the trend factor, adjustments, and discount factor have been applied to the national base rates, to address payment issues and to create incentives for furnishing high quality, patient-centered care. We outlined our proposals for three withhold policies in section III.C.6.g of the proposed rule and in this section of this final rule.

(1) Incorrect Payment Withhold

We proposed to withhold 2 percent of the total episode payments for both the PC and TC of each cancer type. This 2 percent would reserve money to address overpayments that may result from two situations: (1) Duplicate RT services as discussed in section III.C.6.a of the proposed rule; and (2) incomplete episodes as discussed in section III.C.6.a of the proposed rule.

We proposed a withhold for these two circumstances in order to decrease the likelihood of CMS needing to recoup payment, which could cause administrative burden on CMS and potentially disrupt an RO participant's cash flow. We believe that a 2 percent incorrect payment withhold would set aside sufficient funds to capture an RO participant's duplicate RT services and incomplete episodes during the reconciliation process. In the proposed rule, we stated that we anticipate that duplicate RT services requiring reconciliation will be uncommon, and that few overpayments for such services will therefore be subject to our reconciliation process. Claims data from January 1, 2014 through December 31, 2016 show less than 6 percent of episodes had more than one unique TIN or CCN billing for either professional RT services or technical RT services within a single episode. Similarly, our analysis showed that it is uncommon that a RT provider or RT supplier does not furnish a technical component RT service to a beneficiary within 28 days of when a radiation oncologist furnishes an RT treatment planning service to such RO beneficiary.

We proposed to use the annual reconciliation process described in section III.C.11 of this final rule to determine whether an RO participant is eligible to receive back the full 2 percent withhold amount, a portion of it, or must repay funds to CMS. We proposed to define the term ''repayment amount'' to mean the amount owed by an RO participant to CMS, as reflected on a reconciliation report. We proposed to codify the term ''repayment amount'' at § 512.205 of our regulations. In addition, we proposed to define the term ''reconciliation report'' to mean the annual report issued by CMS to an RO participant for each performance year, which specifies the RO participant's reconciliation payment amount or repayment amount. Further, we proposed to codify the term ''reconciliation report'' at § 512.205.

(2) Quality Withhold

We proposed to also apply a 2 percent quality withhold for the PC to the applicable trended national base rates after the case mix and historical experience adjustments and discount factor have been applied. This would allow the Model to include quality measure results as a factor when determining payment to participants under the terms of the APM, which is one of the Advanced APM criteria as codified in 42 CFR 414.1415(b)(1). Professional participants and Dual participants would be able to earn back up to the 2 percent withhold amount each performance year based on their aggregate quality score (AQS). We proposed to define the term ''AQS'' to mean the numeric score calculated for each RO participant based on its performance on, and reporting of, quality measures and clinical data, as described in section III.C.8.f of the proposed rule, which is used to determine an RO participant's quality reconciliation payment amount. We proposed to codify this definition at § 512.205 of our regulations. We proposed that the annual reconciliation process described in section III.C.11 of the proposed rule would determine how much of the 2 percent withhold a Professional participant or Dual participant would receive back.

(3) Patient Experience Withhold

We proposed to apply a 1 percent withhold for the TC to the applicable trended national base rates after the case mix and historical experience adjustments and discount factor have been applied starting in PY3 (January 1, 2022 through December 31, 2022) to account for patient experience in the Model. Under this proposal, Technical participants and Dual participants would be able to earn back up to the full amount of the patient experience withhold for a given PY based on their results from the patient-reported Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Survey for Radiation Therapy (CAHPS® Cancer Care survey) as discussed in section III.C.8.b of the proposed rule.

Like the incorrect payment and quality withholds, the initial reconciliation process discussed in section III.C.11 of the proposed rule would determine how much of the 1 percent patient experience withhold a participant will receive back.

We proposed the incorrect payment withhold, the quality withhold, and the patient experience withhold be included in the RO Model's pricing methodology. The following is a summary of the public comments we received on this proposal and our responses to those comments:

Comment: Many commenters expressed concerns with the incorrect payment withhold, the quality withhold, and the patient experience withhold and the financial burden that these withholds could pose for RO participants. A few commenters requested that CMS explain the rationale for the withholds over other means of accounting for patient experience and quality in the Model. A few commenters stated that the withholds are punitive in nature as they occur prior to the delivery of services. A commenter noted that the funds withheld, which are eventually paid to the participant through the reconciliation process, are not subject to coinsurance collection from beneficiaries or from beneficiaries' supplemental insurance. A commenter stated that withholds applied to the TC in particular will make it difficult to keep up with debt service.

Several commenters expressed concern over the incorrect payment withhold in particular. A few commenters suggested eliminating the incorrect payment withhold. A commenter called attention to the CMS claim that it is uncommon that a RT provider or RT supplier does not furnish a technical component RT service to a beneficiary within 28 days of when the radiation oncologist furnishes an RT treatment planning service to such RO beneficiary, and that, therefore, the additional cash flow burden the incorrect episode withhold would place on RO participants is not warranted. A commenter suggested recouping funds from participants for duplicate services and incomplete episodes in the subsequent performance year rather than implementing a withhold structure to prospectively account for those funds. The commenter argued that this would reduce RO participants' financial exposure.

One commenter specifically addressed the patient experience withhold. This commenter disagreed with the 1 percent patient experience withhold starting in PY3, stating that patient experience surveys that are mailed out have varying response rates, do not adequately capture performance, and as such the 1 percent patient experience withhold is unreasonable.

This commenter argued that the patient experience surveys should only serve as supplemental data collection.

Response: We thank these commenters for expressing their concerns and for their suggestions. Although we expect incomplete episodes and duplicate payments to be uncommon, we believe that the burden of recoupment (if we were to not do a withhold) would outweigh the burden of withholding funds until annual reconciliation for those RO episodes that require reconciliation.

Yet, given stakeholders' concerns regarding the cash flow burden that the withholds may cause and given that funds withheld are not subject to coinsurance collection from beneficiaries or from beneficiaries' supplemental insurance, we are finalizing a reduced incorrect payment withhold of 1 percent rather than 2 percent. The reduction of this withhold will also ease the burden of keeping up with debt service as a commenter noted. We believe that the upfront quality withhold will provide the incentive for RO participants to provide high-quality care. Further, we believe that the predetermined withholds help support the Model goal of providing RO participants with prospective, predictable payments. As for effectiveness of the patient experience surveys, we refer commenters to section III.C.8, where quality measures are discussed in detail. We note that we would propose specific benchmarks for the patient experience measures in future rule-making.

After considering public comments, we are finalizing our proposals on incorrect payment withhold, quality withhold, and patient experience withhold, with modifications. We are finalizing the quality withhold amounts as proposed beginning in PY1 (January 1, 2021, through December 31, 2021) and the patient experience withhold as proposed beginning in PY3 (January 1, 2023 through December 31, 2023), but we will reduce the incorrect payment withhold to 1 percent beginning in PY1. Based on the concerns raised by commenters, we intend to reevaluate this amount and need for the incorrect payment withhold in PY3. Additionally, we have modified the text of the regulation at § 512.255(h), (i), and (j) to describe how incorrect payment withhold, quality withhold, and patient experience withhold would be applied to the national base rates, in a manner consistent with the regulatory text for how other adjustments (for example, the discount factor and geographic adjustment) are applied to the national base rate.

h. Adjustment for Geography

As noted in the proposed rule, geographic adjustments are standard Medicare adjustments that occur in the claims system. Even though the Model will establish a common payment amount for the same RT services regardless of where they are furnished, payment will still be processed through the current claims systems, with adjustments as discussed in section III.C.7 of the proposed and this final rule, for OPPS and PFS. We proposed that geographic adjustments would be calculated within those shared systems after CMS submits RO Model payment files to the Medicare Administrative Contractors that contain RO participant-specific calculations of payment from steps (a) through (g). We proposed to adjust the trended national base rates that have been adjusted for each RO participant's case mix, historical experience and after which the discount factor and withholds have been applied, for local cost and wage indices based on where RT services are furnished, pursuant to existing geographic adjustment processes in the OPPS and PFS.

OPPS automatically applies a wage index adjustment based on the current year post-reclassification hospital wage index to 60 percent (the labor-related share) of the OPPS payment rate. We stated in the proposed rule that no additional changes to the OPPS Pricer are needed to ensure geographic adjustment.

The PFS geographic adjustment has three components that are applied separately to the three RVU components that underlie the PFS—Work, PE and MP. To calculate a locality-adjusted payment rate for the RO participants paid under PFS, we proposed to create a set of RO Model-specific RVUs using the national (unadjusted) payment rates for each HCPCS code of the included RT services for each cancer type included in the RO Model. First, the trended national base rates for the PC and TC would be divided by the PFS conversion factor (CF) for the upcoming year to create an RO Model-specific RVU value for the PC and TC payment amounts. Next, since the PFS geographic adjustments are applied separately to the three RVU components (Work, PE, and MP), these RO Model-specific RVUs would be split into RO Model-specific Work, PE, and MP RVUs. The 2015–2017 episodes that had the majority of radiation treatment services furnished at an HOPD and that were attributed to an HOPD would be used to calculate the implied RVU shares, or the proportional weights of each of the three components (Work, PE, and MP) that make up the value of the RO Model-specific RVUs. Existing radiation oncology HCPCS codes that are included in the bundled RO Model codes but paid only through the OPPS would not be included in the calculation. The RVU shares would be calculated as the volume-weighted Work, PE, and MP shares of each included existing HCPCS code's total RVUs in the PFS. The PCs and TCs for the RO episodes would have different RO Model-specific RVU shares, but these shares would not vary by cancer type. Table 4 of the proposed rule (at 84 FR 34510) provided the proposed relative weight of each for the PCs and TCs of the RO Model-specific RVUs share.

We indicated in the proposed rule that we would include these RO Model-specific RVUs in the same process that calculates geographically adjusted payment amounts for other HCPCS codes under the PFS with Work, PE, and MP and their respective RVU value applied to each RO Model HCPCS code.

We proposed to apply the OPPS Pricer as is automatically applied under OPPS outside of the Model. We proposed to use RO Model-specific RVU shares to apply PFS RVU components (Work, PE, and MP) to the new RO Model payment amounts in the same way they are used to adjust payments for PFS services. See RVU shares in Table 7.

The following is a summary of the public comments we received on the proposal to adjust for geography, and our responses to those comments:

Comment: A few commenters stated that all components of the pricing methodology should be based on geographically standardized payments as it would be inappropriate for CMS to compare geographically-adjusted historical payments with non-geographically-adjusted predicted payments. A couple of commenters stated that the adjustment for geography was unnecessary or inappropriate. A commenter explained that the geographic adjustment was inappropriate, because the national market determines competition and purchase price in the field of radiation oncology. Another commenter agreed that the adjustment was unnecessary, but explained that it was unnecessary not because of the national market argument, but because the national base rates are set using 2015–2017 claims data to which the GPCI had already been applied.

Response: We thank these commenters for these suggestions. We would like to clarify that we construct and calculate the payment amounts for

the PC and TC of each episode as the product of: (a) The OPPS or PFS national payment rates for each of the RT services included in the Model multiplied by (b) the volume of each professional or technical RT service included on a paid claim line during each episode. Episode payments under the Model are standardized in the sense that their basis is service volume and national fee schedule prices. Moreover, the calculations that determine the trend factors as well as the case mix and historical experience adjustments are based on these standardized payments that are without geographic adjustment. As previously stated, this method of geographic adjustment is the standard way we pay through PFS and OPPS, and we want to recognize differences in payment based on geographic area. We have no way of determining whether the national market determines competition or purchase price in the field of radiation oncology, as a commenter suggested. Importantly, we want to design episode payments in such a way that they could be implemented on a broader scale, if the Model is successful.

After considering public comments, we are finalizing our proposal on the geographic adjustment with modification to clarify that although the RO Model-specific RVU values are derived from the national base rates which we are finalizing to be based on 2016–2018 episodes that had the majority of radiation treatment services furnished at an HOPD and that were attributed to an HOPD, we will use only 2018 episodes to calculate the implied RVU shares, or the proportional weights of each of the three components (Work, PE, and MP). These RVU shares are part of the calculus determining the RO Model-specific RVU values.

TABLE 7: RVU SHARES

RVU Shares					
Professional Component			Technical Component		
WORK	PE	MP	WORK	PE	MP
0.66	0.3	0.04	0	0.99	0.01

i. Applying Coinsurance

We proposed to calculate the coinsurance amount for an RO beneficiary after applying, as appropriate, the case mix and historical experience adjustments, withholds, discount factors, and geographic adjustments to the trended national base rates for the cancer type billed by the RO participant for the RO beneficiary's treatment. Under current policy, Medicare FFS beneficiaries are generally required to pay 20 percent of the allowed charge for services furnished by HOPDs and physicians (for example, those services paid for under the OPPS and PFS, respectively). We proposed that this policy remain the same under the RO Model. RO beneficiaries will pay 20 percent of each of the bundled PC and TC payments for their cancer type, regardless of what their total coinsurance payment amount would have been under the FFS payment system.

In the proposed rule (84 FR 34510 through 34511), we stated that maintaining the 20 percent coinsurance payment would help preserve the integrity of the Model test and the goals guiding its policies. Adopting an alternative coinsurance policy that would maintain the coinsurance that would apply in the absence in the Model, where volume and modality type would dictate coinsurance amounts, would change the overall payment that RO participants would receive. This would skew Model results as it would preserve the incentive to use more fractions and certain modality types so that a higher payment amount could be achieved.

In the proposed rule, we noted that, depending on the choice of modality and number of fractions administered by the RO participant during the course of treatment, the coinsurance payment amount of the bundled rate may occasionally be higher than what a beneficiary or secondary insurer would otherwise pay under Medicare FFS. However, because the PC and TC would be subject to withholds and discounts described in the previous section, we stated in the proposed rule that we believed that, on average, the total coinsurance paid by RO beneficiaries would be lower than what they would have paid under Medicare FFS for all of the services included in an RO episode. In other words, the withholds and discount factors would, on average, be expected to reduce the total amount RO beneficiaries or secondary insurers will owe RO participants.

In the proposed rule, we also explained that because episode payment amounts under the RO Model would include payments for RT services that would likely be provided over multiple visits, the beneficiary coinsurance payment for each of the episode's payment amounts would consequently be higher than it would otherwise be for a single RT service visit. For RO beneficiaries who do not have a secondary insurer, we stated in the proposed rule that we would encourage RO participants to collect coinsurance for services furnished under the RO Model in multiple installments via a payment plan (provided the RO participants would inform patients of the installment plan's availability only during the course of the actual billing process).

In addition, for the TC, we proposed to continue to apply the limit on beneficiary liability for copayment for a procedure (as described in in section 1833(t)(8)(C)(i) of the Act) to the applicable trended national base rates after the case mix and historical experience adjustments, discount factor, applicable withholds, and geographic adjustment have been applied.

We solicited public comment on our proposal to apply the standard coinsurance of 20 percent to the trended national base rates for the cancer type billed by the RO participant for the RO beneficiary's treatment after the case mix and historical experience adjustments, withholds, discount factors, and geographic adjustments have been applied.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters requested clarification as to the role of secondary payers, MediGap, and Medicaid and whether secondary payers would be held accountable if the RO episode is not allowed and payment is recouped. A commenter requested

clarification as to whether CMS would provide information to insurance entities that receive crossover or secondary claims under the Model. A commenter recommended that CMS follow current Coordination of Benefits rules and transmit no-pay claims for RT services under the RO Model as ''paid'' to supplemental insurers for secondary payment under FFS.

Response: We appreciate the commenters concerns. CMS liaisons to the secondary payers will provide RO Model-specific information to those payers including how the RO Model-specific HCPCS shall be processed. Current Coordination of Benefits rules shall continue to apply. As noted in the proposed rule, we expect to provide RO participants with additional instructions for billing, particularly as it pertains to secondary payers and collecting beneficiary coinsurance. Additional instructions will be made available through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A few commenters expressed concern that the Model's policy of imposing a 20 percent coinsurance payment on the episode payment amount will be confusing to beneficiaries. Some commenters requested specific guidance on creating a payment plan for beneficiaries and expressed concern that participants will not have the billing staff to implement payment plans for beneficiaries. A few commenters disagreed with CMS' proposal to encourage RO participants to implement payment plans for beneficiaries but to restrict RO participants' ability to inform patients of the payment plan's availability to the time of the actual billing process. Those commenters argue that this delay, waiting until the course of the actual billing process, conflicts with CMS' price transparency proposal that patients know their financial responsibilities prior to receiving services. A few commenters added that CMS should not dictate when this discussion occurs. A commenter requested clarification as to whether uncollected beneficiary coinsurance under the RO Model remains subject to additional payment under the Medicare bad debt provision.

Response: It is important to note that RO participants should expect to receive beneficiary coinsurance in the same manner as they do for FFS. All the standard rules and regulations under FFS pertaining to beneficiary coinsurance apply under the RO Model, including the Medicare bad debt provision. We do not believe that beneficiaries would be confused by 20 percent of episode payment as 20 percent is the standard coinsurance policy under Medicare. Although we encourage RO participants to implement payment plans for RO beneficiaries, neither the proposed rule nor the final rule requires RO participants to implement payment plans. At this time, we are not providing specific guidance on creating payment plans because we believe that RO participants who choose to implement a payment plan for beneficiaries should have the flexibility to create one that meets their needs. We agree with the commenter that patients should be informed of the availability of the payment plan before they receive services under the RO Model. However, the availability of payment plans may not be used as a marketing tool to influence beneficiary choice of health care provider. Accordingly, we are finalizing at § 512.255(b)(12) a provision that (1) permits RO participants to collect beneficiary coinsurance payments for services furnished under the RO Model in multiple installments via a payment plan, (2) prohibits RO participants from using the availability of payment plans as a marketing tool to influence beneficiary choice of health care provider, and (3) provides that an RO participant offering such a payment plan may inform the beneficiary of the availability of the payment plan prior to or during the initial treatment planning session and as necessary thereafter.

Comment: Several commenters expressed concerns that beneficiaries who receive fewer or lower-cost RT services than average for their cancer type would pay more in cost-sharing in a participating region than if they had received the same treatment in a non-participating region. A commenter noted that although many patients have supplemental insurance that will shield them from higher cost-sharing amounts, some beneficiaries may be financially harmed by this approach. A few commenters suggested CMS set beneficiary cost-sharing at the lesser of (a) what the beneficiary would have paid in cost-sharing under Medicare FFS payment amounts for the specific services the patient received, or (b) 20 percent of the bundled payment amount. Several commenters suggested that CMS should base beneficiary coinsurance on no-pay FFS claims for services provided during an RO episode. A commenter suggested removing the requirement of beneficiary coinsurance of 20 percent on each of the episode's payment amounts in a specific instance, such as when a beneficiary ends treatment after receiving a single radiation treatment.

Response: We thank these commenters for expressing their concerns and for their suggestions. Although a beneficiary's coinsurance obligation under most RO episodes may not be the same as it would be under Medicare FFS, we believe that, on average, the total coinsurance paid by RO beneficiaries would be lower than what they would have paid under Medicare FFS for all of the services included in an RO episode. The average payment amounts from which the 20 percent of coinsurance is determined is reduced by both the discount factor and the withholds. There may be cases where the beneficiary coinsurance is slightly higher than what the RO beneficiary would have owed under FFS. Yet, for a bundled payment approach that moves away from FFS volume-based incentives to payment based on the average cost of care, this is unavoidable. This would present a payment issue in that either CMS or the RO participant may need to absorb any potential reduction in episode payment. Furthermore, we did not propose to base beneficiary coinsurance on no-pay FFS claims because, if we did so, then a significant portion of the payments that an RO participant received under the Model would be premised on FFS payment and be subject to the usual FFS volume-based incentives. To avoid compromising the integrity of the Model test in this way, we are not waiving the 20 percent beneficiary coinsurance requirement based on the beneficiary receiving a limited number of RT services, such as one RT service.

However, we are not finalizing our coinsurance proposal with respect to a subset of incomplete episodes, specifically those in which: (1) The TC is not initiated within 28 days following the PC; (2) the RO beneficiary ceases to have traditional FFS Medicare prior to the date upon which a TC is initiated, even if that date is within 28 days following the PC; or (3) the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished.

Thus, the beneficiaries who receive RT services in this subset of incomplete episodes would pay the coinsurance amount of 20 percent of the FFS amounts for those services. We note that RO participants that set up coinsurance payment plans may be able to charge and adjust coinsurance more timely and accurately for incomplete episodes; but in some circumstances the true amount owed by the beneficiary may not be determined until the reconciliation process has occurred.

In instances where an RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer at any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and EOE modifier, provided that a Technical participant or the same Dual participant furnishes a technical component RT service to the RO beneficiary within 28 days of such initial treatment planning service, the RO beneficiary would pay 20 percent of the first installment of the RO episode. However, if the RO participant bills the Model-specific HCPCS code and EOE modifier with a date of service that is prior to the date that the RO beneficiary ceases to have traditional FFS Medicare, then the beneficiary coinsurance payment equals 20 percent of the full episode payment amount for the PC or TC, as applicable. Because these policies would only apply to a relatively small number of RO episodes, we do not believe that it would be unduly burdensome for RO participants to administer or affect the integrity of the Model test and the goals guiding its policies.

We are finalizing, in part, our proposal related to coinsurance. Specifically, we are codifying at 512.255(b)(12) the requirement that RO participants offering a payment plan may not use the availability of the payment plan as a marketing tool and may inform the beneficiary of the availability of the payment plan prior to or during the initial treatment planning session and as necessary thereafter. With respect to a subset of incomplete episodes, we are not finalizing our proposal that beneficiaries pay 20 percent of the episode payment. Accordingly, the beneficiary will owe 20 percent of the FFS amount for RT services furnished during an incomplete episode in which (1) the TC is not initiated within 28 days following the PC, (2) the RO beneficiary ceases to have traditional FFS Medicare prior to the date upon which a TC is initiated, even if that date is within 28 days following the PC, or (3) the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished.

j. Example of Participant-Specific Professional Episode Payment and Participant-Specific Technical Episode Payment for an Episode Involving Lung Cancer in PY1

Table 8 and Table 9 illustrate possible participant-specific professional and technical episode payments paid by CMS to one entity (Dual participant) or two entities (Professional participant and Technical participant) for the furnishing of RT professional services and RT technical services to an RO beneficiary for an RO episode of lung cancer. Table 8 and Table 9 are updated versions of Table 5 and Table 6 of the proposed rule, respectively, that reflect policies described in section III.C.5. of this final rule. Table 5 and Table 6 are displayed in the proposed rule at 84 FR 34511 and 34512. Tables 8 and 9 also reflect the following technical changes: (1) The change in sequence related to the geographic adjustment discussed in section III.C.6.h. of this final rule; (2) a change in the way the withhold calculation is displayed in the proposed rule example; (3) a change in the way discount factor and withholds are displayed in the proposed rule example; and (4) a change in the way the total episode payment amount is split between the SOE payment and EOE payment. As a result of these technical changes, Tables 8 and 9 properly reflect the way in which the claims systems process payment. First, the geographic adjustment comes in the proper sequence, prior to the case mix and historical experience adjustments, discount factor and withholds. Second, the withhold calculation properly accounts for 1 percent for the incorrect payment withhold and 2 percent for the quality withhold for the professional component. The corresponding proposed rule table, Table 5, incorrectly had the withholds multiplied together, resulting in slightly lower withheld amounts. Third, the discount factor and withholds now display the percentage of reduction as finalized, rather than the inverse of those percentages as was shown in the proposed rule at Tables 5 and 6.

Finally, Tables 8 and 9 properly reflect the way in which the claims systems split total payment between SOE and EOE payments. The claims systems begin with half the trended national base rate amount that corresponds with the RO Model-specific HCPCS code listed on the claim submitted by the RO participant for the cancer type and component (professional or technical) billed. The claims systems then apply the appropriate adjustments, discount factor, and withholds to that amount. Tables 8 and 9 reflect this by splitting payment at the offset (see Tables 8 and 9, row (d)) rather than at the end, as the proposed rule example has displayed (see rows (s) and (t) in Table 5 at 84 FR 34511 and Table 6 at 84 FR 3512).

Please note that Table 8, which displays the participant-specific professional episode payment example does not include any withhold amount that the RO participant would be eligible to receive back or repayment if more money was needed beyond the withhold amount from the RO participant. It also does not include any MIPS adjustment that applies to the RO participant.

TABLE 8: EXAMPLE: PARTICIPANT-SPECIFIC PROFESSIONAL EPISODE PAYMENT FOR LUNG CANCER PY1 ALL NUMBERS ARE ILLUSTRATIVE ONLY

	Professional Component	
	Amount	**Formula**
National Base Rate (a)	$2,155.00	
Trend Factor (b)	1.04	
Subtotal (c)	$2,241.20	c = a * b
SPLIT for SOE/EOE payments (d)	$1,120.60	d =c/2
Geographic Adjustment (e)	1.02	
Subtotal1 (f)	$1,143.01	f = d * e
Case Mix Adjustment (g)	0.02	For example (102-100) / 100
Historical Experience Adjuster (h)	0.14	For example (116-102) / 100
PY1 Blend (i)	0.90	
Adjustments combined (j)	1.15	j = g + (h * i) + 1
Subtotal (k)	$1,309.89	k = j * f
Discount Factor (l)	0.0375	
Subtotal (m)	$1,260.77	m = (1-l) * k
Withhold #1 (Incorrect Payment) (n)	0.01	
Withhold #2 (Quality Performance) (o)	0.02	
Total Withhold (p)	0.03	p = n + o
Half of Total Episode Payment to RO Participant without sequestration (q)	$1,222.95	q = (1-p) * m
Beneficiary Coinsurance for SOE payment Determined (r)	$244.59	r = q * 0.20
SOE Participant Payment	$978.36	s = q * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (t) [t = half of the total participant-specific professional episode payment]	$958.79	t = s * 0.98
Episode Payment 1: SOE (u)*	**$958.79**	**u = t**
Episode Payment 2: EOE (v)*	**$958.79**	**v = t**
Total Episode Payment to RO Participant (w)	**$2,406.76**	**w = u+v+2r**

^ All numbers are rounded to two decimal places.

Table 9 details the participant-specific technical episode payment paid by CMS to a single TIN or single CCN for the furnishing of RT technical services to an RO beneficiary for an RO episode of lung cancer. The participant-specific technical episode payment in this example does not include any rural sole community hospital adjustment that the RO participant would be eligible to receive. Also, please note that for the participant-specific technical payment amount, the beneficiary coinsurance cannot exceed the inpatient deductible limit under OPPS.

TABLE 9: EXAMPLE: PARTICIPANT-SPECIFIC TECHNICAL EPISODE PAYMENT FOR LUNG CANCER IN PY1

	Technical Component	
	Amount	**Formula**
National Base Rate (a)	$11,451.00	
Trend Factor (b)	1.04	
Subtotal (c)	$11,909.04	c = a * b
SPLIT for SOE/EOE payments (d)	$5,954.52	d =c/2
Geographic Adjustment (e)	1.02	
Subtotal1 (f)	$6,073.61	f = d * e
Case Mix Adjustment (g)	0.02	For example (102-100) / 100
Historical Experience Adjuster (h)	0.11	For example (116-102) / 100
PY1 Blend (i)	0.90	
Adjustments combined (j)	1.12	j = g + (h * i) + 1
Subtotal (k)	$6,796.37	k = j * f
Discount Factor (l)	0.0475	
Subtotal (m)	$6,473.54	m = (1 - l) * k
Withhold #1 (Incorrect Payment) (n)	0.01	
Withhold #2 (Patient Experience) - not applied until PY3 (o)		
Total Withhold (p)	0.01	p = n + o
Half of Total Episode Payment to RO Participant without sequestration (q)	$6,408.81	q = (1 - p) * m
Beneficiary Coinsurance for SOE payment Determined (r)	$1,281.76	r = q * 0.20
SOE Participant Payment	$5,127.05	s = q * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (t) [t = half of the total participant-specific professional episode payment]	$5,024.50	t = s * 0.98
Episode Payment 1: SOE (u)*	**$5,024.50**	**u = t**
Episode Payment 2: EOE (v)*	**$5,024.50**	**v = t**
Total Episode Payment to RO Participant (w)	**$12,612.53**	**w = u+v+2r**

^ All numbers are rounded to two decimal places.

After considering public comments on our proposed pricing methodology, as previously summarized, we are finalizing the pricing methodology as proposed with the following modifications. We are also providing Table 10, which summarizes the data sources and time periods used to determine the values of key pricing components as a result of these modifications.

(1) Change the name of the ''efficiency factor'' of the historical experience adjustment to ''blend.''

(2) Reduce the discount rate of the PC and TC from 4 and 5 percent to 3.75 and 4.75 percent, respectively.

(3) Reduce the incorrect payment withhold from 2 percent to 1 percent.

(4) Apply a stop-loss limit of 20 percent for the RO participants that have fewer than 60 episodes during 2016–2018 and that were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of this final rule.

We are also making the following modifications, which are not being codified in regulation text, to our pricing methodology policy:

(1) Change the baseline from which the national base rates, Winsorization thresholds, case mix coefficients, case mix values, and historical experience adjustments are derived from 2015–2017 to 2016–2018.

(2) Change the sequence of the proposed eight primary steps to the pricing methodology, that is apply the geographic adjustment to the trended national base rates prior to the case mix and historical experience adjustments and prior to the discount factor and withholds.

(3) Update the years used in the trend factor's numerator and denominator calculation. For the trend factor's numerator calculation, the most recent calendar year with complete data used to determine the average number of times each HCPCS code was furnished will be 2018 for PY1, 2019 for PY2, and so forth. The trend factor's denominator calculation will use data from 2018 to determine (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applying)

was furnished and (b) the corresponding FFS payment rate.

(4) Update the years used to determine the case mix values, beginning with 2016–2018 for PY1, 2017–2019 for PY2, and so on.

(5) Align the approach to deriving expected payment amounts for each episode in the case mix adjustment with how the predicted payment amounts are calculated by using regression models for both calculations; for the expected payment amounts, the regression model would be a simple one that contains cancer type only on the right hand side rather than using the average Winsorized baseline expenditures by cancer type).

(6) Update the years used to determine whether an HOPD or freestanding radiation therapy center has fewer than sixty episodes, making them ineligible to receive a historical experience adjustment, from 2015–2017 to 2016–2018 to mirror the change in baseline noted in (1).

(7) Update the years used to determine whether an HOPD or freestanding radiation therapy center has fewer than sixty episodes, making them ineligible to receive case mix adjustment, beginning with 2016–2018 for PY1, 2017–2019 for PY2, and so on.

(8) Update the episodes used to determine the RVU shares of the PFS geographic adjustment from 2015–2017 episodes to 2018 episodes.

Please note that we will review utilization data in non-RO participants' 2020 episodes to assess the impact of the PHE on RT treatment patterns and whether an alternative method is needed to determine the trend factor for PY3 to prevent the PY3 trend factor from being artificially low or high due to the PHE. If we find an alternative method is necessary, we will propose this in future rulemaking.

TABLE 10: DATA SOURCES AND TIME PERIODS USED TO DETERMINE VALUES OF THE RO MODEL'S KEY PRICING COMPONENTS

Key Components	Data Source	PY 1 (2021)	PY 2 (2022)	PY 3 (2023)	PY 4 (2024)	PY 5 (2025)
National Base Rates	HOPD episodes	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Trend factor	Non-participant episodes	(2018 volume * 2021 rates) / (2018 volume * 2018 rates)	(2019 volume * 2022 rates) / (2018 volume * 2018 rates)	(2020 volume * 2023 rates) / (2018 volume * 2018 rates)	(2021 volume * 2024 rates) / (2018 volume * 2018 rates)	(2022volume * 2025 rates) / (2018 volume * 2018 rates)
Winsorization thresholds	HOPD episodes	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Case mix coefficients	HOPD episodes	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Case mix values [and whether eligible (>60 episodes) to receive case mix adjustment]	Participant-specific	2016-2018	2017-2019	2018-2020	2019-2021	2020-2022
Historical Experience adjustment [and whether eligible (>60 episodes) to receive historical experience adjustment]	Participant-specific	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Blend for RO participant with historical experience adjustment greater than 0.0	N/A	0.90	0.85	0.80	0.75	0.70
Blend for RO participant with historical experience adjustment equal to or less than 0.0	N/A	0.90	0.90	0.90	0.90	0.90
RVU shares used in the PFS geographic adjustment	HOPD episodes	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2018	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2018	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2018	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2018	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2018
Low Volume Opt-Out Eligibility (<20 episodes)	Participant-specific	2019	2020	2021	2022	2023

7. Professional and Technical Billing and Payment

Similar to the way many procedure codes have professional and technical components as identified in the CMS National PFS Relative Value File, we proposed that all RO Model episodes would be split into two components, the PC and the TC, to allow for use of current claims systems for PFS and OPPS to be used to adjudicate RO Model claims. As stated in the proposed

rule, we believe that the best design for a prospective episode payment system for RT services would be to pay the full participant-specific professional and technical episode payment amounts in two installments. We believe that two payments reduce the amount of money that may need to be recouped due to incomplete episodes and the likelihood that the limit on beneficiary liability for copayment for a procedure provided in an HOPD (as described in section 1833(t)(8)(C)(i) of the Act) is met.

Accordingly, we proposed that we would pay for complete episodes in two installments: One tied to when the episode begins, and another tied to when the episode ends. Under this proposed policy, a Professional participant would receive two installment payments for furnishing the PC of an episode, a Technical participant would receive two installment payments for furnishing the TC of an episode, and a Dual participant would receive two installment payments for furnishing the PC and TC of an episode.

To reduce burden on RO participants, we proposed that we would make the prospective episode payments for RT services covered under the RO Model using the existing Medicare payment systems by making RO Model-specific revisions to the current Medicare FFS claims processing systems. We proposed that we would make changes to the current Medicare payment systems using the standard Medicare Fee for Service operations policy related Change Requests (CRs).

As proposed, our design for testing a prospective episode payment model (that is, the RO Model) for RT services would require making prospective episode payments for all RT services included in an episode, as discussed in section III.C.5 of this final rule, instead of using Medicare FFS payments for services provided during an episode. We proposed that local coverage determinations (LCDs), which provide information about the conditions under which a service is reasonable and necessary, would still apply to all RT services provided in an episode.

In the proposed rule, we stated that Professional participants and Dual participants would be required to bill a new model-specific HCPCS code and a modifier indicating the start of an episode (SOE modifier) for the PC once the treatment planning service is furnished. We proposed that we would develop a new HCPCS code (and modifiers, as appropriate) for the PC of each of the included cancer types under the Model. The two payments for the PC of the episode would cover all RT services provided by the physician during the episode. As stated in the proposed rule, payment for the PC would be made through the PFS and would only be paid to physician group practices (as identified by their respective TINs).

Under our proposed billing policy, a Professional participant or Dual participant that furnishes the PC of the episode would be required to bill one of the new RO Model-specific HCPCS codes and an SOE modifier. As stated in the proposed rule, this would indicate within the claims systems that an episode has started. Upon submission of a claim with an RO Model-specific HCPCS code and an SOE modifier, we would pay the first half of the payment for the PC of the episode to the Professional participant or Dual participant. A Professional participant or Dual participant would be required to bill the same RO Model-specific HCPCS code that initiated the episode with a modifier indicating the EOE after the end of the 90-day episode. This would indicate that the episode has ended. Upon submission of a claim with an RO Model-specific HCPCS codes and EOE modifier, we proposed that we would pay the second half of the payment for the PC of the episode to the Professional participant or Dual participant.

Under our proposed billing policy, a Technical participant or a Dual participant that furnishes the TC of an episode would be required to bill a new RO Model-specific HCPCS code with a SOE modifier. We proposed that we would pay the first half of the payment for the TC of the episode when a Technical participant or Dual participant furnishes the TC of the episode and bills for it using an RO Model-specific HCPCS code with a SOE modifier. We proposed that we would pay the second half of the payment for the TC of the episode after the end of the episode. We proposed that the Technical participant or Dual participant would be required to bill the same RO Model-specific HCPCS code with an EOE modifier that initiated the episode. As stated in the proposed rule, this would indicate that the episode has ended.

Similar to the way PCs are billed, we proposed that we would develop new HCPCS codes (and any modifiers) for the TC of each of the included cancer types. We proposed that payment for the TC would be made through either the OPPS or PFS to the Technical participant or Dual participant that furnished TC of the episode. We proposed that the two payments for the TC of the episode would cover the provision of equipment, supplies, personnel, and costs related to the radiation treatment during the episode.

We proposed that the TC of the episode would begin on or after the date that the PC of the episode is initiated and that it would last until the PC of the episode concludes. Accordingly, the portion of the episode during which the TC is furnished may be up to 90 days long, but could be shorter due to the time between when the treatment planning service is furnished to the RO beneficiary and when RT treatment begins. We proposed this because the treatment planning service and the actual RT treatment do not always occur on the same day.

We proposed that RO participants would be required to submit encounter data (no-pay) claims that would include all RT services identified on the RO Model Bundled HCPCS list (See Table 2) as those services are furnished and that would otherwise be billed under the Medicare FFS systems. We proposed that we would monitor trends in utilization of RT services during the RO Model. We proposed that these claims would not be paid because the bundled payments cover RT services provided during the episode. We proposed that the encounter data would be used for evaluation and model monitoring, specifically trending utilization of RT services, and other CMS research.

We proposed that if an RO participant provides clinically appropriate RT services during the 28 days after an episode ends, then that RO participant would be required to bill Medicare FFS for those RT services. We proposed that a new episode would not be initiated during the 28 days after an episode ends. As we explain in section III.C.5.b(3) of this final rule, we refer to this 28-day period as the ''clean period.''

In the event that an RO beneficiary changes RT provider or RT supplier after the SOE claim has been paid, we proposed that CMS would subtract the first episode payment paid to the RO participant from the FFS payments owed to the RO participant for services furnished to the beneficiary before the transition occurred and listed on the no-pay claims. We proposed that this adjustment would occur during the annual reconciliation process described in section III.C.11 of this final rule. We proposed that the subsequent provider or supplier (whether or not they are an RO participant) would bill FFS for furnished RT services.

Similarly, in the event that a beneficiary dies, or chooses to defer treatment after the PC has been initiated and the SOE claim paid but before the TC of the episode has been initiated

(also referred to as an incomplete episode), during the annual reconciliation process we proposed that CMS would subtract the first episode payment paid to the Professional participant or Dual participant from the FFS payments owed to that RO participant for services furnished to the beneficiary and listed on the no-pay claims before the transition occurred.

In the event that traditional Medicare stops being the primary payer after the SOE claims for the PC and TC were paid, we proposed that any submitted EOE claims would be returned and the RO participant(s) would only receive the first episode payment, regardless of whether treatment was completed. If a beneficiary dies or selects the Medicare hospice benefit (MHB) after both the PC and the TC of the episode have been initiated, we proposed that the RO participant(s) would be instructed to bill EOE claims and would be paid the second half of the episode payment amounts regardless of whether treatment was completed.

In the proposed rule we acknowledged that there may be instances where new providers and suppliers begin furnishing RT services in a CBSA selected for participation in the RO Model. We proposed that these new providers and suppliers would be RO participants and noted that they would have to be identified as such in the claims systems. When a claim is submitted with an RO Model-specific HCPCS code for a site of service that is located within one of the CBSAs randomly selected for participation, as identified by the service location's ZIP Code, but the CCN or TIN is not yet identified as an RO participant in the claims systems, we proposed that the claim would be paid using the rate assigned to that RO Model-specific HCPCS code without the adjustments. Once we are aware of these new providers and suppliers, we proposed that they would be identified in the claims system and would be paid using Model-specific HCPCS code with or without the adjustments, depending on whether the TIN or CCN new to the Model is a result of a merger, acquisition, or other new clinical or business relationship and whether there is sufficient data to calculate those adjustments as described in the pricing methodology section III.C.6 of this final rule.

We proposed that lists of RO Model-specific HCPCS codes would be made available on the RO Model website prior to the Model performance period. In addition, we noted in the proposed rule that we expect to provide RO participants with additional instructions for billing the RO Model-specific HCPCS codes through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

The following is a summary of the public comments received on these proposals and our response:

Comment: Several commenters expressed concern that billing systems are not ready for a prospective payment model as they are designed to bill after the services are furnished and not before, and that this could pose significant financial risk. Commenters stated that the RO Model as proposed introduces new billing and collection processes to include new HCPCS and modifiers, billing at the start of and at the end of services, and the submission of no-pay claims detailing the actual services provided. Commenters further stated that the complexity of learning new codes and tracking episode dates creates administrative burden for RO participants. Commenters noted that many health care providers and health systems do not complete their billing internally, and instead rely on external third party vendors so RO participants will require time to determine how to best partner with these vendors to ensure appropriate billing.

Many commenters expressed concern around the lack of details regarding billing requirements for the proposed RO Model. Multiple commenters requested that we clarify in our billing instructions that we will require providers and suppliers billing individual patient encounters to use HIPAA-mandated transaction code sets (that is, CPT® and HCPCS Level II codes) for Professional/Dual participant services on 1500/837P claims and hospital outpatient participant services on UB04/837I. Commenters stated that it was particularly important that charges meet the requirements of the Provider Reimbursement Manual Part 1 section 2202.4, which mandate that charges be related consistently to the cost of the services and uniformly applied to all patients, whether Medicare, Medicaid, or commercial patients. Commenters stated that the RO Model cannot alter these requirements because doing so could undermine the validity of the hospital cost reporting process. Commenters requested that we address the following items for the new prospective HCPCS codes and the no-pay claims: (1) The type of claim form; (2) necessary claim lines; (3) items that should be excluded from the claim; and (4) ability to move the zero-pay HCPCS codes to the non-billable column on the claim. Commenters asked for clarification on encounter claim data submission under the Model. A commenter noted operational concerns with the zero charge encounter bills the RO Model requires participants to submit. The commenter stated that automated internal accounting software generates both claims and internal cost accounting reports and that setting charges to zero dollars would wreak havoc on internal cost tracking and would create significant administrative burden. The commenter requested that CMS permit the original HCPCS charges to be listed in the non-covered charges' claim column while zero dollars would be submitted in the covered charges field.

Response: We appreciate the commenters concern. We believe that we have created a billing process that will be easily implemented within current systems because it is based on how FFS claims are submitted today. To facilitate understanding and implementation, we encourage RO participants to access forthcoming instructions for billing the RO Model-specific HCPCS codes and related modifiers and condition code provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A commenter requested that CMS not withhold payments due to incomplete episodes during the test period, as this could ultimately create significant cash flow issues. Instead, the commenter suggested that CMS could utilize the new HCPCS codes and modifiers intended as no-pay, initial and ending payments as place holders to assess the various scenarios for at least 3 years. This 3-year testing period would at a minimum identify the scenarios and allow time for CMS to assess, realize impact, and provide data to the public for public comment.

Response: We thank the commenter for the suggestion. In the final rule at § 512.255(h), we have reduced the incorrect payment withhold from the proposed 2 percent to 1 percent, which is proportional to the occurrence of incomplete episodes per our claims data. The amount of the incorrect withhold that the RO participant earns back is determined during the annual reconciliation process described in section III.C.11.

Comment: Many commenters expressed concern around the proposed billing timing requirements, stating that it was not clear from the proposed rule how Technical participants would know when a Professional participant started an episode for one of their patients at the time that patient presented for radiation therapy treatment.

Commenters were concerned that without this knowledge, unnecessary incomplete episodes might result. However, these commenters were also concerned that the burden of coordination of episode start dates between professional and Technical participants could greatly increase the administrative burden of the Model.

One commenter stated that unique logic would have to be established for each patient to track how many days the Technical participant's billing team would need to zero out claims since RT start dates within the 90-day period will vary. Other commenters noted that when entities billing TC and PC services are clinically, financially, and legally separate, the likelihood of their ability to coordinate care declines. Noting that Health Information Exchanges are not yet broadly available and that sharing of information is not the same as coordinating care, a commenter requested a delay in implementation to allow participants to establish the formal or informal relationships likely necessary to succeed in the proposed Model. Another commenter recommended that CMS include in the Model a methodology by which it would notify Technical participants of the start of an episode. A commenter noted that CMS stated that the technical billing component will be driven off a signed radiation prescription. As there is a professional as well as technical component of the simulation session, the commenter stated that CMS should use the professional simulation session claim to trigger for the technical SOE.

Response: We appreciate the commenters' concerns. We believe it to be an established standard of care that RT delivery services cannot be administered to a patient without a signed radiation prescription and the final treatment plan. Thus, we proposed that the Professional participant will provide the Technical participant with a signed and dated radiation prescription and treatment plan, all of which is usually done electronically. This will inform the Technical participant of when the RO episode began, allowing them to determine the date of the end of the RO episode. The submission and payment of TC claims is not dependent on the submission of PC claims. If the TC claim with the SOE modifier is received first, the claims system will estimate the first day of the episode. A similar process will occur for EOE claims. When claims for only one component are submitted (either PC or TC), an RO episode would not have occurred because an RO episode begins when both the PC is initiated and the TC is initiated within 28 days. In these circumstances, the component that is submitted will be addressed during the reconciliation process finalized in section III.C.11, and the payments will be reconciled so that the RO participant receives the FFS amount based on the no-pay claims instead of the participant-specific episode payment. We encourage RO participants to access forthcoming instructions provided by CMS for billing the RO Model-specific HCPCS codes and related modifiers and condition code provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: Commenters requested clarification on how billing was to be done when either the technical component of the services and/or the professional component of the services extends beyond the 90-day episode triggered by the planning services.

Response: To clarify, as stated in the proposed rule, all RT services provided within the 28-day clean period (that is, days 91–118) following a 90-day RO episode will be billed FFS. In these situations, the RT provider or RT supplier will bill individual HCPCS or CPT® codes for each RT service furnished as they would outside of the RO Model. If RT services are still being provided after 118 days, the RO participant will submit a SOE claim for a new RO episode. We encourage RO participants to access forthcoming instructions for billing RT services during the Model performance period provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: Multiple commenters expressed concerns about the timing of our proposed payments. A commenter stated that the time estimates CMS has made available show that almost two thirds of all episodes are completed within 50 days while other commenters noted most services are completed within a month of initiating treatment. Commenters noted that under our proposal, most providers and suppliers would have to wait more than a month to be able to bill for care that has already been provided. Commenters expressed concerns that delayed payments will impact their cash flows, creating hardships in their ability to pay bills, to order medical supplies and to provide the necessary staffing coverage. Commenters also expressed concern that patient access might become an issue due to these cash flow delays and that beneficiaries might have to drive further to get care when staffing is compromised because of delayed payments. A commenter suggested that full payment at the beginning of the episode, rather than payment in two installments, would improve cash flow and reduce administrative burden by not requiring an EOE claim. Other commenters requested that providers and suppliers be able to receive the 2nd payment sooner than 90 days, ideally when the services complete. A commenter requested that CMS consider adding a modifier to signal a course of radiation is completed and that CMS should make the 2nd half of the payment at the time that completion claim is submitted rather than waiting for the end of the 90-day period. In addition, that commenter also stated that adding a modifier to the start and end of a course of treatment would signal if a new course, not related to previous course, started during the 90-day time frame.

Response: We thank the commenters for expressing their concerns and for their suggestions. Based on these comments, we are modifying our policy to permit an RO participant to submit the EOE claim after the RT course of treatment has ended, but no earlier than 28 days after the initial treatment planning service was furnished. We believe that 28 days after the initial treatment planning service was furnished is the earliest that EOE claims should be submitted, because if the TC has not been furnished to an RO beneficiary after 28 days, this would be an incomplete episode, as defined at § 512.205. To ensure that a Professional participant or a Dual participant does not bill an EOE claim for an incomplete episode, they should not submit an EOE claim before 28 days after the initial treatment planning service has been furnished to minimize the need to reconcile the EOE payments against the incorrect payment withhold. Regardless of when the EOE claim is submitted, the episode duration remains 90 days. Any RT services furnished after the EOE claim is submitted will not be paid separately during the remainder of the RO episode. We will monitor the Medicare claims system to identify potentially adverse changes in referral, practice, or treatment delivery patterns and subsequent billing patterns. This modification does not require a change to the regulatory text at § 512.260.

Comment: Some commenters stated that CMS does not describe how a Professional participant (that is, the individual radiation oncologist or the radiation oncology physician group/practice TIN) who is selected to be in the Model via an included ZIP Code, but who furnishes their RT services at an exempt facility (ASC, PCH, CAH), is to bill for those encounters. The

commenters questioned how a non-participant RT provider or RT supplier would be protected from having a large volume of incomplete episodes. A commenter noted that during the August 22, 2019 Open Door Forum Listening Session on the Radiation Oncology Model, CMS staff stated they would create a modifier for Professional participants to use to indicate that RT services were furnished by a non-participant. Commenters requested that CMS consider an alternative to a new modifier that does not require any changes in how professionals bill their radiation oncologist services. A commenter suggested that CMS use the location of services in item number 32 and the NPI in item 32a on the 837P/1500 claim form, which is mandated on the 837P/1500 claim form, to exclude the services from the RO Model. Commenters also suggested that instead of creating another modifier, CMS could direct Professional participants who deliver services at exempt facilities to bill the usual radiation oncology HCPCS codes, and to not initiate an episode by excluding the RO Model-specific HCPCS code. Commenters further requested that if CMS believes it must require the use of a new modifier to signify services in an exempt facility, we should allow the modifier to be reported with the usual RT planning, simulation, and management CPT® and HCPCS codes rather than asking for the RO Model-specific HCPCS code to be reported.

Response: CMS worked closely with the Provider Billing Group in the Center for Medicare, the Medicare Administrative Contractors, and the Shared System Maintainers to establish the least burdensome way to submit claims for instances that do not follow the standard course of an episode. We determined that the use of an established modifier for professional claims and a condition code for HOPD claims would be the best way to indicate that certain services fall outside of an RO episode and should be paid FFS. When services are furnished by a participant and a non-participant, these scenarios would be considered incomplete episodes. We encourage RO participants to access forthcoming instructions for billing RT services during the Model performance period provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A commenter requested clarification on billing when one physician provides EBRT and a different physician, either co-located in the same facility or in a different facility, provides brachytherapy services. The commenter wanted clarification on when the brachytherapy physician would be considered part of the RO Model and when the brachytherapy physician would be paid FFS. A commenter requested that CMS provide clarification regarding how the agency will handle a second claim for a case that has already received an episodic payment associated with a second physician who bills the brachytherapy insertion codes. The commenter stated that accommodations should be made to pay the insertion codes at the FFS rate when a second physician is involved to prevent cash flow issues that could result if the second claim were held up as part of the RO Model reconciliation process.

Response: When RT services are furnished by an RO participant and a non-participant or when the PC is furnished by more than one Professional participant or Dual participant, or when the TC is provided by more than one Technical participant or Dual participant, these scenarios would be considered duplicate services. The RO beneficiary would remain under the care of the RO participant that initiated the PC and/or TC, and in many circumstances, the duplicate RT service would be a different modality than what is furnished by the RO participant. The RO participant(s) that bills the SOE and EOE claims would receive the bundled payment and the RT provider and/or RT supplier furnishing one or more duplicate RT services would bill claims using the designated modifier or condition code to indicate that they should be paid FFS. Thus, cash flow would not be affected by this. We encourage RO participants to access forthcoming instructions for billing RT services during the Model performance period provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: Some commenters expressed concerned about specific considerations related to the proposed 90-day episodic billing time frame. Commenters agreed with our assumption that RT services would generally be completed within the 90-day episodic period and a new RO episode would not begin until at least 28 days have elapsed, but commenters noted that there are times when extenuating circumstances like an inpatient admission or preplanned patient travel that can cause the outpatient RT services to begin after the 28-day window. From an operational standpoint, commenters were concerned that if the treatment does not begin within the 28-day period, but the physician plans to treat the patient with RT services, that there may be no ''trigger'' to begin an episode of care. Commenters requested that we clarify how Medicare Administrative Contractors will manage PC and TC claims after the 28-day window between the treatment planning code and the treatment delivery code has passed without triggering an episode. Commenters also requested that we provide answers to the following questions: Would all subsequent PC and TC claims be paid as FFS? Would the TC claims (either with the RO Model-specific HCPCS code or FFS HCPCS code) and the second PC episode payment claims be denied and then reconciled as per the incomplete episode policy in the proposal? Would all TC claims after the 28-day window be paid under FFS and the initial episode PC payment be the only amount reconciled? The commenter urged CMS to pay all CPT®/HCPCS codes that are billed outside of the 28-day window (that is an incomplete episode) as FFS.

Response: We appreciate the commenters' concerns. Medicare claims data analyzed during the design of the RO Model, show that in 84 percent of episodes RT is delivered within 14 days of the planning service and within 28 days for the remaining 16 percent. There will be billing instructions that address how to submit claims for those instances that do not follow the standard course of an episode. In these situations, the RT provider or RT supplier will bill individual HCPCS or CPT® codes for each RT service furnished as they would outside of the RO Model. These scenarios would be considered incomplete episodes. We encourage RO participants to access forthcoming instructions for billing RT services during the Model performance period provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A commenter expressed appreciation that CMS has taken into consideration situations in which a patient passes or is transferred to hospice care during an RO episode, noting that in these situations, CMS proposed to provide full payment and not to consider these two scenarios as incomplete episodes.

Response: We thank the commenter for the support and note that we are finalizing the policy to provide full payment for RO episodes in which a patient passes or is transferred to hospice care during an RO episode.

Comment: A commenter requested that we change the proposed policy in

cases where the patient moves from traditional Medicare FFS as their primary payer to a Medicare Advantage plan during an episode. As proposed, the commenter noted that CMS would pay 50 percent of both the PC and TC to participants, regardless of whether the RT was complete. The commenter stated that they believe this payment policy would not fairly reimburse RO participants for services rendered, and recommended that we drop these episodes and revert retrospectively to FFS payments for the services that were billed to Medicare Part A and B, in the same manner that we proposed to do for other categories of incomplete episodes.

Response: We thank the commenter for their concern and suggestion. Our analysis indicates that for episodes where a beneficiary moves from traditional Medicare as their primary payer to a Medicare Advantage plan during the RO episode, the average cost is less than 50 percent of those episodes when compared to episodes where a beneficiary had Medicare as their primary payer for the full 90-day episode. Thus, we believe that paying the SOE PC and TC only in these cases is appropriate. Our data also shows that switching payers during an episode rarely occurs. When an RO beneficiary ceases to have traditional Medicare as his or her primary payer during an RO episode, the RO participant will not be paid the EOE PC or TC because CMS cannot process claims for a beneficiary with dates of service on or after the date that traditional Medicare is no longer the primary payer. We believe that finalizing our proposal with the modification allowing the EOE claim to be submitted and paid at the completion of the planned course of treatment, instead of waiting for 90 days, will mitigate this concern. If the RO beneficiary has traditional Medicare as of the date of service on the EOE claim, the RO participant will be paid both installments of the episode payment.

Comment: Several commenters expressed concern about our proposed policy that local coverage determinations would still apply to all RT services provided in an episode. A commenter noted that at this time, there are few LCDs in publication and that most radiation oncology specific LCDs have been retired, with the exception of those for proton therapy and a few other LCDs for IMRT, SRS and SBRT. The commenter further noted that currently there are no active LCDs for standard external beam, 3D conformal, brachytherapy or radiopharmaceutical therapy, and that multiple MACs have never published radiation oncology LCDs. The commenter stated that the IOM publications by CMS provide few instructions specific to radiation oncology techniques, required documentation, and coverage requirements, which leads to inconsistency across the specialty. The commenter asked if there is a reason there are not more LCDs or possible National Coverage Determinations (NCDs) if there is an expectation that radiation oncology facilities are to follow a common set of guidelines and expectations for coverage. Another commenter stated that LCDs are a form of prior authorization and requested that CMS abandon the use of LCDs to determine coverage for those services delivered to Medicare beneficiaries as part of the RO Model. The commenter stated that the establishment of episode-based payments effectively decouples payment from modality of treatment and that LCDs or other methods of prior authorization should not apply for the RO Model.

Response: LCDs are decisions made by a Medicare Administrative Contractor (MAC) whether to cover a particular item or service in a MAC's jurisdiction (region) in accordance with section 1862(a)(1)(A) of the Social Security Act. The MAC's decision is based on whether the service or item is considered reasonable and necessary. The MACs will not have the ability to apply LCDs to RO Model claims because only the RO Model-specific HCPCS codes appear on the claim and these codes are not included in any current LCDs. When we monitor utilization of RT services during the Model, as described in section III.C.14.a, we will use the reasonable and necessary provisions as stated in applicable LCDs as one of our monitoring tools.

Comment: A commenter requested that we address prior authorization, which the commenter asserted could impact the outcomes and treatment choices in this Model. The commenter expressed concern that prior authorization requirements could increase administrative burden on participating clinicians who seek to deliver the highest quality of care and delay timely payment for covered services.

Response: We thank the commenter for voicing these concerns. RO Model services are not subject to prior authorization.

Comment: Commenters asked if allowable rates will be available for the new codes 30 days prior to program start date. Commenters asked if there will be an RVU associated with the new start and end codes and if there be unique start and end codes per diagnosis.

Response: The RO Model-specific HCPCS codes will be posted on the RO Model website at least 30 days prior to the start of the Model. As described in section III.C.6.h, there are RVUs associated with the RO Model-specific HCPCS codes, but the SOE and which are modifiers, not codes do not have RVUs associated with them.

Comment: A commenter stated that the RO Model will require staff to determine which patients are primary Medicare from all other payers and establish separate processes between payers and between those who fall under the RO Model parameters and those who do not. The commenter stated this would include creating two sets of coding and billing processes just for primary Medicare beneficiaries: One to report services included in the RO Model and one to report services not included and billed as fee-for-service for those services provided to a beneficiary who must participate in the Model but for whom some services provided are not included and billed differently.

Response: It is our understanding that RT providers and RT suppliers furnish and bill for RT services for patients with a variety of insurers and thus already have processes in place to accommodate multiple payer requirements. To clarify, non-included services will be billed separately and in the same manner as they would in the absence of the RO Model.

Comment: A commenter asked us to clarify if the 8 percent non-sequestration reconciliation withhold will be processed at the claim level so that adjustments can be applied to the original claims via remits.

Response: We believe the ''8 percent'' used by the commenter refers to the total of the discounts and withholds. The discounts and withholds are not subject to sequestration upon submission of an RO Model claim. Sequestration will be applied to reconciliation payment calculation that are based on FFS payments.

Comment: Commenters expressed concern about specific billing situations and asked for clarification on several situations. A commenter asked for clarification on how organizations should handle or bill for treatment of new manifestations of same cancer diagnosis within the same 90-day window (estimated 10–20 percent of patients). Another commenter, citing an example of a prostate cancer patient with bone metastasis or a lung cancer patient with brain metastasis, inquired if a patient presents with two separate diagnoses that are included within the Model, would the HCPCS codes be reported for both cancer type codes or

would one take precedence over another? Commenters asked if this would this be considered a single episode or separate episodes? Commenters also sought clarification on billing for non-RO Model codes. If a patient in an RO episode also is treated for a non-model code (for example, metastasis to adrenal gland), would those services be billed and paid for under FFS even though an RO episode is running concurrently? A commenter also asked for clarification on how RO participants should bill for non-model services which, if not for the Model, would be bundled under the existing OPPS RO Comprehensive ambulatory payment classification (C–APC)? The commenter recommended that providers and suppliers be permitted to bill separately under the OPPS for these other non-Model HCPCS and CPT® codes.

Response: Only one RO Model-specific HCPCS code will apply to an RO episode even if the RO beneficiary has more than one included cancer type for which they are receiving RT services. The RO participant can choose which RO Model-specific HCPCS to include on both the SOE and EOE claims. For example, the RO beneficiary is being treated with RT services for breast cancer and brain metastasis, the RO participant would likely choose the RO Model-specific HCPCS for breast cancer, which is appropriate. If an RO beneficiary has more than one included cancer type, but is receiving RT services for just one, the RO participant is expected to put the corresponding RO Model-specific HCPCS code on the SOE and EOE claims. For example, the RO beneficiary has breast cancer, but is being treated with RT services for just their brain metastasis, the RO participant must choose the RO Model-specific HCPCS for brain metastasis. If an RO beneficiary also receives included RT services for a non-included cancer type, FFS claims would be submitted with the corresponding ICD–10 codes and HCPCS codes. As proposed, the SOE and EOE claims must include the same RO Model-specific HCPCS code. RT services not included in Table 2 shall be billed FFS. To clarify, non-included services will be billed separately and in the same manner as they would in the absence of the RO Model.

Comment: Commenters sought clarification on secondary billing under the Model, requesting that we provide clarification in the final rule regarding the role of secondary payers and how they will be engaged as part of the claims processing and billing associated with implementing the Model. Typically, a secondary bill is sent directly from Medicare to the secondary payer. If a no-pay bill is sent to a secondary payer, it would not be paid. Commenters noted that it was particularly important for all participants to follow usual coding and billing pursuant to HIPAA transaction sets due to the impact on a beneficiary's secondary and MediGap insurance. Commenters noted that CMS did not address this topic in the Proposed Rule and stated that they expect that the Innovation Center would define new claim adjustment reason codes (CARC) and remittance advice reason codes (RARC) so this insurance, when secondary to Medicare, will not process co-payments for individual services. Instead, they will process applicable co-payments associated with each of the professional, dual, and technical episode payments when made and explained on the remittance advice from Medicare. Commenters asked that CMS verify and explain this process in the Final Rule to enable RO participants to better understand these important operational issues.

Commenters requested that CMS verify and explain the process for communication to secondary and MediGap insurance (that is, CARC/RARC codes) to ensure all participants have a clear understanding of the operational process for reimbursement. Commenters also noted that as other payers would be following typical FFS payment methodology, the ''M'' codes would not be accepted either. Commenters requested that we address the following questions: Will the Medicare beneficiary then be at risk for the 20 percent liability if denied? How would secondary payers adjudicate these claims? Many payers have 60-day timely filing deadline. With the proposed billing model, commenters expressed concern that they would be at risk of timely filing for certain payers if those claims are not adjudicated.

Response: CMS liaisons to the secondary payers will provide RO Model-specific information to those payers including how the RO Model-specific HCPCS shall be processed. As noted in the proposed rule, we expect to provide RO participants with additional instructions for billing, particularly as it pertains to secondary payers and collecting beneficiary coinsurance. Additional instructions will be made available through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A commenter asked if hospitals are still allowed to add facility fees to their fees under the Model. If so, the commenter stated that the playing field would not be level and would favor HOPD over freestanding radiation therapy centers. The commenter also requested that we clarify if facility fees were included in our computation finding that freestanding centers billed more than HOPPS facilities. If so, the commenter requested that hospitals not be allowed to charge facility fees under the RO Model.

Response: As proposed, only RO Model-specific HCPCS codes are allowed on the SOE and EOE claims. Thus, this should not be a concern.

Comment: A commenter suggested that CMS should publish online an explicit list of providers and suppliers excluded from the Model including their names, addresses, and NPIs to ensure there's no confusion about which providers and suppliers are excluded from the Model. The commenter stated that this information would also emphasize that, should any of the professionals furnish services at a location included in the RO Model and their TIN/ZIP Code is not otherwise excluded from the Model, the participant would be required to report the HCPCS Level II code for the cancer type and the appropriate modifier(s). The commenter also suggested that, if CMS believes it must require the use of a new modifier to signify services in a provider or supplier excluded from the Model, the agency allow the modifier to be reported with the usual RT planning, simulation, and management CPT® and HCPCS codes rather than ask for the cancer type HCPCS code to be reported. The PRT recommends that CMS utilize the information already required by HIPAA transaction sets (NPI, names, and addresses) for professional claims in order to determine if a provider or supplier is excluded from the Model, rather than creating a new modifier and additional operational burden for RT professionals.

Response: Only RO participants can use the RO Model-specific HCPCS codes. The claims system will determine inclusion in the Model by the site of service ZIP Code included on the claim. Non-participants would not be required to use a modifier to indicate they are not subject to RO Model billing requirements. To facilitate understanding and implementation of the billing and payment requirements, we encourage RO participants to access additional instructions for billing during the RO Model and using the RO Model-specific HCPCS codes provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A commenter stated that freestanding centers are not authorized to bill directly to Medicare due to the consolidated billing requirements for SNF and hospital inpatient stays. In this scenario, the commenter believed the treatment delivery code would not be received for beneficiaries during a SNF or hospital inpatient stay who are also treated with RT services in a freestanding radiation therapy center.

Response: We have programmed the claims system to bypass all professional and institutional SNF consolidated billing edits/IURs for RO Model claims for any RO beneficiary that is currently in a Skilled Nursing Facility (SNF) stay.

Based on these public comments we are finalizing our proposals related to billing and payment at § 512.260 and § 512.265, with modification. Specifically, we are adding a new paragraph (d) to § 512.260 to codify the requirement that an RO participant submit no-pay claims for any medically necessary RT services furnished to an RO beneficiary during an RO episode pursuant to existing FFS billing processes in the OPPS and PFS, as was described in this section of the final rule. Additionally, as noted earlier in this section of the final rule, we are permitting an RO participant to submit the EOE claim after the RT course of treatment has ended, but no earlier than 28 days after the initial treatment planning service was furnished. Regardless of when the EOE claim is submitted, the episode duration remains 90 days. Any RT services furnished after the EOE claim is submitted will not be paid separately during the remainder of the RO episode.

Further, we would like to clarify that we are finalizing at § 512.245(b) that if an RO beneficiary dies after both the PC and the TC of the RO episode have been initiated, we proposed that the RO participant(s) would be instructed to bill EOE claims and would be paid the second half of the episode payment amounts regardless of whether treatment was completed. And, if an RO beneficiary elects the MHB not only after the PC and TC of an RO episode has been initiated but also before the TC is initiated as long as the TC is initiated within 28 days following the initial treatment planning service (PC), the RO participant(s) will receive both installments of the episode payment amount (upon billing the RO Model-specific HCPCS codes and the SOE and EOE modifiers) regardless of whether the RO episode has been completed. We recognize that the TC may not always be furnished on the same day, as the PC, or within a few weeks of the PC, and we would like our policy not to delay hospice referrals.

8. Quality

We proposed to implement and score a set of quality measures, along with the clinical data elements (proposed in section III.C.8.e of the proposed rule (84 FR 34514) and discussed in section III.C.8.e of this final rule) according to the Aggregate Quality Score (AQS) methodology (described in section III.C.8.f of the proposed rule (84 FR 34519)). We proposed that beginning in PY1, the AQS would be applied to the quality withhold (described in section III.C.6.g(2) of proposed rule (84 FR 34509) and discussed in this final rule) to calculate the quality reconciliation payment amount due to a Professional participant or Dual participant as specified in section III.C.11 of the proposed rule (84 FR 34527) and this final rule. As proposed, results from selected patient experience measures based on the CAHPS® Cancer Care survey would be incorporated into the AQS for Professional participants and Dual participants starting in PY3. For Technical participants, results from these patient experience measures would be incorporated into the AQS starting in PY3 and applied to the patient experience withhold described in section III.C.6.g(3) of the proposed rule (84 FR 34509 through 34510) and this final rule.

a. Measure Selection

We proposed that the following set of quality measures would be included in the RO Model in order to assess the quality of care provided during episodes (84 FR 34514). We proposed that we would begin requiring annual quality measure data submission by Professional participants and Dual participants in March of 2021[44] for episodes starting and ending in PY1. Participants would continue to be required to submit quality measure data annually every March through the remainder of the Model performance period as described in section III.C.8.c of the proposed rule (84 FR 34517 through 34518) and this final rule. These quality measures would be used to determine a participant's AQS, as described in section III.C.8.f of the proposed rule (84 FR 34519) and this final rule, and subsequent quality reconciliation amount, as described in section III.C.11 of the proposed rule (84 FR 34527) and this final rule.

We proposed that the AQS would be based on each Professional participant's and Dual participant's: (1) Performance on the set of evidenced-based quality measures in section III.C.8.b of the proposed rule (84 FR 34515 through 34517) and this final rule compared to those measures' quality performance benchmarks; (2) reporting of data for the pay-for-reporting measures (those without established performance benchmarks) in section III.C.8.b(4) of the proposed rule (84 FR 34515 through 34517) and this final rule; and (3) reporting of clinical data elements on applicable RO beneficiaries in section III.C.8.e of the proposed rule (84 FR 34518) and this final rule. As stated in the section III.C.8.f.(1) of the proposed rule (84 FR 34519), in the absence of a MIPS performance benchmark, national benchmark, or historical performance from which to calculate a Model-specific benchmark from previous years' historical performance, a quality measure will be included in the calculation of the AQS as pay-for-reporting until a benchmark is established that will enable it to be pay-for-performance. Based on the considerations set forth in the proposed rule, we proposed the following measures for the RO Model beginning in PY1 and continuing thereafter:

- Oncology: Medical and Radiation—Plan of Care for Pain—*NQF*[45] *#0383; CMS Quality ID #144*
- Preventive Care and Screening: Screening for Depression and Follow-Up Plan—*NQF #0418; CMS Quality ID #134*
- Advance Care Plan—*NQF #0326; CMS Quality ID #047*
- Treatment Summary Communication—Radiation Oncology

We proposed adopting this set of quality measures for the RO Model for two reasons. First, the RO Model is designed to preserve or enhance quality of care, and these quality measures would allow us to quantify the impact of the RO Model on quality of care, RT services and processes, outcomes, patient satisfaction, and organizational structures and systems. Second, we believe the RO Model measure set would satisfy the quality measure-related requirements for the RO Model to qualify as an Advanced APM, and a MIPS APM, which we discuss in greater detail in section III.C.9 of this final rule. Because they have already been adopted in MIPS, we believe that the following measures meet the requirements of 42

[44] We are finalizing the inclusion of quality measures in the RO Model in section III.C.8.b, and finalizing that the first annual quality measure data submission will occur in March 2022 as finalized in section III.C.8.c.

[45] National Quality Forum.

CFR 414.1415(b)(2): (1) Oncology: Medical and Radiation—Plan of Care for Pain; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan. We further believe that the Treatment Summary Communication—Radiation Oncology measure is evidence-based, reliable, and valid because it has been developed by stakeholders to ensure timely handoff communication and care coordination to referring health care providers and patients receiving radiation therapy treatment. We acknowledge that we did not propose an outcome measure for the RO Model as required under 42 CFR 414.1415; however, as we explained in the proposed rule (84 FR 34515), this is because there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first Qualifying APM Participants (QP) Performance Period. We have determined there are currently no outcome measures available or applicable for the RO Model so this requirement does not apply to the RO Model. However, if a potentially relevant outcome measure becomes available, we would consider whether it is applicable and should be proposed to be included in the RO Model's measure set.

As stated in the proposed rule, we believe our proposed use of quality measures as described in our AQS scoring methodology in section III.C.8.f of the proposed rule (84 FR 34519) and this final rule would meet the current quality measure and cost/utilization MIPS APM criterion under 42 CFR 414.1370(b)(3). In selecting the proposed measure set for the RO Model, we sought to prioritize quality measures that have been endorsed by a consensus-based entity or have a strong evidence-based focus and have been tested for reliability and validity. We focused on measures that would provide insight and understanding into the Model's effectiveness and that would facilitate achievement of the Model's care quality goals. We also sought to include quality measures that align with existing quality measures already in use in other CMS quality reporting programs, such as MIPS, so that Professional and Dual participants would be familiar with the measures used in the Model. Finally, we considered cross-cutting measures that would allow comparisons of quality across episode payment models and other CMS model tests.

As we stated in the proposed rule, we believe the proposed measure set would provide the Model with sufficient measures for the Model performance period to monitor quality improvement in the radiation oncology sector, and to calculate overall performance using the AQS methodology; however, CMS may adjust the measure set in future PYs by adding or removing measures as needed. If changes to the measure set are necessary, we will propose those changes in future rulemaking.[46]

We solicited comment on this proposal. The following is a summary of the public comments received on this proposal and our response:

Comment: Several commenters supported CMS' proposal to include quality measures and believed that quality measures will ensure that quality care is delivered under the RO Model.

Response: We thank the commenters and appreciate their support.

Comment: A few commenters expressed support for use of NQF-endorsed measures generally. Other commenters specifically opposed the inclusion of any measure that is not NQF-endorsed in the RO Model.

Response: While NQF endorsement is not required when selecting measures for the RO Model, we agree with the commenters that NQF endorsement is one of several important criteria to consider. Three of the quality measures that we proposed for the Model are currently NQF-endorsed. A fourth, the measure ''Treatment Summary Communication,'' was initially endorsed by NQF in 2008, but was not subsequently brought by the measure steward for maintenance/re-endorsement. However, we believe the information captured by this measure is relevant to the RO Model and critical to patients' care continuity and coordination. We believe that any measure that is evidence based and would support the goals of the Model, that has been tested to produce valid and reliable results, and that is effective without being overly burdensome, may be appropriate for inclusion in the Model. Therefore, we do not believe that the lack of current NQF endorsement alone should preclude a measure's adoption since endorsement, as it is only one of several considerations.

Comment: A commenter recommended that CMS add additional measures to the RO Model and allow participants the opportunity to select a subset of measures from the larger set to report.

Response: In selecting measures for the RO Model, we sought to include a set of meaningful, parsimonious measures, reflective of the CMS Meaningful Measures framework[47] that balances the need for data about participant performance without creating undue burden on participants. One set of measures used by all RO participants will provide insight for CMS and the field as a whole into how care quality compares across multiple markets. Selective reporting of measures would hinder the ability of CMS to measure or analyze the impact of the Model on quality.

Comment: A few commenters expressed their belief that the Model should only include measures related to patient safety and health care provider engagement to ensure the delivery of high-quality care within the Model.

Response: We agree that patient safety is of paramount importance; we will assess patient safety via claims, site visits, and data that RO participants are required to submit for monitoring and evaluation. However, we believe it is important to capture elements of quality care that go beyond patient safety and health care provider engagement. The selected measures will encourage providers and suppliers to engage with CMS and their patients to ensure that patients are receiving high-quality care. All measures were selected based on clinical appropriateness for RT services spanning a 90-day episode period. Additionally the Model must include a sufficient set of quality measures to qualify as a MIPS APM and an Advanced APM.

Comment: A couple of commenters recommended that national accreditation through the American College of Radiology (ACRO) or American Society for Radiation Oncology (ASTRO) should be sufficient to meet quality standards for the Model and that accredited PGPs in the Model should not need to report additional quality data to CMS. The commenters believed that the collection and submission of additional quality data to CMS is unlikely to add value to the effort to improving radiation oncology care. A commenter supported accreditation and believed it enhances quality of care. Another commenter supported American College of Radiology (ACR) accreditation for larger

[46] When there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns, CMS will take immediate action to remove a measure from the program and not wait for the annual rulemaking cycle. In such situations, we would promptly retire such measures followed by subsequent confirmation of the retirement in the next rulemaking. When we do so, we will notify participants and the public through the usual communication channels, which include RO Model website and emails to participants.

[47] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

centers with a full-time radiologist on site.

Response: We agree with the commenters that accreditation by nationally recognized organizations, such as the ACR, ACRO, and ASTRO, may be an indicator of the overall quality of care provided by a RT provider or RT supplier. However, we do not believe that accreditation provides a full picture of quality care delivery in radiation oncology. As noted earlier in this final rule, the Model must include a set of quality measures to qualify as a MIPS APM and an Advanced APM, and as such, accreditation is not able to replace the RO quality measures without compromising the Model's qualification as a MIPS APM and Advanced APM. In addition, while we are not using accreditation status as a proxy for quality, as stated in section III.C.13.c we may at some point use an optional web-based survey to gather data from participants on administrative data points, including their accreditation status, indicating the importance of this information to understanding participants' activities.

Comment: We received numerous comments requesting the addition or development of additional RT measures to ensure the provision of high-quality care. Commenters specifically recommended the following topics for measures: Tracking the toxicity of treatment; the utilization of surface guided radiation therapy (SGRT); compliance with dose limits and radiation exposure; hospice referrals; and innovation in patient care management (for example, phone and email contact). Other commenters recommended that CMS consider quality measures supported by ASTRO, including: Cancer Stage Documented; External Beam Radiotherapy for Bone Metastases; Hormonal Therapy for Stage IC–IIIC; ER/PR Positive Breast Cancer; Adjuvant Hormonal Therapy for High-Risk Patients; and Chemotherapy for AJCC Stage III Colon Cancer Patients. A commenter recommended that CMS communicate a commitment to adopt clinical and staging measures by PY2. Another commenter requested CMS develop a process to accept recommendations of potential measures to be considered for implementation in the RO Model.

Response: We appreciate the suggestions of additional quality measures. As previously discussed, we proposed the four measures and the CAHPS® Cancer Care survey described in the proposed rule for PY1 because we believe these measures will allow us to monitor and evaluate quality in the radiation oncology sector; they align with existing measures being used in quality programs; and they will allow the Model to qualify as an Advanced APM and a MIPS APM. However, we will consider revisions to this measure set for future model years. We will continue to monitor other measures that become available and meet the criteria for the Model, including seeking opportunities to align with quality measure efforts conducted by professional societies. As we consider additional measures for inclusion in the Model, we will consider which measures will allow the most meaningful and parsimonious measure set to ensure continued RT quality, while requiring the least amount of burden on providers and suppliers. Throughout the Model performance period, we will be seeking input from stakeholders on potential quality measure while continuing to monitor the RT field for new and promising measures.

Comment: We received many comments related to measuring RO Model outcomes addressing multiple topics including: (1) The importance of including an outcome measure in APMs; (2) suggestions for making progress on creating a radiation therapy-specific outcome measure for future implementation; and (3) alternatives to a clinical outcomes measure that CMS can use to track outcomes for RO beneficiaries. Many commenters expressed support for inclusion of an outcome measure related to RT care, with some commenters noting that an outcome measure is preferred for an Advanced APM.

Some commenters believe that an outcome measure is important for the Model to evaluate whether a high level of care quality is maintained throughout the Model performance period, with a commenter requesting an outcome measure specifically to ensure that hypofractionation does not cause harm. A commenter recommended that quality programs should have outcome, patient experience, and value measures. On the topic of outcome measure development, several commenters suggested that CMS collaborate with professional and specialty societies to identify metrics that meaningfully measure quality of cancer care and impact on outcomes (including survival). A commenter also recommended that CMS track patient outcomes via a Medicare-certified Qualified Clinical Data Registry (QCDR). Another commenter recommended using a clinical outcomes measures related to patient safety (including the incidence of various side effects that may accompany overexposure of healthy tissue to radiation) and the efficacy of treatment.

MedPAC specifically recommended using three claims-based measures, the second and third of which are currently used in the OCM: (1) The risk-adjusted proportion of patients with all-cause hospital admissions within the six-month episode, (2) risk-adjusted proportion of patients with all-cause emergency department (ED) visits or observation stays that did not result in a hospital admission within the six-month episode, and (3) proportion of patients that died who were admitted to hospice for three days or more.

Response: For PY1, we proposed four measures. Several outcome measures (some of which are registry-based measures), including those suggested by commenters, were considered prior to the publication of the proposed rule. In the end, we did not include these outcome measures in the proposed measure set due to concerns over the significant challenge of attributing outcomes—such as those suggested by MedPAC including hospital admissions, ED visits, or proportion of patients that died who were admitted to hospice—directly to RT services.

We would have liked to use the same OCM outcome measures for the RO Model, but ultimately decided that it would be difficult to discern whether these outcomes occurred due to complications from RT service, chemotherapy by medical oncologists, or for other various reasons. As such, we believe that these measures would not meaningfully indicate high- versus low-quality RO participants. As stated in the proposed rule (84 FR 34514), while we believe it is preferable to include an outcome measure in an Advanced APM, there are currently no outcome measures specific to RO available for implementation. We appreciate commenters' suggestions for understanding outcomes related to care delivered under the RO Model, including the suggestion that CMS use QCDRs to track outcomes. We will monitor the progress in this area but note that Professional participants and Dual participants are not required to contract with a QCDR; thus we will not use these entities as a means of collecting outcome measures. We will continue to assess and consider advancements made by professional and specialty societies in the development of quality metrics to identify the availability of metrics that meaningfully measure quality of RT care and impact on outcomes (including survival). As these are identified, we will consider proposing an appropriate outcome measure in future rulemaking.

Comment: A commenter recommended developing an outcome registry for incidents such as bone marrow transplants, CAR–T cell therapy, fractures, pain, hospitalizations, and other complications. Another commenter encouraged CMS to develop a central reporting mechanism for patients receiving relatively new, relatively expensive technologies and their outcomes.

Response: CMS is not developing a registry for use in the RO Model, but we appreciate this comment and acknowledge the value of registries to track treatment effects and health outcomes, while not increasing data collection burden for providers and suppliers. We will monitor registry development and assess the feasibility of using such registry data in the future.

Comment: A commenter urged CMS to consider the relationship between the 90-day episode period and the timing included in the RO Model's measure specifications, and requested CMS properly scope the measures to reflect care that is within the control of the radiation oncologist specifically within the 90-day episode window.

Response: We believe that the measures we are adopting are appropriate for inclusion in the RO Model. We selected all measures based on clinical appropriateness for RT services spanning a 90-day episode period. The measures are scoped to certain specifications, including time, which are important for validity and reliability of the measure results. We believe that radiation oncologists have an important role to play in ensuring that their patients have a plan to address beneficiary pain, that they communicate treatment with other providers and suppliers to ensure the RO beneficiaries are receiving coordinated care, and that they have been screened for depression and have an advance care plan. By encouraging radiation oncologists to provide guidance and care coordination as well as engage with patients throughout their treatments, we believe these measures will improve both patients' outcomes and their experience of care. We believe both depression screening and advance care planning help RO beneficiaries ensure they are engaged and pursuing the best course of treatment for them.

Comment: A commenter expressed concern that the proposed quality measures are insufficient to measure whether RO participants are using high-quality equipment and other infrastructure they believe correlate with providing high-value care. This commenter recommended including quality measures that reflect variation in accreditation and equipment used for treatment.

Response: We appreciate the role of high-quality equipment in the delivery of care. We also understand that to achieve accreditation, a clinical organization must demonstrate high standards of patient care. We also note that, as discussed in section III.C.13.c, we may request the optional submission of additional administrative data through web-based surveys, such as how frequently the radiation machine is used on an average day and the RO participant's accreditation status. However, we continue to believe that quality measurement must be outcome-based, focusing on the patient and the episode of care, and not be based solely on the equipment or accreditation status. We will use clinical data elements in the RO Model to support monitoring and evaluation of the Model and may use these data to begin developing new outcome-based quality measures that may capture the effect of quality equipment and infrastructure.

Comment: Several commenters recommended a voluntary phase-in period to collect quality measure data, which they believe would allow practices to become operational within the Model and provide better data. A couple of commenters urged CMS to provide additional details on quality measure and clinical data element collection and submission processes to give RO participants additional time to prepare their systems and comply with these requirements.

Response: We do not believe a voluntary phase-in period is necessary for the RO Model. RO participants' first submission for the set of quality measures for PY1 (beginning on January 1, 2021) as described in section III.C.8.b will begin in March 2022, as finalized in section III.C.8.c. We believe beginning the Model performance period on January 1, 2021 Model will allow RO participants to review and to develop best practices to facilitate their data collection and to work with EHR vendors to seek additional EHR support. We will provide additional information about measure collection on the RO Model website: *https://innovation.cms.gov/initiatives/radiation-oncology-model/.*

Comment: A commenter expressed concern that EHR vendors will use the new requirements to generate additional fees for their products, thereby placing RO participants, especially those that are small and rural, at greater financial risk.

Response: We understand the commenter's concern about the cost of these requirements, but we note that three of the four proposed quality measures are already included in the MIPS program, so we expect that some of these measures may already be familiar to EHR vendors. In regard to small and rural providers and suppliers, please see section III.C.3.c of this final rule, which outlines the opt-out option for low-volume providers and suppliers.

Comment: A few commenters opposed the implementation of quality measures in the RO Model and suggested not implementing quality measures in the Model at all, stating their view that the measures would not yield information reflective of quality in a radiation oncology practice and would do little to encourage actual improvement in the quality of patient care.

Response: We disagree with commenters' assertions regarding the impact of quality measurement in the RO Model. We believe that including appropriate quality measures in the RO Model—as in other Innovation Center Alternative Payment Models (APMs)—is critical to monitoring beneficiary care and ensuring that quality of care is preserved or enhanced within an episode payment model in which CMS expenditures are reduced. Quality measures are in alignment with the CMS and Innovation Center goals of providing effective, safe, efficient, patient-centered, equitable, and timely care. Furthermore, if we did not finalize quality measures for the RO Model, it would not satisfy the requirements of an Advanced APM, nor a MIPS APM.

b. RO Model Measures and CAHPS® Cancer Care Survey for Radiation Therapy

As we discussed in the proposed rule (84 FR 34515), we selected the four quality measures for the RO Model after conducting a comprehensive environmental scan that included stakeholder and clinician input and compiling a measure inventory. Three of the four measures are currently NQF-endorsed [48] process measures approved for MIPS.[49] We proposed for the three NQF-endorsed measures approved for MIPS (Plan of Care for Pain; Screening for Depression and Follow-Up Plan; and Advance Care Plan) to be applied as pay-for-performance, given that baseline performance data has been established.[50] The fourth measure in the

[48] NQF endorsement summaries: *http://www.qualityforum.org/News_And_Resources/Endorsement_Summaries/Endorsement_Summaries.aspx.*

[49] See the CY 2018 QPP final rule (82 FR 53568).

[50] Baseline performance is based on the entirety of data submitted to meet MIPS data reporting

RO Model (Treatment Summary Communication) would be applied as pay-for-reporting until such time that a benchmark can be developed, which is expected to be PY3, as discussed in section III.C.8.b of the proposed rule (84 FR 34515) and this final rule. As described in the proposed rule, all four measures are clinically appropriate for radiation oncology and were selected based on clinical appropriateness to cover RT spanning the 90-day episode period. These measures ensure coverage across the full range of cancer types included in the RO Model, and provide us the ability to accurately measure changes or improvements related to the Model's aims. In addition, we proposed the CAHPS® Cancer Care survey to collect information we believe is appropriate and specific to a patient's experience during an episode. We noted in the proposed rule that we believe these measures and the CAHPS® Cancer Care survey [51] will allow the RO Model to develop an Aggregate Quality Score (AQS) in our pay-for-performance methodology (described in section III.C.8.f of this final rule) that incorporates performance measurement with a focus on clinical care and patient experience.

(1) Oncology: Medical and Radiation—Plan of Care for Pain (NQF #0383; CMS Quality ID #144)

We proposed the *Oncology: Medical and Radiation—Plan of Care for Pain* (''Plan of Care for Pain'') measure in the RO Model (84 FR 34515). This is a process measure that assesses whether a plan of care for pain has been documented for patients with cancer who report having pain. This measure assesses the ''[p]ercentage of patients, regardless of age, with a diagnosis of cancer who are currently receiving chemotherapy or RT that have moderate or severe pain for which there is a documented plan of care to address pain in the first two visits.'' [52] As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50843), pain is the most common symptom in cancer, occurring ''in approximately one quarter of patients with newly diagnosed malignancies, one third of patients undergoing treatment, and three quarters of patients with advanced disease.'' [53] Proper pain management is critical to achieving pain control. This measure aims to improve attention to pain management and requires a plan of care for cancer patients who report having pain to allow for individualized treatment.

As we noted in the proposed rule (84 FR 34515), we believe this measure is appropriate for inclusion in the RO Model because it is specific to an episode of care. It considers the quality of care of medical and radiation oncology and is NQF-endorsed. As we proposed, the RO Model would adopt the measure according to the most recent specifications, which are under review at NQF in Fall 2019 (and as of the drafting of this final rule are still under review). The current measure specifications are being used for payment determination within the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (beginning in FY2016 as PCH–15), the Oncology Care Model (OCM) (beginning in 2016 as a component of OCM–4), and the Merit-Based Incentive Payment System (MIPS) (beginning in CY2017 as CMS #144). We explained in the proposed rule that as long as the measure remains reliable and relevant to the RO Model's goals, we would continue to include the measure in the Model regardless of whether or not the measure is used in other CMS programs. If in the future we believe it necessary to remove the measure from the RO Model, then we will propose to do so through notice and comment rulemaking.

We noted in the proposed rule that this measure was currently undergoing triennial review for NQF endorsement via the NQF's Fall 2019 Cycle and while we expected changes to the measure specifications, we did not believe these changes would change the fundamental basis of the measure, nor did we believe they would impact the measure's appropriateness for inclusion in the RO Model. As of the drafting of this final rule, this measure is still under NQF review, but as we explained in the proposed rule, NQF endorsement is a factor in our decision to implement the Plan of Care for Pain measure, but it is not the only factor. If the measure were to lose its NQF endorsement, we noted in the proposed rule that we may choose to retain it so long as we believe it continues to support CMS and HHS policy goals. Therefore, we proposed the Plan of Care for Pain measure with the associated specifications available beginning in PY1. This measure would be a pay-for-performance measure and scored in accordance with our methodology in section III.C.8.f of this final rule.

As proposed (84 FR 34517), and as discussed further in section III.C.8.c of this final rule, we would require Professional participants and Dual participants to report quality measure data to the RO Model secure data portal in the manner consistent with that submission portal and the measure specification. At the time of the proposed rule and at the time of the writing of the final rule, the current version of the Plan of Care for Pain measure specification requires that data will be reported for the performance year that covers the date of encounter. The measure numerator includes patient visits that included a documented plan of care to address pain. The measure denominator includes all visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain. Any exclusions can be found in the detailed measure specification linked in this section of this final rule.

For the RO Model, we proposed to use the CQM [54] specifications for this measure. Detailed measure specifications may be found at: *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2020_Measure_144_MIPSCQM.pdf.*

The following is a summary of the public comments received on this proposal and our response:

Comment: A few commenters expressed support for implementing the Plan of Care for Pain measure, believing that the assessment reflected by this measure will improve the quality of patient care. A commenter asked CMMI to clarify the measure specification that would be used beginning in 2020, noting the specifications were changed for the 2019 MIPS performance year, but the measure steward is reverting to the 2018 specifications (to include those who report all pain, versus the 2019 specifications that only included reports of moderate or severe pain).

Response: We agree that this measure reflects an important area of assessment. We also note that where one measure is being used in multiple CMS programs, we seek to align measure specifications across programs and use the most up-to-date version as appropriate. As

requirements for these measures and are not specific to radiation oncology performance.

[51] As discussed in section III.C.8.b(5) and III.C.8.f, the CAHPS® Cancer Care survey would be administered beginning in October, 2020, and we would seek to include measures in the aggregate quality score beginning in PY3.

[52] Oncology: Medical and Radiation—Plan of Care for Pain. American Society of Clinical Oncology. In Review for Maintenance of Endorsement by the National Quality Forum (NQF #0383). Last Updated: June 26, 2018.

[53] Swarm RA, Abernethy AP, Anghelescu DL, et al. Adult Cancer Pain: Clinical Practice Guidelines in Oncology. *Journal of the National Comprehensive Cancer Network: JNCCN.* 2013;11(8):992–1022. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915297/.*

[54] We note that we proposed to use ''registry specifications.'' For consistency with QPP, we are now referring to registry specifications as CQM specifications to align with QPP's terminology.

discussed in section III.C.8.d, measures also undergo non-substantive technical maintenance and we intend to use the most recent specifications unless those specifications are inconsistent with the specifications used in MIPS. In those situations, we would use the MIPS specifications. Thus, for each PY, we will utilize the specifications of the measure that aligns with the most recent MIPS year specifications.[55]

After consideration of the comments we received, we are finalizing as proposed to include the Oncology: Medical and Radiation—Plan of Care for Pain (NQF #0383; CMS Quality ID #144) Measure as a pay-for-performance measure beginning in PY1.

(2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS Quality ID #134)

We proposed the *Preventive Care and Screening: Screening for Depression and Follow-Up Plan* (''Screening for Depression and Follow-Up Plan'') measure in the RO Model (84 FR 34516). This is a process measure that assesses the ''[p]ercentage of patients screened for clinical depression with an age-appropriate, standardized tool and who have had a follow-up care plan documented in the medical record.'' [56] As we noted in the proposed rule, we believe this clinical topic is appropriate for an episode of care even though it is not specific to RT. We explained that we believe inclusion of this measure is desirable to screen and treat the potential mental health effects of RT, which is important because some of the side effects of RT have been identified as having a detrimental effect on a patient's quality of life and could potentially impact the patient beyond physical discomfort or pain.[57] [58] [59] [60] [61] [62] We noted that this measure has been used for payment determination within OCM (beginning in 2016 as OCM–5) and MIPS (beginning in CY2018 as CMS #134) and is NQF endorsed. We also indicated that if we were to remove the measure from the RO Model, we would use notice and comment in rulemaking. As proposed, this measure would be a pay-for-performance measure beginning in PY1 and scored in accordance with our methodology described in section III.C.8.f of this final rule.

As noted in the proposed rule, discussed further in section III.C.8.c of this final rule, we would require Professional participants and Dual participants to report quality measure data to the RO Model secure data portal in the manner consistent with that submission portal and the measure specification. The Screening for Depression and Follow-Up Plan measure specification states the data will be reported for the performance year that covers the date of encounter. The measure numerator includes patients screened for depression on the date of the encounter using an age-appropriate standardized tool and, if the screening is positive, a follow-up plan is documented on the date of the positive screen. The measure denominator includes all patients aged 12 years and older before the beginning of the measurement period with at least one eligible encounter during the measurement period. Any exclusions can be found in the detailed measure specification linked in this section in this final rule.

For the RO Model, we would use the CQM [63] specifications for this measure. Detailed measure specifications may be found at: *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2020_Measure_134_MIPSCQM.pdf.*

The following is a summary of the public comments received on this proposal and our response:

Comment: A few commenters supported this measure. A commenter asserted the measure should be broadened to include screening for distress (for example, anxiety, stress, and social isolation) and whether follow-up care is being sought. Another commenter who supported the measure recommended an exception be written into the specifications to exclude patients who were screened less than six months prior to the encounter within the measurement period. The commenter explained that this exception could be utilized to guard against the perception of gaming that the commenter believes exists in OCM practices that are screening patients for depression on a quarterly (or more frequent) basis, to perform better on the measure. This commenter also noted that the frequency of screening places burden on patients.

Response: We appreciate commenters' support for including this measure in the Model. We respect the commenter's concerns regarding the perception of gaming as related to this measure. While we understand the importance of mitigating gaming, we do not concur with the commenter's perception of gaming in OCM practices. CMS is not the measure steward, however, we will share the commenters' feedback on potential changes to the specifications with the measure steward for consideration especially with respect in recognition of the perception of gaming.

Comment: A few commenters recommended against adopting this measure, noting that (1) it is considered topped-out; (2) it is outside of the direct control of radiation oncologists (that is, typically the responsibility of primary care physicians or medical oncologists), and therefore not directly applicable to the RO Model; and (3) calculating the measure imposes a burden on providers and suppliers because the data is not captured in a discrete field in the medical record. These commenters suggested that CMS work with specialty societies, radiation oncologists, and other stakeholders to develop and validate appropriate measures for radiation therapy.

Response: We appreciate all of the comments regarding this measure and acknowledge the concerns that some commenters expressed. The RO Model will use the MIPS CQM version of this measure. For providers and suppliers that participated in MIPS and submitted the measure through the MIPS CQM, this measure is not topped-out. Further, even if this measure were to become

[55] We intend to align with the most recent MIPS year specifications for each measure that is included in MIPS because such alignment will reduce burden for RO participants and permit comparisons between the MIPS and RO participants.

[56] Preventive Care and Screening: Screening for Depression and Follow-Up Plan. Centers for Medicare & Medicaid Services. Endorsed by the National Quality Forum (NQF #0418). Last Updated: Jun 28, 2017.

[57] Siu AL, and the U.S. Preventive Services Task Force USPSTF. Screening for Depression in Adults: U.S. Preventive Services Task Force Recommendation Statement. JAMA. 2016;315(4):380–387. doi:10.1001/jama.2015.18392, *https://jamanetwork.com/journals/jama/fullarticle/2484345.*

[58] Meijer, A., Roseman, M., Milette, K., Coyne, J.C., Stefanek, M.E., Ziegelstein, R.C., . . . Thombs, B.D. (2011). Depression screening and patient outcomes in cancer: A systematic review. PloS one, 6(11), e27181. *https://doi.org/10.1371/journal.pone.0027181.*

[59] Li, M., Kennedy, E.B., Byrne, N., Gérin-Lajoie, C., Katz, M.R., Keshavarz, H., . . . Green, E. (2016). Management of Depression in Patients With Cancer: A Clinical Practice Guideline. Journal of Oncology Practice, 12(8), 747–756. *https://ascopubs.org/doi/10.1200/JOP.2016.011072.*

[60] Pinquart, M., & Duberstein, P.R. (2010). Depression and cancer mortality: A meta-analysis. Psychological Medicine, 40(11), 1797–1810. doi:10.1017/s0033291709992285, *https://pubmed.ncbi.nlm.nih.gov/20085667/.*

[61] Massie, M.J. (2004). Prevalence of Depression in Patients With Cancer. Journal of the National Cancer Institute Monographs, 2004(32), 57–71. *https://doi.org/10.1093/jncimonographs/lgh014.*

[62] Linden, W., Vodermaier, A., Mackenzie, R., & Greig, D. (2012). Anxiety and depression after cancer diagnosis: Prevalence rates by cancer type, gender, and age. Journal of Affective Disorders, 141(2–3), 343–351. doi:10.1016/j.jad.2012.03.025, *https://pubmed.ncbi.nlm.nih.gov/22727334/.*

[63] We note that we proposed to use ''registry specifications.'' For consistency with QPP, we are now referring to registry specifications as CQM specifications to align with QPP's terminology.

topped-out for the population of providers and suppliers who participate in MIPS, there is value to implementing measures that have topped-out in order to prevent a decrease in performance on this aspect of care. Further, establishing continuity in the quality measures implemented in the RO Model and MIPS will be a key factor in our assessment of the RO Model's performance over time, as it will allow for data comparison between the participating entities in each respective program. While screening for depression and follow-up care is not traditionally within the purview of radiation oncologists, we believe the RO Model presents an opportunity to address the need for more comprehensive understanding of patients' health when undergoing RT services. Care can be delivered more effectively when RO participants understand their patients' mental health, and the ramifications of their mental health on their care planning and care delivery. Specifically, we note this measure requires that a follow-up plan is documented on the day of a positive screening. In regard to provider and supplier burden, we expect that—given this is an existing MIPS measure—data are captured in EHRs, and/or EHR vendors will have capacity to establish needed collection fields. We will continue to monitor our measure set and other measures as they become available to ensure the RO Model measure set remains appropriate, meaningful and parsimonious.

Comment: A commenter recommended categorizing this measure as pay-for-reporting in the AQS methodology (as opposed to pay-for-performance) until a benchmark is established specific to radiation oncology patients, noting that the current MIPS benchmark for this measure would create an inappropriate cohort comparison.

Response: We believe that setting discrete benchmarks for different specialties does not align with CMS' goals for quality improvement. In addition, discrete benchmarks would create undue complexity and possible confusion for RO participants who also participate in MIPS to have potentially two different benchmarks. Therefore, we will use the MIPS benchmark and finalize this measure as Pay-for-Performance in PY1.

After consideration of the comments we received, we are finalizing the proposal to include the Preventive Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS Quality ID #134) Measure as a pay-for-performance measure beginning in PY1.

(3) Advance Care Plan (NQF #0326; CMS Quality ID #047)

We proposed to include the *Advance Care Plan* measure in the RO Model (84 FR 34517). The Advance Care Plan measure is a process measure that describes percentage of patients aged 65 years and older that have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan. This measure is not unique to the radiation oncology, but, as proposed, we believe that it would be appropriate for the RO Model because we believe that it is essential that a patient's wishes regarding medical treatment are established as much as possible prior to incapacity.

This measure is NQF endorsed [64] and has been collected for MIPS (beginning in CY2018 as CMS #047), making its data collection processes reasonably well established. If it becomes necessary to remove the measure from the Model, we would do so through notice and comment rulemaking. As proposed, this measure would be a pay-for-performance measure beginning in PY1 and scored in accordance with our methodology in section III.C.8.f of this rule.

As proposed (84 FR 34517), and as discussed further in section III.C.8.c of this rule, we would require Professional participants and Dual participants to report quality measure data the RO Model secure data portal in the manner consistent with that submission portal and the measure specification. The current version (at the time of the proposed rule and the drafting of this final rule) of the Advance Care Plan measure specification states the data will be reported for the performance year that covers the date of documentation in the medical record. The measure numerator includes patients who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan. The measure denominator includes all patients aged 65 years and older. Any exclusions can be found in the detailed measure specification linked in this section of this final rule.

As proposed, for the RO Model, we would use the CQM [65] specifications for this measure. Detailed measure specifications may be found at: *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2020_Measure_047_MIPSCQM.pdf.*

The following is a summary of the public comments received on this proposal and our response:

Comment: A few commenters supported implementing the Advance Care Plan measure. A commenter noted advance care planning is associated with lower rates of ventilation, resuscitation, intensive care unit admission, earlier hospice enrollment, and decreased cost of care at the end of life. Another commenter noted advance care planning is a key activity in cancer care planning and documenting a patient's goals and values can result in more personalized care plans. Finally, a commenter supported this measure but recommended allowing an exclusion for those patients who do not want to participate in advance care planning.

Response: We thank the commenters for their support. Regarding the comment to exclude patients who do not want to participate in advance care planning, we are implementing the measure using the current specifications, which have been tested and validated for reliability. We note that within the current specifications, the numerator captures how many patients were asked if they have an advance care plan and is agnostic as to whether or not they have a plan. Thus, an exclusion for those patients who chose not to have such a plan is not necessary to performance on this measure.

Comment: A few commenters recommended not finalizing the Advance Care Plan measure, because they believe: (1) It is topped-out; (2) it is outside the direct control of radiation oncologists; (3) calculating the measure imposes a substantial burden on RO participants; and (4). this measure does not account for patients' receipt of survivorship care plans and may create duplication of effort.

Response: We appreciate all of the comments regarding this measure and acknowledge the concerns that some commenters expressed. As we stated in our discussion of the Screening for Depression and Follow-Up Plan measure, we are using the MIPS CQM

[64] As of April 2020 this measure is undergoing an annual endorsement update review at NQF. A modified specification was submitted for review by the measure developer.

[65] We note that we proposed to use ''registry specifications.'' For consistency with QPP, we are now referring to registry specifications as CQM specifications to align with QPP's terminology.

version of this measure. This measure is not topped-out for the population of providers and suppliers who participate in MIPS and submitted their data through the MIPS CQM. There is also value to implementing measures that have topped-out, to prevent a decrease in performance on this aspect of care. While advance care planning may not be traditionally within the purview of radiation oncologists, we believe the Model presents an opportunity for RO participants to engage patients in care planning. Further, establishing continuity in the quality measures implemented in the RO Model and MIPS will be a key factor in our assessment of the RO Model's performance over time, as it will allow for data comparison between the participating entities in each respective program. In regard to provider and supplier burden, we expect that—given this is an existing MIPS measure—data are captured in EHRs, and/or EHR vendors will have capacity to establish needed collection fields. Finally, we seek to clarify that the Advance Care Plan measure quantifies the number of patients who have an advance care plan or a surrogate decision-maker documented in the medical record, or documentation that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate. We do not see any overlap between this measure, and the process of providers and suppliers working with patients to develop Survivorship Care Plans. Survivorship Care Plans include information about a patient's treatment, the need for future check-ups and cancer tests, and potential long-term late effects of treatment, as well as ideas for health improvement.[66]

After consideration of the comments we received, we are finalizing as proposed to include the Advance Care Plan (NQF #0326; CMS Quality ID #047) Measure as a pay-for-performance measure beginning in PY1.

(4) Treatment Summary Communication—Radiation Oncology

We proposed the *Treatment Summary Communication—Radiation Oncology* (''Treatment Summary Communication'') measure in the RO Model (84 FR 34517). The Treatment Summary Communication measure is a process measure that assesses the ''[p]ercentage of patients, regardless of age, with a diagnosis of cancer that have undergone brachytherapy or external beam RT who have a treatment summary report in the chart that was communicated to the physician(s) providing continuing care and to the patient within one month of completing treatment.'' [67] As proposed, we believe this measure is appropriate for inclusion in the RO Model because it is specific to an episode of care. This measure assesses care coordination and communication between health care providers during transitions of cancer care treatment and recovery. While this measure is not currently NQF endorsed [68] and has not been used in previous or current CMS quality reporting, it has been used in the oncology field for quality improvement efforts, making considerations regarding data collection reasonably well-established. We would include the measure because, as we stated in the proposed rule, we believe it is valid and relevant to meeting the RO Model's goals. As proposed, this measure would be the one pay-for reporting measure included in the calculation of the AQS until a benchmark is established that will enable it to be pay-for-performance, which is expected to be beginning in PY3.

As proposed (84 FR 34517), and as discussed further in section III.C.8.c of this final rule, we would require Professional participants and Dual participants to report quality measure data to the RO Model secure data portal in the manner consistent with that submission portal and the measure specification. The current version (at the time of the proposed rule and the drafting of this final rule) of the Treatment Summary Communication measure specification states the data will be reported for the performance year that covers the date of the treatment summary report in the chart. The measure numerator includes patients who have a treatment summary report in the chart that was communicated to the physician(s) providing continuing care and to the patient within one month of completing treatment. The measure denominator includes all patients, regardless of age, with a diagnosis of cancer who have undergone brachytherapy or external beam radiation therapy. Any exclusions can be found in the detailed measure specification linked in this section of this final rule.

For the RO Model, we would use the registry specifications for this measure. Detailed measure specifications may be found at: *http://www.qualityforum.org/QPS/0381.*

The following is a summary of the public comments received on this proposal and our response:

Comment: A few commenters expressed support for the measure Treatment Summary Communication. A couple of commenters noted their desire for CMS to collect data beyond what this measure captures, and look at multidisciplinary treatment planning efforts across radiation oncology, surgery, and medical oncology. A couple of commenters expressed support for implementing this measure as pay-for-reporting in PYs 1–2 and encouraged CMS to test the measure for reliability and validity, and provide additional information to RO participants, before transitioning it to a pay-for-performance measure.

Response: We appreciate commenters' support and are finalizing this measure, using the current specifications, which have been tested and validated for reliability, in the RO Model as described in the proposed rule: Pay-for-reporting in PY1 and PY2; and pay-for-performance in PYs 3–5. We believe the measure must be pay-for-reporting in PY1 and PY2 in order to establish historical data to set a benchmark for use during the pay-for-performance years. We plan to provide information regarding the benchmark for the measure Treatment Summary Communication to RO participants via the RO Model website.

Comment: A few commenters expressed concerns regarding the specifications and/or endorsement status of this measure. A commenter specifically noted the measure was withdrawn from NQF consideration by the developer, and not submitted for NQF measure maintenance evaluation, thus it is no longer endorsed. Commenters noted that the lack of endorsed measure specifications can create inconsistency in how the measure is utilized; they also noted that this measure is not widely integrated into EHRs, thus creating burden for RO participants who will need to integrate the measure's data points into their EHRs. Another commenter noted that the measures should be implemented with the original specifications to document treatment summary communications that take place over a four-week period of a patient's care and recommended that CMS align how this measure's data is collected and

[66] *https://www.cancer.net/survivorship/follow-care-after-cancer-treatment/asco-cancer-treatment-and-survivorship-care-plans.*

[67] Oncology: Treatment Summary Communication—Radiation Oncology. American Society for Radiation Oncology. Endorsement removed by the National Quality Forum (NQF #0381). Last Updated: Mar 22, 2018.

[68] Treatment Summary Communication had previously been endorsed by NQF but was not brought by the measure steward for measure maintenance and re-endorsement; thus it is currently not endorsed.

reported—using the original four-week specification—across all CMS reporting programs.

Response: We appreciate commenters' concerns and will finalize the measure specifications as proposed. Where one measure is being used in multiple CMS programs or models, we seek to align measure specifications across programs and models and use the most up-to-date version as appropriate. Regarding NQF endorsement, we agree that NQF endorsement is an important, but not the sole, criterion for identifying measures for implementation. RO participants will be provided with educational materials that provide the specification details for each measure, which addresses the concerns expressed by commenters that lack of current NQF endorsement may lead to inconsistency in how the measure is operationalized within the RO Model.

Comment: A commenter requested clarification about how this measure would be fielded. Another commenter requested clarification that RO participants do not need to send a treatment summary to other PGPs if both have access to the same EHR.

Response: The intent of this measure is to ensure that the radiation oncology treatment documentation is appropriately transitioned to the physician responsible for the patient's ongoing care, as well as to the patient, to ensure safe and timely care coordination and care continuity post-treatment. If the referring PGP and RO participant are using the same EHR, appropriate communication must still occur with the patient, and referring PGP as appropriate, in order to meet the criteria for the measure numerator.

After consideration of the comments we received, we are finalizing as proposed to include the Treatment Summary Communication—Radiation Oncology as a pay-for-reporting measure beginning in PY1.

(5) CAHPS® Cancer Care Survey for Radiation Therapy

We proposed to have a CMS-approved contractor administer the *CAHPS® Cancer Care Survey for Radiation Therapy* (''CAHPS® Cancer Care Survey''), beginning April 1, 2020 and ending in 2025, to account for episodes that were completed in the last quarter of 2024 (84 FR 32517). We would use the CAHPS® Cancer Care Survey for inclusion in the Model as it is appropriate and specific to patient experience of care within an RO episode. Variations of the CAHPS® survey are widely used measures of patient satisfaction and experience of care and are responsive to the increasing shift toward incorporation of patient experience into quality measurement and pay-for-performance programs. Variations of the CAHPS® survey have been used within the PCHQR Program, Hospital OQR Program, MIPS, OCM, and others, making considerations regarding data collection reasonably well-established.

As we indicated in the proposed rule, we plan to propose a set of patient experience domains based on the CAHPS® Cancer Care Survey, which would be included in the AQS as pay-for-performance measures beginning in PY3, in future rulemaking.

The CAHPS® Cancer Care Survey proposed for inclusion in the RO Model may be found at *https://www.ahrq.gov/cahps/surveys-guidance/cancer/index.html.*

We solicited public comment on our proposal to administer the CAHPS® Cancer Care Survey for Radiation Therapy for purposes of testing the RO Model.

Comment: A couple of commenters recommended CMS implement the CAHPS® Cancer Care Survey in the Model earlier than PY3 due to the importance of collecting patient experience data to inform clinical care.

Response: We appreciate commenter's recommendations and agree with sentiment that collecting patient experience data is critical. We will begin fielding the CAHPS® Cancer Care Survey in PY1. The inclusion of patient experience measures in the calculation of the AQS will not begin until PY3, after future rulemaking, due to the time needed to derive and test which domains should be included in the AQS using data collected from the early years of the Model.

Comment: A few commenters requested clarification regarding who would administer the CAHPS® Cancer Care Survey. These commenters also expressed concern that the RO participant would have to bear the administrative and financial cost of fielding the survey.

Response: We would like to clarify that CMS will be accountable for fielding the CAHPS® Cancer Care Survey to RO beneficiaries. RO participants should not experience any additional cost as a result of implementation of the survey.

Comment: Several commenters did not support adopting, or recommended delaying implementation of, the CAHPS® Cancer Care Survey. A commenter asserted the timing of implementation of the RO Model would not allow participants enough time to prepare for fielding the survey. Another commenter stated the lack of current benchmarks would make it difficult to incorporate the measure into the AQS at PY3, and recommended delaying until PY4. A third commenter suggested CMS pilot the CAHPS® Cancer Care Survey before including it as a measure in the AQS. Some commenters did not support adopting the CAHPS® Cancer Care Survey because they believe that it does not elicit meaningful data from patients. The commenters argued that: (1) The time lag between when a patient finishes a course of radiotherapy and when they receive the CAHPS® Cancer Care Survey makes it challenging to remember the specifics of their care experience; (2) the multi-disciplinary nature of oncology care, including RT services, makes it difficult for patients to tease out their specific RT experience; (3) the length of the survey and current administration modes (by mail or telephone, with no electronic option) is overwhelming to patients; (4) the mail or phone nature of fielding CAHPS® has the potential to be viewed by patients as a scam; and (5) the burden on patients who have to fill out multiple surveys, which may create timing issues for RO participants to comply with RO Model deadlines.

Response: We acknowledge there are significant challenges to implementing patient experience measures in any model or program; however, those challenges should not preclude making the effort to collect and analyze data on the patient experience, to achieve the ultimate goal of improving patient care. We note that AHRQ has tested the survey for reliability and validity to address issues of comparability across practices and patient characteristics. As such, we do not believe it is necessary to implement a pilot period prior to including this survey as a part of the AQS. Further, we reiterate that the CAHPS® Cancer Care Survey be fielded starting in PY1 but not included in the AQS methodology as a pay-for-reporting measure until PY3, after future rulemaking. Finally, we do not believe a delay in implementation to help RO participants prepare for fielding the survey is needed, given that CMS will administer the survey.

Comment: Some commenters expressed concern with the use of the CAHPS® Cancer Care Survey for other methodological reasons, including: (1) The survey is not endorsed by NQF; (2) lack of sufficient testing of the survey to ensure comparability of performance scores based on practice size and type, patient characteristics, and/or geographic regions; (3) the need to harmonize the survey with the CAHPS® Hospice survey; (4) the lack of a strategy for ensuring that RO beneficiaries do not

receive both surveys during what is already a stressful and anxious time; (5) inherent biases against HOPDs that may be found in patient experience surveys, due to HOPDs often having fewer resources for staffing, capital, and amenities compared to PGPs and free standing radiation therapy centers, which may correlate with lower patient experience scores; and (6) potential overlap in the CAHPS® Cancer Care Survey and the Outpatient and Ambulatory Surgery (OAS) CAHPS® survey, which could negatively affecting response rates for either or both survey(s). A commenter recommended that CMS investigate electronic modes of fielding the CAHPS® Cancer Care Survey.

Response: We appreciate commenters sharing their methodological concerns and acknowledge that collecting patient experience data is a challenging effort. We will consider these comments as we implement the Model and begin reviewing the survey data, and where necessary, we will seek to address them in future rulemaking. Regarding NQF endorsement, we agree that NQF endorsement is an important, but not the sole, criterion for identifying measures for implementation. Regarding testing the survey in the Model, AHRQ has tested the survey for reliability and validity to address issues of comparability across practices and patient characteristics.

We will begin administering the survey in PY1 for baseline data collection, to set appropriate benchmarks, and to identify other methodological issues such as effects of overlap with OAS CAHPS® on the response rate. We plan to propose via rulemaking a set of patient experience domains based on the CAHPS® Cancer Care Survey, which would be included in the AQS as pay-for-performance measures beginning in PY3. Information on the established benchmarks will be made available on the RO Model website. Regarding survey mode(s) and administration, CMS will be responsible for survey administration to beneficiaries in the RO Model and will ensure survey methods are consistent with the CAHPS® specifications, including potential overlap with other CAHPS® surveys. CMS will field the survey as specified to ensure reliability and validity of survey response data. Further information about the survey development, testing, and fielding can be found on the survey website.[69] We note that the version of the CAHPS® Cancer Care Survey that will be used was specifically developed for radiation therapy, which we believe addresses the commenter's concern about being able to appropriately consider RT care experiences.

Comment: A few commenters suggested creating a new patient experience measure to replace the use of the CAHPS® Cancer Care Survey. A commenter suggested that the patient experience measure should be developed in a way that eliminates bias against HOPDs, which the commenter says often have a less favorable payer mix than PGPs and freestanding radiation therapy centers. Another commenter noted that while patient experience measures are good indicators of whether and how changes are being implemented in care, an actual patient experience measure that reflects the RO Model should be developed at an accelerated pace.

Response: We agree that innovation in the collection of patient experience data is important to pursue, and we welcome advancements in this area. However, we also believe that the need to understand patients' experiences of care is critical, and cannot be delayed while other measures are being developed. For these reasons, we are finalizing adoption of the CAHPS® Cancer Care Survey and will continue to evaluate new measures of patient experience for future consideration.

After reviewing the comments received on our proposed quality measures, we are finalizing, with one modification in regard to the start date, our proposal to include a set of four quality measures for PY1. Instead of submitting quality measures data beginning in March, 2021, as proposed, RO participants will submit data beginning in March, 2022, based on RO episodes in PY1 (January 1, 2021, through December 31, 2021), consistent with other changes to the timing of Model implementation. We are also finalizing our proposal to have a CMS-approved contractor administer the CAHPS® Cancer Care Survey for Radiation Therapy, with a modification that the survey will be administered beginning in April 2021 rather than in 2020.

c. Form, Manner, and Timing for Quality Measure Data Reporting

We proposed to use the following data collection processes for the four quality measures described in section III.C.8.b(1) through (4) of this final rule beginning in PY1 (84 FR 34517).

First, we proposed requiring Professional participants and Dual participants to report aggregated quality measure data, instead of beneficiary-level quality measure data. These data would be used to calculate the participants' quality performance, as discussed in section III.C.8.f(1) of the proposed rule (84 FR 34519) and this final rule, and subsequent quality reconciliation payments on an annual basis.

Second, we proposed requiring that quality measure data be reported for all applicable patients (that is, not just Medicare beneficiaries or beneficiaries with episodes under the Model) based on the numerator and denominator specifications for each measure (84 FR 34517). As proposed, we believe collecting data for all patients who meet the denominator specifications for each measure from a Professional participant or Dual participant, and not just Medicare beneficiaries, is appropriate because it is consistent with the applicable measure specifications, and any segmentation to solely the Medicare populations would be inconsistent with the measure and add substantial reporting burden to RO participants. If a measure is already reported in another program, then the measure data would be submitted to that program's reporting mechanism in a form, manner, and at a time consistent with the other program's requirements, and separately submitted to the RO Model secure data portal in the form, manner and at the time consistent with the RO Model requirements.

As proposed, similar to the approach taken for the QPP,[70] the RO Model would not score measures for a given Professional participant or Dual participant that does not have at least 20 applicable cases according to each measure's specifications. However, unlike the Quality Payment Program, if measures do not have at least 20 applicable cases for the participant, we would not require the measures to be reported. In this situation, an RO participant would enter ''N/A-insufficient cases'' to note that an insufficient number of cases exists for a given measure.

As proposed, we would provide Professional participants and Dual participants with a mechanism to input quality measure data. We would create a template for Professional participants and Dual participants to complete with the specified numerator and denominator for each quality measure (and the number of cases excluded and exempt from the denominator, as per measure specifications' exclusions and exemptions allowances), provide a secure portal, the RO Model secure data

[69] CAHPS® Cancer Care Survey. *https://www.ahrq.gov/cahps/surveys-guidance/cancer/index.html.*

[70] 42 CFR 414.1380(b)(1)(iii).

portal, for data submission, and provide education and outreach on how to use these mechanisms for data collection and where to submit the data prior to the first data submission period.

We proposed that Professional participants and Dual participants would be required to submit quality measure data annually by March 31 following the end of the previous PY to the RO Model secure data portal (84 FR 34518). In developing the March 31 deadline, we considered the quality measure reporting deadlines of other CMS programs in conjunction with the needs of the Model. For PY1, participants will submit quality measure data for the time period noted in the measure specifications. We stated if a measure is calculated on an annual CY basis, participants would not be required to adjust the reporting period to reflect the model time period. We stated that alignment to the measure specifications used in MIPS would likely reduce measure reporting burden for RO participants. RO participants would submit measure data based on the individual measure specifications set forth in sections III.C.8.b(1) through (4), unless CMS were to specify different individual measure specifications. RO Model measure submissions would only satisfy the RO Model requirements. Measures submitted to any other CMS program would need to continue to be made in accordance with that program's requirements unless specifically noted. A schedule for data submission would be posted on the RO Model website: *https://innovation.cms.gov/initiatives/radiation-oncology-model/*.

We proposed to determine that Professional participants and Dual participants successfully collected and submitted quality measure data if the data are accepted in the RO Model secure data portal. Failure to submit quality measure data within the previously discussed requirements would impact the RO participant's AQS, as discussed in section III.C.8.f of the proposed rule (84 FR 34519) and this final rule.

We proposed that the CAHPS® Cancer Care Survey for Radiation Therapy would be administered by a CMS contractor according to the guidelines set forth in the survey administration guide or otherwise specified by CMS. Prior to the first administration of the survey, we would perform education and outreach so RO participants will have the opportunity to become more familiar with the CAHPS® Cancer Care Survey process and ask any questions.

The following is a summary of public comments received and our response:

Comment: Several commenters recommended that CMS pay for RO participants to establish quality data reporting because of the potential for high costs required to collect and report Model quality metrics. A couple of commenters drew comparison to OCM, which the commenters stated included additional payment for collecting quality data. A commenter suggested that CMS could assist with reporting cost by adding a patient management fee.

Response: We thank the commenters for their suggestions. We note that the OCM does not include a payment to participants to collect quality data. To the extent that commenters may be referring to the Monthly Enhanced Oncology Services (MEOS) payment, we note that this payment is for the provision of Enhanced Services, as defined in the OCM Participation Agreement, to OCM Beneficiaries. We would also clarify that CMS will be paying for the administration of the CAHPS® Cancer Care Survey and RO participants will not have additional costs for the survey. We do not believe additional payments or an additional patient management fee are warranted at this time.

Comment: A commenter supported CMS' proposal to align the RO Model with other quality reporting programs and require at least 20 applicable cases according to each measure's specification for scoring purposes.

Response: We thank the commenter for their support.

Comment: A few commenters requested clarity on how participants will report aggregated quality measure data and whether the RO Model secure data portal will function similarly to the MIPS portal.

Response: RO participants will be required to report aggregated numerator and denominator data, not individual patient-level data, for all patients as defined in the measure specifications. The process for submitting data through the RO Model secure data portal will be provided via technical support and education efforts that take place following the final rule publication. We intend to announce the availability of these support and education opportunities on the RO Model website.

Comment: A commenter requested more information on the quality measure and clinical data elements template, and noted that use of a template will increase staff time, practice overhead costs, and because these data elements may not be discrete fields within the EHR, someone may have to transcribe information out of the medical record for submission in either electronic form, or via a template.

Response: We will provide education and outreach to help RO participants understand the quality measures and clinical data elements collection and submission systems, including the template. As discussed in section III.C.8.b, based on stakeholder feedback, we are finalizing the collection of quality measures data beginning in PY1 (January 1, 2021) with the first submission due in March 2022, so RO participants will have additional time to become familiar with the template. As discussed in section III.C.8.e, based on stakeholder feedback, we are finalizing the collection of clinical data elements beginning in PY1 (January 1, 2021) with the first submission due in July 2021. We also note that we plan to provide the final list of clinical data elements on the RO Model website prior to the start of PY1, and provide similar education and outreach. We are committed to working with EHR vendors to facilitate data collection for quality measures and clinical data element.

Comment: A couple of commenters urged CMS to consider allowing practices to use relevant third parties for data collection and reporting, as it does in other quality reporting programs.

Response: We intend to provide additional information about the submission of data, prior to the PY1 data reporting start date on the RO Model website. This information will include whether we find it would be appropriate to permit third-party data submission.

Comment: Many commenters opposed the inclusion of all patients in the measure collection, asserting the Model's quality measure requirements should only include Medicare patients. Several of these commenters noted that including all patients is outside the scope of the Model. Others stated including non-Medicare patients will create additional labor and require additional electronic health record (EHR) updates and, if those updates are not successful, that RO participant will have to provide manual collection and reporting, which they argue is unduly burdensome, especially on mid-size and smaller practices. A couple of commenters expressed concern that reporting data on non-Medicare beneficiaries may result in a violation of privacy.

Response: We are requiring RO participants to report aggregated numerator and denominator data, not individual patient-level data, for all patients as defined in the measure specifications in the manner consistent with the quality measure specifications,

and not just Medicare patients. It is important that the Model collect measures in the manner specified to ensure submission consistency, and reliability of the data to comport with how the measure is currently specified and implemented in MIPS and other quality initiatives. In addition, there is inherent value to including all patients, regardless of payer type, when assessing quality. We believe a policy of submitting aggregated quality measure information in a manner consistent with the measure specifications is not a violation of patient privacy because it does not include the sharing of personally identifiable information. Further, this is consistent with data submission policy in MIPS. Finally, aggregated data can provide valuable population-level perspective on the quality of care delivery.

Comment: A few commenters opposed the proposal to use a separate portal and a new website for data collection and quality measure reporting for measures already submitted to CMS, stating this would create additional operational burden for providers and suppliers. Other commenters expressed concern about the burden, and the potentially significant programming changes required, if RO Model measures were separated from MIPS, and if hospitals were not developing similar systems. Commenters encouraged CMS to simplify quality reporting by using the current quality reporting mechanisms instead of creating yet another process for reporting quality data. A commenter requested clarification on whether quality measure reporting could come from clinical pathways and/or Clinical Decision Support (CDS) systems.

Response: We appreciate the concern regarding establishment of a new infrastructure specific to this model. However, because the RO Model reaches across three different care settings, operational considerations necessitate the creation of one portal that all entities can use. The process for submitting data through the RO Model secure data portal will be provided via technical support and education efforts that take place following the final rule publication, so all RO participants have time to become familiar with the infrastructure and processes prior to required reporting. In addition, we note that the RO Model secure data portal will serve not only as a data submission system, but also as the portal for RO participants to access claims data that they can request through the Model.

Comment: Several commenters opposed the Model's reporting requirements and suggested they be reduced or not finalized because they believe the requirements constitute significant new administrative and financial burdens on providers and suppliers, especially on small providers and suppliers. A couple of commenters urged CMS to carefully consider the burden associated with quality and clinical data collection requirements, and ensure that only the most meaningful and least burdensome information is collected. Commenters noted that RO participants will be spending a significant amount of time and resources shifting their business models to the new alternative payment model.

Response: As part of the Meaningful Measures Initiative, we are committed to quality priorities that align CMS' strategic goals and individual measures and initiatives that demonstrate that quality for our beneficiaries is being achieved. The quality measures chosen for the RO Model address concrete quality topics, which reflect core issues that are important to ensuring high quality care and better patient outcomes during RT treatment. We acknowledge the burden that reporting places on RO participants, and we seek to reduce unnecessary burden, to increase efficiencies, and to improve the beneficiary experience in alignment with the *Patients Over Paperwork Initiative*.[71] We believe the quality measures selected for inclusion in the RO Model balance both the importance of quality measurement and the concerns regarding burden as we strive to select the most parsimonious measure set to ensure quality and support RO Model compliance with other concurrent programs, including MIPs and QPP. Finally, for those practices that have concerns about burden in relation to their volume of radiotherapy patients, we note that the Model includes a low volume opt-out option, described in detail in section III.C.3.c.

Comment: A commenter was supportive of the proposal to not require that measures be submitted via CEHRT.

Response: We appreciate the commenter's support.

Comment: A few commenters recommended that all of the Model's quality measures be scoped as eCQMs so RO participants can use the certified EHR in which they have already invested, instead of utilizing a third-party registry or reverting to claims-based measurement. A commenter strongly rejected any non-eCQMs because of its belief that registry-based measures will significantly increase the burden associated with quality reporting by forcing providers and suppliers to utilize a third-party registry at costs over and above previous investments in EHRs.

Response: We are using the registry specifications for the measures in the RO Model because they are the most widely used method of data submission, which will enable more participants to submit data with the least impact on workflow. Additionally, we believe the data from registry measures are both highly reliable and valid. Further, we agree that eCQMs and CEHRT are valuable tools to help provide patient-centric care and we plan to provide structured data reporting standards so that existing EHRs can be adjusted if necessary in anticipation of the RO Model. Some EHRs may support data extraction, reducing any additional reporting burden on RO participants, which may increase the quality and volume of reporting. We also believe that it is important that RO participants have the option to extract the necessary data elements manually to ensure all RO participants are able to submit the required data.

Comment: A commenter opposed submitting registry-based measures, noting it would stymie CMS' move toward interoperability and electronic end-to-end reporting. The commenter argued that it would require new workflows that will need to be developed in order to accurately attribute patients to the Model from multiple outpatient sites that are not historically attached to our electronic data base.

Response: While we remain committed to moving towards increased interoperability and electronic reporting, we are using the registry specifications for measures in the RO Model because registry data is the most widely used type of data submission tool, which will enable more RO participants to submit data with least impact on workflow. We note that while the data collected via registries are considered reliable and valid, we are not requiring that RO participants utilize a registry data system to satisfy data submission to CMS. The Model will implement this measure based on the specifications used in MIPS, that is, registry data. Additionally, we are not asking RO participants to attribute patients; participants will report aggregate performance, consistent with the measure specifications.

Comment: A few commenters supported the use of EHRs but expressed concern with the feasibility of EHR development in accordance with the Model start date. These commenters

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

asserted their belief that it is unlikely that many, if any, EHR vendors will have adequate time to make meaningful changes to the EHR to reduce the reporting burden on RO participants. Commenters further stated EHR vendors must assess their priorities and planned projects to accommodate the timing of CMS models, and noted this requirement would impact planning because participants must financially plan for the likely significant charges to upgrade current systems, or to plan for new systems, putting them at significant financial risk. These commenters therefore requested CMS delay implementation of this requirement until vendors have enough time to implement and upgrade current systems.

Response: We appreciate commenter's concerns regarding the feasibility of EHR development in accordance with the Model start date. Continued EHR development is an important part of our ongoing effort to support electronic health record data. The Model performance period begins on January 1, 2021, which means the first submission of clinical data elements will not occur until July of 2021 (this submission timeframe is different than that for submitting quality measures, which occurs in March following a PY). This will allow RO participants additional time to work with EHR vendors to develop appropriate fields. We will also provide which clinical data elements are included in the RO Model on the RO Model website and will provide those reporting standards to EHR vendors and the radiation oncology specialty societies prior to their inclusion in the Model. Our goal is to structure data reporting standards so that existing EHRs could be adjusted, if necessary, in anticipation of the measure and clinical date element requirements. Additionally, we note that RO participants will continue to have the option to extract the necessary data elements manually.

After consideration of the commenters' feedback, we are finalizing our proposals for the data collection processes for the four quality measures described in section III.C.8.b(1) through (4) of this final rule beginning in PY1 with the first annual submission in March 2022 and continuing thereafter. The process for submitting data through the RO Model secure data portal will be provided via technical support and education efforts that take place following the final rule publication. We intend to announce the availability of these support and education opportunities on the RO Model website.

d. Maintenance of Technical Specifications for Quality Measures

As part of its regular maintenance process for NQF-endorsed performance measures, NQF requires measure stewards to submit annual measure maintenance updates and undergo Maintenance of Endorsement review every three years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes with NQF on an annual basis. NQF solicits information from measure stewards for annual reviews, and reviews measures for continued endorsement in a specific three-year cycle. We noted in the proposed rule that NQF's annual and/or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to the measures. Additionally, as described in the proposed rule, the Model includes measures that are not NQF-endorsed, but we anticipate they would similarly require non-substantive technical updates to remain current.

We received no comments on this proposal and therefore are finalizing this policy as proposed.

e. Clinical Data Collection

We proposed to collect clinical information on certain RO beneficiaries included in the Model from Professional participants and Dual participants that furnish the PC of an episode for use in the RO Model's pay-for-reporting approach and for monitoring and compliance, which we discussed more fully in sections III.C.8.f(1) and III.C.14 of the proposed rule (84 FR 34519; 84 FR 34531) and this final rule. As proposed (84 FR 34518), on a pay-for-reporting basis, we would require Professional participants and Dual participants to report basic clinical information not available in claims or captured in the quality measures, such as cancer stage, disease involvement, treatment intent, and specific treatment plan information, on RO beneficiaries treated for five types of cancer under the Model: (1) Prostate; (2) breast; (3) lung; (4) bone metastases; and (5) brain metastases, which we proposed to require as part of § 512.275. We would determine the specific data elements and reporting standards prior to PY1 of the Model and would communicate them on the Model website. In addition, as we described in the proposed rule, we proposed to provide education, outreach, and technical assistance in advance of this reporting requirement.

We believe this information is necessary to achieve the Model's goals of eliminating unnecessary or low-value care. We have also heard from many stakeholders that they believe incorporating clinical data is important for developing accurate episode prices and understanding the details of care furnished during the episode that are not available in administrative data sources. As proposed, we would use these data to support clinical monitoring and evaluation of the RO Model. These data may also be used to inform future refinements to the Model. We also proposed that we may also use it to begin developing and testing new radiation oncology-specific quality measures during the Model.

To facilitate data collection, we proposed to share the clinical data elements and reporting standards with EHR vendors and the radiation oncology specialty societies prior to the start of the Model. Our goal is to structure data reporting standards so that existing EHRs could be adjusted in anticipation of this Model. Such changes could allow for seamless data extraction, reduce the additional reporting burden on providers and suppliers, and may increase the quality of reported data. Providers and suppliers may also opt to extract the necessary data elements manually. All Professional participants and Dual participants with RO beneficiaries treated for the five cancer types, as previously listed, would be required to report clinical data through the RO Model secure data portal. We would create a template for RO participants to complete with the specified clinical data elements, provide a secure RO Model secure data portal for data submission, and provide education and outreach on how to use these mechanisms for data collection and where to submit the data prior to the first data submission period.

We also proposed to establish reporting standards. All Professional and Dual participants would be required to submit clinical data twice a year, in July and January,[72] each PY for RO beneficiaries with the applicable cancer types that completed their 90-day RO episode within the previous 6 months. This would be in addition to the submission of quality measure data as described in section III.C.8.c of the proposed rule (84 FR 34519).

We solicited specific comment and feedback on the five cancer types for

[72] We are clarifying that the first submission for PY1 would be made in July of PY1 and the second submission for clinical data for PY1 would be made in January of PY2. The submission schedule for the following PYs would be similar and the final submission for PY5 would occur in January 2026.

which we proposed to collect clinical data, which data elements should be captured for the five cancer types, and potential barriers to collecting data of this type. The following is a summary of the public comments received and our response.

Comment: A couple of commenters supported the collection of clinical data elements because it would require Professional participants and Dual participants to report basic clinical information not available in claims or captured in the proposed quality measures, which the commenters believe will encourage better care. Another commenter supported tracking data on clinical care because it improves patients care.

Response: We thank commenters for supporting our proposal to collect information on clinical data elements.

Comment: A few commenters responded to our request for comments on clinical data elements reporting. A commenter recommended that CMS only request clinical data elements that guide treatment decisions. Another commenter recommended including only the most clinically relevant information. Some commenters provided suggestions for the following clinical data elements: Clinical treatment plan; therapeutic status; elements that would align with the Surveillance, Epidemiology, and End Results (SEER) cancer database; the results of Prostate-Specific Antigen (PSA) tests; information related to the American Joint Committee on Cancer (AJCC) staging system and the histology of the malignancy for lung, breast and prostate; ''D'Amico'' or the National Comprehensive Cancer Network (NCCN) risk grouping; site of the lesion information; existence, and number, of metastases; patient performance status submitted (Karnofsky Performance Status or Eastern Cooperative Oncology Group (ECOG) status); and information relating to whether medical physicists have reviewed the chart. Other commenters recommended collecting data on RO participants' use of standardized clinical pathways and/or CDS and whether the treatment is curative, palliative, or benign. A commenter recommended including the reporting of site of treatment, dose specification (for example, ''95 percent of specified dose to 95 percent of the planning treatment volume'') and number of fractions as clinical data elements. Other commenters suggested that clinical and staging data elements should be collected for complete RO episodes and original primary cancer type for brain and bone metastases.

Response: We thank commenters for their suggestions. We will review each suggestion carefully as we consider which clinical data elements to include as part of the RO Model.

Comment: A few commenters opposed all clinical data reporting requirements. Some commenters opposed the clinical data elements because of the perceived financial burden, noting that without structured EHR fields to report, participants have increased burden to report the measures manually or through a registry, without significant benefit to patients. One of these commenters also expressed concern with the lack of information about how CMS would use this data. Another commenter argued that CMS should only require clinical data submissions once it commits to incorporating those data into payment rates' risk adjustments.

Other commenters urged CMS to carefully weigh the necessary and appropriate uses for the data against the significant time, effort, and administrative burden required in order to report those data. Another commenter opposed clinical data elements reporting because it believes the reporting would be uncompensated and reduce productivity. Another commenter strongly opposed the collection of clinical data elements because the commenter believes much of the clinical data element information that CMS is considering is already available in Surveillance, Epidemiology, and End Results (SEER) Incidence Data.

Response: We believe that collecting clinical data elements for use in the RO Model is necessary to achieve the Model's goals of supporting evidence-based care. We appreciate the recommendation that the Model align with the SEER Incidence Database, however we believe that the geographic areas captured by SEER do not align with the RO Model CBSAs. We have heard from many stakeholders that they believe incorporating clinical data is important for developing accurate episode prices and understanding the details of care furnished during an RO episode that are not available in administrative data sources, specifically claims. We will use these data to support clinical monitoring and evaluation of the RO Model. These data may also be used to inform future refinements to the Model. We may also use it to begin developing and testing new radiation oncology-specific quality measures during the Model. In keeping with our goal of reducing burden, we intend to align with other federal programs to the greatest extent practicable while continuing to collect meaningful and parsimonious data sets.

Comment: A few commenters expressed concern about requiring the reporting of clinical data elements for patients not participating in Medicare. One was concerned that such reporting could impose significant administrative burdens on RO participants in order to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA).

Response: We would like to clarify that while quality measures used in the RO Model will include non-Medicare beneficiary data collected in the aggregate, we intend only to require clinical elements data reporting for Medicare beneficiaries in the Model (RO beneficiaries).

Comment: Several commenters recommended delaying or phasing-in the implementation of the clinical data requirement until the data can be submitted by all RO participants in a useful and meaningful way. A few commenters urged CMS to delay the quality reporting requirements for the Model for at least six months, while another requested 18 months, asserting the lack of granularity in the proposed rule will prevent vendors from updating reporting specifications. A couple of commenters recommended delaying clinical data element collection until PY2.

Response: We thank the commenters for their suggestions on either delaying or phasing in the implementation of the clinical data elements requirement. As discussed in section III.C.1 we are finalizing the Model performance period to begin January 1, 2021, and publishing the final rule several months in advance of this start date, in order to provide RO participants with sufficient time to prepare for their inclusion in the Model. During this time, we plan to provide the clinical data elements on the RO Model website and provide education and outreach support to encourage the efficient collection and submission of this data. We believe finalizing the Model performance period to begin on January 1, 2021, will allow RO participants time to develop best practices to facilitate their data collection, and work with EHR vendors to seek additional EHR support as needed.

Comment: Several commenters urged CMS to consider the HL7® FHIR®-based mCODE™ (Minimal Common Oncology Data Elements) to collect and assemble a core set of structured data elements for oncology EHRs. Commenters recommended mCODE™ based on their belief that the use of mCODE™ would structure data reporting standards so

that existing EHRs could be adjusted in anticipation of this Model, which would allow better data extraction and reduce the additional reporting burden on providers and suppliers, and may increase the quality of reporting and their belief that clinical data elements considered by mCODE™ would address CMS' goal of collecting meaningful clinical data elements information. Another commenter recommended HL7® more generally because of its belief that it would reduce duplicative entries and reduce errors.

Response: Participants will be required to report clinical data through the RO Model secure data portal at the time and in a manner specified by CMS. While we are aware of HL7® mCODE™, we are not confident that it will be immediately accessible to the full breadth of RO participants due to technical requirements of HL7® and it may not be feasible to test and implement by the beginning of the Model performance period; therefore, we believe that our RO Model secure data portal will provide the easiest, most accessible access for most RO participants. We continue to monitor developments in EHR and interoperability. We also continue to engage with health care providers and EHR vendors to align the information about the most meaningful clinical data elements to include in the RO Model, and ensure that the greatest number of RO participants can implement the data collection process with the least amount of burden.

Comment: A commenter strongly urged CMS to encourage implementation of bidirectional data flow between the applicable clinical pathways and/or CDS systems, and the EHR, which it believes would reduce duplicative data entry and time-intensive information searches by the physician when a data element is already present in the EHR.

Response: We thank the commenter for their suggestion and support the improvement of reporting pathways. We encourage RO participants to explore efficiencies within their EHR systems and other data platforms; however, we do not wish to prescribe EHR requirements to participants and vendors.

Comment: A couple of commenters encouraged CMS to partner with the Office of the National Coordinator for Health Information Technology (ONC) to require that certified EHRs store and transmit a minimum set of oncology data elements, which would allow their use under current and future Innovation Center models. Another commenter requested clarification regarding the applicability of the ONC 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rule and expressed concern that while vendors have to comply with federal regulations, they could pass these costs to physicians.[73]

Response: We believe advancing interoperability is an important step in healthcare quality improvement and that putting patients at the center of their health care and ensuring they have access to their health information is highly desirable. We are committed to working with the ONC to address interoperability issues and achieve complete access to health information for patients in the health care system. We will continue to work with ONC and other federal partners toward interoperability and the secure and timely exchange of health information with the clear objectives to improve patient access and care, alleviate health care provider burden, and reduce overall health care costs while considering provider and supplier costs. We will also assess opportunities to coordinate on a minimum set of oncology data elements. Finally, we appreciate and understand the concern that EHR vendors may pass some of the costs of regulatory compliance on to the physicians; however, we believe that is it possible that most of the information requested will already be included as part of the EHR and will provide valuable information to RT providers and RT suppliers.

Comment: A few commenters recommended that CMS should narrow the focus and use of clinical data required for reporting and ensure that all required data elements are consistently documented in structured and discrete fields, and further asserted CMS should not require the submission of any data elements that are not captured in structured fields by most major EHR vendors. These commenters urged CMS to work with EHR vendors prior to the Model start date to establish structured fields for all mandatory reporting requirements.

Response: As we review which clinical data elements are appropriate for inclusion in the RO Model, we will consider which clinical data elements are already documented and available in the structured and discrete fields of the EHR; however, availability in the EHR will not be the sole consideration in determining which clinical data elements to include because we believe that the highest priority with respect to any clinical data elements collected is that they inform our understanding of RT services, and this priority should not be limited to clinical data elements that are already collected. CMS will notify participants via the RO Model website prior to the start of PY1 about which clinical data elements will be included in the Model. RO participants will be required to report clinical data through the RO Model secure data portal.

Comment: A couple of commenters recommended that CMS establish reporting standards and timelines that provide enough time for EHR vendors to implement corresponding report updates that enable discrete capture, and for RO participants to collect complete and accurate clinical data.

Response: We plan to share the proposed clinical data elements and procedural instructions for reporting information at a time and manner specified by CMS with EHR vendors and the radiation oncology specialty societies prior to the start of PY1. Our goal is to structure data reporting so that existing EHRs could be adjusted in anticipation of the RO Model. Such changes could allow for seamless data extraction and reduce the additional reporting burden on RO participants, and may increase the quality of reporting.

Comment: A commenter appreciated the decision that CMS share the planned elements, and procedures for reporting them, with EHR vendors and radiation oncology specialty societies, and requested that CMS also share this information with oncology clinical pathways developers. This commenter encouraged CMS to consider taking clinical pathway extracts of these data to satisfy requisite reporting.

Response: We thank the commenter for the suggestion that CMS consider allowing the submission of clinical pathway extracts of data elements to satisfy this aspect of the reporting requirements. In the process of determining the clinical data elements, CMS will conduct outreach with multiple stakeholders, including oncology clinical pathways developers. However, we do not believe that only using the clinical pathways is a feasible way to collect clinical data elements information across all RO participants at this time. In the future, we will consider ways to integrate clinical pathways into the clinical data element collection process.

After considering public comments, we are finalizing at § 512.275(c) the proposal to collect basic clinical information not available in claims or

[73] *https://www.federalregister.gov/documents/2019/04/23/2019-08178/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification.*

captured in the quality measures, describing cancer stage, disease characteristics, treatment intent, and specific treatment plan information, on RO beneficiaries treated for five types of cancer under the Model: (1) Prostate; (2) breast; (3) lung; (4) bone metastases; and (5) brain metastases. We will determine the specific data elements prior to PY1 of the Model and will communicate them on the RO Model website, with data collection starting in PY1.

We are also clarifying that clinical data will be submitted to CMS consistent with the instructions for reporting such as at the time and manner specified by CMS. We have modified the text of the regulation at § 512.275(c) to clarify that paragraph (c) applies to the reporting of quality measures and clinical data elements and that such reporting is in addition to the reporting described in other sections of this rule. We have also modified the regulatory text at § 512.275(c) such that the list of clinical data element categories we proposed in the proposed rule (that is, cancer stage, disease characteristics, treatment intent, and specific treatment plan information on beneficiaries treated for specific cancer types) is an exhaustive list.

Table 11 includes the four RO Model quality measures and CAHPS® Cancer Care Survey, the level at which measures will be reported, and the measures' status as pay-for-reporting or pay-for-performance, as described in section III.C.8.b of this final rule. The table also includes the RO Model clinical data elements collection, and years, also documented in section III.C.8.e of this final rule.

TABLE 11. RO PARTICIPANT QUALITY MEASURE, CLINICAL DATA, AND PATIENT EXPERIENCE SUBMISSION REQUIREMENTS

RO Participant Data Submission Requirements	Level of Reporting	Pay-for Reporting	Pay-for-Performance
1. Oncology: Medical and Radiation - Plan of Care for Pain- NQF #0383; CMS Quality ID #144	Aggregate	N/A	PYs 1-5
2. Preventive Care and Screening: Screening for Depression and Follow-Up Plan- NQF #0418; CMS Quality ID #134	Aggregate	N/A	PYs 1-5
3. Advance Care Plan- NQF #0326; CMS Quality ID #047	Aggregate	N/A	PYs 1-5
4. Treatment Summary Communication – Radiation Oncology	Aggregate	PYs 1-2	PYs 3-5
5. CAHPS® Cancer Care Survey	N/A: Patient-Reported	N/A	PYs 3-5
Clinical Data Elements	Beneficiary-Level	PYs 1-5	N/A

f. Connect Performance on Quality Measures to Payment

(1) Calculation for the Aggregate Quality Score

We proposed that the AQS would be based on each Professional participants and Dual participant's: (1) Performance on the set of evidenced-based quality measures in section III.C.8.b of the proposed rule (84 FR 34515 through 34517) and this final rule compared to those measures' quality performance benchmarks; (2) reporting of data for the pay-for-reporting measures (those without established performance benchmarks) in section III.C.8.b(4) of the proposed rule (84 FR 34515 through 34517) and this final rule; and (3) reporting of clinical data elements on applicable RO beneficiaries in section III.C.8.e of the proposed rule (84 FR 34518) and this final rule.

A measure's quality performance benchmark is the performance rate a Professional participant or Dual participant must achieve to earn quality points for each measure in section III.C.8.b.[74] We believe a Professional participant's or Dual participant's performance on these quality measures, as well as successful reporting of pay-for-reporting measures and clinical data elements, would appropriately assess the quality of care provided by the Professional participant or Dual participant.

Given the importance of clinical data for monitoring and evaluation of the RO Model, and the potential to use the data for model refinements or quality measure development, we proposed to weight 50 percent of the AQS on the successful reporting of required clinical data and the other 50 percent of the AQS on quality measure reporting and, where applicable, performance on those measures. Mathematically, this weighting would be expressed as follows:

Aggregate Quality Score = Quality measures (0 to 50 points based on weighted measure scores and reporting) + Clinical data (50 points

[74] Benchmarks will be based on existing MIPS benchmarks, or other national benchmark where available. For measures without existing benchmarks, we plan to develop our own benchmarks.

when data is submitted for ≥95% of applicable RO beneficiaries)

We proposed that quality measures would be scored as pay-for-performance or pay-for-reporting, depending on whether established benchmarks exist, as stated in section III.C.8 of this rule. To score measures as pay-for-performance, each Professional participant's and Dual participant's performance rates on each measure would be compared against applicable MIPS program benchmarks, where such benchmarks are available for the measures. We proposed to select the measures as pay-for-performance for PY1 from the list of MIPS quality measures: (1) Advance Care Plan; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; (3) Oncology: Medical and Radiation—Plan of Care for Pain. The MIPS Program awards up to ten points (including partial points) to participants for their performance rates on each measure, and we would score RO participants' quality measure performance similarly using MIPS benchmarks.[75] For example, when a Professional or Dual participant's measured performance reaches the performance level specified for three points, we will award the participant three points. If applicable MIPS benchmarks are not available, we would use other appropriate national benchmarks for the measure where appropriate. If a national benchmark is not available, we would calculate Model-specific benchmarks from the previous year's historical performance data. If historical performance data are not available, then we would score the measure as pay-for-reporting and will provide credit to the Professional participant or Dual participant for reporting the required data for the measure. We would specify quality measure data reporting requirements on the RO Model website. Once benchmarks are established for the pay-for-reporting measures, we would seek to use the benchmarks to score the measures as pay-for-performance in subsequent years.

As stated earlier in this rule, measures may also be scored as pay-for-reporting. Professional participants and Dual participants that report a pay-for-reporting measure in the form, time, and manner specified in the measure specification would receive ten points for the measure. Professional participants and Dual participants that do not submit the measure in the form, time, and manner specified would receive zero points. As discussed in section III.C.8.b(4) of the proposed rule (84 FR 34517) and this final rule, the Treatment Summary Communication measure will be the only pay-for-reporting measure in PY1.

The total points awarded for each measure included in the AQS would also depend on the measure's weight. We would weight all four quality measures (those deemed pay-for-performance as well as pay-for-reporting) equally and aggregate them as half of the AQS. To accomplish that aggregation as half of the AQS, we would award up to ten points for each measure, then recalibrate Professional participants' or Dual participants' measure scores to a denominator of 50 points. CAHPS® Cancer Care Survey for Radiation Therapy results discussed in section III.C.8.b(5) of this final rule would be added into the AQS beginning in PY3, and we would propose the specific weights of the selected measures from the CAHPS® survey in future rulemaking. We would also specify weights for new measures if and when the Model adopts additional measures in the future.

In cases where Professional participants and Dual participants do not have sufficient cases for a given measure—for example, if a measure requires 20 cases during the applicable period for its calculation to be sufficiently reliable for performance scoring purposes—that measure would be excluded from the participant's AQS denominator calculation and the denominator would be recalibrated accordingly to reach a denominator of 50 points. This recalibration is intended to ensure that Professional participants and Dual participants do not receive any benefit or penalty for having insufficient cases for a given measure.

For example, a Professional or Dual participant might have sufficient cases to report numerical data on just three of five RO Model measures, meaning that it has a total of 30 possible points for the quality measures component of its AQS. If the Professional participant or Dual participant received scores on those measures of nine points, four points, and seven points, it will have scored 20 out of 30 possible points on the quality measures component. That score is equivalent to 33.33 points after recalibrating the denominator to 50 points ((20/30) * 50 = 33.33). In instances where a Professional participant or Dual participant fails to report quality reporting data for a measure in the time, form and manner required by the RO Model as described in section III.C.8.c will not meet the reporting requirements and will receive zero out of ten for that measure in the quality portion of the AQS, as the example in Table 13 represents. If the same Professional participant or Dual participant scored the same 20 points on three measures, but failed to report the necessary data on a fourth measure, its AQS denominator would be set at 40 possible points. Its AQS would then be equivalent to 25 points after recalibrating the denominator to 50 points ((20/40) * 50 = 25).

In the proposed rule, we stated that our assessment of whether the Professional or Dual participant has successfully reported clinical data would be based on whether the participant has submitted the data in the time period identified and has furnished the clinical data elements to us as requested, as discussed in section III.C.8.c of the proposed rule (84 FR 34517 through 34518) and this final rule. We stated that Professional participants and Dual participants would either be considered ''successful'' reporters and receive full credit for meeting our requirements, or ''not successful'' reporters and not receive credit. We stated that we would define successful reporting as the submission of clinical data for 95 percent of RO beneficiaries with any of the five diagnoses listed in section III.C.8.e of the proposed rule (84 FR 34518 through 34519) and this final rule. We also stated that if the Professional participant or Dual participant does not successfully report sufficient clinical data to meet the 95 percent threshold, it would receive 0 out of 50 points for the clinical data elements component of the AQS. As previously discussed, we are finalizing our proposed clinical data elements reporting requirements, and we plan to post these requirements via the RO Model website prior to PY1.

To calculate the AQS, we proposed to sum each Professional or Dual participant's points awarded for clinical data reporting with its aggregated points awarded for quality measures to reach a value that would range between 0 and 100 points. As discussed earlier in this rule, we would recalibrate the points we award for measures to a denominator of 50 points. We would then divide the AQS by 100 points to express it as a percentage.

To illustrate the calculation of the AQS score, two examples are included in this final rule. Table 12 details the AQS calculation for a Professional participant or Dual participant that did not meet the minimum case requirements for one of the pay-for-performance measures.

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[75] The benchmarks are published annually at this CMS site: *https://qpp.cms.gov/about/resource-library.*

TABLE 12 EXAMPLE: AQS CALCULATION DETAILS: DID NOT MEET MINIMUM CASE REQUIREMENTS FOR PAY-FOR-PERFORMANCE MEASURE

ALL NUMBERS ARE ILLUSTRATIVE ONLY

	Notes	Participant Score	Maximum Points	Formula
Quality Measures				
Measure 1 (a)	Pay-for-performance	10	10	
Measure 2 (b)	Pay-for-performance	3	10	
Measure 3 (c)	Pay-for-performance *Did not meet minimum case requirements*	0	0	
Measure 4 (d)	Pay-for-reporting	10	10	
Subtotal (e)		23	30	e = a+b+c+d
Weighted to 50% (f)		38.3	50	f = (participant score of e* 50) / maximum points of e
Clinical Data Elements (g)	≥95% of applicable RO beneficiaries	50	50	
Total (h)		88.3	100	h = f+g
AQS (i)		88.3%		i = participant score of h/maximum points of h

Table 13 details the AQS calculation for a Professional or Dual participant that did not meet the reporting requirements for the clinical data elements or the pay-for-reporting measure.

TABLE 13 EXAMPLE: AQS CALCULATION DETAILS: DID NOT MEET REPORTING REQUIREMENTS FOR PAY-FOR-REPORTING MEASURE ALL NUMBERS ARE ILLUSTRATIVE ONLY

	Notes	Participant Score	Maximum Points	Formula
Quality Measures				
Measure 1 (a)	Pay-for-performance	4.5	10	
Measure 2 (b)	Pay-for-performance	5	10	
Measure 3 (c)	Pay-for-performance	1	10	
Measure 4(d)	Pay-for-reporting *Did not report data as required*	0	10	
Subtotal (e)		10.5	40	e = a+b+c+d
Weighted to 50% (f)		13.1	50	f = (participant score of e* 50) / maximum points of e
Clinical Data Elements (g)	<95% of applicable RO beneficiaries	0	50	
Total (h)		13.1	100	h = f+g
AQS (i)		13.1%		i = participant score of h/maximum points of h

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We believe that this method has the benefits of simplicity, normalization of differences in reported measures between RO participants, and appropriate incorporation of clinical data reporting.

We solicited public comment on the calculation for the AQS methodology. The following is a summary of the public comments received on this proposal and our response:

Comment: Several commenters opposed the 95 percent threshold for successful clinical data element reporting based on their belief this threshold would not allow for the various scenarios where obtaining clinical data, especially from the time of initial diagnosis, is not feasible, would require significant time and resources to obtain, or be overly burdensome. A couple of commenters recommended that CMS begin with a 70 percent reporting requirement and reassess whether that level can be increased in future years. A few commenters recommended a score of 75 percent rather than 95 percent. A commenter recommended a score of 80 percent to receive full credit for reporting clinical data elements in the AQS. A commenter recommended that we adopt a partial points policy for clinical data elements reporting so that participants are not confronted with a pass/fail requirement in the AQS.

Response: We thank commenters for this feedback. We remain concerned that adopting a lower threshold than the proposed 95 percent for successful clinical data elements reporting would result in RO participants reporting data that is less useful for future quality measure development.

Comment: A commenter urged CMS to adopt a three- to six-month reporting window for clinical data elements, which would allow RO participants to abstract and validate data for reporting to CMS following completion of an RO episode. The commenter suggested that the time period for submission should be contingent on volume and practice resources and suggested that RO participants should be given 90 days for 75 percent of submissions, and 180 days for 85 percent submissions.

Response: We believe 95 percent is the appropriate threshold for clinical data element reporting because of the value in obtaining this information, which we believe will allow us to ensure that the data collected are as complete as practicable and provide an accurate reflection of the clinical profile of the RO participant's patient population. We believe that staggering the requirements will increase the operational complexity of the Model and make it harder for participants to comply with the requirements, whereas maintaining the 95 percent requirement as a consistent and simple standard of reporting submitted twice a year in July and in January ensures that RO participants understand what is expected of them well ahead of time.

Comment: A commenter encouraged CMS to maintain the link between quality measures and prospective payments, which would allow the Model to qualify as an Advanced APM because then the Advanced APM bonus would be available to participating radiation oncologists if they are designated as Qualified APM Participants.

Response: We thank the commenter and agree regarding the benefits associated with maintaining the link between quality measures and prospective payments. Our intent is to ensure that the Model will qualify as an Advanced APM starting in PY1.

Comment: A commenter argued that the Model's relative scoring methodology, where RO participants are assessed against each other rather than against absolute benchmarks, means that RO participants can be penalized significantly on measures even when they perform at high levels, as measured by percentages. The commenter noted that this result means little differentiation among health care providers' performance but significant differences in payments and suggested that CMS instead consider adopting an absolute scoring method. The commenter also argued that scoring RO participants against each other discourages sharing lessons learned or best practices, which the commenter believed is not an optimal quality improvement strategy.

Response: We understand the commenter's concerns but disagree with the commenter's assessment of a relative scoring method rather than absolute performance scoring. The principal advantage of a relative performance scoring system is that it bases performance goals on real-world performance rather than on goals that could otherwise be perceived as arbitrary. While MIPS benchmarks are adopted in advance, they are based on historical performance data and thus allow us to assess practices based on real-world performance. We expect RO participants to strive to deliver high quality evidence-based care for all patients consistent with established and emerging best practices. However, we will consider the commenter's concern as we adopt benchmarks in future years for the Treatment Summary Communication and CAHPS® Cancer Care survey measures.

Comment: A few commenters noted that the proposed rule did not specify which benchmarks or data collection types CMS would use for RO Model measures. A commenter recommended CMS adopt MIPS benchmarks and data collections to ensure an easy transition and maintain alignment between quality reporting programs. A commenter suggested that an RO participant's performance could be based on regional or national comparisons, while another recommended using performance-level quintiles. A commenter recommended using the MIPS benchmarks to align the Model's quality reporting with other CMS programs.

Response: We would like to clarify that, as stated in the proposed rule (footnote 57 at 84 FR 34519), we would base benchmarks on MIPS benchmarks where available, and that we would develop benchmarks for those measures that do not have MIPS benchmarks. We agree with the commenter that adopting MIPS benchmarks where available will align the Model and MIPS. We would also like to clarify that we proposed to adopt the registry specifications for the Model's measures—see, for example, 84 FR 34516 (''For the RO Model, we propose to use the registry specifications for [the Plan of Care for Pain] measure'') which include data collection procedures.

Comment: Some commenters noted that some of the 2019 MIPS benchmarks are topped-out for some of the Model's measures and expressed concern that RO participants will therefore not receive the full 10 points for submitting data on those measures. A commenter argued that CMS should provide as much flexibility as possible to RO participants earning points so that they can earn back their quality withholds. Another commenter recommended that scoring should be stratified by performance-level quintiles.

Response: We thank the commenters for this feedback. As we noted in section III.C.8.b, there can be value to retaining topped-out measures. We further note that in the absence of other clinically appropriate measures, retaining topped-out measures may give us the best possible assessment of clinical care quality available. We believe we have adopted an effective and parsimonious measure set aimed precisely at the commenter's goal of providing as much flexibility as possible to RO participants to earn points. We are finalizing the list of measures and scoring methodology as proposed and encourage stakeholders to continue new measure development efforts.

Comment: Some commenters recommended that CMS calculate the AQS using pay-for-reporting on the four quality measures for at least the Model's first year—with a commenter extending that recommendation to the second year—before transitioning to a pay-for-performance program. A commenter asserted this delay would permit participants to become familiar with the Model's quality measures and implement workflow changes. Another commenter argued that such a delay would enable the agency to clarify its benchmarks for quality reporting and provide participants enough time to become familiar with them. The commenter also recommended that we provide confidential feedback reports with performance information that can be reviewed and corrected, as done in other CMS quality programs.

Response: We thank the commenters for this feedback. We note that RO participants will not be required to submit quality measure data on PY1 RO episodes until March 2022, which also provides time for familiarization. During PY1 and before the first submission in March 2022, we will provide education, outreach, and feedback reports to help participants understand the quality and clinical data elements collection and submission systems. Between the availability of national benchmarks for the three pay-for-performance measures and the time period in which RO participants will have access to information about these measures, we believe it is appropriate to retain these measures as pay-for-performance beginning in PY1 as originally proposed. Starting in PY2 (once quality measure data for PY1 has been submitted) and continuing thereafter, we intend to provide detailed and actionable information to RO participants related to their performance in the Model, as described in section III.C.14.c. of the proposed rule (84 FR 34532). We intend to determine the design of and frequency of those reports in conjunction with the RO Model implementation and monitoring contractor.

Comment: A commenter stated its appreciation for our proposals to align our quality programs and for establishing a clear distinction between pay-for-performance and pay-for-reporting requirements.

Response: We thank the commenter for supporting our plan to align quality programs and distinguish our reporting requirements.

After consideration of the public comments that we have received, we are finalizing the AQS calculation as proposed and finalizing the definition of the AQS at § 512.205.

(2) Applying the AQS to the Quality Withhold

We proposed to use the following method to apply the AQS to the amount of the quality withhold that could be earned back by an RO participant (84 FR 34522). We would multiply the Professional participant's or Dual participant's AQS (as a percentage) against the 2 percent quality withhold amount. For example, if a Professional participant or Dual participant received an AQS of 88.3 out of a possible 100, then the Professional participant or Dual participant would receive a 1.77 percent quality reconciliation payment amount (0.883 * 2.0 = 1.77%). If the total episode payment amount for this RO participant after applying the trend factor, adjustments, and discount factor was $2,465.68,[76] the example AQS of 88.3 would result in a quality

[76] This number refers to the result in line (j) in Table 5 from the proposed rule.

reconciliation payment amount of $43.64 ($2,465.68 * 1.77% = $43.64).[77]

We proposed to continue to weight measures equally in PY1 through PY5 unless we determined that the Model needs to emphasize specific clinical transformation priorities or added new measures. Any updates to the scoring methodology in future PYs will be proposed and finalized through notice and comment rulemaking. There may be some variation in the measures that we score to calculate the AQS for Professional participants and Dual participants should they be unable to report numerical data for certain measures due to sample size constraints or other reasons. However, as discussed in the proposed rule, we do not anticipate that variation will create any methodological problems for the Model's scoring purposes.

The AQS would be calculated approximately eight months after the end of each PY and applied to calculate the quality withhold payment amount for the relevant PY. Any portion of the quality withhold that is earned back would be distributed in an annual lump sum during the reconciliation process as described in section III.C.11 of this final rule.

We solicited public comments on our proposal to apply the AQS to the amount of the quality withhold in section III.C.6.g(2) of the proposed rule (84 FR 34509).

The following is a summary of the public comments received on this proposal and our response:

Comment: A commenter expressed concern about the AQS's structure and its interactions with incentives, noting that every participant would receive the quality withhold, but top performers would receive incentive payments over a year later. The commenter also asserted that most practices would receive a net payment cut because they would not earn the full withhold back.

Response: We thank the commenter for these concerns. However, we view the trade-offs associated with the Model's incentive payment timing as necessary within the framework of an episode-payment model that will, by design, accelerate much of the episode-based payments to RO participants. We will endeavor to calculate individual quality measure scores and an annual AQS, produce reports, and determine payment adjustments as swiftly as possible. While we agree with the commenter's sentiment that some RO participants will see a payment reduction, we note that the number of participants and the amount of the reduction will depend on a number of factors, including episode price as determined by the pricing methodology discussed in section III.C.6, and their performance on the AQS. We note that in any case, one of the benefits of the RO Model is bundling payments for all included RT services rather than remitting them piecemeal over the course of the RO episode. Finally, we note that section III.C.7 of this final rule states that RO participants will be able to receive EOE payments as early as day 28 of the RO episode, a change from the proposal to reimburse the final half of the episode payment after the 90-day episode period is over.

Comment: A commenter suggested that CMS consider rewarding top-performing providers and suppliers with additional reimbursements rather than subjecting them to a quality withhold. The commenter argued that this type of incentive structure would be consistent with the Quality Payment Program and would move Medicare policy away from focusing on penalties, as the commenter suggested has been prevalent in hospital quality programs.

Response: With respect to the AQS, RO participants will not be able to earn back more than the quality withhold. However, we believe that top performers in the Model will have the opportunity, via the Model's payment methodology, and the Advanced APM and MIPs incentives, to earn total payments in excess of their historical payments. For this reason, we believe that the Model's design serves to incentivize all RO participants to strive for high quality and earn the available incentive payments.

Comment: A commenter expressed support for the Model's proposed measures but argued that it is unrealistic to expect RO participants to score 100 percent for all measures. The commenter suggested that we adopt an 80 percent performance threshold for full credit within the quality portion of the AQS.

Response: We thank the commenter for this suggestion, but we do not believe that establishing firm thresholds within the AQS calculation would serve our quality improvement goals. We continue to believe that the Model's scoring structure must encourage consistent improvement in the Model's quality metrics, and we are concerned that establishing a scoring threshold as suggested by the commenter would offer disincentives for continued improvement. While we agree with the commenter that we do not expect RO participants to score 100 percent on all quality measures, we do not agree that we should therefore adopt a scoring ''curve'' or other form of adjustment that would offer full credit for performance at levels below the measure's benchmark.

After consideration of the public comments that we have received, we are finalizing our proposed policy to apply the AQS to the Quality Withhold to begin in PY1 as finalized in section III.6.g(2).

9. The RO Model as an Advanced Alternative Payment Model (Advanced APM) and a Merit-Based Incentive Payment System APM (MIPS APM)

As we stated in the proposed rule, we anticipate that the RO Model will be both an Advanced APM and a MIPS APM. For purposes of the Quality Payment Program, the RO participant, specifically either a Dual participant or a Professional participant, would be the APM Entity.

We proposed that we would establish an ''individual practitioner list'' under the RO Model (84 FR 34522). We proposed that this list would be created by CMS and sent to Dual participants and Professional participants to review, revise, certify, and return to CMS so that CMS would be able to make QP determinations and calculate any applicable APM Incentive Payments, and to identify any MIPS eligible clinicians who would be scored for MIPS based on their participation in this MIPS APM. The individual practitioner list would serve as the Participation List (as defined in the Quality Payment Program regulations at 42 CFR 414.1305) for the RO Model. We proposed to codify the term ''individual practitioner list'' for purposes of the RO Model in § 512.205 of our proposed regulations.

We proposed, at 84 FR 34522, that the individuals included on the individual practitioner list would include physician radiation oncologists who are eligible clinicians participating in the RO Model with either a Dual participant or a Professional participant as described in section III.C.3.b of this final rule. Eligible clinicians who are identified on the Participation List for an Advanced APM during a QP Performance Period may be determined to be Qualifying APM Participants (QPs) as specified in our regulations at 42 CFR 414.1425, 414.1435, and 414.1440. Similarly, under the current Quality Payment Program rules, MIPS eligible clinicians identified on the Participation List for the performance period of an APM Entity participating in a MIPS APM would be scored for MIPS using the APM scoring standard as provided in our regulation at 42 CFR 414.1370.

[77] This number is prior to the geographic adjustment and sequestration being applied.

We proposed that only Professional participant physicians and Dual participant physicians included on the individual practitioner list would be considered eligible clinicians participating in the RO Model, for purposes of the Quality Payment Program.

We proposed that we would create and provide each Dual participant and Professional participant with an individual practitioner list prior to the start of each PY (84 FR 34522). We proposed that the Dual participants and Professional participants must review and certify the individual participant list within 30 days of receipt of such list in a form and manner specified by CMS. In the case of a Dual participant or Professional participant that begins the RO Model after the start of PY, but at least 30 days prior to the final QP snapshot date of that PY, we proposed that CMS would create and provide the new Dual participant or Professional participant with an individual practitioner list.

In order to certify the list, we proposed that an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the list (84 FR 34522). We proposed that the certified individual practitioner list would include all individual practitioners who have reassigned their rights to receive Medicare payment for the provision of RT services to the TIN of the RO participant. We proposed that the individual with the authority to bind the RO participant must agree to comply with the requirements of the RO Model before the RO participant certifies the list. We note that we did not propose that HOPDs that are Technical participants be a part of this list process because as HOPDs they are paid by OPPS, which is not subject to the Quality Payment Program. The RO participants may make changes to the individual practitioner list that has been certified at the beginning of the performance year. In order to make additions to the list, we proposed that the RO participant must notify CMS within 15 days of an individual practitioner becoming a Medicare-enrolled supplier that bills for RT services under a billing number assigned to the TIN of the RO participant; the timely addition would be effective on the date specified in the notice furnished to CMS, but not earlier than 15 days before the date of the notice. If the RO participant fails to submit timely notice of the addition, the addition would be effective on the date of the notice. We proposed that the notice must be submitted in a form and manner specified by CMS.

We proposed that in order to remove an individual practitioner from the list, the RO participant must notify CMS within 15 days after an individual practitioner ceases to be a Medicare-enrolled supplier that bills for RT services under a billing number assigned to the TIN of the RO participant; the timely removal would be effective on the date specified in the notice furnished to CMS, but not earlier than 15 days before the date of the notice (84 FR 34522). If the RO participant fails to submit timely notice of the removal, the removal would be effective on the date of the notice. The notice must be submitted in a form and manner specified by CMS. Further, we proposed that the RO participant must ensure that the individuals included on the individual practitioner list maintain compliance with the regulation at § 424.516, including notifying CMS of any reportable changes in status or information (84 FR 34522–34523). We proposed that the certified individual practitioner list would be used for purposes related to QP determinations as specified in 42 CFR part 414 subpart O. We also stated that if the Dual participant or Professional participant did not verify and certify the individual practitioner list by the deadline specified by CMS, the unverified list would be used for scoring under MIPS using the APM scoring standard (84 FR 34523). We proposed to codify these provisions relating to the individual practitioner list at § 512.217.

We proposed that in order to be an Advanced APM, the RO Model must meet the criteria specified in our regulation at 42 CFR 414.1415 (84 FR 34523). First, in order to be an Advanced APM, an APM must require participants to use certified EHR technology (CEHRT). For QP Performance Periods beginning in 2019, to meet this requirement, an Advanced APM must require at least 75 percent of eligible clinicians in the APM Entity or, for APMs in which HOPDs are the APM Entities, each HOPD, to use CEHRT to document and communicate clinical care to their patients or other health care providers pursuant to 42 CFR 414.1415(a)(1)(i). We proposed that during the Model performance period, the RO participant would be required to annually certify its intent to use CEHRT throughout such model year in a manner sufficient to meet the requirements pursuant to 42 CFR 414.1415(a). Further, we proposed that within 30 days of the start of PY1, the RO participant would be required to certify its intent to use CEHRT throughout such model year in a manner sufficient to meet the requirements pursuant to 42 CFR 414.1415(a). Annual certification would be required prior to the start of each subsequent PY.

We solicited public comments on our proposal. The following is a summary of the public comments received on this proposal and our responses:

Comment: A commenter commended CMS' dedication to implementing more Advanced APMs that would allow specialists the opportunity to become a QP. Specifically, the commenter suggested that there is insufficient opportunity for specialists to qualify for QP status under the Quality Payment Program, and therefore the commenter applauds CMS' dedication to improving this.

Response: We appreciate this commenter's support of our proposal.

Comment: A commenter requested clarification on the RO Model's status as an Advanced APM. Specifically, this commenter stated that its radiation oncologists are part of a larger multi-specialty practice that currently reports to CMS under the MIPS program. The commenter requested clarification on whether the entire group would be participating as an Advanced APM Entity or just the radiation oncologists.

Response: In the proposed rule, we proposed that we will provide RO participants with an individual practitioner list. We also proposed a process whereby RO participants would review, have the opportunity to modify, and certify this list. The certified list that includes only physician radiation oncologists who have reassigned their rights to receive Medicare payment for the provision of RT services to the TIN of the RO participant would be used for purposes related to QP determinations as specified in 42 CFR part 414 subpart O. Only those individual practitioners included on the certified list would be considered participants under the RO Model for purposes of the Quality Payment Program, including identifying eligible clinicians who would be eligible to attain QP status under the Model. On further reflection, we have reconsidered our statement in the proposed rule that an unverified list would be used for scoring under MIPS. After further consideration, we are concerned that use of an unverified list might result in incorrect or unauthorized payments and adjustments under the Quality Payment Program, potentially jeopardizing program integrity.

Comment: A couple of commenters opposed the processes proposed around the Individual Practitioner List. One commenter opposed the proposal that

the Individual Practitioner List must be reviewed and certified annually, stating that this was too great an administrative burden for participants. Another commenter requested that CMS allow participants to have 60 days to notify CMS of changes to the QP list, rather than 15 days as proposed. This commenter suggested that if RO participants meet this 60-day reporting deadline, the changes would take effect as of the effective date specified in the notice to CMS. If participants do not meet this deadline, then addition or removal would be effective on the date that the participant notifies CMS.

Response: We disagree with the commenter who believes the annual certification process of the individual practitioner list is unduly burdensome. We have proposed this certification process so that the RO participant would have the chance to review and verify that the list we intend to use for QP determinations is accurate, and if it is not accurate, to notify us of the inaccuracies so a correct list can be used for those determinations. We proposed this process to limit burden on RO participants, as we will be creating a draft version for their review rather than asking RO participants to draft and compile a list for our review that would then need to be certified. Further, we proposed that if the RO participant does not certify the list we will still use the uncertified list for MIPS scoring. While we had previously proposed to still use an uncertified list, we are not finalizing this provision. Upon further consideration and based on commenters' requests for clarity around the RO Model's status as an Advanced APM, we are instead finalizing that RO participants on an uncertified list would not be considered participants in an APM Entity for purposes of the Quality Payment Program as defined at § 414.1305. We are codifying these provisions relating to the individual practitioner list at § 512.217.

We also disagree with the commenter who proposed that RO participants should have 60 days to notify us of changes to their individual practitioner list. However, we agree that 15 days may be an insufficient period of time for participants to review, correct, and return the list to us. We will modify this proposal to allow for a 30-day period. We believe 30 days will be a sufficient amount of time for RO participants to review and submit corrections, as other models currently being tested by the Innovation Center also require 30-day period to review and return similar lists. Further, we believe 30 days is a reasonable compromise between the commenter's proposed 60-day period and our original 15-day proposal.

Comment: A few commenters stated that some practices may need a hardship exemption from the proposed Model requirements to use the 2015 Edition CEHRT due to insufficient internet connectivity, extreme and uncontrollable circumstances, or lack of control over the availability of CEHRT. One of these commenters stated that low-volume practices are excluded from the Quality Payment Program's Merit-based Incentive Payment System (MIPS) and its Promoting Interoperability performance category requirement to use 2015 Edition CEHRT, which is a proposed requirement for the RO Model. This commenter further maintained that including low-volume practices in the RO Model would require these practices, which haven't had to use 2015 Edition CEHRT under MIPS, to make significant financial investments in technology and substantial time investments in software installations and training while adapting to the new value-based reimbursement methodology, which would be detrimental to these practices' ability to continue operations and reduce access for patients to receive radiation therapy. This commenter also stated that practices with insufficient internet connectivity, which are typically located in rural areas, are allowed to annually apply for a hardship exception from the MIPS Promoting Interoperability performance category and its requirement to use 2015 Edition CEHRT, and if these practices are included in the RO Model, they will be forced to invest significant resources and time as participants of the RO Model and could be forced to discontinue operations, decreasing access to cancer treatment options for patients.

Response: There are very few RT providers and RT suppliers in these rural areas such that, if included in the RO Model, the rural areas would likely not generate enough episodes to be included in the Model. As such, we believe that our proposed CEHRT requirements are not unduly burdensome for rural RT providers and RT suppliers, and a hardship exemption from the CEHRT requirement is unnecessary. We would note that while we do not believe a hardship exemption is necessary for the CEHRT requirement, we are finalizing in section III.C.3.c a low volume opt-out that may help address these commenters' concerns.

Comment: A couple of commenters requested clarification on which edition of CEHRT CMS is requiring for RO participants to use. One of these commenters recommended that the edition that RO uses should align with other quality reporting programs. This commenter also questioned why participants must certify their intent to use CEHRT at the beginning of the performance year, and not at the end.

Response: In the RO Model, we have proposed to align our CEHRT requirements with the regulatory requirements of the Quality Payment Program as stated at 42 CFR 414.1415(a). This relies on the definition of CEHRT as defined, and periodically updated, at 42 CFR 414.1305, which currently specifies the use of 2015 Edition Base EHR edition (as defined at 45 CFR 170.102) and has been certified to the 2015 Edition health IT certification criteria. Using this definition of CEHRT aligns RO Model requirements with the requirements of the Quality Payment Program as well as other Advanced APMs being tested by the Innovation Center. We believe certifying an intent to use CEHRT at the beginning of the performance year, as opposed to the end of the performance year, is appropriate and it aligns with requirements in other Advanced APMs being tested by the Innovation Center.

After considering public comments, we are finalizing with modification our proposals relating to the RO Model as an Advanced APM regarding the CEHRT and Participation List requirements. We clarify that MIPS eligible clinicians identified on the Participation List of an APM Entity participating in a MIPS APM for the performance period are eligible to be scored as part of an APM Entity group, as described at 42 CFR 414.1305. We are also finalizing, with modification, that if the Dual participant or Professional participant does not verify and certify the individual practitioner list by the deadline specified by CMS, RO participants on the unverified list are not recognized as participants in an APM Entity for purposes of the Quality Payment Program. We have codified at § 512.217(a) that we will create and provide each Dual participant and Professional participant with an individual practitioner list, upon the start of each performance year. We have made edits to § 512.217(b) for clarity and readability. That provision has been revised to state that, within 30 days of receipt of the individual practitioner list, the RO participant must review the individual practitioner list, correct any inaccuracies in accordance with to § 512.217(d), and certify the list (as corrected, if applicable) in a form and manner specified by CMS and in accordance with § 512.217(c).

We have also made edits to § 512.217(d) for clarity and readability. This provision has been revised to state that, the RO participant must notify CMS of a change, including additions or removals, to its individual practitioner list within 30 days. Further, we have clarified at § 512.217(d)(2)(i) that the removal of an individual practitioner from the RO participant's individual practitioner list is effective on the date that the individual ceases to be an individual practitioner as defined at § 512.205.

Next in the proposed rule, at 84 FR 34523, we explained the second criterion to be an Advanced APM, which is that an APM must include quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM as specified at 42 CFR 414.145(b)(1). Effective January 1, 2020 at least one of the quality measures upon which the APM bases payment must meet at least one of the following criteria: (a) Finalized on the MIPS final list of measures, as described in 42 CFR 414.1330; (b) endorsed by a consensus-based entity; or (c) determined by CMS to be evidenced-based, reliable, and valid.

We noted in the proposed rule that we discussed the RO Model's quality measure set in section III.C.8.b of the proposed rule. We discussed our intention to use the results of the following quality measures when determining payment to Professional participants and Dual participants under the terms of the RO Model, as discussed in detail in section III.C.8.f of the proposed rule and this final rule: (1) Oncology: Medical and Radiation—Plan of Care for Pain; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan; and (4) Treatment Summary Communication—Radiation Oncology. The quality measures we proposed to use for the RO Model are measures that are either finalized on the MIPS final list of measures, or determined by CMS to be evidence based, reliable, and valid. As we indicated in the proposed rule, we believe that these measures would meet the criteria under 42 CFR 414.1415(b) (84 FR 34523).

In addition to the quality measure requirements listed earlier, under 42 CFR 414.1415(b)(3), the quality measures upon which an Advanced APM bases payment must include at least one outcome measure. This requirement does not apply if CMS determines that there are no available or applicable outcome measures included in the MIPS quality measures list for the APM's first QP Performance Period. We noted in the proposed rule that there currently are no such outcome measures available or applicable for the RO Model's first QP Performance Period (84 FR 34523). If a potentially relevant outcome measure becomes available, we would consider it for inclusion in the RO Model's measure set.

The third criterion to be an Advanced APM is that the APM must require participating APM Entities to bear financial risk for monetary losses of more than a nominal amount or, be a Medical Home Model expanded under the Innovation Center's authority, in accordance with section 1115A(c) of the Act. As we stated in the proposed rule, we expect that the RO Model will meet the generally applicable financial risk standard in accordance with 42 CFR 414.1415 because there is no minimum (or maximum) financial stop-loss for RO participants, meaning RO participants would be at risk for all of the RT services beyond the episode payment amount (84 FR 34523).

The regulation at 42 CFR 414.1415(c)(1) requires that ''to be an Advanced APM, an APM must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified QP Performance Period, do one or more of the following: (i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians; (ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or (iii) Require the APM Entity to owe payment(s) to CMS.'' We stated in the proposed rule that the RO Model would meet this standard because CMS would not pay the RO participant more for RT services than the episode payment amount (84 FR 34523).

The regulation at 42 CFR 414.1415(c)(3) sets the standard for a nominal amount of risk for Advanced APMs other than Medical Home Models at either ''eight percent of the average estimated total Medicare Parts A and B revenues of participating APM Entities'' for QP Performance Periods in 2017 through 2024 or ''three percent of the expected expenditures for which the APM Entity is responsible for under the APM'' for all QP Performance Periods.

For the RO Model, as we discussed in the proposed rule (84 FR 34523), the APM Entities would be at risk for all costs associated with RT services as discussed in section III.C.5.c of the proposed rule and this final rule beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment, and therefore, would be at 100 percent risk for all expenditures in excess of the expected amount of expenditures, which are the previously discussed episode payments. As proposed, RO participants would not receive any additional payment or reconciliation from CMS (beyond the participant-specific professional episode payment or participant-specific technical episode payment) to account for any additional medically necessary RT services furnished during the 90-day episode. Effectively, this means that when actual expenditures for which the APM Entity was responsible under the APM exceed expected expenditures, the RO participant would be responsible for 100 percent of those costs without any stop-loss or cap on potential losses. This would satisfy the requirement under 42 CFR 414.1415(c)(3)(i)(B) because, for example, if actual expenditures are 3 percent more, or 5 percent more, or 7 percent more than the expected expenditures for which an RO participant is responsible under the model, the RO participant is 100 percent liable for those additional 3 percent, 5 percent, or 7 percent of costs without any limit to the total amount of losses they may incur.

Additionally, as we stated in the proposed rule (84 FR 34523–34524), we anticipated that the RO Model would meet the criteria to be a MIPS APM under the Quality Payment Program starting in PY1 (January 1, 2020) if the start date is finalized as January 1, 2020 or in PY2 (January 1, 2021) if finalized as April 1, 2020. MIPS APMs, as defined in 42 CFR 414.1305, are APMs that meet the criteria specified under 42 CFR 414.1370(b). Currently, pursuant to 42 CFR 414.1370(a), MIPS eligible clinicians who are identified on a Participation List for the performance period of an APM Entity participating in a MIPS APM are scored under MIPS using the APM scoring standard. We proposed to use the same individual practitioner list developed to identify the relevant eligible clinicians for purposes of making QP determinations and applying the APM scoring standard under the Quality Payment Program.

In the CY 2021 PFS proposed rule, we proposed to terminate the APM scoring standard effective January 1, 2021 (85 FR 50303). We also proposed to establish a new APM Performance Pathway, which, if finalized, would be an optional MIPS reporting and scoring pathway for MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of a MIPS APM (85 FR 50285). We also proposed to allow APM Entities to report to MIPS via any available submission

mechanism, on behalf of all MIPS eligible clinicians in the APM Entity group (85 FR 50304). If these proposals are finalized in the forthcoming CY 2021 PFS final rule, MIPS eligible clinicians participating in the RO Model would have the option to report to MIPS using the APM Performance Pathway, and they would have the option to report to MIPS as individuals, groups, or APM Entities.

In the proposed rule we noted that the following proposals would apply to any APM Incentive Payments made for eligible clinicians who become QPs through participation in the RO Model:

- Our proposals regarding monitoring, audits and record retention, and remedial action, as discussed in section II.F and III.C.14 of the proposed rule. Under our monitoring policy, RO participants would be monitored for compliance with the RO Model requirements. CMS may, based on the results of such monitoring, deny an eligible clinician who is participating in the RO Model QP status if the eligible clinician or the eligible clinician's APM entity (that is, the respective RO participant) is non-compliant with RO Model requirements.
- Our proposal in section III.C.10.c, of the proposed rule which explains that technical component payments under the RO Model would not be included in the aggregate payment amount for covered professional services that is used to calculate the amount of the APM Incentive Payment.

We solicited comment on our proposals. The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters expressed concern regarding the risk that will be involved for participants in the RO Model. A commenter stated that if the RO Model is structured as largely as proposed, then participation will be a significant, risky, and costly undertaking. One of these commenters requested that CMS redesign the Model payment to allow for two-sided risk. Another commenter expressed concern with the lack of a cap on downside risk and opposed the current, uncapped risk structure. This commenter suggested that the RO Model should establish risk at the levels finalized by CMS for other APMs. A few commenters requested that CMS include stop-loss provisions in the RO Model. These commenters stated that RO Participants would bear 100 percent of the risk for all RT services provided in excess of the bundle payments, and that this high degree of risk is inappropriate for a mandatory model. They also maintained that this lack of stop-loss protection runs counter to the majority of CMS APMs such as the BPCI Advanced Model, the CJR Model, the Shared Savings Program, and OCM, which all cap downside risk. These commenters suggest that CMS should establish a stop-loss provision to mitigate this high degree of risk and to ensure that the RO Model does not place substantial financial burden on RO participants. A commenter suggested implementing a stop-loss provision using the encounter data CMS proposes to require participants to submit.

Response: We appreciate the commenters' concerns and feedback around the level of risk in the RO Model, and regarding a stop-loss provision under the Model. We believe that the heavy weight of the RO participants' historical experience in their participant-specific RO payment amount, combined with the low volume opt-out option (see section III.C.3.c), minimizes the potential losses that an RO participant may face. However, we understand that there are some circumstances where RO participants that have fewer than 60 episodes in the baseline period will not qualify to receive a historical experience adjustment and may experience significant increases or reductions to what they were historically paid in FFS. We are adopting a stop-loss limit of 20 percent to the RO Model for these RO participants that were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of this final rule. Please reference section III.C.6.e(4) for more information on the stop-loss policy.

We understand the commenters' concerns with the level of risk in this Model compared with other Innovation Center models. Section 1833(z)(3)(D) of the Act, as added by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), established certain requirements for APMs including a requirement that an APM Entity bear financial risk for monetary losses that are in excess of a nominal amount or be a medical home expanding under 111A(c) of the Act. In rulemaking, we have established this generally applicable nominal amount standard to mean that an Advanced APM must put the APM Entities at risk for at least eight percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers participating APM Entities or at least 3 percent of the expected expenditures for which an APM Entity is responsible under the APM, as codified in § 410.1415(c)(3). In designing and implementing other models, we have established various levels of risk at and above these minimum amounts. As such, we believe that the level of risk we have established for the RO Model, is above the minimum level specified in the generally applicable nominal amount standard that we established for the Quality Payment Program. Furthermore, the level of risk is appropriate and in line with the levels of risk of other Advanced APMs being tested by the Innovation Center, including the stop-loss policy described in section III.C.6e(4) The stop-loss limit of 20 percent aligns with stop-loss limits set by other models such as the BPCI Advanced and CJR Models. Further, we would like to note that the RO Model does have two-sided risk; participants that provide services more efficiently than the RO episode price yield savings, while those that provide services less efficiently than the RO episode price yield losses.

Comment: A commenter requested that providers and suppliers that are required to participate in the RO Model should have every possible assurance that their participation will qualify them for exemption from MIPS and will earn them the APM incentive for participation in an Advanced APM. This commenter stated that they understand that CMS cannot guarantee that providers and suppliers will meet the minimum payment or patient volume requirement to be a qualifying participant, but the agency should finalize a structure that squarely satisfies each of the requirements for an Advanced APM.

Response: We appreciate the commenter's views on the design of the RO Model as an Advanced APM. We believe that we have designed the Model in such a way that we expect that the RO Model will be determined to be both an Advanced APM and a MIPS APM starting on January 1, 2021. As such, all eligible clinicians participating in the RO Model will have the opportunity to become QPs or Partial QPs based on meeting the relevant payment or patient count thresholds, and thereby exempt from the MIPS reporting requirements and payment adjustment for the relevant year. Under the structure of the Quality Payment Program, not all eligible clinicians in the RO Model will necessarily achieve QP status or earn an APM Incentive Payment for their participation in the Advanced APM, but we believe there are other inherent benefits to the RO participant. Furthermore, based on our actuarial analysis we believe that most eligible clinicians will achieve QP status during the course of the RO Model.

Other benefits for participating in the RO Model as it is designed as an Advanced APM and a MIPS APM include a chance to be an early adopter of a value-based payment arrangement model. As CMS in general, and the health care industry specifically, turns to more value-based payment arrangements, early adopters of these models may have an advantage over their peers who have not participated in these models. Additionally, eligible clinicians in the RO Model who are MIPS eligible clinicians (those not excluded from MIPS as QPs, Partial QPs, or on another basis) will be considered participants in a MIPS APM for purposes of MIPS reporting and scoring rules.

Comment: MedPAC did not support CMS' proposal that the RO Model would qualify to be an Advanced APM. MedPAC stated that the RO Model does not meet two of the principles that MedPAC has developed for Advanced APMs: Clinicians should receive a 5 percent incentive payment only if the eligible entity in which they participate is successful in controlling cost, improving quality, or both; and the eligible entity should be at financial risk for total Part A and Part B spending. MedPAC stated that incentive payments should not be awarded for simply participating in an APM entity but should be contingent on quality and spending performance. They stated that the RO Model does not follow this first principle, as clinicians who participate in the RO Model through an eligible entity and have a sufficient share of revenue coming through the Model would receive an incentive payment, whether or not the entity limits costs per episode or improves quality. MedPAC also stated that the RO Model does not follow their second principle, to help move the fee-for-service (FFS) payment system from volume to value, encourage care coordination, and more broadly reform the delivery system, as the RO Model entities are only responsible for spending on certain RT services within a 90-day episode of care. They are not held accountable for spending on other services provided to beneficiaries in the Model, such as E&M visits, tests, ED visits, or hospital admissions. Entities would also have an incentive to reduce the cost per episode while increasing the total number of episodes. In addition, there is not a single entity that would be responsible for episode spending because CMS would make separate episode payments for the TC and PC portions of the episode, unless an entity is a Dual participant that provides both the TC and PC portions of an episode. MedPAC further disagreed with CMS' decision to not propose any outcome measures for the Model, and they disagree with CMS' determination that there are currently no outcome measures available or applicable for the RO Model. MedPAC states that OCM uses three claims-based outcome measures to determine performance-based payments: Risk-adjusted proportion of patients with all-cause hospital admissions within the six-month episode, risk-adjusted proportion of patients with all-cause emergency department (ED) visits or observation stays that did not result in a hospital admission within the six-month episode, and proportion of patients that died who were admitted to hospice for three days or more. MedPAC stated that CMS should consider using similar outcome measures for the RO Model, as both OCM and the RO Model focus on cancer treatment. They also stated that use of claims-based outcome measures in the RO Model would enable CMS to hold providers and suppliers accountable for the quality of their care and allow CMS to evaluate whether prospective episode payments for RT services reduce spending without causing negative outcomes. Finally, MedPAC stated that claims-based outcome measures, such as readmission rates, do not impose a reporting burden on providers and suppliers and are part of MIPS.

Response: We appreciate MedPAC's analysis of the Quality Payment Program and the RO Model, but we disagree that the RO Model should not qualify as an Advanced APM. We believe the additional principles that MedPAC has established can be used as analytic tools when analyzing Advanced APMs, they do not align with or take the place of the statutory criteria for APMs and eligible APM Entities established in § 1833(z)(3)(C) and (D) of the Act and codified at 42 CFR 414.1415, and as such are not necessary requirements when making an Advanced APM determination. Specifically, as codified at 42 CFR 414.1415, the criteria for Advanced APMs are as follows: (1) The APM requires use of CEHRT, (2) payment under the APM is based on MIPS-comparable quality measures, and (3) the APM requires participants to assume more than nominal financial risk. As articulated in this section of this final rule, we believe that the RO Model satisfies each of these criteria.

Required use of CEHRT: During the Model performance period, the RO participant will be required to annually certify its intent to use CEHRT throughout such model year in a manner sufficient to meet the requirements pursuant to 42 CFR 414.1415(a). Further, within 30 days of the start of PY1, the RO participant will be required to certify its intent to use CEHRT throughout such model year in a manner sufficient to meet the requirements pursuant to 42 CFR 414.1415(a).

Payment based on MIPS-comparable quality measures: We intend to use the results of the following quality measures when determining payment to Professional participants and Dual participants under the terms of the RO Model, as discussed in detail in section III.C.8.f of this final rule: (1) Oncology: Medical and Radiation—Plan of Care for Pain; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan; and (4) Treatment Summary Communication—Radiation Oncology. Further, the quality measures we use for the RO Model are measures that are either finalized on the MIPS final list of measures, or determined by CMS to be evidence-based, reliable, and valid. In addition to the quality measure requirements listed earlier, under 42 CFR 414.1415(b)(3), the quality measures upon which an Advanced APM bases payment must include at least one outcome measure. This requirement does not apply if CMS determines that there are no available or applicable outcome measures included in the MIPS quality measures list for the APM's first QP Performance Period. CMS has determined that there currently are no such outcome measures available or applicable for the RO Model's first QP Performance Period.

Furthermore, with regards to MedPAC's comments about the RO Model using similar outcome measures that are employed by OCM, we thank MedPAC for the suggestion. We considered using the same OCM outcome measures for the RO Model, but ultimately decided that it would be difficult to discern whether these outcomes occurred due to complications from RT services, chemotherapy by medical oncologists, or for other various reasons. As such, we believe that these measures would not meaningfully indicate high- versus low-quality RO participants.

Financial Risk: The regulation at 42 CFR 414.1415(c)(1) requires that ''to be an Advanced APM, an APM must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified QP Performance Period, do one or more of the following: (i) Withhold payment for services to the APM Entity or the APM Entity's eligible

clinicians; (ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or (iii) Require the APM Entity to owe payment(s) to CMS.'' As we explained in the proposed rule and in this section of the final rule, the RO Model would meet this standard because CMS would not pay the RO participant more for RT services than the episode payment amount.

The regulation at 42 CFR 414.1415(c)(3) sets the standard for a nominal amount of risk for Advanced APMs other than Medical Home Models at either ''eight percent of the average estimated total Medicare Parts A and B revenues of participating APM Entities'' for QP Performance Periods in 2017 through 2024 or ''three percent of the expected expenditures for which the APM Entity is responsible for under the APM'' for all QP Performance Periods. For the RO Model, most APM Entities, with the exception of those RO participants that qualify for the stop-loss policy as described in section III.C.6.e(4) and codified at § 512.285(f), would be at risk for all costs associated with RT services (described in section III.C.5.c of this final rule) beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment, and therefore, would be at 100 percent risk for all expenditures in excess of the expected amount of expenditures, which are the previously discussed episode payments. RO participants would not receive any additional payment or reconciliation from CMS (beyond the participant-specific professional episode payment or participant-specific technical episode payment) to account for any additional medically necessary RT services furnished during the 90-day episode. Effectively, this means that when actual expenditures for which the APM Entity was responsible under the APM exceed expected expenditures, the RO participant would be responsible for 100 percent of those costs without any stop-loss or cap on potential losses, except for the participants that qualify for the stop-loss policy, as previously stated. This would satisfy the requirement under 42 CFR 414.1415(c)(3)(i)(B) because, for example, if actual expenditures are 3 percent more, or 5 percent more, or 7 percent more than the expected expenditures for which RO participants are responsible under the Model, RO participants are 100 percent liable for those additional 3 percent, 5 percent, or 7 percent of costs. Most participants are without any limit to the total amount of losses they may incur. For the subset of RO participants that are limited to the total amount of losses they may incur because they are eligible for the stop-loss policy, that limit is set to 20 percent of expected expenditures for which the RO participants are responsible for under the RO Model.

Finally, while MedPAC has created these additional principles that it believes should be achieved for a model to be an Advanced APM, these additional principles have not been codified in the Quality Payment Program regulations as necessary requirements of Advanced APMs. Even though meeting these principles is not a requirement for Advanced APM status, we are responding to these comments to better explain our reasoning behind the RO Model being proposed as an Advanced APM.

First, regarding the APM Incentive Payment, MedPAC believes the APM incentive payment should only be paid if the APM participant is successful in controlling cost, improving quality, or both, and if the APM participant is at financial risk for total Part A and Part B spending. The Quality Payment Program statute and regulations provide different standards for eligible clinicians to earn an APM incentive payment, and for an APM to be considered an Advanced APM, based on the required assumption of financial risk; the Quality Payment Program provides for the APM incentive payment to encourage clinicians to move into value-based payment through Advanced APMs. Additionally, in the RO Model we are specifically testing different pricing methodologies for the RT services provided, not the other costs associated with the beneficiary's care.

Second, regarding the move from FFS payments to a value-based payment system, MedPAC believes that since RO participants are only held accountable for spending on certain RT services within the episode of care and not held accountable for spending on other services provided to the RO beneficiary, the RO participants are not properly incentivized to reduce the total cost of care. We generally disagree that such broad incentives are necessary for Advanced APM status. Specifically, the Advanced APM criterion codified at 42 CFR 414.1415(c) does not specify that a financial risk must be based on a total cost of care arrangement. Additionally, we did not design the RO Model to be a total cost of care model. Instead it was designed so that each RO episode only covers RT services. We limited the Model in this way because we believe that these services are in the control of the RT provider and RT supplier, and they are the entities at risk in the Model. Further, there has never been a requirement in the Quality Payment Program that one entity must be at risk for the entire cost of the episode. As we have previously stated, in the RO Model we are specifically testing different pricing methodologies for the RT services provided, not the other costs associated with the beneficiary.

Comment: A commenter suggested that CMS should structure the final RO Model so that all RO participants will be QPs in an Advanced APM for purposes of the Quality Payment Program, assuming minimum participation requirements are met. Additionally, although we did not request comments on our projection, discussed further in section VII.C.3 of the Regulatory Impact Analysis, that 83 percent of physician participants, measured by their unique NPI, would achieve QP status and receive the APM Incentive Payment under the Quality Payment Program at some point (for at least one QP Performance Period) during the Model performance period, some commenters suggested that all physicians participating in the RO Model should receive the APM incentive payment as compensation for participation in a mandatory model that requires quality measure and clinical data reporting. Commenters stated that CMS was issuing an unfunded mandate in cases where physicians did not receive the APM Incentive Payment.

Response: Under the structure of the Quality Payment Program, not all eligible clinicians will necessarily earn an APM Incentive Payment for their participation in an Advanced APM. Specifically, in accordance with 42 CFR 414.1430, eligible clinicians must achieve certain threshold levels of participation in the Advanced APM in terms of payment amounts or patient counts in order to achieve QP status and qualify for an APM Incentive Payment. Therefore, we believe there are other inherent benefits to the RO participant including the chance to be an early adopter of a value-based payment arrangement. As CMS in general, and the health care industry specifically, turns to more value-based payment arrangements, early adopters of these models will have an advantage over their peers who have not participated in these models. Additionally, eligible clinicians in the RO Model who are MIPS eligible clinicians (those not excluded from MIPS as QPs, Partial QPs, or on another basis) will be considered participants in a MIPS APM for purposes of MIPS reporting and scoring rules.

We appreciate the comments on our QP projections, but we must use the APM Incentive Payment calculation

methodology as specified at 42 CFR 414.1450 to determine which eligible clinicians meet the QP threshold required to achieve QP status and receive the APM Incentive Payment. As such, just as we cannot summarily award QP status to all RO participants, we cannot automatically make an APM Incentive Payment to all eligible clinicians in the RO Model. All eligible clinicians are required to meet the QP threshold for Medicare Part B professional services payments or patients in an Advanced APM in order to achieve QP status and receive the APM incentive payment. In addition to the 83 percent of RO Model physicians who are expected to be QPs, 9 percent are expected to be partial QPs at some point during the Model performance period, resulting in 92 percent of RO Model physicians becoming QPs or partial QPs at some point. We would note that while partial QPs do not earn the APM Incentive Payment, they do have the option to decide whether to be subject to the MIPS reporting requirements and payment adjustment, which would otherwise be required.

Comment: A commenter requested that the 5 percent APM incentive payment that is available through 2024 should be extended as the RO Model is just becoming available to radiation oncologists, and prior to this, the radiation oncology community has not had an Advanced APM available that would qualify physicians in the radiation oncology specialty for this bonus.

Response: We appreciate the commenter's feedback on the availability of the APM Incentive Payment to eligible clinicians who have been determined to be QPs participating in Advanced APMs. The APM Incentive Payment is limited based on statute to payment years 2019 through 2024 as specified in section 1833(z)(1)(A) of the Act.

After considering public comments, we are finalizing our proposals, with modification, that, effective January 1, 2021, at least one of the quality measures upon which the RO Model bases payment will meet at least one of the following criteria: (a) Finalized on the MIPS final list of measures, as described in 42 CFR 414.1330; (b) endorsed by a consensus-based entity; or (c) determined by CMS to be evidenced-based, reliable, and valid. This modification means that quality data collection and reporting for the RO Model will begin with PY1 on January 1, 2021, which means that we expect the Model to qualify as both an Advanced APM and a MIPS APM beginning on January 1, 2021. Final CMS determinations of Advanced APMs and MIPS APMs for the 2021 performance period will be announced via the Quality Payment Program website at *https://qpp.cms.gov/*. We are finalizing our proposal to use the results of the following quality measures, finalized in section III.C.8.b of this final rule, when determining payment to Professional participants and Dual participants under the terms of the RO Model, as discussed in detail in section III.C.8.f: (1) Oncology: Medical and Radiation—Plan of Care for Pain; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan; and (4) Treatment Summary Communication—Radiation Oncology. As there currently are no available or applicable outcome measures included in the MIPS quality measures list for the RO's Model's first QP Performance Period, we will not be including an outcome measure in this final rule. However, if a potentially relevant outcome measure becomes available, we would consider whether such an outcome measure should be included in the RO Model's measure set, and if so, use notice and comment rulemaking to propose adding it.

We are finalizing with modification, that most APM Entities, the RO participants, with the exception of those RO participants that qualify for the stop-loss provision as described in (see section III.C.6.e(4) and codified at § 512.285(f), will be at risk for all costs associated with RT services, as defined in section III.C.5.c of this final rule, beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment, and therefore, will be at 100 percent risk for all expenditures in excess of the expected amount of expenditures, which are the previously discussed episode payments. As discussed earlier in this section, based on these finalized provisions, the RO Model would meet the criteria to be an Advanced APM.

Based on the changes we made to the start date of the Model performance period in this final rule, we anticipate that the finalized RO Model will meet the criteria to be a MIPS APM under the Quality Payment Program starting in PY1 on January 1, 2021, instead of the proposed PY1 (January 1, 2020) or PY2 (January 1, 2021) as we had indicated in the proposed rule. We are also finalizing with modification to use the individual practitioner list to identify the relevant eligible clinicians for purposes of making QP determinations and determining those MIPS eligible clinicians who are also considered participants in a MIPS APM under the Quality Payment Program. We also clarify that currently, MIPS APMs, as defined in 42 CFR 414.1305, are APMs that meet the criteria specified under 42 CFR 414.1370(b). As indicated in the current 42 CFR 414.1370(a), participants in a MIPS APM are those MIPS eligible clinicians who are identified on a Participation List of an APM Entity participating in a MIPS APM for the performance period. We are using the same individual practitioner list developed to identify the eligible clinicians in the APM Entity for purposes of the Quality Payment Program.

We also note that we are finalizing that all requirements concerning the review and certification of the individual practitioner list will be required in PY1 (beginning January 1, 2021). This includes the requirement that Dual participants and Professional participants must review and certify the first individual practitioner list within 30 days of receiving the list upon the start of PY1. Further, we are finalizing as proposed, and codified at § 512.220(b), that participants must use certified EHR technology (CEHRT), that the RO participant must annually certify its intent to use CEHRT during the Model performance period, and that the RO participant will be required to certify its intent to use CEHRT within 30 days of the start of PY1.

Finally, we note that the following provisions being finalized in other sections of this final rule will apply to any APM Incentive Payments made for eligible clinicians who become QPs through participation in the RO Model:

- Our finalized provisions regarding monitoring, audits and record retention, and remedial action, as described in section II.F and III.C.14.
- Our finalized provision in section III.C.10.c, which explains that technical component payments under the RO Model will not be included in the aggregate payment amount for covered professional services that is used to calculate the amount of the APM Incentive Payment.

10. Medicare Program Waivers

As explained in the proposed rule, we believe it would be necessary to waive certain requirements of title XVIII of the Act solely for purposes of carrying out the testing of the RO Model under section 1115A (b) of the Act. Each of the waivers, which we discussed in detail, would be necessary to ensure that the Model test's design provides additional flexibilities to RO participants, including flexibilities around certain Medicare program requirements.

a. Waiver of Hospital Outpatient Quality Reporting (OQR) Program Payment Adjustment

In the proposed rule, we stated that we believe that it would be necessary for purposes of testing the RO Model to waive the Hospital OQR Program payment reduction authorized under section 1833(t)(17)(A) of the Act. Under the Hospital OQR Program, subsection (d) hospitals are required to submit data on measures on the quality of care furnished by hospitals in outpatient settings. Further, section 1833(t)(17)(A)(i) of the Act states that subsection (d) hospitals that fail to meet Hospital OQR Program requirements receive a two percentage point reduction to their outpatient department (OPD) fee schedule increase factor. The fee schedule increase factor is applied annually to increase the OPPS conversion factor, which is then multiplied by the relative payment weight for a particular Ambulatory Payment Classification (APC) to determine the payment amount for the APC. Not all OPPS items and services are included in APCs for which the payment is determined using the conversion factor. For this reason, we only apply the 2 percent reduction to APCs—identified by status indicators—for which the payment is calculated by multiplying the relative payment weight by the conversion factor.

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in a form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for many services under the OPPS. To reduce the OPD fee schedule increase factor for hospitals that fail to meet the Hospital OQR Program reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. Thus, our policy is to apply the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for a year (83 FR 59108–59110).

In the proposed rule, we proposed that for purposes of APCs that contain RO Model-specific HCPCS codes, we would waive the requirement under section 1833(t)(17)(A)(i) of the Act that the Secretary reduce the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act for a year by 2.0 percentage points for a subsection (d) hospital that does not submit, to the Secretary in accordance with paragraph (17), data required to be submitted on measures selected under that paragraph with respect to such a year. RO Model-specific HCPCS codes would be mapped to RO Model-specific APCs for payment purposes under the OPPS. This waiver would apply only to the APCs that include only the new HCPCS codes that are created for the RO Model, rather than all APCs that package radiation HCPCS codes, and would only apply when a hospital does not meet requirements under the Hospital OQR Program and would otherwise be subject to the 2.0 percentage point reduction. Only Technical participants using the RO Model-specific HCPCS codes would be paid under the Model; APCs not included in the Model, and thus not using the RO Model-specific HCPCS codes, would continue to be paid under the OPPS and subject to the 2.0 percentage point reduction under the Hospital OQR Program when applicable. We stated in the proposed rule that we believed this waiver would be necessary in order to equally evaluate participating HOPDs and freestanding radiation oncology centers on both cost and quality.

The RO Model is a test of a site-neutral pricing methodology, where payment rates are calculated in the same manner regardless of the setting (in this case, HOPDs and freestanding radiation therapy centers) and paid prospectively based on episodes of care. While payment amounts may vary across RO participants, the calculation of how much each RO participant would be paid for the PC and TC of the RO episode is designed to be as similar as possible, irrespective of whether the RO participant is an HOPD or a freestanding radiation therapy center. Therefore, in the proposed rule we stated our belief that applying the Hospital OQR Program payment reduction would undermine our goal of site-neutral payments under the RO Model because it could affect HOPDs, but not freestanding radiation therapy centers, creating additional variables that could complicate a neutral comparison. As we stated in the proposed rule, if the requirement to apply the Hospital OQR Program payment reduction were not waived, the participant-specific technical episode payments made with respect to services furnished by RO participants in HOPDs that are billed under the technical RO Model-specific HCPCS codes may be decreased due to the Hospital OQR Program payment reduction. Meanwhile, the Hospital OQR Program payment reduction would not apply to participating freestanding radiation therapy centers, which are paid under the PFS not OPPS. In the proposed rule, we discussed our belief that the potential differences between participant-specific technical episode payments made for services furnished in HOPDs and those made under the PFS that would be caused by the application of the Hospital OQR Program payment reduction would be problematic for the RO Model test by creating potentially misaligned incentives for RO participants. The Hospital OQR Program payment reduction may interfere with how the RO Model pricing methodology has been conceptualized and therefore impact the model evaluation by introducing additional variability into RO participants' payments, thereby making it harder to discern whether the episode-based bundled payment approach is successful.

For these reasons, we believed that it would be necessary to waive the requirement to apply the Hospital OQR Program payment reduction under section 1833(t)(17)(A)(i) of the Act and 42 CFR 414.1405(e) that may otherwise apply to payments made for services billed under the technical RO Model-specific HCPCS codes. As such, we proposed to waive application of the 2.0 percentage point reduction under section 1833(t)(17) of the Act for only those APCs that include only RO Model-specific HCPCS codes during the Model performance period.

We solicited comment on our proposal to waive application of the Hospital OQR Program 2.0 percentage

point reduction through use of the reporting ratio for APCs that include the new HCPCS codes that are created for the RO Model during the Model performance period. We received no comments, and therefore, are finalizing our proposal as proposed.

b. Waiver of the Requirement To Apply the MIPS Payment Adjustment Factors to Certain RO Model Payments

As we stated in the proposed rule, under section 1848(q)(6)(E) of the Act and 42 CFR 414.1405(e), the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) generally apply to the amount otherwise paid under Medicare Part B with respect to covered professional services furnished by a MIPS eligible clinician during the applicable MIPS payment year. We proposed to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and 42 CFR 414.1405(e) that may otherwise apply to payments made for services furnished by a MIPS eligible clinician and billed under the professional RO Model-specific HCPCS codes because we believed that it would be necessary solely for purposes of testing the RO Model.

The RO Model is a test of a site-neutral pricing methodology, where payment rates are calculated in the same manner regardless of the setting and paid prospectively based on episodes of care. While payment amounts may vary across RO participants, the calculation of how much each RO participant would be paid for the PC and TC of the RO episode is designed to be as similar as possible, irrespective of whether the RO participant is an HOPD or a freestanding radiation therapy center. Therefore, in the proposed rule we stated our belief that applying the MIPS payment adjustment factors would undermine our goal of site-neutral payments under the RO Model.

As we stated in the proposed rule, if the requirement to apply the MIPS payment adjustment factors were not waived, the participant-specific technical episode payments made with respect to services furnished by MIPS eligible clinicians in freestanding radiation therapy centers that are billed under the professional RO Model-specific HCPCS codes may be increased or decreased due to the MIPS payment adjustment factors. In contrast, the MIPS payment adjustment factors would not apply to payments of claims processed under the OPPS, and as a result, would not apply to the participant-specific technical episode payments made to participating HOPDs. In the proposed rule, we stated our belief that the potential differences between participant-specific technical episode payments made for services furnished in freestanding radiation therapy centers and those made under the OPPS that would be caused by the application of the MIPS payment adjustment factors would be problematic for the RO Model test by creating potentially misaligned incentives for RO participants as well as other challenges for the Model evaluation. Further we stated our belief that without this waiver, RO participants may be incentivized to change their behavior and steer beneficiaries towards freestanding radiation therapy centers if they expect the MIPS payment adjustment factors will be positive, and away from freestanding radiation therapy centers if they expect the MIPS payment adjustment factors will be negative.

Dual and professional RO participants that bill for the participant-specific professional episode payments for RT services using RO Model-specific HCPCS codes will be subject to payment adjustments under the Model based on quality performance through the quality withhold. The MIPS payment adjustment factors are determined in part based on a MIPS eligible clinician's performance on quality measures for a performance period. In the proposed rule, we stated our belief that subjecting an RO participant to payment consequences under both MIPS and the Model for potentially the same quality performance could have unintended consequences. The MIPS payment adjustment factors may interfere with how the RO Model pricing methodology has been conceptualized and therefore impact the model evaluation by introducing additional variability into RO participants' payments thereby making it harder to discern whether the episode-based bundled payment approach is successful. For these reasons, in the proposed rule we stated our belief that it would be necessary to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and 42 CFR 414.1405(e) that may otherwise apply to payments made for services billed under the professional RO Model-specific HCPCS codes.

We solicited comment on our proposal to waive the MIPS payment adjustment factors. The following is a summary of the public comments received on this proposal and our response:

Comment: Many commenters disagreed with this proposal, arguing that it would unfairly penalize clinicians for their efforts to comply with MIPS requirements, particularly in MIPS performance years 2018 and 2019, prior to the Model start. In particular, clinicians who performed well in MIPS believed that waiving MIPS payment adjustments would result in lower RO Model payments than they were due, based on their positive performance in MIPS.

Response: We understand commenters' concerns regarding fair payment for participation in MIPS. Upon further consideration, we are not finalizing our proposal to waive the MIPS payment adjustment factors for the PC of RO Model payments. We believe the concerns raised by commenters outweigh our original policy rationale in that CMS does not want to create a general disincentive for participation in Advanced APMs by waiving MIPS Adjustments that may positively impact RO participants' payments. As such, we are finalizing that the MIPS payment adjustment factors will apply to participant-specific professional episode payments for the PC of RT services furnished by a MIPS eligible clinician. The MIPS payment adjustment factors will also continue to apply to RO participants' payments for covered professional services furnished by a MIPS eligible clinician that are outside the RO Model as they usually would. Because we expect that the RO Model will be an Advanced APM, we anticipate that many eligible clinicians in the Model will achieve the Qualifying APM Participant (QP) threshold and will be excluded from MIPS, starting in QPP performance year 2021 (payment year 2023).

After considering public comments, we are finalizing our proposal at § 512.280(c) with modification to only waive the MIPS payment adjustment factors for the TC of RO Model payments. We are not finalizing our proposal to waive the MIPS payment adjustment factors for the PC of RO Model payments. We have modified the text of the regulation at § 512.280(c) to more closely align with the proposed policy as described in the preamble to the proposed rule. If an RO participant does not earn a positive MIPS adjustment, payments for the PC will be reduced by the MACs as they would be outside the RO Model.

c. Waiver of Requirement To Include Technical Component Payments in Calculation of the APM Incentive Payment Amount

In the proposed rule, we stated that we believed that it would be necessary for purposes of testing the RO Model to

exclude payments for the technical RO Model-specific HCPCS codes (to the extent they might be considered payments for covered professional services as defined in section 1848(k)(3)(A) of the Act) from the ''estimated aggregate payment amounts for covered professional services'' used to calculate the APM Incentive Payment amount under § 1833(z)(1)(A) of the Act and codified at 42 CFR 414.1450(b). We specifically believe it is necessary to exclude the technical RO Model-specific HCPCS codes from the calculation of estimated aggregate payments for covered professional services as defined in 42 CFR 414.1450(b)(1). The RO Model HCPCS codes are split into a professional component and a technical component to reflect the two types of services provided in the Model by the three different RO participant types: PGPs, HOPDs, and freestanding radiation therapy centers, across different service sites. RO participants will bill the Model-specific HCPCS codes that are relevant to their RO participant type.

In the proposed rule, we discussed our belief that this waiver was necessary because, under 42 CFR 414.1450, the APM Incentive Payment amount for an eligible clinician who is a QP is equal to 5 percent of his/her prior year estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act. The technical RO Model-specific HCPCS codes include the codes that we have developed to bill the services on the included RT services list that are considered ''technical'' (those that represent the cost of the equipment, supplies and personnel used to perform the procedure).

If the requirement to include payments for the technical RO Model-specific HCPCS codes in the calculation of the APM Incentive Payment amount were not waived, PGPs furnishing RT services in freestanding radiation therapy centers (which are paid under the PFS) participating in the Model will have technical RT services included in the calculation of the APM Incentive Payment amount, but PGPs furnishing RT services in HOPDs (which are paid under OPPS) participating in the Model would not have technical RT services included in the calculation of the APM Incentive Payment amount. We believe these potential differences between participant-specific technical episode payments processed and made under the PFS and those made under the OPPS would be problematic for the Model test by creating potentially misaligned incentives between and among RO participants, as well as other challenges for the Model evaluation. Specifically, we believe that, without this waiver, some RO participants may change their billing behavior by shifting the setting in which they furnish RT services from HOPDs to freestanding radiation therapy centers in order to increase the amount of participant-specific technical episode payments, producing unwarranted increases in their APM Incentive Payment amount. In the proposed rule, we discussed our belief that this would prejudice the model testing of site neutral payments as well as potentially interfering with the Model's design to incentivize participants to preserve or improve quality by tying performance to incentive payments if participant behavior is focused on maximizing the APM Incentive Payment.

For these reasons, we stated our belief that it would be necessary to waive the requirements of 42 CFR 414.1450(b) to the extent they would require inclusion of the technical RO Model-specific HCPCS codes as covered professional services when calculating the APM Incentive Payment amount.

We solicited public comments on our proposal to exclude the Technical Component from the APM Incentive Payment calculation. The following is a summary of the public comments received on this proposal and our response:

Comment: Many commenters disagreed with this proposal, stating that not including the TC in the payment amount used to calculate the APM Incentive Payment could make it difficult to offset any reduced payments that occur as a result of RO Model participation. Several commenters stated that not including the TC in the APM Incentive Payment calculation undercuts the spirit and letter of MACRA's intent of encouraging clinicians to assume risk and participate in APMs. These commenters stated this was the case because a lower APM Incentive Payment, resulting from exclusion of the TC in the payment calculation, would fail to adequately compensate eligible clinicians for participation in the RO Model, which is an Advanced APM. A few commenters suggested including a portion of the TC payment in the APM Incentive calculation, as opposed to none of it.

Response: We disagree with commenters' recommendations to include part or all of the TC in the payment amount used to calculate the APM Incentive Payment. The reasons for this policy are threefold. First, the TC payment of the RO Model is, generally speaking, not a payment for professional services. Rather, it is a payment for technical services (those that represent the cost of equipment, supplies, and personnel used to perform a procedure). We do not believe it would be appropriate under the RO Model for payments for technical services to be included in the APM Incentive Payment calculation. Second, inclusion of the TC payment of the RO Model in the APM Incentive Payment calculation would potentially prejudice the Model testing of site neutral payments, since PGPs furnishing RT services in HOPDs (which are paid under OPPS) would not have the TC included in the calculation. We believe that if we included the TC payment of the RO Model in the APM Incentive Payment calculation, we would create a situation that may inadvertently incentivize Professional participants to change their treatment pathways so that TC services are furnished in a freestanding radiation therapy center instead of an HOPD in an attempt to increase the amount of services rendered that would count towards their APM Incentive Payment. By not including the TC payment of the RO Model in the APM Incentive Payment calculation, we will be treating the TC payment the same no matter where the location the service is rendered and thus preventing potentially prejudicing the Model testing of site neutral payments.

After considering public comments, we are finalizing our proposal at § 512.280(d) to exclude the TC payment of the RO Model from the APM Incentive Payment calculation, with a modification to clarify that CMS is waiving the requirements of § 414.1450(b) of 42 CFR chapter IV for this purpose. Additionally, we would note that we have revised our projections regarding the number of expected QPs in the RO Model to also include physicians participating in the RO Model who we would expect to qualify as partial QPs under the Quality Payment Program.

d. General Payment Waivers

In the proposed rule, we discussed our belief that it is necessary for purposes of testing the RO Model to waive requirements of certain sections of the Act, specifically with regard to how payments are made, in order to allow the RO Model's prospective episode payment to be fully tested. Therefore, we proposed to waive:

- Section 1848(a)(1) of the Act that requires payment for physicians' services to be determined under the PFS to allow the professional and technical component payments for RT services to be made as set forth in the RO Model. We believe that waiving section 1848(a)(1) of the Act will be necessary

because otherwise many of the RO Model payment rates will be set by the PFS;

- Section 1833(t)(1)(A) of the Act that requires payment for outpatient department (OPD) services to be determined under the OPPS to allow the payments for technical component services to be paid as set forth in the RO Model because otherwise the participant-specific technical episode payment will be set by the OPPS (we note that the waiver of OPPS payment will be limited to RT services under the RO Model); and
- Section 1833(t)(16)(D) of the Act regarding payment for stereotactic radiosurgery (a type of RT covered by the RO Model) to allow the payments for technical component services to be paid as set forth in the RO Model because RO Model payment amounts would be modality agnostic and episodic such that all treatments and duration of treatment for this cancer type are paid the same amount.

We proposed to waive these requirements because these statutory provisions establish the current Medicare FFS payment methodology. Without waiving these specific provisions of the Act, we would not be able to fully test whether the prospective episode pricing methodology tested under the RO Model (as discussed in section III.C.6 of this final rule) was effective at reducing program expenditures while preserving or enhancing the quality of care. Specifically, the RO Model will test whether adjusting the current fee-for-service payments for RT services to a prospective episode-based payment model will incentivize physicians to deliver higher-value RT care. Without waiving the requirements of statutory provisions that currently determine payments for RT services, payment for RT services would be made using the current FFS payment methodology and not the pricing methodology we are testing through the Model.

We solicited public comments on the general payment waivers. The following is a summary of the public comments received on this proposal and our response:

Comment: Some commenters stated that CMS will not be able to fully test the RO Model as proposed unless CMS also waives section 1833(t)(2)(H) of the Act, which provides that ''with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered [outpatient department services] that classify such devices separately from the other services (or group of services)'' paid under the OPPS ''in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.''

Response: We appreciate these comments and agree that in order to finalize the RO Model as proposed a waiver of section 1833(t)(2)(H) is necessary. In particular, section 1833(t)(2)(H) requires separate payment for devices of brachytherapy, but the RO Model will utilize episode-based payment, which means that CMS will make a single payment for the radiation service including for brachytherapy and any other services that were furnished as part of the episode.

Comment: A commenter stated that CMS should not waive section 1833(t)(2)(H) of the Act, but should instead incorporate the requirements of that provision into the proposed RO Model by paying separately for brachytherapy sources outside of the RO Model payment bundles using Medicare's current system of coding and reimbursement for brachytherapy sources.

Response: We appreciate the comment, but disagree that we should pay separately in the RO Model for brachytherapy source payments provided in HOPDs. One of the primary objectives for the RO Model is to test an episode-based payment. Without waiving this provision, we would not be testing the RO Model as an episode-based payment model as proposed and intended.

We received no comments on the general payment waivers we proposed and therefore are finalizing these provisions without modification. Additionally, after considering public comments, we are also finalizing an additional waiver of section 1833(t)(2)(H) of the Act as some commenters have suggested. This provision requires separate payment of brachytherapy sources provided in HOPDs. As we are testing new payment methodologies for RT services including brachytherapy sources provided in HOPDs, we believe that it is necessary to waive this provision of the Act.

e. Waiver of Appeals Requirements

In the proposed rule, we discussed our belief that it was necessary for purposes of testing the RO Model to waive section 1869 of the Act specific to claims appeals to the extent otherwise applicable. We proposed to implement this waiver so that RO participants may utilize the timely error and reconsideration request process specific to the RO Model in section III.C.12 of this rule to review potential RO Model reconciliation errors. We noted in the proposed rule that, if RO participants have general Medicare claims issues they wish to appeal (Medicare claims issues experienced by the RO participant that occur outside the scope of the RO Model, but during their participation in the RO Model), then the RO participants should continue to use the standard CMS claims appeals procedures under section 1869 of the Act.

We proposed to implement this waiver because the pricing methodology for the RO Model is unique and as such we have developed a separate timely error notice and reconsideration request process that RO participants will use in lieu of the claims appeals process under section 1869 of the Act.

In section III.C.12 of the proposed rule (84 FR 34528 through 34529), we discussed the process for RO participants to contest the calculation of their reconciliation payment amounts, the calculation of their reconciliation repayment amounts, and the calculation of their AQS. Reconciliation payment amount means a payment made by CMS to an RO participant as determined in accordance with § 512.285. This process would ensure that individuals involved in adjudicating these timely error notices and reconsideration requests on these issues would be familiar with the payment model being implemented and would ensure that these issues are resolved in an efficient manner by individuals with knowledge of the payment model.

Our proposal does not limit Medicare beneficiaries' right to the claims appeals process under section 1869. We noted, in the specific circumstance wherein a health care provider acts on behalf of the beneficiary in a claims appeal, section 1869 applies.

We solicited public comments on the waiver of appeal requirements. The following is a summary of the public comments received on this proposal and our response:

Comment: A commenter supported the fact that our proposal does not limit Medicare beneficiaries' right to the claims appeals process under section 1869. The commenter believed it is imperative that RO beneficiaries have the same rights as other Medicare beneficiaries to appeal coverage decisions they believe to be unfounded.

Response: We appreciate the commenter's support.

After considering public comments, we are finalizing, without modification, our proposed waiver of appeals

requirements, specifically to waive section 1869 of the Act specific to claims appeals for RO Model claims.

f. Waiver of Amendments Made by Section 603 of the Bipartisan Budget Act of 2015

In the proposed rule, we discussed our belief that it was necessary for purposes of testing the RO Model to waive application of the PFS relativity adjuster which applies to payments under the PFS for ''non-excepted'' items and services identified by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), which amended section 1833(t)(1)(B)(v) of the Act and added paragraph (t) (21) to the Social Security Act. Sections 1833(t)(1)(B)(v) and (t) (21) of the Act exclude certain items and services furnished by certain off-campus provider-based departments (non-excepted off-campus provider-based departments (PBDs)) from the definition of covered outpatient department services for purposes of OPPS payment, and direct payment for those services to be made ''under the applicable payment system'' beginning January 1, 2017. We established the PFS as the ''applicable payment system'' for most non-excepted items and services furnished in non-excepted off-campus PBDs (81 FR 79699) and, in order to facilitate payment under the PFS, we apply a PFS relativity adjuster that is currently set at 40 percent of the OPPS rate (82 FR 53027). We also require OPDs to use the modifier ''PN'' on applicable OPPS claim lines to identify non-excepted items and services furnished in non-excepted off-campus PBDs. The modifier triggers application of the PFS relativity adjuster in CMS' claims processing systems.

Under the RO Model, we proposed to waive requirements under section 1833(t)(1)(B)(v) and (t)(21) of the Act for all RO Model-specific payments to applicable OPDs. If a non-excepted off-campus PBD were to participate in the RO Model, it would be required to submit RO Model claims consistent with our professional and technical billing proposals in section III.C.7. In addition, we proposed to not apply the PFS relativity adjuster to the RO Model payment and instead pay these participants in the same manner as other RO participants because the RO Model pricing methodology's design as discussed in section III.C.6.c of this final rule sets site-neutral national base rates, and adding the PFS relativity adjuster to the RO Model payment for RO participants that are non-excepted off-campus PBDs would disrupt this approach and introduce a payment differential. In the proposed rule, we discussed our belief that this waiver was necessary to allow for consistent model evaluation and ensure site neutrality in RO Model payments, which is a key feature of the RO Model.

We solicited public comments on payment waivers. We received no comments on this policy and are finalizing it as proposed.

11. Reconciliation Process

We proposed that we would conduct an annual reconciliation for each RO participant after each PY to reconcile payments owed to the RO participant with payments owed to CMS due to the withhold policies discussed in section III.C.6.g of the proposed rule (84 FR 34527). We proposed that this annual reconciliation would occur in the August following a PY in order to allow time for claims run-out, data collection, reporting, and calculating results.[78]

In the example we provided in the proposed rule, the annual reconciliation for PY1 would apply to episodes initiated January 1, 2020 (or April 1, 2020) through December 31, 2020, and the annual reconciliation for PY1 would occur in August of 2021. We stated that an annual reconciliation is appropriate because incomplete episodes and duplicate RT services as described in section III.C.6.a of the proposed rule and this final rule may result in additional payment owed to an RO participant or owed to CMS for RT services furnished to an RO beneficiary in those cases.

The following is a summary of the comments we received on the proposal for the annual reconciliation to occur in August following a PY and our responses to these comments:

Comment: Many commenters expressed concern about the annual reconciliation taking place in August of the following PY, citing issues of health care provider burden, financial hardship, and patient access to care. A commenter requested that CMS prospectively reimburse RO participants for their payment withholds to ensure that they do not have a gap in revenue. Another commenter recommended that reconciliation should be conducted every six months. Another commenter suggested that the RO Model implement a reconciliation to occur immediately following the performance year with a final reconciliation to account for claims runout.

Response: Changes made elsewhere in this final rule reduce the financial burden associated with the timing of reconciliations. Specifically, as noted in section III.C.6.g of this final rule, we will reduce the incorrect payment withhold from 2 percent to 1 percent and not begin the quality withhold until PY1. The patient experience withhold will not begin until PY3. If reconciliation were to be conducted every six months, this would require RO participants to submit quality measure data more frequently, which would increase provider burden.

We would like to clarify that we are adding a definition at § 512.205 for ''initial reconciliation,'' which means the first reconciliation of a PY that occurs as early as August following the applicable PY. We also are finalizing the definition of ''true-up reconciliation'' at § 512.205 to mean the process to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial reconciliation and after a 12-month claims run out for all RO episodes initiated in the applicable PY. We also would like to clarify that the true-up reconciliation process is only related to the incorrect payment withhold, and we will not conduct a true-up reconciliation for the quality withhold or the patient experience withhold.

Moreover, an additional reconciliation, if done a few months prior to what we call the initial reconciliation before allowing for a reasonable claim run-out, would be based on incomplete data. We believe this would unduly complicate the reconciliation process. In the case of an initial reconciliation, CMS calculations will use claims data available at that time for claims run-out and expect to provide RO participants with a reconciliation report in August of the subsequent year following the applicable PY. With respect to the concerns about patient access to care, the commenter did not explain how the timing of reconciliation in a mandatory model would affect patient access to care. We do not expect that reconciliation timing will have any impact on patient access to care. With respect to the commenter who requested that CMS prospectively reimburse RO participants for their payment withholds, we understand the commenter to be requesting that CMS eliminate the payment withhold. We decline to do so because the withhold reserves money for purposes of reconciling duplicate RT services and incomplete episodes, which protects the financial integrity of the model and reduces any immediate negative financial impact on RO participants due to reconciliation. As a result of the stop-

[78] Claims run-out is the period of time that CMS allows for the timely submission of claims by providers and suppliers before reconciliation.

loss policy described in section III.C.6.e(4) we are finalizing this provision with modification to add a stop-loss reconciliation amount to the reconciliation process, as codified at § 512.285(f). We would like to clarify that we are adding a definition at § 512.205 for ''stop-loss reconciliation,'' which means the amount owed to RO participants that have fewer than 60 episodes during 2016–2018 for the loss incurred under the Model and were furnishing included RT services at November 30, 2020 in the CBSAs selected for participation as described in § 512.285(f).

We have also modified the text of the regulation at § 512.285 to describe how reconciliation payments and repayment amounts are calculated and what details are provided in the reconciliation report as described in the preamble to the proposed rule. We have made a number of non-substantive editorial and organizational changes to streamline and improve the clarity of the regulation text at § 512.285. We note that the proposed rule indicated that reconciliation would occur annually in August. Although this final rule provides that reconciliation will occur annually, we are removing the language indicating that reconciliation will always occur in August, and instead state that initial reconciliation could occur as early as August, because we may require additional flexibility depending on the availability of data and other considerations. If the RO participant fails to timely pay the full repayment amount, CMS will recoup the repayment amount from any payments otherwise owed by CMS to the RO participant, including Medicare payments for items and services unrelated to the RO Model, and interest will be charged in accordance with 42 CFR 405.378.

a. True-Up Process

We proposed that we would conduct an annual true-up of reconciliation for each PY. We proposed to define the term ''true-up'' as the process to calculate additional payments or repayments for incomplete episodes and duplicate RT services that are identified after claims run-out. More specifically, we proposed that we would true-up the PY1 reconciliation approximately one year after the initial reconciliation results were calculated. This would align the PY2 reconciliation of the following year with the PY1 true-up, thereby allowing for a full claims run-out on PY1, and reducing any potential confusion for RO participants that may be caused by receiving multiple reconciliation reports in close succession. We proposed to follow the same process for each subsequent performance year. Under our proposal, we would conduct a true-up of PY1 in August 2022, a true-up of PY2 in August 2023, and so forth.

We solicited public comments on our proposal for a true-up process. The following is a summary of the comment we received on our proposal and our response to the comment:

Comment: A commenter recommended eliminating the true-up process to streamline the reconciliation process.

Response: We thank this commenter for the suggestion. We believe that the true-up process requires little effort on the part of RO participants and that it is necessary to properly account for additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after a full 12-month claims run-out. Eliminating the true-up process could lead to a gaming opportunity where RO participants might wait to submit claims until after the claims run-out period used in the first reconciliation for a PY. The net reconciliation payment or repayment amount owed for the PY is the sum of (h)(1) and (f)(2) in the reconciliation example provided in section III.C.11.b. We are finalizing this provision concerning the true-up process with modification to codify the true-up process at § 512.285(g). We note that in the proposed rule we provided examples of the timing of the PY1 and PY2 true-ups. Given the change in the Model performance period, we are clarifying that we will conduct the PY1 true-up reconciliation as early as August 2023, and the PY2 true-up reconciliation as early as August 2024, and so forth. While we have every expectation that all reconciliations and true-up reconciliations will occur in August, we recognize that in exceptional circumstances, there could be a modest delay in performing such reconciliations. For this reason, we are revising the regulation text at § 512.285(a) to remove reference to conducting annual reconciliations ''in August.''

We are finalizing our definition of ''true-up'' with technical modifications to read as follows: ''*True-up reconciliation* means the process to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial reconciliation and after a 12-month claims run-out for all RO episodes initiated in the applicable PY.'' Specifically, the proposed definition has been revised to replace the term ''payments or repayments'' with the defined terms ''reconciliation payments'' and ''repayment amounts.'' In addition, we have replaced the phrase ''that are identified after claims run-out'' with the more precise ''that are identified after initial reconciliation'' and included the time frame for claims run-out.

b. Reconciliation Amount Calculation

To calculate a reconciliation payment amount either owed to an RO participant by CMS or a reconciliation repayment amount owed to CMS by an RO participant, we proposed to use the following process:

- Calculate the incorrect episode payment amount. We proposed to sum all money the RO participant owes CMS due to incomplete episodes and duplicate services, and subtract the amount from the incorrect payment withhold amount (that is, the cumulative withhold of 2 percent on episode payment amounts for all RO episodes furnished during that PY by that RO participant).[79] This would determine the amount owed to the RO participant by CMS based on total payments made to the RO participant for incomplete episodes and duplicate RT services for a given PY, if applicable. An RO participant would receive the full incorrect payment withhold amount if it had no duplicate RT services or incomplete episodes (as explained in section III.C.6.g). In instances where there are duplicate RT services or incomplete episodes, the RO participant would owe a repayment amount to CMS if the amount of all duplicate RT services and incomplete episodes exceeds the incorrect payment withhold amount.
- For Professional participants during the Model's performance period: We proposed that if the RO participant is a Professional participant, then we would add the Professional participant's incorrect episode payment amount to the quality reconciliation amount. The quality reconciliation amount would be determined by multiplying the participant's AQS (as a percentage) against the total two-percentage point maximum amount as described in section III.C.8.f(2).
- For Technical participants in PY1 and PY2: We proposed that if the RO participant is a Technical participant then the Technical participant's reconciliation amount would be equal to

[79] Please note that the final rule reduced the incorrect payment withhold amount from the proposed 2 percent to 1 percent, discussed in section III.C.6.g of this final rule.

the incorrect episode payment amount. There would be no further additions or subtractions.

- For Technical participants in PY3, PY4, and PY5: We proposed to add the Technical participant's incorrect episode payment amount to the patient experience reconciliation amount, in section III.C.6.g(3). Technical participants and Dual participants could earn up to the full amount of the patient experience withhold (1 percent of the technical episode payment amounts) for a given performance year based on their results from the patient-reported CAHPS® Cancer Care Radiation Therapy Survey.
- For Dual participants in PY1 and PY2: We proposed to add the Dual participant's incorrect episode payment amount to the quality reconciliation amount. The quality reconciliation amount would be determined by multiplying the Dual participant's AQS (in percentage terms) against the total two-percentage point maximum withhold amount as described in section III.C.8.f(2).
- For Dual participants in PY3, PY4, and PY5: We proposed to add the Dual participant's incorrect episode payment amount to the quality reconciliation amount. The quality reconciliation amount would be determined by multiplying the participant's AQS (in percentage terms) against the total two-percentage point maximum withhold amount as described in section III.C.8.f(2). Then, we would add the Dual participant's patient experience reconciliation amount to this total.

The geographic adjustment and the 2 percent adjustment for sequestration would be applied to the incorrect payment withhold, quality withhold, and patient experience withhold amounts during the reconciliation process. Beneficiary coinsurance would be waived for the reconciliation payment and repayment amounts, meaning that the RO participant may not collect 20 percent of what is owed to CMS from the RO beneficiary, and CMS will not collect 20 percent of what it owes the RO participant from the RO beneficiary.

We provided an example reconciliation calculation for a Professional participant in Table 10 of the proposed rule. The numbers listed in that table are illustrative only. In the example in the proposed rule, the incorrect payment withhold amount for the Professional participant would be $6,000 or 2 percent of $300,000 (the total payments for the participant after the trend factor, adjustments, and discount factor have been applied). The Professional participant would owe CMS $3,000 for duplicate payments due to claims submitted on behalf of beneficiaries who received RT services by another RT provider or RT supplier during their RO episode. Lastly, the Professional participant would owe CMS $1,500 for cases of incomplete episodes whereby the PC of the RO episode was billed and due to death or other reason, the TC was not billed by the time of reconciliation. In the example in the proposed rule, the payments for duplicate RT services and incomplete episodes would be subtracted from the incorrect payment withhold amount to render $1,500 due to the RO participant from CMS for the incorrect episode payment amount (a). This amount would then be added to the quality reconciliation amount (b). The quality withhold amount for this RO participant would be $6,000 or 2 percent of $300,000. This RO participant's performance on the AQS would entitle them to 85 percent of the quality withhold, and, therefore, when the quality reconciliation amount (b) is added to the incorrect payment withhold amount (a), and a total reconciliation payment of $6,600 (c) is due to the RO participant from CMS for that performance year. We note that the example in the proposed rule does not include the geographic adjustment or the 2 percent adjustment for sequestration.

We solicited public comment on our proposal on calculating reconciliation amounts. The following is a summary of the comments we received on our proposal and our responses to these comments:

Comment: A commenter requested clarification as to how beneficiary coinsurance would be accounted for in reconciliation and repayment amounts, stating that there are conflicting interpretations of ''waiving'' beneficiary coinsurance.

Response: To clarify, we are waiving the beneficiary coinsurance obligation when an RO participant owes CMS money (repayment amount) or CMS owes the RO participant money (reconciliation payment). Thus, no beneficiary coinsurance will be collected on these amounts. We have clarified our regulation text on this issue at § 512.285(i)(3). We will provide RO participants with additional instructions for billing, particularly as it pertains to how beneficiary coinsurance will be accounted for in reconciliation. Additional instructions will be made available through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A commenter requested that detailed information be provided on reconciliation reports so that RO participants could attribute data by clinician and category.

Response: We thank the commenter for this suggestion and we will take this into consideration as we design the reconciliation reports.

After considering public comments on section III.C.11 of the proposed rule, we are finalizing our proposed provisions at § 512.285 that the reconciliation process will occur annually, with each RO participant receiving a reconciliation report that indicates the reconciliation payment amount they are due or the repayment amount owed to CMS. Please note that because of the change to the incorrect payment withhold in this final rule, described in section III.C.11 of this rule, we have provided an updated example reconciliation calculation for a Professional participant in Table 14, which reflects that change. The numbers listed in the table are illustrative only. In this example, the total incorrect payment withhold amount for this Professional participant is $3,000 or 1 percent of $300,000 (the total payment amounts for the RO episodes initiated in the PY for this RO participant after the trend factor, adjustments, and discount factor have been applied). The Professional participant owes CMS $3,000 for duplicate RT services due to claims submitted on behalf of RO beneficiaries who received any included RT services (duplicate RT services) from another RT provider or RT supplier during their RO episode. Lastly, in this example, the Professional participant owes CMS $1,500 for cases of incomplete episodes where the PC of the RO episode was billed, and due to death or another reason, the TC was not billed by the time of reconciliation and for cases of incomplete episodes where the RO beneficiary switched RT provider or RT supplier before all the included RT services in the RO episode had been furnished. In this example, the payments for duplicate RT services and incomplete episodes would be subtracted from the incorrect payment withhold amount to render $1,500 due to CMS from the RO participant for the incorrect episode payment amount (a). This amount is then added to the quality reconciliation amount (b). The quality withhold amount for this participant is $6,000 or 2 percent of $300,000. This RO participant's performance on the AQS entitles him or her to 85 percent of the quality withhold, and, therefore, when the quality reconciliation amount (b) is added to the incorrect payment withhold amount (a), and a total

reconciliation payment of $3,600 (d) is due to the RO participant from CMS for that performance year. We note that in this example the RO participant did not qualify to receive a stop-loss reconciliation amount (c) as codified at § 512.285(f) and, therefore, no value is listed. We note that this example does not include the geographic adjustment or the 2 percent adjustment for sequestration.

We are finalizing the reconciliation process at § 512.285 as proposed with the following clarification: CMS uses the reconciliation process to identify any reconciliation payment owed to an RO participant or any repayment amount owed by an RO participant to CMS. For instance, in the case where the SOE for the PC is billed, yet the SOE for the TC is not billed, CMS will owe the RO participant only the FFS amount for the RT services included in the PC that was billed by the RO participant for that RO beneficiary. If, in this case, the RO participant was paid $2,000 for the first episode payment of the PC and only furnished one planning service, which under FFS would be reimbursed at $200, and no SOE for the TC was billed within 28 days, then the RO participant's repayment amount would be $1,800 for this RO episode, and this would be accounted for during reconciliation. Also, for any incomplete episode that is reconciled to FFS amounts because the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished, the RO beneficiary owes the RO participant(s) that initiated the PC or TC 20 percent of the FFS amount for the RT services that were furnished during that RO episode, not 20 percent of the episode bundled payment (see section III.C.6.i of this final rule). For any RO episode that involves one or more duplicate RT services, the payment for the RO participant that initiated the PC or TC will be reconciled by reducing the RO participant's episode payment by the FFS amount of the duplicate RT services furnished by the RT provider or RT supplier that did not initiate the PC or TC.

This means that for any RO episode that involves one or more duplicate RT services, the RO participant that initiated the PC or TC is owed the bundled payment less the FFS amount for the RT services furnished by the RT provider or RT supplier that did not initiate the PC or TC. The other RT provider or RT supplier that furnished RT services to that beneficiary, whether an RO participant or not, will be paid FFS for those RT services. The FFS amount to be subtracted from the bundled payment of the RO participant that initiated the PC or TC of that RO episode, however, cannot exceed the participant-specific professional episode payment amount or the participant-specific technical episode payment amount that the RO participant received for the RO episode. If the FFS amount to be subtracted for duplicate RT services exceeds the participant-specific professional episode payment amount or the participant-specific technical episode payment amount, CMS will not subtract more than the participant-specific professional episode payment amount or participant-specific technical episode payment amount received by the RO participant.

TABLE 14: EXAMPLE RECONCILIATION CALCULATION FOR A PROFESSIONAL PARTICIPANT

Professional participant	Formula	Example
Sum of the episode payment amounts (after trend factor, adjustments, and discount factor have been applied)		$300,000
Total Incorrect Payment Withhold Amount (a_1)	a_1	$3,000
Total Duplicate RT Services Amount (a_2)	a_2	($3,000)
Total Incomplete Episode Amount (a_3)	a_3	($1,500)
Incorrect Episode Payment Reconciliation Amount (a)	$a = a_1 + a_2 + a_3$	($1,500)
Quality Withhold (b_1)	b_1	$6,000
AQS (b_2)	b_2	0.85
Quality Reconciliation Amount (b)	$b = b_1 * b_2$	$5,100
Stop-loss Reconciliation Amount (c)	c	
Reconciliation Payment/(Repayment Amount, if this were to be negative, indicating an amount owed to CMS by the RO participant) (d)	d = a + b + c	$3,600

12. Timely Error Notice and Reconsideration Request Processes

In the proposed rule, we stated that we believed it would be necessary to implement timely error notice and reconsideration request processes under which RO participants may dispute suspected errors in the calculation of their reconciliation payment amount or repayment amount (in section III.C.11 of the proposed rule and this final rule), or AQS (in section III.C.8.f of the proposed rule and this final rule) as reflected on an RO reconciliation report that has not been deemed final. Therefore, we proposed a policy that would permit RO participants to contest errors found in the RO reconciliation report, but not the RO Model pricing methodology or AQS methodology. We note that, if RO participants have Medicare FFS claims

or decisions they wish to appeal (that is, Medicare FFS issues experienced by the RO participant that occur outside the scope of the RO Model but during their participation in the RO Model), then the RO participants should continue to use the standard CMS procedures through their Medicare Administrative Contractor.

Section 1869 of the Act provides for a process for Medicare beneficiaries, providers, and suppliers to appeal certain claims decisions made by CMS. However, we proposed that we would waive the requirements of section 1869 of the Act specific to claims appeals as necessary solely for purposes of testing the RO Model. Specifically, we believe it would be necessary to establish a means for RO participants to dispute suspected errors in the calculation of their reconciliation payment amount, repayment amount, or AQS. Having RO participants utilize the standard claims appeals process under section 1869 of the Act to appeal the calculation of their reconciliation payment amount, repayment amount, or AQS would not lead to timely resolution of disputes because MACs and other CMS officials would not have access to beneficiary attribution data, and the standard claims appeals process hierarchy would not engage the Innovation Center and its contractors until late in the process. Accordingly, we proposed a two-level process for RO participants to request reconsideration of determinations related to calculation of their reconciliation payment, repayment amount, or AQS under the RO Model. The first level would be a timely error notice process and the second level to be reconsideration review process, as subsequently discussed. The processes here are based on the processes implemented under certain models currently being tested by the Innovation Center.

As proposed, only RO participants may utilize the first and second level of the reconsideration process, unless otherwise stated in other sections of this subpart. We believe that only RO participants should be able to utilize the process because non-participants would not receive calculation of a reconciliation payment amount, repayment amount, or AQS, and would generally have access to the section 1869 claims appeals processes to appeal the payments they receive under the Medicare program.

1. Timely Error Notice

As we explained in the proposed rule, in some models currently being tested by the Innovation Center, CMS provides model participants with a courtesy copy of the settlement report for their review, allowing them to dispute suspected calculation errors in that report before the payment determination is deemed final. Other models currently being tested by the Innovation Center make model-specific payments in response to claims or on the basis of model beneficiary attribution that are similarly subject to a model-specific process for resolving disputes. In some models currently being tested by the Innovation Center, these reconsideration processes involve two levels of review.

Building off of these existing processes, we proposed for the first level of the reconsideration process to be a timely error notice. Specifically, RO participants could provide written notice to CMS of a suspected error in the calculation of their reconciliation payment amount, repayment amount, or AQS for which a determination has not yet been deemed to be final under the terms of this part. As proposed, the RO participant would have 30 days from the date the RO reconciliation report is issued to provide their timely error notice (see § 512.290). This would be subject to the limitations on administrative and judicial review as previously described in section II.K. Specifically, an RO participant could not use the timely error notice process to dispute a determination that is precluded from administrative and judicial review under section 1115A(d)(2) of the Act and § 512.170. We proposed that this written notice must be submitted in a form and manner specified by CMS. Unless the RO participant provides such notice, the RO participant's reconciliation payment amount, repayment amount, or AQS would be deemed final after 30 days, and CMS would proceed with payment or repayment, as applicable. If CMS receives a timely notice of an error, we would respond in writing within 30 days to either confirm that there was a calculation error or to verify that the calculation is correct. CMS would reserve the right to an extension upon written notice to the RO participant. We proposed to codify this timely error notice policy at § 512.290(a).

We solicited comment on this proposal. The following is a summary of the public comments received on this proposal and our response:

Comment: Two commenters requested additional time to review reconciliation reports and submit potential errors to CMS. A commenter suggested extending the timeline to a 90-day period for participants to review and submit a timely error notice. Another commenter suggested extending the timeline to a 45-day period for participants to review and submit a timely error notice.

Response: We agree with commenters that providing additional time may benefit some RO participants in identifying and understanding calculation errors. We would note that increasing the timeline to 45 days, as a commenter suggested, would align our processes with those used in the CJR model. We want to reiterate that we are committed to paying RO participants accurately and correctly and believe that the calculation error process serves an important function in achieving that goal. The procedures for processing and issuing reconciliation payment amounts and repayment amounts that we are finalizing in section III.C.11 of this final rule require specific timeframes in order to process these payments properly and promptly. As such we believe the need for extending the deadline for submission of notices of calculation error should be balanced with our goal to issue reconciliation payment amounts and repayment amounts promptly. Therefore, to address the commenters' concerns while balancing our need to finalize payment determinations promptly, this final rule provides that a notice of calculation error must be received by CMS within 45 days after the issuance of a reconciliation report.

After considering public comments, we are finalizing our proposed timely error notice provisions with a modification of extending the amount of time that RO participants have to submit their timely error notice, which must be received by CMS within 45 days after the issuance of a reconciliation report, at § 512.290(a). Additionally, we are modifying the regulatory text at § 512.290(a) to align the regulatory text with the proposal discussed in the preamble of the proposed rule that would permit RO participants to contest errors found in the RO reconciliation report, but not the RO Model pricing methodology or AQS methodology. We are removing proposed § 512.290(a)(4), which stated that an RO participant must have submitted a timely error notice on an issue not precluded from administrative or judicial review as a condition of using the reconsideration review process described in § 512.290(b). That provision is unnecessary because § 512.290(b) specifies that the reconsideration process may be invoked only to contest CMS' response to a timely error notice. Finally, we have made technical changes in § 512.290(a) to refer to the timely error notice in a consistent manner.

2. Reconsideration Review

We also proposed a second level of the reconsideration process that would permit RO participants to dispute CMS' response to the RO participant's identification of errors in the timely error notice, by requesting a reconsideration review by a CMS reconsideration official. As is the case for many models currently being tested by the Innovation Center, we proposed that the CMS reconsideration official will be a designee of CMS who is authorized to receive such requests who was not involved in the responding to the RO participant's timely error notice. To be considered, we proposed that the reconsideration review request must be submitted to CMS within 10 days of the issue date of CMS' written response to the timely error notice. The reconsideration review request would be submitted in a form and manner specified by CMS.

As there will not otherwise be a timely error notice response for the reconsideration official to review, in order to access the reconsideration review process, we proposed that an RO participant must have timely submitted a timely error notice to CMS in the form and manner specified by CMS, and this timely error notice must not have been precluded from administrative and judicial review. Specifically, where the RO participant does not timely submit a timely error notice with respect to a particular reconciliation payment amount, reconciliation repayment amount, or AQS, we proposed that the reconsideration review process would not be available to the RO participant with respect to the RO participant's reconciliation payment amount, the calculation of the RO participant's repayment amount, or the calculation of the RO participant's AQS.

In the proposed rule, we explained that if the RO participant did timely submit a timely error notice and the RO participant is dissatisfied with CMS' response to the timely error notice, the RO participant would be permitted to request reconsideration review by a CMS reconsideration review official. To be considered, we proposed that the reconsideration review request must be submitted within 10 days of the date of CMS's response to the timely error notice and must provide a detailed explanation of the basis for the dispute, including supporting documentation for the RO participant's assertion that CMS or its representatives did not accurately calculate the reconciliation payment amount, repayment amount, or AQS in accordance with the terms of the RO Model.

As proposed, the reconsideration review would be an on-the-record review (a review of the memoranda or briefs and evidence only) conducted by a CMS reconsideration official. The CMS reconsideration official would make reasonable efforts to notify the RO participant and CMS in writing within 15 days of receiving the RO participant's reconsideration review request of the following: The issues in dispute, the briefing schedule, and the review procedures. The briefing schedule and review procedures would lay out the timing for the RO participant and CMS to submit their position papers and any other documents in support of their position papers; the review procedures would lay out the procedures the reconsideration official will utilize when reviewing the reconsideration review request. In the proposed rule, we proposed that the CMS reconsideration official would make all reasonable efforts to complete the on-the-record review of all the documents submitted by the RO participant and issue a written determination within 60 days after the submission of the final position paper in accordance with the reconsideration official's briefing schedule. As this would be the final step of the Innovation Center administrative dispute resolution process, we proposed that the determination made by the CMS reconsideration official would be binding and not subject to further review. This reconsideration review process is consistent with other resolution processes used throughout the agency. We proposed to codify this reconsideration review process at § 512.290(b).

We solicited public comment on our provisions regarding the reconsideration review process. The following is a summary of the public comments received on this proposal and our responses to these comments:

Comment: A few commenters requested additional time for RO participants to submit a reconsideration request.

Response: We appreciate these comments and are sympathetic to the requests from commenters for more time for RO participants during the reconsideration review process, however we believe our modification to the timeline of the timely error notice deadline allows RO participants more time to contemplate their error notice because we have given them more time to flesh out the issues before submitting a timely error notice. Further, with the extended timeline for submission of timely error notices and the 10-day deadline for reconsideration requests is consistent with the timelines around timely error and reconsideration requests in the CJR Model.

We are committed to paying RO participants accurately and correctly and believe that the timely error and reconsideration review processes as proposed serve an important function in achieving that goal. The procedures for processing and issuing reconciliation payment amounts and repayment amounts that we are finalizing in section III.C.11 of this final rule require specific timeframes in order to process these payments properly and promptly. Similar processes have been developed and are utilized in other CMS models. As such we believe the need for extending the deadline for submission of reconsideration review requests should be balanced with our goal to issue reconciliation payment amounts and repayment amounts promptly.

Comment: A commenter suggested that CMS should be held to a similarly strict time standard for the reconsideration review process as the RO participant is. They further suggest that CMS should be strictly bound to a timeline, and not have the flexibility allowed by making all reasonable efforts to respond to the reconsideration review within 60 days of receipt of the final position paper. The commenter believes CMS and the RO participant should be given the same amount of time during their portions of the reconsideration review, and if CMS goes over that time limit, the RO participant's position should be accepted and the final payment amount, repayment amount, or AQS should reflect that.

Response: We appreciate the commenter's suggestion that we must also adhere to a time standard when responding to the RO participant during the reconsideration review process. We would reiterate that we are committed to paying RO participants accurately and correctly, and we believe that the timely error and reconsideration review processes as proposed serve an important function in achieving that goal. We note that the proposed timeline and the flexibility proposed for our final decision on the reconsideration review aligns with the timelines being utilized in other models being tested by the Innovation Center. As such, we believe the timeline as proposed is appropriate, and we will commit to sticking to the timeline as proposed unless it is wholly unreasonable for the CMS reconsideration official to fully review and decide upon the issue in the time given.

After considering public comments, we are finalizing our proposed reconsideration review provisions with

non-substantive editorial and organizational changes to streamline and improve the clarity of the regulation text at § 512.290(b).

13. Data Sharing

CMS has experience with a range of efforts designed to improve care coordination and the quality of care, and decrease the cost of care for beneficiaries, including models tested under section 1115A, most of which make certain types of data available upon request to model participants. Based on the design elements of each model, the Innovation Center may offer participants the opportunity to request different types of data, so that they can redesign their care pathways to preserve or improve quality and coordinate care for model beneficiaries. Furthermore, as described in sections II.E and II.G of this final rule, we believe it is necessary for the Innovation Center to require certain data to be reported by model participants to CMS in order to evaluate and monitor the model, including the model participant's participation in the model, which could then also be used to inform the public and other model participants regarding the impact of the model on both program spending and the quality of care.

a. Data Privacy Compliance

In § 512.275(a), we proposed that as a condition of their receipt of patient-identifiable data from CMS for purposes of the RO Model, RO participants would be required to comply with all applicable laws pertaining to any patient-identifiable data requested from CMS under the terms of the RO Model and the terms of any other written agreement entered into by the RO participant and CMS as a condition of the RO participant receiving such data (84 FR 34530). Such laws could include, without limitation, the privacy and security standards promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as modified, and the Health Information Technology for Economic and Clinical Health Act (HITECH). Additionally, we proposed to require RO participants contractually bind all downstream recipients of CMS data to the same terms and conditions to which the RO participant was itself bound in its agreements with CMS as a condition of the downstream recipient's receipt of the data from the RO participant. As we noted in the proposed rule, binding RO participants and their downstream recipients to such written requirements was necessary if CMS was to protect the individually identifiable health information data that it be shared with RO participants and their downstream recipients for care redesign and other forms of quality improvement as well as care coordination purposes.

The following is a summary of the public comments received on this proposal and our responses to the comments:

Comment: A commenter expressed concern that the use of third party companies to collect and analyze data on the RO participants' behalf will cause additional burdens on RO participants to ensure that no HIPAA requirements or agreement terms and conditions violations occur with the handling of patient-identifiable data by multiple parties.

Response: The requirement that RO participants contractually bind their downstream recipients in writing to comply with applicable law and the program requirements in the RO participants' agreements with CMS is necessary to protect the individually identifiable health information data. Furthermore, in the case of covered entities and their business associates, the privacy and security requirements promulgated under HIPAA, as modified, and HITECH would have applied to such parties regardless of what these program regulations provide—we merely highlighted the applicability of these and other legal mandates. Therefore, in light of our program interests and the various already applicable laws, we are finalizing this policy with references to the existing privacy and security requirements under HIPAA, as modified, and HITECH.

Comment: A commenter recommended that CMS add an additional requirement to this Model such that data related to cancer staging information be stored as discrete data in the EHR or specialty-focused health IT record, and made available to external systems through a FHIR® (Fast Healthcare Interoperability Resources)-based application programming interface.

Response: We appreciate this commenter's suggestion. We believe that the requirement that RO participants comply with all applicable laws relating to patient-identifiable data is sufficient and that adding additional requirements as suggested by the commenter at this time may present a logical outgrowth problem as well as a burden for the RO participants. However, we will take this recommendation under consideration for future rulemaking.

After considering public comments, we are finalizing the provisions at § 512.275(a), with modifications to the regulatory text to align the regulatory text with the proposals discussed in the preamble. These modifications specifically add ''patient-identifiable derivative data'' to the regulatory text. Although this language was included in the proposed rule's preamble text, it was inadvertently left out of the regulatory text.

b. RO Participant Public Release of Patient De-Identified Information

We did not propose to restrict RO participants' ability to publicly release patient de-identified information that references the RO participant's participation in the RO Model. In the proposed rule, we stated our belief that such information could potentially be included in press releases, journal articles, research articles, descriptive articles, external reports, and statistical/analytical materials describing the RO participant's participation and patient results in the RO Model if such information has been de-identified in accordance with HIPAA requirements in 45 CFR 164.514(b) (84 FR 34530). Those requirements define the data elements that would need to be removed to qualify as de-identified under that regulatory scheme. However, in order to ensure external stakeholders understand that information the RO participant releases represents their own content and opinions, and does not reflect the input or opinions of CMS, we proposed to require the RO participant to include a disclaimer on the first page of any such publicly released document, the content of which materially and substantially references or relies upon the RO participant's participation in the RO Model. We proposed to codify such a disclaimer at § 512.120(c)(2) (providing ''The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document.'') We proposed to require the use of this disclaimer so that the public, and RO beneficiaries in particular, are not misled into believing that RO participants are speaking on behalf of the agency.

The following is a summary of the public comment received on this proposal and our response to the comment:

Comment: We received a comment supporting our proposal to require RO participants to include a disclaimer on all descriptive model materials and activities.

Response: We thank you for your support.

After considering the public comment received on this proposal, we are finalizing this proposal without modification at § 512.275(b).

c. Data Submitted by RO Participants

In addition to the quality measures and clinical data discussed in section III.C.8 of the proposed rule (84 FR 34514 through 34522) and this final rule, we proposed that RO participants supply and/or confirm a limited amount of summary information to CMS. This information includes the RO participant's TIN in the case of a freestanding radiation therapy center and PGP, or CCN in the case of an HOPD. We proposed to require RO participants supply and/or confirm the NPIs for the physicians who bill for RT services using the applicable TINs. In the proposed rule, we also proposed that RO participants may be required to provide information on the number of Medicare and non-Medicare patients treated with radiation during their participation in the Model. We proposed to require RO participants' submission of additional administrative data upon a request from CMS, such as the RO participant's costs to provide care (such as the acquisition cost of a linear accelerator) and how frequently the radiation machine is used on an average day; current EHR vendor(s); and accreditation status. We proposed to elicit this through annual web-based surveys. We stated in the proposed rule that we would use the data requested under the RO Model to monitor and assess participants' office activities, benchmarks, and track to participant compliance with applicable laws and program requirements. 84 FR 34530.

The following is a summary of the public comments received on this proposal and our responses to these comments:

Comment: A commenter expressed support of requiring RO participants' submission of their accreditation status.

Response: We thank this commenter for supporting this proposed policy.

Comment: A few commenters requested that comprehensive radiation oncology accreditation standards be used to ensure that the quality and compliance standards are met. One of these commenters argued that utilizing such accreditation programs as a part of CMS' monitoring and assessment to efforts to ensure compliance with legal and model agreement requirements would ensure that facilities demonstrate their systems, personnel, policies and procedures meet standards for high-quality patient care. That commenter also requested that the accreditation requirement take effect in 2024, allowing for a phase-in/transition period so that all RO Participants could prepare and complete the RO Model review process. This commenter further requested that accreditation be used in lieu of the monitoring requirements.

Response: We agree with the commenters that accreditation by nationally recognized organizations, such as the ACR, ACRO, and ASTRO, may be an indicator of the overall quality of care provided by a RT provider or RT supplier. As noted earlier in this final rule, the Model must include a set of quality measures to qualify as a MIPS APM and an Advanced APM, and as such, accreditation is not able to replace the RO quality measures without compromising the Model's qualification as a MIPS APM and Advanced APM. In addition, we do not believe that accreditation provides a full picture of quality care delivery in radiation oncology. Although we are not using accreditation status as a proxy for quality, as stated in section III.C.13.c we may at some point use an optional web-based survey to gather data from participants on administrative data points, including their accreditation status, indicating the importance of this information to understanding participants' activities. To add clarity to this policy, CMS will not use the submission of accreditation status information in lieu of the quality and compliance reporting requirements. We are finalizing this policy with modification that in response to a request made by CMS, RO participants may volunteer to submit administrative data related to their accreditation status.

Comment: A couple of commenters indicated that the proposed annual mandatory survey that CMS may use to request additional information, such as the cost of providing care, frequency of equipment use, EHR vendors, and accreditation status does not have a direct relation to the Model. A commenter further believed that such information may include proprietary information and requested that the data collected by CMS be aggregated and blinded.

Response: We thank these commenters for their feedback on our proposed annual survey. We disagree with the commenter that the additional administrative data does not have a direct relation to the RO Model. As stated in the proposed rule at 84 FR 34530, the data requested will be used to better understand participants' office activities, benchmarks, and to track participant compliance with the RO Model requirements. We agree with the commenter that the data could contain proprietary information and note that we will handle the data in accordance with applicable laws, including but not limited to FOIA. In light of these commenters' concerns, we are modifying the proposal such that if additional administrative data is requested, the RO participants' submission of such administrative data will be optional.

After considering public comments, we are finalizing this proposal with modification. Requests by CMS for administrative data related to the cost of providing care, frequency of equipment use, EHR vendors, and accreditation status will be optional for RO participants.

d. Data Provided to RO Participants

Thirty (30) days prior to the start of each PY, we proposed to provide RO participants with updated participant-specific professional episode payment and technical episode payment amounts for each included cancer type. RO participants, to the extent allowed by HIPAA and other applicable law, could reuse individually identifiable claims data that they request from CMS for care coordination or quality improvement work in their assessment of CMS' calculation of their participant-specific episode payment amounts and/or amounts included in the reconciliation calculations used to determine the reconciliation payment amount or repayment amount, as applicable. To seek such care coordination and quality improvement data, we proposed that RO participants should use a Participant Data Request and Attestation (DRA) form, if appropriate for that RO participant's situation, which will be available on the Radiation Oncology Administrative Portal (ROAP). Throughout the Model performance period, RO participants may request to continue to receive these data until the final reconciliation and final true-up process has been completed if they continue to use such data for care coordination and quality improvement purposes. At the conclusion of this process, the RO participant would be required to maintain or destroy all data in its possession in accordance with the DRA and applicable law.

We proposed that the RO participant may reuse original or derivative data without prior written authorization from us for clinical treatment, care management and coordination, quality improvement activities, and provider incentive design and implementation, but would not be permitted to disseminate individually identifiable original or derived information from the files specified in the Model DRA to

anyone who is not a HIPAA Covered Entity Participant or individual practitioner in a treatment relationship with the subject Model beneficiary; a HIPAA Business Associate of such a Covered Entity Participant or individual practitioner; the participant's business associate, where that participant is itself a HIPAA Covered Entity; the participant's sub-business associate, which is hired by the RO participant to carry out work on behalf of the Covered Entity Participant or individual practitioners; or a non-participant HIPAA Covered Entity in a treatment relationship with the subject Model beneficiary.

When using or disclosing PHI or personally identifiable information (PII) obtained from files specified in the DRA, we proposed that the RO participant would be required to make ''reasonable efforts to limit'' the information to the ''minimum necessary'' as defined by 45 CFR 164.502(b) and 164.514(d) to accomplish the intended purpose of the use, disclosure or request. The RO participant would be required to further limit its disclosure of such information to what is permitted by applicable law, including the regulations promulgated under the regulations promulgated under the HIPAA and HITECH laws at 45 CFR part 160 and subparts A and E of part 164, and the types of disclosures that the Innovation Center itself would be permitted to make under the ''routine uses'' in the applicable systems of records notices listed in the DRA. The RO participant may link individually identifiable information specified in the DRA (including directly or indirectly identifiable data) or derivative data to other sources of individually identifiable health information, such as other medical records available to the participant and its individual practitioner. The RO participant would be authorized to disseminate such data that has been linked to other sources of individually identifiable health information provided such data has been de-identified in accordance with HIPAA requirements in 45 CFR 164.514(b).

We solicited public comment on our proposal. The following is a summary of the public comment received on this proposal and our response:

Comment: A commenter requested that CMS provide RO participants with data on a monthly basis, as this commenter believed this is the standard in other APMs. Some commenters requested that the participant-specific professional episode payment and participant-specific technical episode payment amounts for each included cancer type be provided to RO participants 90 to 180 days prior to the start of each PY. These commenters believed that 30 days in advance is inadequate to analyze the data and take appropriate action with participant partners on a timely basis.

Response: We understand these commenters' concerns, yet there are a number of reasons why CMS is unable to provide participant-specific professional episode payment and participant-specific technical episode payment amounts and these amounts 90 to 180 days prior to the start of each PY. First, certain pricing components used to determine the participant-specific professional episode payment and technical payment amounts are derived from current Medicare rates, which are not published until November before the start of the PY for which they would apply (see section III.C.6.c(1)). Instead, as explained in section III.C.6.c(1) of this final rule, CMS will provide each RO participant its case mix and historical experience adjustments for both the PC and TC, rather than their participant-specific professional and technical episode payment amounts, because exact figures for the participant-specific professional and technical episode payment amounts will not be known to CMS prior to the start of the PY for which they would apply. Furthermore, we disagree with the commenter that it is standard practice in other APMs to provide participants with data on a monthly basis. The data provided to model participants varies across APMs and many factors contribute to the feasibility of providing such data (for example, such as scope of the model). At this time, given the scope of this Model, we believe it is impracticable to provide RO participants with data on a monthly basis. Therefore, we are finalizing with the modification that we will provide RO participants with their case mix and historical experience adjustments for the professional and technical components at least thirty (30) days prior to the start of each PY (see regulatory text at § 512.255).

f. Access To Share Beneficiary Identifiable Data

As discussed earlier in this final rule, in advance of each PY and any other time deemed necessary by us, we will offer the RO participant an opportunity to request certain data and reports through a standardized DRA, if appropriate to that RO participant's situation. The data and reports provided to the RO participant in response to a DRA will not include any beneficiary-level claims data regarding utilization of substance use disorder services unless the requestor provides a 42 CFR part 2-compliant authorization from each individual about whom they seek such data. While the proffered DRA form was drafted with the assumption that most RO participants seeking claims data will do so under the HIPAA Privacy Rule provisions governing ''health care operations'' disclosures under 45 CFR 164.506(c)(4), in offering RO participants the opportunity to use that form to request beneficiary-identifiable claims data, we do not represent that the RO participant or any of its individual practitioners has met all applicable HIPAA requirements for requesting data under 45 CFR 164.506(c)(4). The RO participant and its individual practitioners should consult their own counsel to make those determinations prior to requesting data using the DRA form.

Agreeing to the terms of the DRA, the RO participant, at a minimum, will agree to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use of or access to it. The safeguards will be required to provide a level and scope of security that is not less than the level and scope of security requirements established for federal agencies by the Office of Management and Budget (OMB) in OMB Circular No. A–130, Appendix I—Responsibilities for Protecting and Managing Federal Information Resources (available at *https://www.whitehouse.gov/omb/information-for-agencies/circulars/*) as well as Federal Information Processing Standard 200 entitled ''Minimum Security Requirements for Federal Information and Information Systems'' (available at *http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf*); and, NIST Special Publication 800–53 ''Recommended Security Controls for Federal Information Systems'' (available at *http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf*). We proposed that the RO participant would be required to acknowledge that the use of unsecured telecommunications, including insufficiently secured transmissions over the internet, to transmit directly or indirectly identifiable information from the files specified in the DRA or any such derivative data files will be strictly prohibited. Further, the RO participant would be required to agree that the data specified in the DRA will not be physically moved, transmitted, or disclosed in any way from or by the site of the Data Custodian indicated in the

DRA without written approval from CMS, unless such movement, transmission, or disclosure is required by a law. At the conclusion of the RO Model and reconciliation process, the RO participant would be required to maintain or destroy all CMS data and any individually identifiable derivative in its possession as provided by the DRA and any other applicable written agreements with CMS.

The following is a summary of the public comment received on section III.13.f of the proposed rule and our response:

Comment: A commenter requested that beneficiaries be informed, prior to participating in the RO Model, that CMS proposes to collect quality, clinical, and administrative data and would share with RO participants certain de-identified beneficiary data, and how it will be used by CMS and RO participants.

Response: For information relating to the data that CMS proposes to collect from RO participants, please see sections III.C.8, III.C.8.c (quality measures) and III.C.8.e (clinical data elements) of this rule. We are finalizing as proposed that RO participants will be required to provide beneficiaries with the beneficiary notification letter during the initial treatment planning session which will detail, among other things, the RO beneficiary's right to refuse having his or her Medicare claims data shared with the RO participant for care coordination and quality improvement purposes under § 512.225(a)(2). Beneficiaries who do not wish to have their claims data shared with the RO participant for care coordination and quality improvement purposes under the Model would be able to notify their respective RO participant; in such cases the RO participant must provide notification in writing to CMS within 30 days of when the beneficiary notifies the RO participant.

After considering public comments, we are finalizing our proposed data sharing policies with the modification that requests by CMS for administrative data related to the cost of providing care, frequency of equipment use, EHR vendors, and accreditation status will be optional for the RO participant. We are codifying these policies at our regulation at § 512.275(a)–(b).

14. Monitoring and Compliance

We proposed at 84 FR 34531 that the general provisions relating to monitoring and compliance in section II.I of this rule would apply to the RO Model. Specifically, RO participants would be required to cooperate with the model monitoring and evaluation activities in accordance with § 512.130, comply with the government's right to audit, inspect, investigate, and evaluate any documents or other evidence regarding implementation of the RO Model under § 512.135(a), and to retain and provide the government with access to records in accordance with §§ 512.135(b) and (c). Additionally, CMS would conduct model monitoring activities with respect to the RO Model in accordance with § 512.150(b). In the proposed rule we discussed our belief that the general provisions relating to monitoring and compliance would be appropriate for the RO Model, because we must closely monitor the implementation and outcomes of the RO Model throughout its duration. The purpose of monitoring would be to ensure that the Model is implemented safely and appropriately; that RO participants comply with the terms and conditions of this rule; and to protect RO beneficiaries from potential harms that may result from the activities of an RO participant.

Consistent with § 512.150(b), we anticipated that monitoring activities may include documentation requests sent to RO participants and individual practitioners on the individual practitioner list; audits of claims data, quality measures, medical records, and other data from RO participants and clinicians on the individual practitioner list; interviews with members of the staff and leadership of the RO participant and clinicians on the individual practitioner list; interviews with beneficiaries and their caregivers; site visits; monitoring quality outcomes and clinical data, if applicable; and tracking patient complaints and appeals. We also discussed in the proposed rule (84 FR 34531 through 34532) that we anticipated using the most recent claims data available to track utilization as described in section III.C.7 of this final rule, and beneficiary outcomes under the Model. More specifically, we proposed to track utilization of certain types of treatments, beneficiary hospitalization and emergency department use, and fractionation (numbers of treatments) against historical treatment patterns for each participant. In the proposed rule, we discussed our belief that this type of monitoring was important because as RO participants transition from receiving FFS payment to receiving new (episode-based) payment, and we noted that we want to ensure to the greatest extent possible that the Model is effective and that RO Model beneficiaries continue to receive high-quality and medically appropriate care.

Additionally, we explained in the proposed rule that we may employ longer-term analytic strategies to confirm our ongoing analyses and detect subtler 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. This work may involve pairing clinical data with claims data to identify specific issues by cancer type.

The following is a summary of the public comments received on this proposal and our responses to the comments:

Comment: A commenter expressed support of the proposed monitoring activities. Another commenter expressed support of our proposal to monitor longer-term analytic strategies to confirm ongoing analyses.

Response: We thank these commenters for their support.

Comment: A commenter requested that CMS clearly define the monitoring activities and the effect the RO Model will have on beneficiaries. This commenter has also requested details on how CMS will ensure patient stakeholder groups have access to resulting data as well as how patient advocate groups will be able to provide input on what is and is not working from the patient perspective.

Response: We believe that the RO Model will improve quality of care for RO beneficiaries receiving treatment from RO participants, and we believe that the monitoring activities as described in section III.C.14 will help us to understand whether there are any unintended consequences. As it relates to beneficiaries, we will closely monitor beneficiary and patient complaints and survey responses to determine what is or is not working during the test of the Model and to mitigate unforeseen adverse impact on RO beneficiaries. With respect to patient stakeholder groups having access to resulting data, while we did not propose to share specific data from our monitoring and oversight of the Model with patient stakeholder groups, we will consider that in future rulemaking. Additionally, as discussed in section III.C.13.b, we finalized our proposal to not restrict RO participants' ability to publicly release patient de-identified information that references the RO participant's participation in the RO Model. Thus, RO participants may share with patient stakeholder groups the information CMS shares with the RO participants based on monitoring and oversight of their performance. Therefore, patient

stakeholder groups may have access to such resulting data that is released by RO participants. We welcome input from patient advocate groups on the patient perspective on the RO Model at any time.

We note that an Annual Evaluation Report will be publicly released for each year of the RO Model, as is required for all Innovation Center models by section 1115A(b)(4). The independent evaluation will rigorously assess the impact of the RO Model on quality, expenditures, utilization, RO beneficiary and RO participant experiences with RT service use, and quality of care, as well as on costs to RO beneficiaries and to Medicare. Detailed methodologies and data sources used to create these estimates will be included in each Annual Evaluation Report (additional information on the Evaluation can be found in section III.C.16).

Comment: A commenter expressed concern that this Model will cause a shift in treatment to modalities that treat tumors with large doses of radiation over a shorter time frame, and that providers and suppliers will rapidly transition to stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) without having the proper staff or necessary equipment to safely perform such procedures. This commenter has requested that CMS implement a program to track beneficiary outcomes both in terms of survival and toxicity to avoid unintended consequences. The commenter recommended that providers and suppliers track and report this outcomes data via a Medicare Certified Quality Clinical Data Registry (QCDR) like the Registry for Performance and Clinical Outcomes in Radiology (RPCR).

Response: We thank the commenter for this comment and appreciate their concern. CMS will take these suggestions into consideration. At this time, we believe that the Model is designed in a way that we will be able to adequately monitor RO beneficiary outcomes and treatment delivery patterns to assess whether there are unintended consequences without needing to use a Medicare QCDR. Please see section III.C.14.b for more information relating to the monitoring activities.

Comment: A commenter requested clarification regarding onsite quality and clinical element data audits.

Response: To clarify, we may utilize onsite audits, conducted by a contractor, of quality and clinical data elements to monitor RO Participants for model compliance. Audits of quality and clinical data may also be used to ensure that the Model is effective and that RO Model beneficiaries continue receiving high-quality and medically appropriate care. Site visits may be used to better understand how RO participants manage services, use evidence-based care, and practice patient-centered care. Site visit activities may include, but are not limited to, interviewing RO participant(s) and staff, reviewing records, and observing treatments.

a. Monitoring for Utilization/Costs and Quality of Care

We proposed to monitor RO participants for compliance with RO Model requirements. We anticipated monitoring to detect possible attempts to manipulate the system through patient recruitment and billing practices. The pricing methodology requires certain assumptions about patient characteristics, such as diagnoses, age, and stage of disease, based on the historical case mix of the individual participants. It also assigns payments by cancer type. Because of these features, participants could attempt to manipulate patient recruitment in order to maximize revenue (for example, cherry-picking, lemon-dropping, or shifting patients to a site of service for which the participant bills Medicare that is not in a CBSA randomly selected for participation). As explained in the proposed rule, we anticipated monitoring compliance with RO Model-specific billing guidelines and adherence to current LCDs, which provide information about the only reasonable and necessary conditions of coverage allowed. We also intended to monitor patient and provider and supplier characteristics, such as variations in size, profit status, and episode utilization patterns, over time to detect changes that might suggest attempts at such manipulation.

To allow us to conduct this monitoring, we proposed that RO participants would report data on program activities and beneficiaries consistent with the data collection policies in section III.C.8 of this rule. These data would be analyzed by CMS or our designee for quality, consistency, and completeness; further information on this analysis would be provided to RO participants in a time and manner specified by CMS prior to collection of this data. We would use existing authority to audit claims and services, to use the Quality Improvement Organization (QIO) to assess for quality issues, to investigate allegations of patient harm, and to monitor the impact of the RO Model quality metrics. We noted in the proposed rule that we may monitor participants to detect issues with beneficiary experience of care, access to care, or quality of care. We also indicated that we may monitor the Medicare claims system to identify potentially adverse changes in referral, practice, or treatment delivery patterns.

We solicited public comment on our proposal. The following is a summary of the public comments received on this proposal and our responses to the comments:

Comment: A commenter indicated that discriminatory practices and attempts to game the system must be prevented and eliminated.

Response: As we discussed in the proposed rule and this final rule, we are aware that RO participants might manipulate patient recruitment to maximize revenue. For that reason, we explained that we would be monitoring compliance with RO Model-specific billing guidelines and adherence to LCDs, as well as our intention to monitor patient and provider and supplier characteristics over time to detect changes that might suggest attempts at such manipulation. We believe that the monitoring and compliance requirements will mitigate gaming and discriminatory practices by RO participants.

Comment: A commenter appreciated the decision that CMS share the planned clinical data elements and reporting standards with EHR vendors and radiation oncology specialty societies, and requested that CMS also share this information with oncology clinical pathways developers.

Response: We plan to share the clinical data elements and the reporting process publicly via the RO Model website (see sections III.C.8 and III.C.8.e of this final rule). We appreciate the suggestion specific to pathway developers and will take this into consideration.

Comment: Two commenters asked CMS to provide specifics on how it will monitor and intervene on potential unintended consequences of the Model.

Response: As we previously stated, data submitted by RO participants will be analyzed by CMS or our designee for quality, consistency, and completeness. Further information on this analysis will be provided to RO participants in a time and manner specified by CMS prior to collection of this data. We will use existing authority to audit claims and services, to use the QIO to assess for quality issues, to use our authority to investigate allegations of patient harm, and to monitor the impact of the RO Model quality metrics. We may monitor RO participants to detect issues with

beneficiary experience of care, access to care, or quality of care. We may monitor the Medicare claims system to identify potentially adverse changes in referral, practice, or treatment delivery patterns. Should unforeseen consequences arise during the Model test, we will take appropriate measures, including those outlined in § 512.160 or modifying the regulatory requirements for compliance, to mitigate such consequences.

b. Monitoring for Model Compliance

We had proposed to require all participants to annually attest in a form and manner specified by CMS that they will use CEHRT throughout such PY in a manner sufficient to meet the requirements as set forth in 42 CFR 414.1415(a)(1)(i), and as stated in the proposed rule at 84 FR 34522 through 34524. In addition, we proposed that each Technical participant and Dual participant be required to attest annually that it actively participates in a radiation oncology-specific AHRQ-listed patient safety organization (PSO). This attestation would be required to ensure compliance with this RO Model requirement. CMS may change these attestation intervals throughout the Model upon advanced written notice to the RO participants. We proposed to codify these RO Model requirements at § 512.220(a)(3). We noted that CMS may monitor the accuracy of such attestations and that false attestations will be punishable under applicable federal law, including but not limited to the remedial action set forth in § 512.160(b).

In addition, we proposed to monitor for compliance with the other RO Model requirements listed in this section through site visits and medical record audits conducted in accordance with § 512.150, and as stated in the proposed rule at 84 FR 34581 through 34582. We proposed to codify at § 512.220(a)(2) our requirement that all Professional participants and Dual participants document in the medical record that the participant: (i) Has discussed goals of care with each RO beneficiary before initiating treatment and communicated to the RO beneficiary whether the treatment intent is curative or palliative; (ii) adheres to nationally recognized, evidence-based clinical treatment guidelines when appropriate in treating RO beneficiaries, or documents in the medical record the rationale for the departure from these guidelines; (iii) assesses the RO beneficiaries' tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnoses; (iv) assesses the RO beneficiary's performance status as a quantitative measure determined by the physician; (v) sends a treatment summary to each RO beneficiary's referring physician within three months of the end of treatment to coordinate care; (vi) discusses with each RO beneficiary prior to treatment delivery his or her inclusion in, and cost-sharing responsibilities under, the RO Model; and (vii) performs and documents Peer Review (audit and feedback on treatment plans) for 50 percent of new patients in PY1, for 55 percent of new patients in PY2, for 60 percent of new patients in PY3, for 65 percent of new patients in PY4, and for 70 percent of new patients in PY5 preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within 2 weeks of the start of treatment, as stated in the proposed rule at 84 FR 34585 through 34586.

The following is a summary of the public comments received on this proposal and our responses to these comments:

Comment: A commenter expressed support of the required medical record documentation regarding the goals of care, the treatment intent, the beneficiary's inclusion in the RO Model, and the cost-sharing responsibilities. This commenter urged CMS to develop and consumer test language for providers and suppliers to use in discussing these complex issues.

Response: We appreciate the commenter's support and suggestion. We will consider developing guidance materials that RO participants may use to ensure adherence to the Model requirements. Should such materials be developed, the RO participants will be notified and those materials will be made available on the RO Model website at *https://innovation.cms.gov/initiatives/radiation-oncology-model/.*

Comment: A commenter expressed concern that the Innovation Center would not have the resources to effectively monitor the number of proposed RO participants.

Response: We will be utilizing a contractor to effectively monitor the activities of the RO participants.

Comment: A couple of commenters expressed frustration with the EHR data reporting requirements and asserted that these requirements would be administratively burdensome for RO participants.

Response: We appreciate the commenters' concerns; however, we disagree with these commenters' argument that such reporting requirements are excessively burdensome. Many of these requirements are already being captured by RT providers and RT suppliers prior to the implementation of this Model as part of the Quality Payment Program, accreditation, licensing, and delivery of high-quality care. Furthermore, these seven medical record documentations are critical for high-quality care and necessary for evaluation of this Model. Therefore, we are finalizing this policy as proposed.

Comment: A couple of commenters requested that the EHR/medical record documentation requirements be eliminated from the Model requirements. These commenters indicated that these data elements are not always captured in discrete fields.

Response: We will not be eliminating these documentation requirements from the Model as they are a necessary component of the Model. As stated earlier in this rule's comments and responses, we believe that delaying the start date for the Model, and therefore the collection of clinical data elements, until January 1, 2021, and publishing the final rule several months before the Model performance period, will allow participants time to become comfortable with other aspects of the Model and develop best practices to facilitate their data collection and work with EHR vendors to seek additional EHR support. As such, we are finalizing the requirement that RO participants document the seven medical record documentations set forth in section III.C.14.b with the modification that this requirement begin in PY1 instead of at the start of the Model.

Comment: A commenter expressed support for the PSO participation requirement.

Response: We thank the commenter for this support.

Comment: A few commenters were concerned with the proposed requirement of attesting annually to active participation in a radiation oncology-specific PSO. These commenters requested clarity on the PSO requirement and asked whether participation in any PSO could meet the compliance requirement as one of these commenters noted that there are fees associated with joining a PSO. There were also concerns with the time and resources it takes to join a PSO.

Response: After reviewing these comments, we are finalizing this proposed policy with modification. RO participants will annually attest to whether they actively participate in a patient safety organization, but we will no longer require that the participant be in a radiation oncology-specific PSO. Instead, RO participants will be in compliance so long as they annually attest to active participation with any PSO. We believe that this modification

will alleviate the commenter's concern of paying additional fees to participate with a radiation oncology-specific PSO when an RO participant is already participating in a non-radiation oncology-specific PSO. We are also removing the text ''PSO provider service agreement'' and replacing it with ''for example, by maintaining a contractual or similar relationship with a PSO for the receipt and review of patient safety work product'' for alignment with the terminology used by AHRQ. Additionally, the PSO requirement will be effective beginning in PY1. For those RO participants that are not in a PSO, they can use the time period from the publication of this final rule until the attestation period near the end of PY1 to initiate participation with a PSO.

Comment: A commenter recommended that we collect data on participation in the Radiation Oncology Incident Learning System (RO–ILS).

Response: We thank this commenter for the suggestion. At this time, we will not be modifying our proposed monitoring policies to include data collection on participation in the RO–ILS because we believe that our monitoring policies as finalized are appropriate for the monitoring and evaluation of this Model.

Comment: A commenter thanked CMS for recognizing the importance of nationally recognized, evidence-based clinical practice guidelines. This commenter has noted that CMS can determine guideline adherence through the use of various HIT systems and real-time clinical decision support applications which can be integrated into electronic health record (EHR) systems. A couple of commenters requested clarification on the requirement to discuss goals of care with each Medicare beneficiary as the treatment intent is not always provided as a data field in oncologist's information systems.

Response: We appreciate the commenter bringing HIT systems and real-time clinical decision support applications to our attention, and we note that we do not believe that these systems are necessary at this point. We also appreciate the commenters' requests for clarification on the requirement to discuss goals of care with each RO beneficiary. To add clarity, we are committed to supporting the efforts of RO participants to work with their EHR vendors to facilitate this change to capture the seven activities required under the Model. We believe that publishing the final rule several months before the Model performance period will allow RO participants and EHR vendors to prepare for participation in the Model. Therefore, we are finalizing our monitoring policies related to the use of nationally recognized, evidence-based clinical practice guidelines as proposed.

Comment: A commenter requested that CMS provide a list of approved, nationally recognized, evidence-based clinical treatment guidelines to RO participants.

Response: We do not believe that it is necessary for us to provide such a list as radiation oncologists have the knowledge and ability to determine what nationally recognized, evidence-based clinical treatment guidelines are applicable to their patient population.

Comment: A commenter requested clarification on how clinical decision support will be assessed and documented if it is not common in radiation oncology software. Specifically, this commenter expressed concerns with documenting adherence to nationally recognized, evidence-based treatment guidelines or rationale for departure from those guidelines.

Response: We believe that publishing the final rule more than 60 days prior to the start date will provide RO participants with time to facilitate medical record software updates to include appropriate fields to comply with the data submission and monitoring requirements of the Model.

Comment: A commenter supported the qualified peer review requirement as being consistent with the CMS ''Patients over Paperwork'' initiative.

Response: We thank the commenter for this support.

Comment: Some commenters expressed concerns with the peer review requirements as being onerous for RO participants, particularly single practitioners and those practicing in underserved areas (that is, rural and some urban settings). These commenters asked for either the elimination of or a phased-in approach for the peer review requirements. A commenter requested that there be an exemption to those small/rural practices that show good-faith in trying to comply.

Response: We understand commenters' concerns with the proposed policy on peer review as this currently may not be a common practice among certain RT providers and RT suppliers, but this is common practice for larger RT providers and RT suppliers and those seeking accreditation. After considering comments received, we are finalizing with modification the peer review requirement. The peer review requirements will be finalized as proposed with reporting to begin in PY1. A good faith exemption for those small/rural practices would require future rulemaking with a public comment period. We will take your request for an exemption for small/rural practices under consideration and proceed with future rulemaking should it become necessary during the test of this Model. However, we believe that the use of CBSAs as the geographic unit of selection minimizes the number of rural providers and suppliers that will be selected in the Model. We have also finalized an option for low-volume RT providers and RT suppliers to opt out of the Model as described in section III.C.3.c of this final rule and codified at § 512.210(c).

Comment: A commenter has inquired how TNM staging will be used by CMS, and specifically asked whether it would be used in the AJCC staging system. Additionally, this commenter has requested clarification on how CMS will handle cancer types that do not have a TNM staging system.

Response: We appreciate the importance of staging in the diagnosis, prognosis, and treatment of cancer. The four quality measures for the RO Model beginning in PY1 and continuing thereafter, as described in section III.C.8.b of this rule, do not rely on staging data. As we review which clinical data elements are appropriate for inclusion in the RO Model, we will consider staging data if these elements are determined to meet RO Model goals of eliminating unnecessary or low-value care, developing accurate episode prices, or developing new radiation oncology-specific quality measures.

After considering public comments, we are finalizing our proposed policies on monitoring for Model compliance with the modifications, as previously discussed, related to active participation in a PSO (the PSO requirement will be effective beginning in PY1, but RO participants are not required to be in a radiation oncology-specific PSO) and peer review (will begin in PY1). We are codifying these policies at §§ 512.150 and 512.220.

c. Performance Feedback

We proposed to provide detailed and actionable information regarding RO participant performance related to the RO Model. We stated in the proposed rule that we intend to leverage the clinical data to be collected through the RO Model secure data portal, quality measure results reported by RO participants, claims data, and compliance monitoring data to provide information to participants on their adherence to evidence-based practice guidelines, quality and patient experience measures, and other quality initiatives. We discussed our belief that

these reports can drive important conversations and support quality improvement progress. The design of and frequency with which these reports would be provided to participants would be determined in conjunction with the RO Model implementation and monitoring contractor.

We solicited public comment on our proposal. We received no comments on this proposal and therefore are finalizing this policy as proposed.

d. Remedial Action for Non-Compliance

We refer readers to section II.I of this final rule for our proposals regarding remedial action.

15. Beneficiary Protections

We proposed to require Professional participants and Dual participants to notify RO beneficiaries that the RO participant was participating in this RO Model by providing written notice to each RO beneficiary during the RO beneficiary's initial treatment planning session. In the proposed rule, we noted that we intended to provide a notification template that RO participants may personalize with their contact information and logo, which would explain that the RO participant is participating in the RO Model and would include information regarding RO beneficiary cost-sharing responsibilities and an RO beneficiary's right to refuse having his or her data shared under § 512.225(a)(2). Beneficiaries who do not wish to have their claims data shared for care coordination and quality improvement purposes under the Model would be able to notify their respective RO participant. In such cases, the RO participant must notify in writing CMS within 30 days of when the RO beneficiary notifies the RO participant.

We discussed in our proposed rule our belief that it will be important that RO participants provide RO beneficiaries with a standardized, CMS-developed RO beneficiary notice in order to limit the potential for fraud and abuse, including patient steering. The required RO Model beneficiary notice would be exempt from the provision at § 512.120(c)(2), and discussed in section II.D.3 of this rule, that requires a standard disclaimer statement on all descriptive model materials. In the proposed rule, we discussed our belief that the disclaimer statement should not apply to the RO Model beneficiary notice, because RO participants would be required to use standardized language developed by CMS. We proposed for these policies to be in § 512.225(c).

The beneficiary notice would include, along with other pertinent information, how to contact CMS with questions. Specifically, if beneficiaries have any questions or concern with their physicians, we stated in the proposed rule that we encouraged them to telephonically contact the CMS using 1–800–MEDICARE, or their local Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC–QIOs) (local BFCC–QIO contact information can be located here: *https://www.qioprogram.org/locate-your-qio*).

We solicited public comment on the beneficiary protections. In this section of this rule, we summarize and respond to the public comments received on this proposal.

Comment: A commenter requested that CMS make a concerted public effort toward educating all beneficiaries who may be impacted by the Model about the unique coinsurance requirements inherent to the Model's design.

Response: As required by § 512.225(a)(3) of this final rule, RO participants must notify all RO beneficiaries to whom they furnish included RT services regarding their cost-sharing responsibilities. Such notice will be furnished through the beneficiary notification letter provided by the RO participant during the initial treatment planning session and may be discussed prior in accordance with § 512.225(a)–(c) of this final rule. The beneficiary notification requirement will begin in PY1.

Comment: We received some comments on the beneficiary notification letter. These commenters requested that we eliminate the requirement for the RO participant to notify the beneficiaries as such notification is administratively burdensome. A commenter also expressed concerns with the timing of the beneficiary notification letter. A commenter requested that CMS provide this notice within the *Medicare & You* annual publication as well as on the *Medicare.gov* website. Another commenter requested that if we finalize the notification letter as proposed then to draft the notice with simple language at less than a 6th grade reading level.

Response: After considering comments, we are finalizing as proposed that we will draft the beneficiary notification template that RO participants may personalize with their contact information and logo, which will explain that the RO participant is participating in the RO Model and will include information regarding RO beneficiary cost-sharing responsibilities and an RO beneficiary's right to refuse having his or her data shared under § 512.225(a)(2). We believe that having a template with only minimal modifications (RO participant contact information, logo, and date) will not lead to potentially inaccurate information being delivered to beneficiaries. Further, after considering comments regarding administrative burden, we are finalizing as proposed that RO participants provide this written notice to each beneficiary during the initial treatment planning session. We do not believe that a written notice that has minimal modification by the RO participant is an administrative burden on RO participants. Additionally, we believe that this notice serves an important function to ensure that beneficiaries are aware of the Model and how they may be impacted by it, as well as allowing them to choose a non-participant health care provider should they wish.

We appreciate the comment about having additional sources for the beneficiary notification such as the *Medicare.gov* website, and we will consider ways to provide RO beneficiaries with details about the RO Model. We recognize that the *Medicare & You* publication has included language about model tests in the past. However, that publication cannot provide beneficiaries with the specific details and parameters for every model test. Therefore, we will consider other ways to provide RO beneficiaries with details about the RO Model. Additionally, as we draft the beneficiary notification letter, we will ensure that the language used is simple to provide beneficiaries with the necessary information to convey that they are receiving treatment from an RO participant.

Comment: A commenter supported the proposal that CMS draft the beneficiary notification letter template.

Response: We appreciate this commenter's support.

Comment: A commenter noted that the RO Model references patient navigators in its discussion of the Oncology Care Model, but there is an absence of provisions calling for the inclusion of such within the RO Model. This commenter believes that the episodic nature of radiation oncology coupled with the potential number of health care provider touchpoints for patients in the RO Model augments the importance of patient navigators in ensuring an effective continuum of care for patients receiving RT. This commenter voiced a strong recommendation to include a prominent role for patient navigators in the RO Model.

Response: We thank this commenter for highlighting the important role patient navigators have. To the extent that an RO participant wishes to include patient navigators in the care team, this will be permissible, but at this time, we will not be formally incorporating a requirement that RO participants include patient navigators in the care of RO beneficiaries. We do not believe that there is a demonstrated need for patient navigation at this time in radiation oncology, particularly as many radiation oncology patients who also receive chemotherapy typically receive care management services from their medical oncologist. However, after the Model is implemented, we will assess the need for patient navigators and, if needed, make modifications to the RO Model through future rulemaking.

Comment: A commenter has expressed concerns that the proposed RO Model will create a burden on patients, such as increasing the need for those patients to drive farther to obtain the same quality of care.

Response: We do not agree with the commenter's assertion that the Model will increase the need for beneficiaries to drive farther. We believe that providing site-neutral, more predictable or foreseeable payments to RO participants will help patients because we anticipate that the Model will lead to lower costs overall while maintaining or improving quality of care. The RO beneficiaries receiving care from RO participants will maintain the same protections as those beneficiaries outside of the Model, including the right to choose their health care providers.

After considering public comments, we are finalizing our proposed provisions on beneficiary protections with the modification of non-substantive changes to the proposed provisions at § 512.225 in this final rule to improve readability. The beneficiary notification requirement will begin in PY1. Specifically, we are codifying the beneficiary notification requirement at § 512.225. Furthermore, we are codifying at § 512.225(a)(1) that starting in PY1, Professional participants and Dual participants must notify each RO beneficiary to whom it furnishes included RT services that the RO participant is participating in the RO Model. We are codifying at § 512.225(a)(2) that starting in PY1, Professional participants and Dual participants must notify each RO beneficiary to whom it furnishes included RT services that the RO beneficiary has the opportunity to decline claims data sharing for care coordination and quality improvement purposes; and that if an RO beneficiary declines claims data sharing for care coordination and quality improvement purposes, then the RO participant must inform CMS within 30 days of receiving notification from the RO beneficiary that the beneficiary is declining to have their claims data shared in that manner. We are codifying at § 512.225(a)(3) that starting in PY1, Professional participants and Dual participants must notify each RO beneficiary to whom it furnishes included RT services of the RO beneficiary's cost-sharing responsibilities.

16. Evaluation

As stated in the proposed rule, an evaluation of the RO Model would be required to be conducted in accordance with section 1115A(b)(4) of the Act, which requires the Secretary to evaluate each model tested by the Innovation Center (84 FR 34533).

As stated in the proposed rule our evaluation would focus primarily on the question: Do the changes that comprise the RO Model result in improved quality or reduced spending for those beneficiaries receiving RT services during the model period? Conversely, if the RO Model has no effect we would expect that Medicare spending per episode or quality measures for beneficiaries associated with those episodes do not differ between RT providers and suppliers in CBSAs selected as Participants in the Model compared to those in the comparison group. We will also analyze other data to understand how the Model is successful in achieving improved quality and reduced expenditures. These analyses may include changes in RT utilization patterns (including the number of fractions and types of RT), RT costs for Medicare FFS beneficiaries in the RO Model (including Medicare-Medicaid dually eligible beneficiaries), changes in utilization and costs with other services that may be affected as a result of the RO Model (such as emergency department services, imaging, prescription drugs, and inpatient hospital care), performance on clinical care process measures (such as adhering to evidence-based guidelines), patient experience of care, and provider and supplier experience of care. The evaluation would inform the Secretary and policymakers about the impact of the model relative to the current Medicare fee structure for RT services, assessing the impacts on beneficiaries, health care providers, markets, and the Medicare program. The evaluation would take into account other models and any changes in Medicare payment policy during the Model performance period (84 FR 34533).

In addition to assessing the impact of the Model in achieving improved quality and reduced Medicare expenditures, we stated in the proposed rule that the evaluation is likely to address secondary questions to provide context for answers to the primary question. As stated in the proposed rule, these questions include (but will not be limited to): Did utilization patterns with respect to modality or number of fractions per episode change under the model? If the Model results in lower Medicare expenditures, what aspects of the Model reduced spending and were those changes different across subgroups of beneficiaries or related to observable geographic or socio-economic factors? Did any observed differences in concordance with evidence-based guidelines vary by cancer type or by treatment modality? Did patient experience of care improve? Did the Model affect access to RT or other services overall or for vulnerable populations? Were there design and implementation issues with the RO Model? What changes did participating radiation oncologists and other RO care team members experience under the Model? Did any unintended consequences of the Model emerge? Was there any observable overlap between the RO Model and other Innovation Center models or CMS/non-CMS initiatives and how could they impact the evaluation findings (84 FR 34533)?

As stated in the proposed rule, CMS anticipated that the evaluation will include a difference-in-differences [80] or similar analytic approach to estimate model effects (84 FR 34533). Where it is available, baseline data for the participants would be obtained for at least one year prior to model implementation. Data would also be collected during model implementation for both participant and comparison groups. The evaluation would control for patient differences and other factors that directly and indirectly affect the RO Model impact estimate, including demographics, comorbidities, program

[80] Difference-in-difference is a statistical technique that compares the intervention (in this case, the RO participant) and comparison (in this case, the Comparison group) groups during the period before the RO Model goes into effect (pre-intervention) and the period during and after the RO Model goes into effect (post-intervention) and uses the difference between intervention and comparison in both periods to estimate the effect of the intervention. A comparison group that is similar to the intervention group is used to help measure the size of the intervention effect by providing a comparison (or 'counterfactual') to what would have happened to the intervention group had the intervention not occurred. This helps the evaluation distinguish between changes occurring for reasons unrelated to the Model when estimating the changes that occurred because of the Model.

eligibility, and other factors. Data to control for patient differences would be obtained primarily from claims and patient surveys.

The evaluation would use a multilevel approach. We would conduct analyses at the CBSA-level, participant-level, and the beneficiary-level. The CBSAs and RT providers and RT suppliers contained within CBSA geographic areas selected for participation, as discussed in section III.C.3.d, will have been randomly assigned for the duration of the evaluation, allowing us to use scientifically rigorous methods for evaluating the effect of the Model.

We referred readers to section II.E of the proposed rule for our proposed policy on RO participant cooperation with the RO Model's evaluation and monitoring policies. We solicited public comment on our proposed approach related to the evaluation of the RO Model. In this section of the rule, we summarize and respond to the public comments received on this proposal.

Comment: A few commenters expressed concern about possible unforeseen circumstances and unintended consequences as a result of the Model. A couple of these commenters urged us to evaluate model effects on quality of care and patient access and were concerned the RO Model may impact these outcomes negatively. A commenter suggested we did not have sufficient evidence to proceed with the Model. A different commenter offered support for the proposed evaluation and highlighted the importance of patient experience measures with regards to cancer care.

Response: We appreciate and share the commenters' interest in outcomes related to the Model. In designing the Model and planning the Model's evaluation, CMS considers access to care and quality of care to be outcomes that must be examined. We have a monitoring plan for tracking, and an evaluation plan to assess, the Model's impact on these outcomes. We believe collecting and analyzing measures of quality and access to care will help assess the Model's impact on beneficiaries' outcomes and experience during RO episodes. We have detailed the methodology used to create the episodes, set payment rates, and the random selection of Participants in the NPRM, using national FFS Medicare claims. We are finalizing the evaluation and monitoring methods as proposed.

Comment: A commenter encouraged the agency to make it a priority to minimize provider and supplier burden resulting from this Model.

Response: We agree that burden on RO participants should be minimized to the extent possible, and we kept this in mind in the design of the RO Model, including the evaluation. We included features in the Model such as RO participants continuing to submit claims through the existing FFS claims process, and identifying RO participants by ZIP Code (rather than CBSA) to limit burden. We have been mindful to minimize RO participant burden in the design of the evaluation (such as relying on secondary data sources such as FFS claims), but there will be some additional data collection necessary to fully evaluate the Model and conduct all impact estimates.

Comment: A couple of commenters expressed concern that the Model as proposed may lack sufficient data to evaluate the effects of including PBT centers.

Response: We focused the evaluation design on the impacts of the Model at the population level for overall spending and quality across all RT services furnished and not the effects on one potential modality compared to another. While some future sub-analyses may include differences in costs and quality by modality, we will make no impact estimates on cost nor quality where we do not have suitable sample size of RO participants or RO episodes, understanding that any differences we may observe are observational and not causative.

After considering public comments, we are finalizing our proposals on evaluation as proposed.

17. Termination of the RO Model

In the proposed rule, we stated that the general provisions relating to termination of the Model by CMS in section II.J of the proposed rule would apply to the RO Model. We received no comments on the termination of the RO Model. As explained in section II.J. of this final rule, we are finalizing our proposal to apply § 512.165 to the RO Model.

18. Potential Overlap With Other Models Tested Under Section 1115A Authority and CMS Programs

a. Overview

We stated in the proposed rule (84 FR 34533 through 34535) that the RO Model would leverage existing Innovation Center work and initiatives, broadening that experience to RT providers and RT suppliers, a professional population that is not currently the focus of other models tested by the Innovation Center. In the proposed rule, we discussed our belief that the RO Model would be compatible with other CMS models and programs that also provide health care entities with opportunities to improve care and reduce spending. We expected that there would be situations where a Medicare beneficiary in an RO Model episode would also be assigned to, or engage with, another payment model being tested by CMS. Overlap could also occur among providers and suppliers at the individual or organization level; for example, a physician or organization could be participating in multiple models tested by the Innovation Center. We stated that we believe that the RO Model would be compatible with other CMS initiatives that provide opportunities to improve care and reduce spending, especially population-based models, though we recognize the design of some models being tested by the Innovation Center under its section 1115A authority could create unforeseen challenges at the organization, clinician, or beneficiary level. We stated in the proposed rule that we do not envision that the prospective episode payments made under the RO Model would need to be adjusted to reflect payments made under any of the existing models being tested under 1115A of the Act or the Shared Savings Program under section 1899 of the Act. We stated in the proposed rule that if, in the future, we determined that such adjustments are necessary, we would propose overlap policies for the RO Model through notice and comment rulemaking. In this section of this rule, we summarize and respond to the public comments received on the proposal in section III.C.18.a.

Comment: A few commenters generally agreed with CMS' approach not to propose to adjust the RO Model's prospective episode payments to reflect payments made under any of the existing models being tested under section 1115A of the Act or under the Shared Savings Program. They also agreed that other models and programs should be responsible for factoring RO Model payments into their reconciliation calculations.

Response: We appreciate the commenters' support.

Comment: Some commenters requested more information and clearer guidance from CMS on overlap between the RO Model and other CMS initiatives, including all models tested under section 1115A, the Shared Savings Program, and the Quality Payment Program. One of these commenters stated that without details of how CMS proposes to resolve overlaps, providers and suppliers are

unable to accurately forecast how the models may impact future revenues, and they requested that, in the future, CMS needs to provide more specific guidance during the proposal phase, so stakeholders can comment on any potential issues prior to implementation. Another commenter encouraged CMS to provide additional clarity on payment adjustment changes and overlap between the RO model and Quality Payment Program, and stated that such clarity will greatly help them develop forecasting models that can in turn help better support their patient care operations. Another commenter stated that the lack of clarity on model overlap continues to be an issue, and that they have long encouraged CMS to be more deliberate and specific in providing Innovation Center model participants with clear guidance on how scenarios in which Innovation Center models overlap will be treated. This commenter further stated that such clarity is not only beneficial for those providers and suppliers that will be required to participate under the RO Model but, importantly, for those providers and suppliers participating in the other models identified by CMS in the proposed rule. Another commenter agreed with CMS' acknowledgement that accounting resolution will be needed for overlap between the RO Model and other initiatives, but they believe that it is not clear how this accounting resolution would be handled, and specifically requested that CMS clarify how the overlap of the RO Model with other models and programs would be operationalized through program accounting, so that providers and suppliers that participate in multiple initiatives have a clear understanding of the process. Another commenter requested specific clarification on how CMS will resolve the separation of radiation oncologists from overlapping initiatives, for example, the MIPS adjustment earned in previous years and OCM inclusion up to the start date of the RO Model.

Response: We appreciate the commenters' comments, feedback, and suggestions regarding overlap between the RO Model and other CMS initiatives. We will take all of these suggestions into consideration as we implement the RO Model. As stated in the proposed rule, if, in the future, we determine that RO Model payment adjustments are necessary to reflect payments made under any of the existing models being tested under section 1115A of the Act or the Shared Savings Program under section 1899 of the Act, we will propose overlap policies for the RO Model through notice and comment rulemaking. Further, we are not including further explanation in this final rule regarding overlap policies for the RO Model, because we are not putting in place any overlap accounting policies for this Model at this time. As explained previously, the financial methodology and accounting policies under the applicable model tested under section 1115A of the Act or the Shared Savings Program will govern the way in which RO payments are factored into reconciliation calculations under that initiative.

Comment: A few commenters expressed concern that CMS does not have a clear overlap policy that is applied across all programs and models. One of these commenters stated that it is very important for CMS to consider model overlap in the design of new APMs, and they recommended that the goal of CMS models should be to provide APM participants with adequate flexibility to manage overlap based on their unique market situation and fundamentally change care delivery and improve population health, rather than seeking opportunities to leverage market dynamics to reduce costs. This commenter also expressed concern that the proposed models do not place sufficient emphasis on population health and encouraging providers and suppliers to keep patients from getting to later disease stages in the first place.

Another commenter stated that CMS must consider how models will interact with one another and what this means for participation in different models. This commenter recommended that CMS should focus on supporting providers and suppliers currently not participating in an APM and encouraging these providers and suppliers to participate, rather than requiring some providers and suppliers to participate, in a second model, especially without sufficient clarity on how these models may interact. The commenter also supported CMS' goal to transition providers and suppliers to risk-bearing programs and believed CMS will most effectively achieve this goal by focusing on providers and suppliers not currently participating. Another commenter stated concern that the lack of a strict overlap structure undermines the financial integrity of early adopters in high-risk Advanced APM models, as the absence of an established overlap framework effectively creates a disincentive for providers and suppliers to voluntarily bear heightened risk for a total population. The commenter further stated that providers and suppliers are not equipped with enough information to evaluate the potential effect of specialty and other episode payment models on global payments and total cost of care, and there is a finite opportunity for these organizations to reduce costs while maintaining access and quality. To address these concerns, this commenter recommended a hierarchical approach to CMS' and the Innovation Center's model overlap, in which precedence is given to population health risk-bearing entities. The commenter also suggested that CMS use the existing payment model classification framework refined by the Health Care Payment Learning & Action Network (LAN) as a basis for its overlap policy.

Response: We thank the commenters for their comments and suggestions regarding a larger CMS overlap policy. We appreciate this feedback, and will consider all of these recommendations moving forward, in the event that a broader overlap policy is developed for CMS. As stated in the proposed rule, we do not envision that the prospective episode payments made under the RO Model will need to be adjusted to reflect payments made under any of the existing models being tested under section 1115A of the Act or the Shared Savings Program under section 1899 of the Act, but as stated in the proposed rule, if we determine in the future that such adjustments are necessary, we would propose overlap policies for the RO Model through notice and comment rulemaking.

b. Accountable Care Organizations (ACOs)

In the proposed rule, we discussed our belief that there would be potential overlap between the RO Model and ACO initiatives. ACO initiatives include a shared savings component. As a result, providers and suppliers that participate in an ACO are generally prohibited from participating in other CMS models or initiatives involving shared savings.[81] We believed there would be potential for overlap between the RO Model and ACO initiatives but, because the RO Model is an episode-based payment initiative, providers and suppliers participating in the RO Model would not be precluded from also participating in an ACO initiative. Specifically, we believed overlap could likely occur in two instances: (1) The same provider or supplier participates in both a Medicare

[81] The statutory limitation under section 1899(b)(4) of the Social Security Act, only applies to providers and suppliers that participate in Shared Savings Program ACOs. As a policy matter, CMS has elected to impose a similar restriction on some participants in other ACO initiatives through the participation agreements for the various models.

ACO initiative and the RO Model; or (2) a beneficiary that is aligned to an ACO participating in a Medicare ACO initiative receives care at a radiation oncology provider or supplier outside the ACO that is participating in the RO Model.

While shared savings payments made under an ACO initiative have the potential to overlap with discounts and withholds in the RO Model, as we explained in the proposed rule it is difficult to determine the level of potential overlap at this time. It is also difficult to determine how many ACO-aligned beneficiaries will require RT services or if those beneficiaries would seek care from an RO participant. Given that the RO Model is expected to reduce Medicare spending in aggregate, we anticipated that in most cases payments under the RO Model would be less than what Medicare would have paid outside the Model. However, we also noted that it would be possible for RO participants to receive higher Medicare payments under the Model than they did historically, for example, if they have certain experience adjustments. While we expected overall payments for RT services to be lower than they would be absent the Model, we wanted to ensure that a significant proportion of the RO Model discounts, which represent Medicare savings, would not be paid out to ACOs as shared savings.

Due to these factors, in the proposed rule we stated that we intended to continue to review the potential overlap with the ACO initiatives as the RO Model is launched. If substantial overlap occurs, we would consider adjusting the RO Model payments through future rulemaking to ensure Medicare retains the discount amount. ACO initiatives could also consider accounting for RO Model overlap in their own reconciliation calculations. Any changes to the payment calculations under these ACO initiatives that might be necessary to account for overlap with the RO Model would need to be made using the relevant procedures for the applicable ACO initiative. For example, if the Next Generation ACO Model makes any changes to their current payment methodologies to account for the RO Model, it would update their governing documentation as necessary, and would provide information to their participants through their typical channels of communication.

In this section of this rule, we summarize and respond to the public comments received on this proposal.

Comment: A few commenters recommended that CMS not negatively adjust ACO shared savings calculations to account for discounts embedded in RO Model payments.

Response: At this time, we are not planning to negatively adjust ACO financial calculations to account for the RO discount. ACO financial calculations rely on Medicare Part A and Part B claims data as well as non-claims-based payments that are individually identifiable final payments made under a demonstration, pilot, or time limited program and paid from the Medicare Trust Funds. Under the Shared Savings Program, use of a regional growth rate should ultimately account for changes in payment due to the RO Model, in cases where overlap occurs between the RO Model and Shared Savings Program ACOs. The application of a regional growth rate under the Shared Savings Program would account for changes in payment due to the RO Model because the historical benchmark calculated for an ACO would be updated for each performance year of the agreement period using a blend of the national growth rate and a regional growth rate based on the actual Medicare FFS experience in counties where the ACO's beneficiaries reside. Thus, the use of this regional growth rate will naturally update the historical benchmarks of ACOs to account for the effects on spending resulting from implementation of other value-based payment models, including the RO Model, in those counties. For ACO initiatives other than the Shared Savings Program, CMS will determine whether an adjustment to the initiative's calculations is necessary based, for example, on the extent of health care practitioner or beneficiary overlap between that initiative and the RO Model. We intend to continue to review the potential overlap with ACO initiatives as the RO Model is launched. If CMS determines that adjustment to the calculations used in any of these other ACO initiatives is necessary to account for overlap with the RO Model, CMS would make changes to the governing documentation for that ACO initiative, as necessary, and would provide information to the participants in that ACO initiative through its typical channels of communication at that time in the future. Similarly, we will consider adjusting the RO Model payments through future rulemaking if necessary to ensure Medicare retains the discount amount. However, for the reasons as previously described, we are not currently applying any adjustments to the RO Model payments or ACO financial calculations at this time.

Comment: A few commenters recommended that CMS finalize a policy to exclude beneficiaries aligned to an ACO who receive included RT services from attribution to an RO participant under the RO Model. One of these commenters requested that CMS ''provide an exemption for practices that are already contracted with ACOs to provide a four percent or greater discount.'' This commenter believes that ''two percent to four percent should not automatically be withheld up front under the assumption that there were errors in billing'' and that ''this practice is unfair to those that work diligently to bill with accuracy and effectively under ethical billing practices.'' Another commenter suggested that CMS should exclude all beneficiaries aligned to ACOs from attribution to participants in any other payment models to reduce duplicative care coordination efforts and create a clear, transparent and understandable policy across all models tested under section 1115A of the Act.

Response: We appreciate the commenters' feedback. We did not propose to exclude RT practices participating in ACOs from the RO Model, and we are finalizing our proposed policy to allow ACO-aligned beneficiaries to be attributed to practices participating in the RO Model for the following reasons. First, we believe that excluding beneficiaries that have been aligned to an ACO from the RO Model would be operationally challenging for RO participants who will be billing prospective RO Model payments and may not be aware in real time that the beneficiaries are aligned to an ACO. Further, we believe the incentives under the RO Model and the ACO initiatives are aligned appropriately to support high-quality care, and to the extent that RO participants provide more efficient care to ACO-aligned beneficiaries, this could benefit the performance of the ACO and provide higher-quality care to Medicare beneficiaries with cancer who receive RT services.

c. Oncology Care Model (OCM)

OCM seeks to provide higher quality, more highly coordinated oncology care at the same or lower cost to Medicare. OCM episodes encompass a 6-month period that is triggered by the receipt of chemotherapy and incorporate all aspects of care during that timeframe, including RT services. Because OCM and the RO Model both involve care for patients with a cancer diagnosis who receive RT services, we stated in the proposed rule that we expect that there will be beneficiaries who would be in both OCM episodes and the RO Model episodes.

Under OCM, physician practices may receive a performance-based payment (PBP) for episodes of care surrounding chemotherapy administration to cancer

patients. OCM is an episode payment model that incentivizes care coordination and management and seeks to improve care and reduce costs for cancer patients receiving chemotherapy. Given the significant cost of RT, OCM episodes that include RT services receive a risk adjustment when calculating episode benchmarks, with the goal of mitigating incentives to shift these services outside the episode (for example, by delaying the provision of RT services until after the 6-month episode ends).

As we explained in the proposed rule, practices participating in OCM receive a monthly payment per OCM beneficiary to support enhanced services such as patient navigation and care planning. Practices may also earn a PBP for reductions in the total cost of care compared to episodes' target amount, with the amount of PBP being adjusted by the practice's performance on quality measures. OCM offers participating practices the option of requesting a two-sided risk arrangement, in which episode expenditures that exceed the target amount or the target amount plus the minimum threshold for OCM recoupment (depending on the specific two-sided risk arrangement requested) would be recouped by CMS from the practice. OCM requires participating practices who have not earned a PBP by the initial reconciliation of the model's fourth performance period to move to a two-sided risk arrangement or terminate their participation in the model.

As we proposed in section III.C.7 of the proposed rule and are finalizing in section III.C.7 of this final rule, the RO Model will include prospective episode payments for RT services furnished during a 90-day episode of care. The RO Model is not a total cost of care model and includes only RT services in the episode payment. Since the RO Model makes prospective payments for only the RT services provided during an episode, a practice participating in the RO Model would receive the same prospective episode payment for RT services regardless of its participation in OCM.

Conversely, OCM is a total cost of care model so any changes in the cost of RT services during an OCM episode could affect OCM episode expenditures, and therefore, have the potential to affect a participating practice's PBP or recoupment. We stated in the proposed rule that when the RO Model episode occurs completely before or completely after the OCM episode, then the RT services that are part of that RO Model episode would not be included in the OCM episode, and the OCM reconciliation calculations would be unaffected. If an entire RO Model episode (90-days of RT services) occurs completely during a 6-month OCM episode, then the associated RO payments for RT services would be included in the OCM episode. In addition, to account for the savings generated by the RO Model discount and withhold amounts, we stated in the proposed rule that we would add the RO Model's discount and withhold amounts to the total cost of the OCM episode during OCM's reconciliation process to ensure that there is no double counting of savings and no double payment of the withhold amounts between the two models.

In those cases where the RO Model episode would occur partially within an OCM episode and partially before or after the OCM episode, we proposed to allocate the RO Model payments for RT services and the RO Model discount and withhold amounts to the OCM episode on a prorated basis, based on the number of days of overlap. In this case, the prorated portion of the payment under the RO Model, based on the number of days of overlap with the OCM episode, would be included in the OCM episode's expenditures as well as the prorated portion of the RO Model discount and withhold amounts, again based on the number of days of overlap with the OCM episode. We stated that including the prorated discount and withhold amounts would ensure that there is no double counting of savings and no double payment of the withhold amounts between the two models.

In those cases where the RO Model episode occurs entirely within or partially before or after the OCM episode, for the purpose of calculating OCM episode costs, we stated in the proposed rule that we would assume that all withholds are eventually paid to the RO Participant under the RO Model, and that there are no payments to recoup. We stated that we believe a process to allocate exact amounts paid to the participants with different reconciliation timelines between the two models would be operationally complex.

We stated in the proposed rule that we intend to continue to review the potential overlap with OCM if the RO Model is finalized, including whether there are implications for OCM's prediction model for setting risk-adjusted target episode prices, which include receipt of RT services. We further stated that since prospective episode payments made under the RO Model would not be affected by OCM, OCM would account for RO Model overlap in its reconciliation calculations, and OCM participants would be notified and provided with further information through OCM's typical channels of communication. In this section of this rule, we summarize and respond to the public comments received on this proposal.

Comment: Many commenters agreed with CMS' proposed approach for accounting for overlap between OCM and the RO Model. Some commenters requested additional details regarding the proration methodology, and a commenter specifically requested further clarification regarding how prorated payments will be determined and how prorated payments will be distributed to providers and suppliers. One commenter requested that CMS clarify and reconsider how the RO Model will overlap with the OCM in a manner that allows for full and fair participation in both models. This commenter suggested that it would be more appropriate and fairer to RT providers and RT suppliers participating in both models to use the final discounted amount of the RO Model payment as the payment to the RO participant for purposes of the OCM reconciliation calculation. This commenter stated that RO participants would receive no financial credit under the RO Model for adjusting their spending to make do with lower payment under the discounts, so there is no double-counting of savings if that discount is also included in the OCM calculation. The commenter also stated that there is no guarantee that RO participants will earn the withhold amounts back after reconciliation under the RO Model; and that even if they do, it likely will not be without the RO participant incurring other costs to comply with quality reporting requirements. Therefore, this commenter suggested that the fairer and more accurate approach would be to deduct the discount amount from the OCM reconciliation calculation, and to deduct the amount of withholding that is not regained through quality performance.

Response: We appreciate the commenters' support for the proposed approach to account for overlap between the OCM and RO Model. We anticipate that roughly 30 percent of OCM practices that provide RT services will participate in the RO Model. Since OCM is a total cost of care model, any changes in the cost of RT services during an OCM episode could affect OCM episode expenditures, and therefore have the potential to affect a participating practice's PBP or recoupment. We proposed a proration approach to account for changes in OCM episode expenditures due to RO

Model overlap, and to ensure there is no double counting of savings or double payment of the withhold amounts between the two models.

Regarding the comments about the proration methodology, we refer readers to our description of the OCM proration methodology set forth in the proposed rule, where we described how, in cases where the RO episode occurs partially within an OCM episode and partially before or after the OCM episode, we proposed to allocate the RO Model payments for RT services and the RO Model discount and withhold amounts to the OCM episode's expenditures on a prorated basis, based on the number of days of overlap. As we discussed in the proposed rule, including the RO discount and withhold amounts (on a prorated basis for cases where the RO episode occurs partially within an OCM episode and partially before or after the OCM episode) in the calculation of OCM episode expenditures would ensure that there is no double counting of savings and no double payment of the withhold amounts between the two models. For cases where the RO episode occurs entirely within or partially before or after the OCM episode, for the purpose of calculating OCM episode costs, we stated that we would assume that all withholds are eventually paid to the RO participant under the RO Model, and that there are no payments to recoup. As we discussed in the proposed rule, we believe a process to allocate exact amounts paid to the RO participants when the OCM and the RO Model have different reconciliation timelines would be operationally complex. Further detail about how OCM will account for RO Model overlap in its reconciliation calculations will be provided to OCM practices through OCM's typical communication channels. Of note, any RO episode payments that are prorated as part of the OCM reconciliation calculations will not be distributed to the RO participant or OCM participant; rather, these amounts will be included in the OCM reconciliation calculations that determine the amount of any OCM PBP or OCM recoupment. RO episode payments would not change as a result of any overlap with an OCM episode.

We believe the proposed approach to handling the RO Model discount and withholds in the OCM reconciliation calculation is fair to participants in both models and allows for full participation in both models, while also preventing us from double-counting and double-paying savings to Medicare. Of note, RO participants receive the same RO payment amount regardless of how many RT services are delivered; thus, RO participants may keep the savings that accrue for RO episodes where payment under Medicare FFS would have been less than the RO participant-specific episode payment. Since the RO participant would retain these savings, we continue to believe that the best way to ensure that Medicare savings (captured through the RO Model discount) are not paid out through the OCM reconciliation is by adding the RO Model discounts and withholds to the RO participant-specific episode payments included in the OCM reconciliation calculations. Additionally, we are not able to synchronize the timing of the OCM and RO Model reconciliations such that we could incorporate the amount of the quality withhold that is paid to the RO participant during reconciliation.

Comment: A few commenters requested that CMS not make changes to the OCM target price setting methodology based on RO Model payments.

Response: We noted in the proposed rule that overlap with the RO Model may have implications for the appropriateness of OCM's prediction model for setting risk-adjusted target prices. We are continuing to consider whether any potential changes to OCM's prediction model would be needed, and we appreciate this input from the commenters. If we make changes to the OCM prediction model, OCM practices would be notified through OCM's typical communication channels.

Comment: A few commenters requested clarity and guidance from CMS about whether the RO Model and OCM payments are paid separately or bundled together.

Response: The RO Model and OCM are separate and distinct payment models and any model payments will be paid separately and not bundled together. Furthermore, as stated in the proposed rule, a practice participating in the RO Model will receive the same prospective episode payment for RT services, regardless of its participation in OCM, because the RO Model makes prospective payments for only the RT services provided during an RO episode.

Comment: A commenter suggested the OCM participants should be exempt from the RO Model. A couple of commenters suggested that OCM participants should not be required to participate in the RO Model until their performance under OCM has been completed.

Response: We appreciate the commenter's suggestion about excluding OCM participants from the RO Model. However, we disagree with the commenters' recommendation that OCM participants should be exempt from the RO Model, and with the recommendation that OCM participants not be required to participate in the RO Model until performance under OCM has concluded. We believe that it is important to allow eligible health care providers to participate in both models because both models involve care for patients with a cancer diagnosis. We also believe that participation in both models could benefit beneficiaries in both the RO Model and OCM by aligning payment incentives across both models. We did not propose to exclude OCM participants from the RO Model as we believe that this approach would curtail the number, and potentially alter the composition, of RT providers and RT suppliers available to participate in the RO Model, which could affect our ability to detect an impact of the RO Model. Further, by not excluding voluntary OCM participants, we could avoid a possible selection effect in the RO Model.

After review of public comments and for the reasons discussed, we are finalizing our proposed approach for addressing overlap between OCM and the RO Model as proposed.

d. Bundled Payments for Care Improvement (BPCI) Advanced

As we explained in the proposed rule, the BPCI Advanced Model is testing a new iteration of bundled payments for 34 clinical episodes (30 inpatient and 3 outpatient, and 1 multi-setting).[82] The BPCI Advanced Model is based on a total cost of care approach with certain MS–DRG exclusions. While there are no cancer episodes included in the design of the BPCI Advanced Model, a beneficiary in an RO episode could be treated by a provider or supplier that is participating in the BPCI Advanced Model for one of the 34 clinical episodes included in the BPCI Advanced Model. Since prospective episode payments made under the RO Model would not be affected by the BPCI Advanced Model, the BPCI Advanced Model would determine whether to account for RO Model overlap in its reconciliation calculations, and CMS would provide further information to the BPCI Advanced Model participants through an amendment to their participation agreement. In this section of this rule, we summarize and respond to the public comments received on this proposal.

[82] Major joint replacement of the lower extremity is a multi-setting Clinical Episode category. Total Knee Arthroplasty (TKA) procedures can trigger episodes in both inpatient and outpatient settings.

Comment: A commenter recommended that potential RO Model overlap with the BPCI Advanced Model be addressed through a notice and public comment process, rather than through a mandatory amendment to the BPCI Advanced Model participant agreements. A commenter stated that there may be potential overlap with the BPCI Advanced Model, as a Medicare beneficiary in an RO episode could be treated by a health care provider that is participating in the BPCI Advanced Model. This commenter requested clarification in this case, on how to know which model the patient would be attributed to and how the services would be reimbursed. This commenter also recommended that CMS address the potential overlap on how patients should be attributed between the BPCI Advanced Model and the RO Model, and they requested further clarification regarding how services will be reimbursed under the RO and BPCI Advanced Models before the start date to assist hospitals in effective planning for their participation.

Response: We appreciate the commenter's concerns and suggestions. The BPCI Advanced Model payment polices are governed by participation agreements with each model participant; we cannot amend those agreements by notice and comment rulemaking. Accordingly, we are finalizing as proposed (84 FR 34535) that the BPCI Advanced Model team will determine whether and how to account for RO Model overlap in its reconciliation calculations. Regarding the commenter who requested clarification on how to know which model the patient would be attributed to and how the services would be reimbursed, as we stated in the proposed rule, a beneficiary in an RO episode could be treated by a provider or supplier that is participating in the BPCI Advanced Model, and prospective episode payments made under the RO Model would not be affected by the BPCI Advanced Model. As such, the BPCI Advanced Model would determine whether to account for RO Model overlap in its reconciliation calculations, and the BPCI Advanced Model participants will receive further information from CMS if the BPCI Advanced Model team determines to make changes to their reconciliation policy.

19. Decision Not To Include a Hardship Exemption

As discussed in the proposed rule (84 FR 34535), we did not believe that a hardship exemption for participation in the Model is necessary, since the Model's pricing methodology gives significant weight to historical experience in determining the amounts for participant-specific professional episode payments and participant-specific technical episode payments. This is particularly evident in PY1, where the efficiency factor in section III.C.6.e(2) of the proposed and final rules is 0.90 for all RO participants. Accordingly, we did not propose such an exemption in the proposed rule, and will not include such an exemption in this final rule.

However, in the proposed rule, we welcomed public input on whether a possible hardship exemption for RO participants under the Model might be necessary or appropriate, and if so, how it might be designed and structured while still allowing CMS to test the Model. As we stated in the proposed rule, we intend to use the input we received on this issue to consider whether a hardship exemption might be appropriate in subsequent rulemaking for a future PY. In this section of this rule, we summarize the public comments we received.

Comment: Many commenters disagreed with CMS' decision not to include a model participation hardship exemption for RO participants. A commenter requested that CMS establish a hardship exemption process for RT providers and RT suppliers that can show they serve a patient base consisting predominantly of Medicare beneficiaries, given that these providers and suppliers would face disproportionate impact from mandatory participation in the Model and would be at a significant disadvantage compared to other participants as well as RT providers and RT suppliers not included in the Model.

Some commenters requested a hardship exemption specific to rural practices. These commenters maintained that patients living in rural areas would be disparately impacted by the mandatory requirement of the proposed RO Model, and other commenters stated that rural practices will experience undue burdens if they are required to participate in the RO Model.

A few commenters recommended that CMS provide hardship exemptions for RO participants facing public health emergencies or natural disasters, such as wild fires, earthquakes, or hurricanes, to ensure that they are not unfairly penalized due to these circumstances. These commenters stated that hardship exemptions for extreme and uncontrollable circumstances have recently been implemented in other APMs, including the Shared Savings Program and the Comprehensive Care for Joint Replacement Model, and also in the Quality Payment Program.

We appreciate the commenters' feedback on this issue. We will consider these comments when determining whether a hardship exemption is appropriate for proposing in subsequent rulemaking for a future PY. We will continue to monitor the need for a hardship exemption under the RO Model.

IV. End-Stage Renal Disease (ESRD) Treatment Choices Model

A. Introduction

The purpose of this section of the final rule is to implement a new payment model called the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model, referred to in this section IV of the final rule as ''the Model,'' under the authority of the Innovation Center. The intent of the ETC Model is to test whether adjusting the current Medicare fee-for-service (FFS) payments for dialysis services will incentivize ESRD facilities and clinicians managing adult Medicare FFS beneficiaries with ESRD, referred to herein as Managing Clinicians, to work with their patients to achieve increased rates of home dialysis utilization and kidney transplantation and, as a result, improve or maintain the quality of care and reduce Medicare expenditures. Both of these modalities (home dialysis and transplantation) have support among health care providers and patients as preferable alternatives to in-center hemodialysis (HD), but the utilization rate of these services in the United States (U.S.) has been below such rates in other developed nations.[83] On July 18, 2019, we published a proposed rule in the **Federal Register** titled ''Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures'' (84 FR 34478) and sought public comment on the proposed ETC Model. In response, CMS received 104 comment submissions from physicians, dialysis providers, patient groups, industry groups, and others. Summaries of these comments, and our responses, are found throughout this section of the final rule.

In the ETC Model, CMS will adjust Medicare payments under the ESRD Prospective Payment System (PPS) to ESRD facilities and payments under the

[83] United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018. Volume 2: End-stage Renal Disease (ESRD) in the United States. Chapter 11: International Comparisons. Figures 11–15, 11–16.

Medicare Physician Fee Schedule (PFS) to Managing Clinicians paid the ESRD Monthly Capitation Payment (MCP) selected for participation in the Model. The payment adjustments will include an upward adjustment on home dialysis and home dialysis-related claims with claim service dates during the initial three years of the ETC Model, that is, between January 1, 2021 and December 31, 2023. In addition, we will make an upward or downward performance-based adjustment on all dialysis claims and dialysis-related claims with claim service dates between July 1, 2022 and June 30, 2027, depending on the rates of home dialysis utilization, and of kidney transplant waitlisting and living donor transplants among the beneficiaries attributed to these participating ESRD facilities and Managing Clinicians. The ETC Model will test whether such payment adjustments can reduce total program expenditures and improve or maintain quality of care for Medicare beneficiaries with ESRD.

B. Background

1. Rationale for the ESRD Treatment Choices Model

As discussed in the proposed rule, beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation in order to survive, as their kidneys are no longer able to perform life-sustaining functions. In recent years, ESRD Beneficiaries have accounted for about 1 percent of the Medicare population and accounted for approximately 7 percent of total fee-for-service Medicare spending.[84] Beneficiaries with ESRD face the need for coordinating treatment for many disease complications and comorbidities, while experiencing high rates of hospital admissions and readmissions and a mortality rate greatly exceeding that of the general Medicare population. In addition, studies during the past decade have reported higher mortality rates for dialysis patients in the U.S. compared to other countries.[85] [86]

ESRD is a uniquely burdensome condition; with uncertain survival, patient experience represents a critical dimension for assessing treatment. The substantially higher expenditures and hospitalization rates for ESRD Beneficiaries compared to the overall Medicare population, and higher mortality than in other countries indicate a population with poor clinical outcomes and potentially avoidable expenditures. We anticipate that the ETC Model will maintain or improve the quality of care for ESRD Beneficiaries and reduce expenditures for the Medicare program by creating incentives for health care providers to assist beneficiaries, together with their families and caregivers, to choose the optimal renal replacement modality for the beneficiary.

As we discussed in the proposed rule, the majority of ESRD patients receiving dialysis receive HD in an ESRD facility. At the end of 2016, 63.1 percent of all prevalent ESRD patients—meaning patients already diagnosed with ESRD—in the U.S. were receiving HD, 7.0 percent were being treated with peritoneal dialysis (PD), and 29.6 percent had a functioning kidney transplant.[87] Among HD cases, 98.0 percent used in-center HD, and 2.0 percent used home hemodialysis (HHD).[88] PD is rarely conducted within a facility. In the proposed rule and in section IV.B.2 of this final rule, we describe how current Medicare payment rules and a lack of beneficiary education result in a bias toward in-center HD, which is often not preferred by patients or practitioners. With the ETC Model, we will test whether new payment adjustments will lead to greater rates of home dialysis (both PD and HHD) and kidney transplantation. In both the proposed rule and this final rule, we provide evidence from published literature to support the projection that higher utilization rates for these specific interventions would likely reduce Medicare expenditures, while preserving or enhancing the quality of care for beneficiaries and, at the same time, enhance beneficiary choice, independence, and quality of life.

The following is a summary of the comments received on the rationale for testing the proposed ETC Model and our responses.

Comment: Several commenters stated that they support the rationale, as described in the proposed rule and previously in this final rule, for testing the ETC Model. Several commenters stated that the evidence suggests that home dialysis and transplantation are associated with lower costs and better outcomes than in-center dialysis for patients with ESRD, and that the current payment system does not encourage the use of these alternative modalities. A few commenters stated that payment adjustments like those we proposed for use in the ETC Model can impact participant behavior in supporting these alternative modalities. A few commenters stated that containment of dialysis costs is an important goal for the Model.

Response: We thank the commenters for their feedback and support.

Comment: Several commenters stated that they did not believe payment adjustments could change participant behavior to increase rates of home dialysis and transplantation. A commenter stated that any payment adjustments are unlikely to overcome barriers that currently prevent the use of home dialysis and transplantation such as socioeconomic issues, race, immunologic barriers, a lack of caregiver support, housing insecurity and home environments that are unable to store supplies and equipment. A commenter stated that the evidence that home dialysis is associated with better outcomes and lower costs is mixed, so the payment adjustments proposed for use in the Model are unlikely to achieve the stated goals. A commenter stated that, if under current payment conditions patient preference is not driving renal replacement modality selection, then changing payment incentives will not move patient preference to the center of the decision-making process.

Response: We thank the commenters for their feedback. The purpose of the ETC Model is to test whether the payment adjustments included in the Model will reduce Medicare expenditures while improving or maintaining quality of care. CMS believes that these payment adjustments will accomplish these goals by encouraging participating Managing Clinicians and ESRD facilities to support beneficiaries choosing home dialysis and transplantation. The purpose of the Model and CMS's evaluation thereof is to determine if this is the case.

a. Home Dialysis

As we noted in the proposed rule, there are two general types of dialysis: HD, in which an artificial filter outside of the body is used to clean the blood;

[84] Kirchoff SM. Medicare Coverage of End-Stage Renal Disease (ESRD). Congressional Research Service. August 16, 2018. p. 1.

[85] Foley RN, Hakim RM. Why Is the Mortality of Dialysis Patients in the United States Much Higher than the Rest of the World? Journal of the American Society of Nephrology. 2009; 20(7):1432–1435. doi:*https://doi.org/10.1681/ASN.2009030282.*

[86] Robinson B, Zhang J, Morgenstern H, et al. Worldwide, mortality is a high risk soon after initiation of hemodialysis. Kidney International.2014;85(1):158–165. Doi:10.1038/ki.2013.252.

[87] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

[88] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

and PD, in which the patient's peritoneum, covering the abdominal organs, is used as the dialysis membrane. HD is conducted at an ESRD facility, usually 3 times a week, or at a patient's home, often at a greater frequency. PD most commonly occurs at the patient's home. (Although PD can be furnished within an ESRD facility, it is very rare. In providing background information for the ETC Model in the proposed rule and in this final rule, we consider PD to be exclusively a home modality.) Whether a patient selects HD or PD may depend on a number of factors, such as patient education before dialysis initiation, social and care partner support, socioeconomic factors, and patient perceptions and preference.[89] [90]

As discussed in the proposed rule, when Medicare began coverage for individuals on the basis of ESRD in 1973, more than 40 percent of dialysis patients in the U.S. were on HHD. More favorable reimbursement for outpatient dialysis and the introduction in the 1970s of continuous ambulatory peritoneal dialysis, which required less intensive training, contributed to a relative decline in HHD utilization.[91] Overall, the proportion of home dialysis patients in the U.S. declined from 1988 to 2012, with the number of home dialysis patients increasing at a slower rate relative to the total number of all dialysis patients. As cited in a U.S. Government Accountability Office (GAO) report, according to U.S. Renal Data System (USRDS) data, approximately 16 percent of the 104,000 dialysis patients in the U.S. received home dialysis in 1988; however, by 2012, the rates of HHD and PD utilization were 2 and 9 percent, respectively.[92]

Additionally, as outlined in the proposed rule, an annual analysis performed by the USRDS in 2018 compared the rates of dialysis modalities for prevalent dialysis patients in the U.S. to 63 selected countries or regions around the world. In 2016, the U.S. ranked 27th in the percentage of beneficiaries that were dialyzing at home (12 percent). For example, the U.S. rate of home dialysis is significantly below those of Hong Kong (74 percent), New Zealand (47 percent), Australia (28 percent), and Canada (25 percent).[93]

As discussed in the proposed rule, a 2011 report on home dialysis in the U.S. related the relatively low rate of home dialysis in this country to factors that included educational barriers, the monthly visit requirement for the MCP under the PFS, the need for home care partner support, as well as philosophies and business practices of dialysis providers, such as staffing allocations, lack of independence for home dialysis clinics, and business-oriented restrictions that lead to inefficient supply distribution. The report recommended consolidated, collaborative efforts to enhance patient education among nephrology practices, dialysis provider organizations, hospital systems and kidney-related organizations, as well as additional educational opportunities and training for nephrologists and dialysis staff. With regard to CMS's requirement starting in 2011 that the physician or non-physician practitioner furnish at least one in-person patient visit per month for home dialysis MCP services, the report noted that CMS allows discretion to Medicare contractors to allow payment without a visit so long as there is evidence for the provision of services throughout the month. Nevertheless, the report concluded that notwithstanding this allowance the stated policy might potentially be a disincentive for physicians to promote home dialysis. The report further commented that the low rate of home dialysis in the U.S. may result in part from patients' inability to perform self-care, and suggested providing support for home care partners. With respect to dialysis providers' business practices and philosophies, the report noted that dialysis providers differ in many ways and have different experiences that deserve attention and consideration with regard to potentially posing a barrier to the provision of home dialysis.[94]

As we noted in the proposed rule, the high rate of incident dialysis patients beginning dialysis through in-center HD in the U.S. is driven by a variety of factors including ease of initiation, physician experience and training, misinformation around other modalities, inadequate education for chronic kidney disease (CKD) beneficiaries, built-up capacity at ESRD facilities, and a lack of infrastructure to support home dialysis.[95] (Provision of home dialysis requires a system of distribution of supplies to patients, as well as allocation of staff and space within facilities for education, training, clinic visits, and supervision). One study indicated that patients' perceived knowledge about various ESRD therapies was correlated with their understanding of the advantages and disadvantages of the available treatment options.[96] As discussed in the proposed rule, researchers have reported that greater support, training, and education to nephrologists, other clinicians, and patients would increase the use of both HHD and PD. A prospective evaluation of dialysis modality eligibility among patients with CKD stages III to V enrolled in a North American cohort study showed that as many as 85 percent were medically eligible for PD.[97] However, in one study, only one-third of ESRD patients beginning maintenance dialysis were presented with PD as an option, and only 12 percent of patients were presented with HHD as an option.[98] As shown by a national pre-ESRD education initiative, pre-dialysis education results in a 2- to 3- fold increase in the rate of patients initiating home dialysis compared with the U.S. home dialysis rate.[99] Another study reported 42 percent of patients

[89] Stack AG. Determinants of Modality Selection among Incident US Dialysis Patients: Results from a National Study. Journal of the American Society of Nephrology. 2002; 13: 1279–1287. Doi 1046–6673/1305–1279.

[90] Miskulin DC, et al. Comorbidity and Other Factors Associated With Modality Selection in Incident Dialysis Patients: The CHOICE Study. American Journal of Kidney Diseases. 2002; 39(2): 324–336. Doi 10.1053/ajkd.2002.30552.

[91] Blagg CR. A Brief History of Home Hemodialysis. Annals in Renal Replacement Therapy. 1996; 3: 99–105.

[92] Unites States Government Accountability Office. End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis (GAO–16–125). October 2015.

[93] United States Renal Data System, Annual Data Report, 2018. Volume 2, Chapter 11: International Comparisons. Figure F11.12.

[94] Golper TA, Saxena AB, Piraino B, Teitelbaum, I, Burkart, J, Finkelstein FO, Abu-Alfa A. Systematic Barriers to the Effective Delivery of Home Dialysis in the United States: A Report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis. American Journal of Kidney Diseases. 2011; 58(6): 879–885.doi:10.1053/j.ajkd.2011.06.028.

[95] Ghaffarri A, Kalantar-Zadeh K, Lee J, Maddux F, Moran J, Nissenson A. PD First: Peritoneal Dialysis as the Default Transition to Dialysis Therapy. Seminars in Dialysis. 2013; 26(6): 706–713. doi: 10.1111/sdi.12125.

[96] Finkelstein FO, Story K, Firanek C, Barr P, et al. Perceived knowledge among patients cared for by nephrologists about chronic kidney disease and end-stage renal disease therapies. *Kidney International* 2008; 9: 1178–1184. *https://doi.org/10.1038/ki.2008.376*.

[97] Mendelssohn DC. Mujais SK, Soroka, SD, et al. A prospective evaluation of renal replacement therapy modality eligibility. Nephrology Dialysis Transplantation. 2009; 24(2): 555–561. doi: *https://doi.org/10/1093/ndt/gfn484*.

[98] Mehrotra R, Marsh D, Vonesh E, Peters V, Nissenson A. Patient education and access of ESRD patients to renal replacement therapies beyond in-center hemodialysis. Kidney International. 2005; 68(1):378–390.

[99] Lacson E, Wang W, DeVries C, Leste K, Hakim RM, Lazarus M, Pulliam J. Effects of a Nationwide Predialysis Educational Program on Modality Choice, Vascular Access, and Patient Outcomes. American Journal of Kidney Diseases. 2011; 58(2): 235–242.doi:10.1053/j.ajkd.2011.04.015.

preferring PD when the option was presented to them.[100]

Recent studies show substantial support among nephrologists and patients for dialysis treatment at home.[101] [102] [103] [104] [105] As we noted in the proposed rule, we believe that increasing rates of home dialysis has the potential to not only reduce Medicare expenditures, but also to preserve or enhance the quality of care for ESRD Beneficiaries.

As discussed in the proposed rule, research suggests that dialyzing at home is associated with lower overall medical expenditures than dialyzing in-center. Key factors that may be related to lower expenditures include potentially lower rates of infection associated with dialysis treatment, fewer hospitalizations, cost differentials between PD and HD services and supplies, and lower operating costs for dialysis providers for providing home dialysis.[106] [107] [108] [109] [110] (Most studies on the comparative cost and effectiveness of different dialysis modalities assess PD versus HD. As noted in the proposed rule, we believe that since the extent of in-center PD is negligible, and only approximately 2 percent of HD occurs at home, these studies are suitable for drawing conclusions regarding home versus in-center dialysis.) However, research on cost differences between in-center dialysis and home dialysis is limited to comparing costs for patients who currently dialyze at home to those who do not. As previously discussed in the proposed rule and in this final rule, there are currently barriers to dialyzing at home that may result in selection bias. Put another way, beneficiaries who currently dialyze at home may be different in some way from beneficiaries who dialyze in-center that is otherwise the cause of the observed difference in overall medical expenditures. Patients may differ in terms of age, gender, race, and clinical issues such as presence of diabetes and origin of ESRD.[111] Despite selection bias present in existing research, we stated in the proposed rule our expectation that increasing rates of home dialysis will likely decrease Medicare expenditures for ESRD Beneficiaries, and this is something we would assess as part of our evaluation of the ETC Model.

In addition, as we discussed in the proposed rule, current research on patients in the U.S. and Canada indicates similar, or better, patient survival outcomes for PD compared to HD.[112] [113] [114] (As previously noted, most research on the comparative effectiveness of different dialysis modalities compares PD to HD, but—as noted in the proposed rule—we believe these studies are suitable for comparing home to in-center dialysis, given that in-center PD is negligible and only approximately 2 percent of HD is conducted at home.) The USRDS shows lower adjusted all-cause mortality rates for 2013 through 2016 for PD compared to HD.[115] Therefore, as noted in the proposed rule, we believe increased rates of PD associated with increased rates of home dialysis prompted by the proposed Model would at least maintain, and may improve, quality of care provided to ESRD Beneficiaries. While studies from several nations observe that the survival advantage for PD may be attenuated following the early years of dialysis treatment (1 to 3 years), and also that advanced age and certain comorbidities among patients are related to less favorable outcomes for PD, as we discussed in the proposed rule, a component of the Model's evaluation would be to assess the applicability of these findings to the U.S. population and Medicare beneficiaries, specifically if there is sufficient statistical power to detect meaningful variation.[116] [117] [118] [119] [120] [121] [122] Patient benefits of HHD and PD also can include better quality of life and greater independence.[123] [124] [125] As described in greater detail in the proposed rule and throughout section IV of this final rule, one of the aims of the ETC Model is to test whether new payment incentives

[100] Maaroufi A, Fafin C, Mougel S, Favre G, Seitz-Polski P, Jeribi A, Vido S, Dewismi C, Albano L, Esnault V, Moranne O. Patient preferences regarding choice of end-stage renal disease treatment options. American Journal of Nephrology. 2013; 37(4): 359–369. doi: 1159/000348822.

[101] Rivara MB, Mehrotra R. The Changing Landscape of Home Dialysis in the United States. Current Opinion in Nephrology and Hypertension.2014; 23(6):586–591.doi:10.1097/MNH0000000000000066.

[102] Mehrotra R, Chiu YW, Kalantar-Zadeh K, Bargman J, Vonesh E. Similar Outcomes With Hemodialysis and Peritoneal Dialysis in Patients With End-Stage Renal Disease. Archives of Internal Medicine. 2011; 171(2): 110–118. Doi:10.1001/archinternmed.2010.352.

[103] Ghaffari et al. 2013.

[104] Ledebo I, Ronco C. The best dialysis therapy? Results from an international survey among nephrology professionals. Nephrology Dialysis Transplantation.2008;6:403–408.doi:10.1093/ndtplus/sfn148.

[105] Schiller B, Neitzer A, Doss S. Perceptions about renal replacement therapy among nephrology professionals. Nephrology News & Issues. September 2010; 36–44.

[106] Walker R, Marshall MR, Morton RL, McFarlane P, Howard K. The cost-effectiveness of contemporary home hemodialysis modalities compared with facility hemodialysis: A systematic review of full economic evaluations. Nephrology. 2014; 19: 459–470 doi: 10.1111/nep.12269.

[107] Walker R, Howard K, Morton R. Home hemodialysis: A comprehensive review of patient-centered and economic considerations. ClinicoEconomics and Outcomes Research. 2017; 9: 149–161.

[108] Howard K, Salkeld G, White S, McDonald S, Chadban S, Craig J, Cass A. The cost effectiveness of increasing kidney transplantation and home-based dialysis. Nephrology. 2009; 14: 123–132 doi: 10.1111/j.1440–1797.2008.01073.x.

[109] Quinn R, Ravani P, Zhang X, Garg A, Blake P, Austin P, Zacharias JM, Johnson JF, Padeya S, Verreli M, Oliver M. Impact of Modality Choice on Rates of Hospitalization in Patients Eligible for Both Peritoneal Dialysis and Hemodialysis. Peritoneal Dialysis International. 2014; 34(1): 41–48 doi: 10.3447/pdi.2012.00257.

[110] Sinnakirouchenan R, Holley, J. Peritoneal Dialysis Versus Hemodialysis: Risks, Benefits, and Access Issues. Advances in Chronic Kidney Disease. 2011; 18(6): 428–432. doi: 10.1053/j.ackd.2011.09.001.

[111] United States Renal Data System, Annual Data Report, 2018. Volume 2, Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. Table 1.

[112] Wong B, Ravani P, Oliver MJ, Holroyd-Leduc J, Venturato L, Garg AX, Quinn RR. Comparison of Patient Survival Between Hemodialysis and Peritoneal Dialysis Among Patients Eligible for Both Modalities. American Journal of Kidney Diseases. 2018; 71(3) 344–351. doi:10.1053/j.ajkd.2017.08.028.

[113] Kumar VA, Sidell MA, Jones JP, Vonesh EF. Survival of propensity matched incident peritoneal and hemodialysis patients in a United States health care system. Kidney International. 2014; 86: 1016–1022. doi:10.1038/ki.2014.224.

[114] Mehrotra et al. 2011.

[115] United States Renal Data System. Annual Data Report, 2018. Volume 2, Chapter 5: Mortality. Figure 5.1. Mortality rates were adjusted for age, sex, race, ethnicity, primary diagnosis and vintage.

[116] Li KP, Chow KM. Peritoneal Dialysis—First Policy Made Successful: Perspectives and Actions. American Journal of Kidney Diseases. 2013; 62(5): 993–1005. doi: *http://dx/doi.org/10.1053/j.ajkd.2013.03.038.*

[117] Yeates K, Zhu N, Vonesh E, Trpeski L, Blake P, Fenton S. Hemodialysis and peritoneal dialysis are associated with similar outcomes for end-stage renal disease treatment in Canada. Nephrology Dialysis Transplantation. 2012; 27(9): 3568–3575. doi: *https://doi.org/10.1093/ndt/gfr/674.*

[118] Chiu YW, Jiwakanon S, Lukowsky L, Duong U, Kalantar-Zadeh, Mehrotra R. An Update on the Comparisons of Mortality Outcomes of Hemodialysis and Peritoneal Dialysis Patients. Seminars in Nephrology. 2011; 31(2): 152–158. Doi:10.1016/j.semnephrol.2011.01.004.

[119] Mehrotra et al. 2011.

[120] Sinnakirouchenan R, Holley JL. 2011.

[121] Quinn RR, Hux JE, Oliver MJ, Austin, PC, Tonelli M, Laupacis A. Selection Bias Explains Apparent Differential Mortality between Dialysis Modalities. Journal of the American Society of Nephrology. 2011; 22(8) 1534–1542. doi: 10.1681/ASN.2010121232.

[122] Weinhandl ED, Foley RN, Gilbertson DT, Arneson TJ, Snyder JJ, Collins AJ. Propensity-Matched Mortality Comparison of Incident Hemodialysis and Peritoneal Dialysis Patients. Journal of the American Society of Nephrology. 2010; 21(3): 499–506. doi: 10.1681/ASN.2009060635: 10.1681/ASN.2009060635.

[123] Ghaffari et al. 2013.

[124] Rivara and Mehrotra. 2014.

[125] Juergensen E, Wuerth D, Finkelstein SH et al., Hemodialysis and Peritoneal Dialysis: Patients' Assessments of Their Satisfaction with Therapy and the Impact of the Therapy on their Lies. Clinical Journal of American Society of Nephrology. 2006; 1(6): 1191–1196. DOI: *https://doi.org/10.2215/CJN.01220406.*

would lead to greater rates of home dialysis.

The following is a summary of the comments received on the benefits of and barriers to home dialysis and our responses.

Comment: Several commenters expressed support for the association between home dialysis and improved health outcomes in comparison to in center dialysis. Commenters stated that research suggests that HHD facilitates longer, more frequent dialysis, or optimal dialysis dosing for the individual patient, which in turn leads to better health outcomes and quality of life. Commenters also stated that research suggests other benefits to home dialysis, including need for fewer medications, less frequent hospitalizations, and better quality of life. A commenter stated that there is evidence that suggests that HHD can have long term outcomes that are equal to or better than deceased donor transplants. A commenter stated that they believe home dialysis can preserve or enhance the quality of care for ESRD Beneficiaries while reducing Medicare expenditures. Another commenter stated that shifting dialysis provision from in-center dialysis to home dialysis would have positive economic effects, including decreasing costs for dialysis providers, creating economies of scale for home dialysis supplies and logistics, and increasing research and development into new home dialysis technologies.

Response: We thank the commenters for their feedback and support. If the Model increases rates of home dialysis as intended, we will assess the impact of increased rates of home dialysis on quality of care, including—to the extent possible—those particular aspects of care quality identified by commenters. The evaluation plan for the Model is discussed in section IV.C.11 of this final rule.

Comment: Multiple commenters expressed agreement with barriers to the provision of home dialysis services as previously identified in this final rule and in the proposed rule. Commenters specifically identified barriers surrounding limited patient education about and awareness of home dialysis, and lack of familiarity and comfort with prescribing home dialysis among Managing Clinicians. Commenters also identified additional factors that may prevent beneficiaries from selecting home dialysis, including: clinical, mental, and social stability; inadequate or unstable housing conditions; socioeconomic factors; and patient preference. Several commenters identified aspects of the Medicare FFS payment system that disincentivize home dialysis, including the ability for Managing Clinicians to maximize revenue through in-center dialysis over home dialysis, and Medicare requirements around MCP monthly in-person visits for home dialysis beneficiaries. A commenter stated that the requirements for an ESRD facility to become certified to provide home dialysis are burdensome and prevent some ESRD facilities from seeking certification to begin a home dialysis program. Commenters identified system-level factors related to the supply of goods and services necessary to conduct home dialysis, including dialysis supplies in general and PD solution in particular, availability of vascular access services, and lack of new technology and innovation in the home dialysis industry. Commenters discussed a lack of access to primary care, lack of screening for CKD in a primary care setting, and lack of patient education about ESRD and dialysis options before beneficiaries initiate dialysis, as beneficiaries who have access to these services are more likely to initiate dialysis at home. Commenters stated that many of these barriers to home dialysis are outside of the control of Managing Clinicians and ESRD facilities.

Response: We thank the commenters for their feedback. CMS recognizes that there are a variety of barriers that prevent ESRD Beneficiaries from choosing home dialysis at present. ESRD facilities and Managing Clinicians are the clinical experts in dialysis provision in general, and in the clinical and non-clinical needs of individual ESRD Beneficiaries specifically. We therefore believe that ESRD facilities and Managing Clinicians are uniquely positioned to assist ESRD Beneficiaries in overcoming these barriers, given their close care relationship to and frequent interaction with ESRD Beneficiaries. Therefore, we have designed the ETC Model to test whether outcomes-based payment adjustments for ESRD facilities and Managing Clinicians can maintain or improve quality and reduce costs by increasing rates of home dialysis transplant waitlisting, and living donor transplants. The ETC Model is one piece of the Advancing American Kidney Health initiative, a larger HHS effort focused on improving care for patients with kidney disease.[126] The payment adjustments in the ETC Model test one approach to addressing existing disincentives to home dialysis and transplant in the current Medicare FFS payment system.

We recognize that educating patients about their renal replacement options is key to supporting modality selection. As such, we are waiving certain requirements for the Kidney Disease Education (KDE) benefit to allow Managing Clinicians who are ETC Participants additional flexibility to furnish and bill for these educational services under the Model. These waivers are detailed in section IV.C.7.b of this final rule.

In response to the commenters' concerns about system-level factors, including products and services necessary to home dialysis provision, we have designed the benchmarking and scoring methodology, described in section IV.C.5.d of this final rule, to be comparative to account for these types of system-level factors. In the initial years of the Model, participant achievement will be assessed in relation to home dialysis rates among non-participants. As such, any system-level limitations that affect home dialysis rates for ETC Participants are also reflected in the ESRD facilities and Managing Clinicians not participating in the Model that form the basis for the benchmarks.

In response to the commenters' concerns about certification requirements deterring ESRD facilities from operating home dialysis programs, we did not propose to waive Medicare certification requirements as part of this Model, in order to preserve patient health and safety. Additionally, the aggregation approach for this Model, in which all ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area are assessed as one aggregation group with respect to their performance on the home dialysis rate, alleviates the need for individual ESRD facilities to become certified to perform home dialysis.

Comment: Several commenters stated that comparing U.S. rates of home dialysis to other countries, particularly other countries with very high home dialysis rates, is inappropriate, because those countries have different demographic, socioeconomic, and health system factors that impact home dialysis utilization. Several commenters stated that other countries that are more similar to the U.S. in demography, socioeconomic status, and health system structure have home dialysis rates closer to that of the U.S.

Response: We appreciate the commenters' concerns about comparing home dialysis rates in the U.S. to home dialysis rates in other countries. We

[126] E.O. 13879 of July 10, 2019.

acknowledge that there are differences between the U.S. and other countries that may make direct comparisons challenging. We provided the comparison in the proposed and final rules for context but have designed the Model specifically for the U.S. market, in particular the Medicare program.

b. Kidney Transplants

As we discussed in the proposed rule, a kidney transplant involves surgically transplanting one healthy kidney from a living or deceased donor. A kidney-pancreas transplant involves simultaneously transplanting both a kidney and a pancreas, for patients who have kidney failure related to type 1 diabetes mellitus. While the kidney in a kidney transplant may come from a living or deceased donor, a kidney transplant in conjunction with a pancreas or other organ can only come from a deceased donor. As noted in the proposed rule, candidates for kidney transplant undergo a rigorous evaluation by a transplant center prior to placement on a waitlist, and once placed on the waitlist, potential recipients must maintain active status on the waitlist. The United Network for Organ Sharing (UNOS) maintains the waitlist for and conducts matching of deceased donor organs. ESRD Beneficiaries already on dialysis continue to receive regular dialysis treatments while waiting for an appropriate organ.

As cited in the proposed rule, a systematic review of studies worldwide found significantly lower mortality and risk of cardiovascular events associated with kidney transplantation compared with maintenance dialysis.[127] Additionally, this review found that beneficiaries who receive transplants experience a better quality of life than those who receive treatment with chronic dialysis.[128]

As we noted in the proposed rule, per-beneficiary-per-year Medicare expenditures for beneficiaries receiving kidney or kidney-pancreas transplants are often substantially lower than for those on dialysis.[129] The average dialysis patient is admitted to the hospital nearly twice a year, often as a result of infection, and approximately 35.4 percent of dialysis patients who are discharged are re-hospitalized within 30 days of being discharged.[130] Among transplant recipients, there are lower rates of hospitalizations, emergency department visits, and readmissions.[131] As discussed in the proposed rule, while comparisons between patients on dialysis and those with functioning transplants rely on observational data, due to the ethical concerns with conducting clinical trials, the data nonetheless suggest better outcomes for ESRD patients that receive transplants.

Notwithstanding these outcomes, as we discussed in the proposed rule, only 29.6 percent of prevalent ESRD patients in the U.S. had a functioning kidney transplant and only 2.8 percent of incident ESRD patients—meaning patients new to ESRD—received a pre-emptive kidney transplant in 2016.[132] A pre-emptive transplant is a kidney transplant that occurs before the patient requires dialysis. These rates are substantially below those of other developed nations. The U.S. was ranked 39th of 61 reporting countries in kidney transplants per 1,000 dialysis patients in 2016, with 39 transplants per 1,000 dialysis patients in 2016.[133] While the relatively low rate of transplantation in the U.S. may partly reflect the high numbers of dialysis patients and differences in the relative prevalence and incidence of ESRD, as we noted in the proposed rule, there are other likely contributing causes, such as differences in health care systems, the infrastructure supporting transplantation, and cultural factors.[134]

As we discussed in the proposed rule, the main barrier to kidney transplant is the supply of available organs. Medicare is undertaking regulatory efforts to increase organ supply, discussed in the proposed rule and in section IV.B.3.a of this final rule. Further, as discussed in the proposed rule, we believe there are a number of things ESRD facilities and Managing Clinicians can do to assist their beneficiaries in securing a transplant. Access to kidney transplantation can be improved by increasing referrals to the transplant waiting list, increasing rates of deceased and living kidney donation, expanding the pools of potential donors and recipients, and reducing the likelihood that potentially viable organs are discarded.[135] We noted in the proposed rule that we anticipated Managing Clinicians and ESRD facilities selected for participation in the ETC Model would address these areas of improvement through various strategies in order to improve their rates of transplantation. As we noted in the proposed rule, these strategies could include educating beneficiaries about transplantation, coordinating care for beneficiaries as they progress through the transplant waitlist process, and assisting beneficiaries and potential donors with issues surrounding living donation, including support for paired donations and donor chains. In paired donations and donor chains, willing donors who are incompatible with their intended recipient can donate to other candidates on the transplant waitlist in return for a donation from another willing donor who is compatible with their intended recipient.[136]

After increasing during the 1990s, the volume of simultaneous pancreas and kidney transplants has either remained stable or declined slightly since the early 2000s. As we noted in the proposed rule, the reason for this decline is not clear, but is likely to be multifactorial, possibly including a decrease in patients being placed on the waiting list for this procedure, more stringent donor selection, and greater scrutiny of transplant center outcomes.[137]

As we discussed in the proposed rule, under current Medicare payment systems, an ESRD Beneficiary receiving a kidney transplant represents a loss of revenue to the ESRD facility and, to a lesser extent, the Managing Clinician. After a successful transplant occurs, the ESRD facility no longer has a care relationship with the beneficiary, as the

[127] Tonelli M, Weibe N, Knoll G, Bello A, Browne S. Jadhav D, Klarenbach S, Gill J. Systematic Review: Kidney Transplantation Compared with Dialysis in Clinically Relevant Outcomes. American Journal of Transplantation. 2011; 11(10). doi: *https://doi.org/10.1111/j.1600-6143.2011.03686.x.*

[128] Tonelli, M. et al. 2011.

[129] United States Renal Data System.Annual Data Report, 2018. Volume 2. Chapter 9: Healthcare expenditures for Persons with ESRD. Figure F9.8.

[130] United States Renal Data System. Annual Data Report, 2018; Volume 2, Chapter 4: Hospitalizations, Readmissions, Emergency Department Visits, and Observation Stays. Tables F4–1, F4–8.

[131] United States Renal Data System. Annual Data Report, 2018: Volume 2, Chapter 4: Hospitalizations, Readmissions, Emergency Department Visits, and Observation Stays. Tables F4.1, F4.8, and F4.14.

[132] United States Renal Data System. Annual Data Report, 2018; Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

[133] United States Renal Data System. Annual Data Report, 2018. Volume 2. Chapter 11. International Comparisons. Figure 11.16.

[134] United States Renal Data System. Annual Data Report, 2018: Volume 2. Chapter 11. International Comparisons. *https://www.usrds.org/2018/view/v2_11.aspx.*

[135] Serur D, Bingaman A, Smith B. Kidney Transplantation 2017 Breaking Down Barriers and Building Bridges. American Society of Nephrology: Kidney News Online. 2017; 9(4): *kidneynews.org/kidney-news/practice-pointers/kidney-transplantation-2017-breaking-down-barriers-and-building-bridges.*

[136] Segev D, Gentry S, Warren D. Kidney Paired Donation and Optimizing the Use of Live Donor Organs. JAMA. 2005;293(15):1883–1890. doi:10.1001/jama.293.15.1883.

[137] Redfield RR, Scalea JR, Odoricio JS. Simultaneous pancreas and kidney transplantation: Current trends and future directions. Current Opinion in Organ Transplantation. 2015; 20(1): 94–102. Doi:10.1097/MOT.0000000000000146.

beneficiary no longer requires maintenance dialysis. While the Managing Clinician may continue to have a care relationship with the beneficiary post-transplant, payment for physicians' services related to maintaining the health of the transplanted kidney is lower than the MCP for managing dialysis. Whereas a Managing Clinician sees a beneficiary on dialysis and bills for the MCP each month, a post-transplant beneficiary requires fewer visits per year, and these visits are of a lower intensity. As described in greater detail in the proposed rule and throughout this section IV of this final rule, one of the aims of the ETC Model is to test whether new payment incentives would lead to greater rates of kidney transplantation.

The following is a summary of the comments received on the benefits of and barriers to transplantation and our responses.

Comment: Multiple commenters expressed support for the premise that transplantation is the best treatment option for most patients with ESRD. These commenters also stated that research shows that transplantation is associated with better health outcomes, better quality of life, and lower health care expenditures.

Response: We thank the commenters for their feedback and support.

Comment: A commenter stated that rates of transplantation in the U.S. are not directly comparable to rates of transplantation in other countries due to different population characteristics.

Response: We thank the commenter for this feedback. As stated in the proposed rule and earlier in this final rule, we acknowledge that, in addition to variations in the relative prevalence and incidence of ESRD, there are other likely contributing causes to the relatively low rate of transplantation in the U.S. relative to other countries, such as differences in health care systems, the infrastructure supporting transplantation, and cultural factors.[138] As such, while we included information about transplant rates in other countries for comparison, we did not propose to base the design of the Model's transplant component on transplant rates in other countries. We believe that the transplant rate in the U.S. can be higher than it is now, and to that end are testing this Model in conjunction with other efforts to increase transplant rates described in section IV.B.1.a of this final rule.

Comment: Multiple commenters expressed agreement with the barriers to transplantation identified in the proposed rule (also discussed earlier in this final rule). Commenters specifically identified the limited supply of organs for transplantation as the key barrier to transplantation. Several commenters stated that there is significant variation nationally in the patient experience of transplantation, including the supply of organs and transplant center practices. A commenter stated that each transplant center sets its own guidelines for transplant waitlisting, and that some centers exclude patients who do not have financial resources or health insurance coverage beyond Medicare. A commenter described factors that patients have identified as limiting their access to transplant waitlisting, including: The complexity, intensity, and difficulty of the waitlisting process; uncertainty and lack of social, financial, and medical support; cost; and fear of loss of Medicare coverage post-transplant. A commenter stated that lack of access to primary care and early detection of kidney disease is associated with lower likelihood of receiving a transplant.

Response: We thank the commenters for their feedback. CMS recognizes that there are a variety of barriers that prevent ESRD Beneficiaries from receiving a transplant at present. As noted previously in this final rule, we believe that ESRD facilities and Managing Clinicians are uniquely positioned to assist beneficiaries in overcoming barriers to transplantation, for both deceased donor transplantation and living donor transplantation, given their close care relationship to and frequent interaction with ESRD Beneficiaries. Therefore, we have designed the ETC Model to test whether outcomes-based payment adjustments for ESRD facilities and Managing Clinicians can maintain or improve quality and reduce costs by increasing rates of home dialysis and transplantation. As also noted previously in this final rule, the ETC Model is one piece of a larger HHS effort focused on improving care for patients with kidney disease. In particular, we recognize that other transplant providers, including transplant centers and organ procurement organizations (OPOs) are central to the supply and use of deceased donor organs. As such, we are implementing the ETC Learning Collaborative, described in section IV.C.12 of this final rule, to increase the supply and use of deceased donor organs. CMS and HHS have also undertaken other regulatory efforts to increase the supply of organs, including the proposed rule issued December 23, 2019 entitled ''Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization[s]'' (84 FR 70628), and the proposed rule published December 20, 2019 entitled ''Removing Financial Disincentives to Living Organ Donation'' (84 FR 70139). The payment adjustments in the ETC Model test one approach for addressing existing disincentives to transplantation in the current Medicare FFS payment system, including to create incentives to support a beneficiary through the complexity of the transplant process. As described in greater detail in section IV.C.1 of this final rule, we are altering the PPA calculation such that ETC Participant performance will be assessed based on a transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate, rather than a transplant rate focused on the receipt of all kidney transplants including deceased donor transplants. We made this alteration to recognize the role that ETC Participants can currently play in getting patients on the transplant waitlist rate and in increasing the rate of living donor transplants described later on in the rule while allowing the ETC Learning Collaborative and these other CMS and HHS rules (if finalized) time to take effect and to increase the supply of available deceased donor organs. However, as described in greater detail in section IV.C.5.c.(2) of this final rule, it is also our intent to observe the supply of deceased donor organs available for transplantation. Any change from holding ETC Participants accountable for the rate of all kidney transplants including deceased donor transplantation, rather than the rate of kidney transplant waitlisting and living donor transplantation would be proposed through notice and comment rulemaking in the future.

In the final rule, we are clarifying that when referencing kidney transplants in this final rule and the ETC Model regulations, CMS is including any kidney transplant, alone or in conjunction with any other organ, not just a kidney transplant or kidney-pancreas transplant. As discussed in more detail in section IV.C.5 of this final rule, we received a comment that urged CMS to include in the ETC Model kidney transplants in conjunction with any other organ, in addition to the kidney transplants and kidney-pancreas transplants referenced in the proposed

[138] United States Renal Data System. Annual Data Report, 2018: Volume 2. Chapter 11. International Comparisons. *https://www.usrds.org/2018/view/v2_11.aspx.*

rule. By specifying in the proposed rule that we were including kidney and kidney-pancreas transplants under the Model, it was not our intent to imply that we were excluding kidney transplants in conjunction with any other organ. Therefore, as discussed in section IV.C.5 of this final rule, we are clarifying as part of the final definition of kidney transplant that the ETC Model includes kidney transplants that occur alone or in conjunction with any other organ.

c. Addressing Care Deficits Through the ETC Model

Considering patient and clinician support for home dialysis and kidney transplant for ESRD patients, along with evidence that use of these treatment modalities could be increased with education, we proposed to implement the ETC Model to test whether adjusting Medicare payments to ESRD facilities under the ESRD PPS and to Managing Clinicians under the PFS would increase rates of home dialysis, both HHD and PD, and kidney and kidney-pancreas transplantation.

We proposed that the ETC Model would include two types of payment adjustments: The Home Dialysis Payment Adjustment (HDPA) and the Performance Payment Adjustment (PPA). The HDPA would be a positive payment adjustment on home dialysis and home dialysis-related claims during the initial three years of the Model, to provide an up-front incentive for ETC Participants to provide additional support to beneficiaries choosing to dialyze at home. The PPA would be a positive or negative payment adjustment, which would increase over time, on dialysis and dialysis-related claims, both home and in-center, based on the ETC Participant's home dialysis rates and transplant rates during a Measurement Year in comparison to achievement and improvement benchmarks, with the aim of increasing the percent of ESRD Beneficiaries either having received a kidney transplant or receiving home dialysis over the course of the ETC Model. We proposed that the magnitude of the HDPA would decrease as the magnitude of the PPA increases, to shift from a process-based incentive approach (the HDPA) to an outcomes-based incentive approach (the PPA).

The proposed payment adjustments under the ETC Model would apply to all Medicare-certified ESRD facilities, and Managing Clinicians enrolled in Medicare located within Selected Geographic Areas. While we proposed to apply the HDPA to all ETC Participants, the PPA would not apply to certain ESRD facilities and Managing Clinicians managing low volumes of adult ESRD Medicare beneficiaries. Under our proposal, one or both of the payment adjustments under the ETC Model would apply to payments on claims for dialysis and certain dialysis-related services with through dates from January 1, 2020 through June 30, 2026, with the goal of reducing Medicare spending, preserving or enhancing quality of care for beneficiaries, and increasing beneficiary choice regarding ESRD treatment modality.

The following is a summary of the comments received on addressing care deficits through the ETC Model, and our responses.

Comment: Multiple commenters expressed support for the goals of the proposed Model. Commenters expressed support for increasing rates of home dialysis and transplantation, on the grounds that these alternative renal replacement modalities are better for patients with ESRD than in-center dialysis. Several commenters expressed support for the proposed Model's approach to increasing home dialysis and transplantation through payment adjustments, as well as the proposed Model's geographic scope and its mandatory design. These commenters also stated that the proposed Model had the potential to: Create system-wide change; support technological innovation; and facilitate research into factors that impact the provision of dialysis, clinical outcomes related to dialysis modality selection, and patient outcomes.

Response: We thank the commenters for their feedback and support of the Model's goals.

Comment: Multiple commenters stated that they supported the goals of the proposed Model, but expressed reservations about aspects of the Model's design. Several commenters stated that any payment incentives for providers and suppliers need to be balanced against patient preferences and minimizing or avoiding unintended consequences. Several commenters stated that the ETC Model, as proposed, would not address some or all of the key barriers to home dialysis and transplantation, including that the Model, as proposed, had an insufficient focus on prevention and patient education, organ availability, and the supply of trained home dialysis staff including home dialysis nurses, and did not adequately take into account the unique structure of the dialysis market. Several commenters stated that the proposed Model would not sufficiently incentivize ETC Participants to take patient choice into account. Several commenters expressed concern that the ETC Model would harm the KCC Model because the national impact of the ETC Model would deter participation in and the evaluation of the KCC Model.

Response: We thank the commenters for their feedback and support of the Model's goals. In terms of the commenters' concerns that the Model does not address some or all of the key barriers to home dialysis and transplantation and does not sufficiently incentivize supporting patient choice, this Model is one piece of the larger HHS effort to improve care for beneficiaries with kidney disease, which also includes the KCC Model. While the ETC Model focuses primarily on modality selection, other parts of the HHS effort focus more directly on other ways to improve care for beneficiaries with kidney disease, including education and prevention, care coordination, organ supply, and technological innovation. We agree that supporting patient choice in modality selection is vital, and we believe the ETC Model will support providers and suppliers in their ability to assist beneficiaries choosing renal replacement modalities other than in-center dialysis. We address the commenters' specific comments about the interaction with the KCC Model in section IV.C.6 of this final rule, and in other sections of this final rule where particular policies are discussed.

Comment: Multiple commenters stated that they supported the goals of the proposed ETC Model but opposed the Model itself. Several commenters stated that the proposed Model had significant methodological limitations that would lead to unintended consequences and adverse patient outcomes. A commenter stated that the proposed Model would amount to a payment reduction for all dialysis providers. Several commenters stated that, as proposed, methodological flaws with the Model's design would prevent participants from being successful in the Model. In particular, a few commenters stated that small dialysis organizations and rural ESRD facilities would be harmed due to the financial risk in the Model. Several commenters stated that rather than implement the ETC Model, CMS should focus on implementing voluntary models that incentivize dialysis providers to collaborate around care coordination, such as the CEC Model. A commenter stated that, as the current organ allocation system may change, it is inappropriate to test a model around transplantation at this time.

Response: We thank the commenters for their feedback and support of the Model's goals. We address commenters'

specific comments about methodological concerns, the impact of the Model on small and rural ESRD facilities, and the organ allocation system in later sections of this final rule where particular policies are discussed.

Comment: Several commenters stated that supporting patient choice and informed decision-making are vital, and should be the focus of the proposed Model.

Response: We thank the commenters for their feedback, and we agree that supporting patient choice in modality selection is vital. We believe this Model will support beneficiaries' ability to choose renal replacement modalities other than in-center HD.

Comment: Many commenters recommended additional or alternative approaches, outside of the ETC Model, that CMS could take to improve quality of care for Medicare beneficiaries with kidney disease.

Response: We thank commenters for their feedback; however, these suggestions did not address the ETC Model and therefore are out of scope for this rulemaking. We may consider these comments in developing future policies related to beneficiaries with kidney disease.

2. The Medicare ESRD Program

In the proposed rule and in this section of the final rule, we describe current Medicare payment rules and how they may create both positive and negative incentives for the provision of home dialysis services and kidney transplants.

a. History of the Medicare ESRD Program

Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603) extended Medicare coverage to individuals regardless of age who have permanent kidney failure, or ESRD, requiring either dialysis or kidney transplantation to sustain life, and who meet certain other eligibility requirements. Individuals who become eligible for Medicare on the basis of ESRD are eligible for all Medicare-covered items and services, not just those related to ESRD. Subsequently, the ESRD Amendments of 1978 (Pub. L. 95–292) amended Title XVIII of the Act by adding section 1881.

Section 1881 of the Act establishes Medicare payment for services furnished to individuals who have been determined to have ESRD, including payments for self-care home dialysis support services furnished by a provider of services or renal dialysis facility, home dialysis supplies and equipment, and institutional dialysis services and supplies. Section 1881(c)(6) of the Act states: It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated. This provision also directs the Secretary of HHS to consult with appropriate professional and network organizations and consider available evidence relating to developments in research, treatment methods, and technology for home dialysis and transplantation.

Prior to 2011 and the implementation of the ESRD PPS, Medicare had a composite payment system for the costs incurred by ESRD facilities furnishing outpatient maintenance dialysis, including some routinely provided drugs, laboratory tests, and supplies, whether the services were furnished in a facility or at home. (For a discussion of the composite payment system, please see 75 FR 49032). Under this methodology, prior to 2009, CMS differentiated between hospital-based and independent facilities for purposes of setting the payment rates. (Effective January 1, 2009, CMS discontinued the policy of separate payment rates based on this distinction, 75 FR 49034). However, the same rate applied regardless of whether the dialysis was furnished in a facility or at a beneficiary's home (75 FR 49058). The system was relatively comprehensive with respect to the renal dialysis services included as part of the composite payment, but over time a substantial portion of expenditures for renal dialysis services such as drugs and biologicals were not included under the composite payment and paid separately in accordance with the respective fee schedules or other payment methodologies (75 FR 49032). With the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), the Secretary was required to implement a payment system under which a single payment is made for renal dialysis services in lieu of any other payment.

As we described in the proposed rule, in 2008, CMS issued a final rule entitled ''Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities,'' which was the first comprehensive revision since the outset of the Medicare ESRD program in the 1970s. The Conditions for Coverage (CfC) established by this final rule include separate, detailed provisions applicable to home dialysis services, setting substantive standards for treatment at home to ensure that the quality of care is equivalent to that for in-center patients. (73 FR 20369, 20409, April 15, 2008).

As we also noted in the proposed rule, on January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA. The ESRD PPS is discussed in detail in the following section.

b. Current Medicare Coverage of and Payment for ESRD Services

The Medicare program covers a range of services and items associated with ESRD treatment. Medicare Part A generally includes coverage of inpatient dialysis for patients admitted to a hospital or skilled nursing facility for special care, as well as inpatient services for covered kidney transplants. Medicare Part B generally includes coverage of renal dialysis services furnished by Medicare-certified outpatient facilities, including certain dialysis treatment supplies and medications, home dialysis services, support and equipment, and doctor's services during a kidney transplant. Costs for medical care for a kidney donor are covered under either Part A or B, depending on the service. To date, Medicare Part C has been available to ESRD Beneficiaries only in limited circumstances, such as when an individual already was enrolled in a Medicare Advantage (MA) plan at the time of ESRD diagnosis; however, as required under section 17006 of the 21st Century Cures Act, ESRD Beneficiaries will be allowed to enroll in MA plans starting with 2021. Medicare Part D generally provides coverage for outpatient prescription drugs not covered under Part B, including certain renal dialysis drugs with only an oral form of administration (oral-only drugs), and prescription medications for related conditions.

(1) The ESRD PPS Under Medicare Part B

As we discussed in the proposed rule, under the ESRD PPS, a single per treatment payment is made to an ESRD facility for all of the renal dialysis services and items defined in section 1881(b)(14)(B) of the Act and furnished to beneficiaries for the treatment of ESRD in a facility or in a patient's home. The ESRD PPS includes patient-level adjustments for case mix, facility-level adjustments for wage levels, low-volume facilities and rural facilities, and, when applicable, a training add-on for home and self-dialysis modalities, an additional payment for high cost outliers due to unusual variations in the

type or amount of medically necessary care, a transitional drug add-on payment adjustment (TDAPA), and a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES).[139] Under section 1881(b)(14)(F) of the Act, the ESRD PPS payment amounts are increased annually by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

As we noted in the proposed rule, in implementing the ESRD PPS, we have sought to create incentives for providers and suppliers to offer home dialysis instead of just dialysis at a facility. In the CY 2011 ESRD PPS final rule, we noted that in determining payment under the ESRD PPS, we took into account all costs necessary to furnish home dialysis treatments including staff, supplies, and equipment. In that rule, we described that Medicare would continue to pay, on a per treatment basis, the same base rate for both in-facility and home dialysis, as well as for all dialysis treatment modalities furnished by an ESRD facility (HD and the various forms of PD) (75 FR 49057, 49059, 49064). The CY 2011 ESRD PPS final rule also finalized a wage-adjusted add-on per treatment adjustment for home and self-dialysis training under 42 CFR 413.235(c), as CMS recognized that the ESRD PPS base rate alone does not account for the staffing costs associated with one-on-one focused home dialysis training treatments furnished by a registered nurse (75 FR 49064). CMS noted, however, that because the costs associated with the onset of dialysis adjustment and the training add-on adjustment overlap, ESRD facilities would not receive the home dialysis training adjustment in addition to the add-on payment under the ESRD PPS for the first 4 months of dialysis for a Medicare patient (75 FR 49063, 49094).

As we noted in the proposed rule, ESRD PPS payment requirements are set forth in 42 CFR part 413, subpart H. Since the implementation of the ESRD PPS, CMS has published annual rules to make routine updates, policy changes, and clarifications. Payment to ESRD facilities under the ESRD PPS for a calendar year might also be reduced by up to two percent based on their performance under the ESRD QIP, which is authorized by section 1881(h) of the Act. Section 1881(h) of the Act requires the Secretary to select measures, establish performance standards that apply to the measures, and develop a methodology for assessing the total performance for each renal dialysis facility based on the performance standards established with respect to the measures for a performance period. CMS uses notice and comment rulemaking to make substantive updates to the ESRD PPS and ESRD QIP program requirements.

(2) The MCP

As we discussed in the proposed rule, Medicare pays for routine professional services relating to dialysis care directly to a billing physician or non-physician practitioner. When Medicare pays the physician or practitioner separately for routine dialysis-related physicians' services furnished to a dialysis patient, the payment is made under the Medicare physician fee schedule using the MCP method as specified in 42 CFR 414.314. The per-beneficiary per-month MCP is for all routine physicians' services related to the patient's renal condition. Whereas the MCP for patients dialyzing in-center varies based on the number of in-person visits the physician has with the patient during the month, the MCP for patients dialyzing at home is the same regardless of the number of in-person visits.[140]

(3) The Kidney Disease Education Benefit

As we discussed in the proposed rule, in addition to establishing the ESRD PPS, the MIPPA, in section 152(b), amended section 1861(s)(2) of the Act by adding a new subparagraph (EE) ''kidney disease education services'' as a Medicare-covered benefit under Part B for beneficiaries with Stage 4 CKD. Medicare currently covers up to 6 1-hour sessions of KDE services, addressing the choice of treatment (such as in-center HD, home dialysis, or kidney transplant) and the management of comorbidities, among other topics (74 FR 61737, 61894).

However, utilization of KDE services has been low. As we described in the proposed rule, citing the USRDS, GAO reported that less than 2 percent of eligible Medicare beneficiaries used the KDE benefit in 2010 and 2011, the first 2 years it was available, and that use of the benefit has decreased since then.[141] According to GAO, stakeholders have attributed this low usage to the statutory restrictions on which practitioners can provide this service, and also the limitation of eligibility to the specific category of Stage 4 CKD patients. As we noted in the proposed rule, these restrictions are specified in section 1861(ggg)(1) and (2) of the Act. A ''qualified person'' is a physician, physician assistant, or nurse practitioner, or a provider of services located in a rural area. GAO cited literature emphasizing the importance of pre-dialysis education in helping patients to make informed treatment decisions, and indicating that patients who have received such education might be more likely to choose home dialysis.

c. Impacts of Medicare Payment Rules on Home Dialysis

As we discussed in the proposed rule, in the CY 2011 ESRD PPS final rule, we acknowledged concerns from commenters that the proposed ESRD PPS might contribute to decreasing rates of home dialysis. In particular, commenters stated that the single payment method would require ESRD facilities to bear the supply and equipment costs associated with home dialysis modalities, and thus make them less economically feasible. We noted in response that while home dialysis suppliers may not achieve the same economies of scale as ESRD facilities, suppliers would remain able to provide equipment and supplies to multiple ESRD facilities and be able to negotiate competitive prices with ESRD equipment and supply manufacturers (75 FR 49060). Nevertheless, we stated that we would monitor utilization of home dialysis under the ESRD PPS (75 FR 49057, 49060).

As we further discussed in the proposed rule, a May 2015 report from GAO examined the incentives for home dialysis associated with Medicare payments to ESRD facilities and physicians. Citing the USRDS, GAO found a decrease in the percentage of home dialysis patients as a percentage of all dialysis patients between 1988 and 2008, but then a slight increase to 11 percent in 2012.[142] According to GAO, the more recent increase in use of home dialysis was also reflected in CMS data for adult Medicare dialysis patients, showing an increase from 8 percent using home dialysis in January 2010 to about 10 percent as of March 2015.

Although this increase was generally concurrent with the phase-in of the ESRD PPS, the GAO report identified factors that might undermine incentives

[139] After we published the proposed rule to implement the ETC Model, CMS established the TPNIES under the ESRD PPS as part of the CY 2020 ESRD PPS final rule (84 FR 60648). We discuss the implications of this change for the ETC Model payment adjustments in sections IV.C.4.b, and IV.C.5.e(1) of this final rule.

[140] Medicare Claims Processing Manual, Chapter 8, 140; *https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104.c08.pdf.*

[141] United States Government Accountability Office, 2015.

[142] United States Government Accountability Office, 2015.

to encourage home dialysis. According to interviews with stakeholders, facilities' costs for increasing provision of in-center HD may be lower than for either HHD or PD. Although the average cost of an in-center HD treatment is typically higher than the average cost of a PD treatment, ESRD facilities may be able to add an in-center patient without incurring the cost of an additional dialysis machine because each machine can be used by 6 to 8 patients. In contrast, when adding a home dialysis patient, facilities generally incur costs for additional equipment specific to individual patients.[143]

Similarly, GAO received comments from physicians and physician organizations that Medicare payment may lead to a disincentive to prescribe home dialysis, because management of a home dialysis patient often occurs in a private setting and tends to be more comprehensive, while visits to multiple in-center patients may be possible in the same period of time. The GAO report noted, on the other hand, that monthly physician payments for certain patients under 65 who undergo home dialysis training may begin the first month, instead of the fourth, of dialysis, which may provide physicians with an incentive to prescribe home dialysis. In addition, the GAO report stated that Medicare makes a one-time payment for each patient who has completed home dialysis training under the physician's supervision.[144]

The GAO report concluded that interviews with stakeholders indicated potential for further growth, noting that the number and percentage of patients choosing home dialysis had increased in the recent years. The report stated that Medicare payments to facilities and physicians would need to be consistent with the goal of encouraging home dialysis when appropriate. A specific recommendation was to examine Medicare policies regarding monthly Medicare payments to physicians and revise them if necessary to encourage physicians to prescribe home dialysis for patients for whom it is appropriate.[145]

As discussed in the proposed rule, in the CY 2017 ESRD PPS final rule, CMS finalized an increase to the home and self-dialysis training add-on payment adjustment (81 FR 77856), to provide an increase in payment to ESRD facilities for training beneficiaries to dialyze at home.

[143] United States Government Accountability Office, 2015.

[144] United States Government Accountability Office, 2015.

[145] United States Government Accountability Office, 2015.

3. CMS Efforts To Support Modality Choice

While CMS has taken steps in the past to support modality choice, the deficits in care previously described—low rates of home dialysis and kidney transplantation—remain. We noted in the proposed rule our belief that the proposed ETC Model is consistent with several different recent actions to support modality choice for ESRD Beneficiaries, which are described in the proposed rule as well as this final rule.

a. Regulatory Efforts

As discussed in the proposed rule, on September 20, 2018, we published in the **Federal Register** a proposed rule entitled ''Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction'' (83 FR 47686). This rule was finalized without change on September 30, 2019 (84 FR 51732). This final rule, among other things, removed the requirements at 42 CFR 482.82 that required transplant centers to submit clinical experience, outcomes, and other data in order to obtain Medicare re-approval. CMS removed these requirements in order to address the unintended consequences that occurred as a result of the Medicare re-approval requirements, which have resulted in transplant programs potentially avoiding performing transplant procedures on certain patients and many organs with perceived risk factors going unused out of fear of being penalized for outcomes that are non-compliant with § 482.82. Although CMS removed certain requirements at § 482.82, CMS emphasized that transplant programs should focus on maintaining high standards that protect patient health and safety and produce positive outcomes for transplant recipients. As we noted in this final rule, CMS will also do complaint investigations based on public or confidential reports about outcomes or adverse events. These efforts, and the survey of the other Conditions of Participation, will provide sufficient oversight to ensure that transplant programs will continue to achieve and maintain high standards of care. (84 FR 51749).

In addition, as we discussed in the proposed rule, on November 14, 2018, CMS published in the **Federal Register** a final rule entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS'' (CY 2019 ESRD PPS final rule) (83 FR 56922). In that final rule, CMS adopted a new measure for the ESRD Quality Incentive Program (QIP) beginning with PY 2022, entitled the Percentage of Prevalent Patients Waitlisted (PPPW) measure, and placed that measure in the Care Coordination domain for purposes of performance scoring under the program. We stated that the adoption of this measure reflects CMS's belief that ESRD facilities should make better efforts to ensure that their patients are appropriately waitlisted for transplants (83 FR 57006). We also noted in the proposed rule that the proposed ETC Model would provide greater incentives for ESRD facilities and Managing Clinicians participating in the Model to assist ESRD Beneficiaries with navigating the transplant process, including coordinating care to address clinical and non-clinical factors that impact eligibility for wait-listing and transplantation.

b. Alternative Payment Models

Recognizing the importance of ensuring quality coordinated care to beneficiaries with ESRD, in 2015, CMS began testing the Comprehensive ESRD Care (CEC) Model. As we noted in the proposed rule, the CEC Model is an accountable care model in which dialysis facilities, nephrologists, and other health care providers join together to form ESRD Seamless Care Organizations (ESCOs) that are responsible for the cost and quality of care for aligned beneficiaries. Although there are no specific incentives under the CEC Model relating to home dialysis, CMS evaluated whether total cost of care incentives caused an increase in the rate of home dialysis, as would be predicted by some of the literature, during the first two years of the CEC Model. To date, the evaluation has not shown any statistically significant impact on the rates of home dialysis among CEC Model participants.[146] Although the evaluation results available for the CEC Model thus far are limited, as we noted in the proposed rule, based on these

[146] Marrufo G, et al. Comprehensive End-Stage Renal Disease Care (CEC) Model: Performance Year 2 Annual Evaluation Report. CMS Innovation Center. September 2019; *innovation.cms.gov/Files/reports/cec-annrpt-py2.pdf.*

preliminary findings CMS believes that more targeted, system-wide incentives may be necessary to encourage modality choices and that the agency must provide explicit incentives in order to affect behavior changes by providers and suppliers.

On July 10, 2019, CMS announced the Kidney Care Choices (KCC) Model (formerly the Comprehensive Kidney Care (CKC) Model). The KCC Model builds on the existing CEC Model, and includes incentives for coordinating care for aligned beneficiaries with CKD or ESRD and for reducing the total cost of care for these beneficiaries, as well as providing financial incentives for successful transplants. As we noted in the proposed rule, we view the KCC Model as complementary to the ETC Model, as both models incentivize a greater focus on kidney transplants. We proposed that ESRD facilities and Managing Clinicians may participate in both models, as discussed in the proposed rule and section IV.C.6 of this final rule.

C. Provisions of the Proposed Regulation

1. Proposal To Implement the ETC Model

In this section IV of the final rule, we discuss the policies that we proposed for the ETC Model, including model-specific definitions and the general framework for implementation of the ETC Model. The payment adjustments for the proposed ETC Model were designed to support increased utilization of home dialysis modalities and kidney and kidney-pancreas transplants that may, according to the literature described earlier in this section IV of the rule, be subject to barriers. Specifically, with regard to home dialysis, we acknowledged in the proposed rule the possible need for ESRD facilities to invest in new systems that ensure that appropriate equipment and supplies are available in an economical manner to support greater utilization by beneficiaries. We also recognized in the proposed rule that dialysis providers, nephrologists, and other clinicians would need to enhance education and training, both for patients and professionals, that there are barriers to patients choosing and accepting home dialysis modalities, and that the appropriateness of home dialysis as a treatment option varies among patients according to demographic and clinical characteristics, as well as personal choice.

We proposed that the duration of the payment adjustments under the ETC Model would be 6 years and 6 months, beginning on January 1, 2020, and ending on June 30, 2026. We also considered an alternate start date of April 1, 2020, to allow more time to prepare for Model implementation. We noted in the proposed rule that, if the ETC Model were to begin April 1, 2020, all intervals within the timelines outlined in the proposed rule, including the periods of time for which claims would be subject to adjustment by the HDPA and the Measurement Years and Performance Payment Adjustment Periods used for purposes of applying the PPA, would remain the same length, but start and end dates would be adjusted to occur three months later.

We also included in the proposed rule the following proposals for the Model: (a) The method for selecting ESRD facilities and Managing Clinicians for participation; (b) the schedule and methodologies for payment adjustments under the Model, and waivers of Medicare payment requirements necessary solely to test these methodologies under the Model; (c) the performance assessment methodology for ETC Participants, including the proposed methodologies for beneficiary attribution, benchmarking and scoring, and calculating the Modality Performance Score; (d) monitoring and evaluation, including quality measure reporting; and (e) overlap with other CMS models and programs.

We proposed to codify the definitions and policies of the ETC Model at subpart C of part 512 of 42 CFR (proposed §§ 512.300 through 512.397). We discuss the proposed definitions in section IV.C.2 of this final rule and each of the proposed regulatory provisions under the applicable subject area later. Section II of this final rule provides that the general provisions codified at §§ 512.100 through 512.180 apply to both the ETC Model and the RO Model described in section III of this rule.

The following is a summary of the comments received on the proposal to implement the Model, including the proposed start date and duration of the Model, and our responses.

Comment: Many commenters opposed starting the model on January 1, 2020. Commenters stated that January 1, 2020 was too soon, and would not provide ETC Participants sufficient advance notice to prepare for successful participation in the Model and begin working to address barriers to home dialysis and transplantation. In particular, commenters pointed to specific areas in which ETC Participants would need time to prepare, including: Design and implementation of new care processes; development of new relationships with other care providers, particularly transplant providers and vascular access providers; securing supplies necessary to operate and maintain a home dialysis program; training of clinical staff, particularly home dialysis nurses; development of new health information and data systems to track and manage patients; and making decisions about participating in other CMS models and programs. Commenters also recommended delaying the start date to allow CMS to resolve outstanding concerns from the stakeholder community, and to assess the efficacy of the model design. Several commenters suggested that CMS delay the start date to no sooner than April 1, 2020, the alternative start date included in the proposed rule. Several other commenters suggested a longer delay, including suggestions of July 1, 2020, October 1, 2020, and January 1, 2021. Several commenters suggested an indefinite delay, such that the Model would not begin until CMS further consulted with stakeholders to resolve their concerns, including through a second round of notice and comment rulemaking. A commenter suggested that the Model be delayed until potential changes to the organ allocation system are resolved.

Response: We appreciate the feedback from the commenters. After reviewing the concerns raised in the comments received, we agree that implementing the ETC Model on January 1, 2020 would not allow ETC Participants sufficient time to prepare for successful participation in the Model. We appreciate the feedback from the commenters about alternative start dates for the Model that would allow ETC Participants sufficient time to prepare for the Model. We had intended to delay the ETC Model implementation date until July 1, 2020, as had been recommended by some of the commenters, but as we were completing this final rule, the U.S. began responding to an outbreak of respiratory disease caused by a novel coronavirus, referred to as ''coronavirus disease 2019'' (COVID–19), which created a serious public health threat greatly impacting the U.S. health care system. The Secretary of the Department of Health and Human Services, Alex M. Azar II, declared a Public Health Emergency (PHE) on January 31, 2020, retroactively effective from January 27, 2020, to aid the nation's healthcare community in responding to the COVID–19 pandemic. On July 23, 2020, Secretary Azar renewed, effective July 25, 2020, the determination that a PHE exists.

In light of this unprecedented PHE, which continues to strain health care

resources, as well as our understanding that ETC Participants may have limited capacity to meet the ETC Model requirements in 2020, we are delaying implementation until January 1, 2021 to ensure that participation in the ETC Model does not further strain the ETC Participants' capacity, potentially hindering the delivery of safe and efficient dialysis care. We believe this delayed implementation will provide ETC Participants with sufficient time to prepare for participation in the Model and adhere to Model requirements.

Since the Model will begin on January 1, 2021, rather than January 1, 2020 (that is, 12 months later than proposed), all time intervals outlined in the proposed rule, including the periods of time for which claims are adjusted for the HDPA and Measurement Years and Performance Payment Adjustment Periods for the purposes of applying the PPA, will remain the same in length, but will begin and end 12 months later than proposed. For detailed descriptions of these time periods, see sections IV.C.5.d (HDPA) and IV.C.5.a (MYs and PPA Periods) of this final rule. Also, as this final rule was published to the **Federal Register** in September, 2020, ETC Participants have more than 90 days to prepare to participate in the Model, which we believe is sufficient.

In response to the commenters' recommendations that we delay implementation of the ETC Model until we have gone through another round of rulemaking, we have made certain changes to the policies we proposed for the Model in response to the comments we received, as discussed in subsequent sections of this final rule, and we do not believe that it is necessary to conduct an additional round of notice and comment rulemaking before finalizing the rule and implementing the ETC Model. With respect to comments recommending that CMS delay implementation of the Model until changes to the transplant system have had time to take effect, as discussed in section IV.C.5.c.(2) of this final rule, we are altering the MPS calculation such that ETC Participant performance will be assessed based on a transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rather than a transplant rate focused on all kidney transplants including deceased donor transplants. We made this alteration to recognize the role that ETC Participants can currently play in getting patients on the transplant waitlist rate and in increasing the rate of donor transplants while allowing the effects from the ETC Learning Collaborative time to take effect, together with the other proposed rules addressing the transplant system (if finalized), and we do not believe that any further delays are necessary. As discussed in section IV.C.5.c.(2) of this final rule, it is our intent to observe the supply of deceased donor organs available for transplantation.

Comment: Several commenters suggested that the Model have a staggered implementation, with some components of the Model beginning right away and other components phasing in over the duration of the Model. Several commenters suggested using a ''Year 0'' approach, in which ETC Participants would be in the Model for one year before payment adjustments begin. Similarly, several commenters suggested that the downward payment adjustments in the PPA be delayed for some amount of time, either until Measurement Year (MY) 3 or MY4, to give ETC Participants more time to implement changes before they would be subject to downside financial risk, and to allow other changes to the transplant system time to take effect. A commenter suggested that downward payment adjustments should begin in 2021 for large dialysis organizations (LDOs) and in 2022 for all other dialysis organizations.

Response: We do not believe it is necessary to phase-in our implementation of the Model, including the onset of downward payment adjustments. The payment adjustments under the Model already begin with the HDPA, which is an upward payment adjustment only. The Model will be ongoing for 1 year and 6 months before the PPA begins, functionally phasing-in the Model's downward payment adjustment. As discussed in section IV.C.3.a of this final rule, the size of the Model is determined based on the necessary participation and duration to detect a statistically meaningful effect. If we were to further phase-in the implementation of the downward payment adjustments, we would not have sufficient duration to evaluate the effectiveness of the payment adjustments at achieving the Model's goals. While we appreciate the commenters' recommendation that CMS adopt a ''Year 0'' approach, and note that CMS has taken this approach in other models, in the case of the ETC Model a ''Year 0'' would amount to nothing more than a delayed implementation. As discussed earlier in this section IV.C.1 of this final rule, we believe that delaying the implementation of this Model to January 1, 2021, is sufficient to address the commenters' concerns about the lead time needed prior to participation in the Model. We do not believe it is appropriate to stagger the implementation of the payment adjustments to ESRD facilities based on dialysis organization type, as a commenter suggested, as this approach could unfairly advantage ESRD facilities owned by certain types of dialysis organizations over others.

Comment: A few commenters recommended that CMS shorten the duration of the Model test to 3 years, with two optional extension years. Commenters stated that this approach would allow for a more limited test of the Model, and would facilitate extension of the Model if the Model appears to be achieving the intended goals during the initial 3 years. Additionally, commenters suggested that the initial years of the Model be limited to a smaller portion of the country, such as 10 percent, and that CMS increase the size of the Model in future years.

Response: As discussed in the proposed rule and in section IV.C.3.a of this final rule, the geographic scope of the Model is determined based on the scope of participation necessary to detect a statistically meaningful effect. We do not anticipate that we would be able to determine whether the Model is achieving its goals after three years, particularly as we are limiting the Model to a smaller portion of the country than originally proposed, such that we could decide to extend the Model at that time.

Comment: Several commenters stated that CMS should conduct subsequent rulemaking through the duration of the Model to adapt the Model based on observations made during the operation of the Model.

Response: We agree that if it becomes apparent that changes to the Model are needed during the Model's implementation, any potential changes to the ETC Model provisions would be made through subsequent notice and comment rulemaking. As discussed in section II.J of this final rule, we note that section 1115A(b)(3)(B) of the Act requires CMS to modify or terminate the design or implementation of a model test under certain circumstances.

Comment: Several commenters recommended that CMS separate the ETC Model into two separate payment models, one focused on home dialysis and one focused on kidney transplantation. Commenters stated that this approach would account for differences in the barriers to home dialysis and transplantation and the different incentives needed to overcome those barriers. Commenters also stated that this approach would allow CMS to operate smaller model tests that would produce more actionable results.

Response: The ETC Model is designed to test whether the mechanisms included in the Model will achieve the Model's goals, through incentivizing Managing Clinicians and ESRD facilities to support modality choice. We view home dialysis and transplantation as complementary alternative renal replacement modalities, not as separate aims. Therefore, we do not see them as separable into two separate model tests. We disagree that testing two separate models would be needed to produce more actionable results, as the evaluation of the ETC Model is designed to detect an increase in either home dialysis rates, transplant rates, or both.

After considering public comments, we are finalizing our proposed provisions regarding implementation of the ETC Model, with modification to our regulation at § 512.320 to adjust the dates for application of the payment adjustments under the ETC Model. The start date for application of the ETC Model's payment adjustments has changed from applying to claims with a claim through date beginning January 1, 2020, to claims with a claim service date beginning on or after January 1, 2021. The end date for application of such payment adjustments has changed from applying to claims with a claim through date ending June 30, 2026, to claims with a claim service date ending on or before June 30, 2027. We also are modifying which date associated with the claim we are using to determine if the claim is subject to the payment adjustments under the Model. Whereas we proposed using the claim through date, which is the last day on the billing statement for services furnished to the beneficiary, we are finalizing using the date of service on the claim, which is the date on which the service was furnished. We are making this change from using claim through date to using date of service to align with Medicare claims processing standards. While Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service. Therefore, in order to process payment adjustments, we will use the date of service to determine the claims subject to adjustment under the Model.

2. Definitions

We proposed at § 512.310 to define certain terms for the ETC Model. We describe these proposed definitions in context throughout the proposed rule and section IV of this final rule. In addition, we proposed that the definitions proposed in section II of the proposed rule also would apply to the ETC Model. We received comments on our proposed definitions.

After considering public comments, we are finalizing our proposed provisions on the definitions with modification, as described elsewhere in this section IV of this final rule. Specifically, we are codifying in our regulations at § 512.310 to define certain terms for the ETC Model. We have summarized the comments received and responded to them through this section IV of the final rule, where relevant.

3. ETC Participants

a. Mandatory Participation

We proposed to require all Managing Clinicians and all ESRD facilities located in Selected Geographic Areas to participate in the ETC Model. We proposed to define ''selected geographic area(s)'' as those Hospital Referral Regions (HRRs) selected by CMS, as described in the proposed rule and in section IV.C.3.b of this final rule, for purposes of selecting ESRD facilities and Managing Clinicians required to participate in the ETC Model as ETC Participants. Our proposed definition of ''Hospital Referral Regions (HRRs)'' is described in the proposed rule and in section IV.C.3.b of this final rule.

For purposes of the ETC Model, we proposed to define ''ESRD facility'' as defined in 42 CFR 413.171. As we described in the proposed rule, under § 413.171, an ESRD facility is an independent facility or a hospital-based provider of services (as described in 42 CFR 413.174(b) and (c)), including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in § 494.10 and meets the supervision requirements described in 42 CFR part 494, and that furnishes institutional dialysis services and supplies under 42 CFR 410.50 and 410.52. We proposed this definition because this is the definition used by Medicare for the ESRD PPS. We considered creating a definition specific to the ETC Model; however, as noted in the proposed rule, we believe that the ESRD PPS definition of ESRD facility captures all facilities that furnish renal dialysis services that we are seeking to include as participants in the ETC Model.

For purposes of the ETC Model, we proposed to define ''Managing Clinician'' as a Medicare-enrolled physician or non-physician practitioner who furnishes and bills the MCP for managing one or more adult ESRD Beneficiaries. In the proposed rule, we considered limiting the definition to nephrologists, or other specialists who furnish dialysis care to beneficiaries with ESRD, for purposes of the ETC Model. However, as we noted in the proposed rule, analyses of claims data revealed that a variety of clinician specialty types manage ESRD Beneficiaries and bill the MCP, including non-physician practitioners. We continue to believe that the proposed approach to defining Managing Clinicians more accurately captures the set of practitioners we are seeking to include as participants in the ETC Model, rather than limiting the scope to self-identified nephrologists.

As proposed, the ETC Model would require the participation of ESRD facilities and Managing Clinicians in Selected Geographic Areas that might not otherwise participate in a payment model involving payment adjustments based on participants' rates of home dialysis and kidney transplants. Participation in other CMS models focused on ESRD, such as the CEC Model and the KCC Model, is optional. Interested individuals and entities must apply to such models during the applicable application period(s) to participate. To date, we have not tested an ESRD-focused payment model in which ESRD facilities and Managing Clinicians have been required to participate. We considered using a voluntary design for the ETC Model as well; however, as noted in the proposed rule, we believe that a mandatory design has advantages over a voluntary design that are necessary to test this Model, in particular. First, we believe that testing a new payment model specific to encouraging home dialysis and kidney transplants may require the engagement of an even broader set of ESRD care providers than have participated in CMS models to date, including providers and suppliers who would participate only in a mandatory ESRD payment model. As we discussed in the proposed rule, we are concerned that only a non-representative and relatively small sample of providers and suppliers, namely those that already have higher rates of home dialysis or kidney transplants relative to the national benchmarks, would participate in a voluntary model, which would not provide a robust test of the proposed payment incentives. In addition, because kidney and kidney-pancreas transplants are rare events—fewer than 4 percent of ESRD Beneficiaries received such a transplant in 2016—we noted in the proposed rule that we would need a large number of beneficiaries to be included in the model test and comparison groups in order to detect a change in the rate of transplantation under the ETC Model.

Second, as noted in the proposed rule, we believe that a mandatory design combined with randomized selection of a subset of geographic areas would enable CMS to better assess the effect of the Model's interventions on ETC Participants against a contemporaneous comparison group. As described in the proposed rule and elsewhere in this section IV of the final rule, we proposed to require participation by a subset of all ESRD facilities and Managing Clinicians in the U.S., selected based on whether they are located in a Selected Geographic Area. Also, we proposed to evaluate the impact of adjusting payments to Managing Clinicians and ESRD facilities by comparing the clinical and financial outcomes of ESRD facilities and Managing Clinicians located in these Selected Geographic Areas against that of ESRD facilities and Managing Clinicians located in Comparison Geographic Area(s), which we proposed to define as those HRRs that are not Selected Geographic Areas. Because both ETC Participants and those ESRD facilities and Managing Clinicians not selected for participation in the Model would be representative of the larger dialysis market, many of the stakeholders in which operate on a nationwide basis, CMS would be able to generate more generalizable results, assuming randomization creates two groups that are similar to each other. As we noted in the proposed rule, this proposed model design would therefore make it easier for CMS to evaluate the impact of the Model, as required under section 1115A(b)(4) of the Act, and to predict the impact of expanding the Model under section 1115A(c) of the Act, if authorized, while also limiting the scope of the model test to Selected Geographic Areas.

The following is a summary of the comments received on our proposed definitions for Managing Clinician and ESRD facility and our proposal to require participation in the Model by Managing Clinicians and ESRD facilities located in Selected Geographic Areas, and our responses.

Comment: A commenter stated that, for the purposes of the ETC Model, CMS should modify the proposed definition of ESRD facility to require that a facility must either have or be in a network under common ownership with ESRD facilities that have the capacity to furnish in-center dialysis.

Response: We believe that adopting this commenter's recommendation would be equivalent to excluding ESRD facilities owned by dialysis organizations that provide home dialysis only. We do not believe that it is necessary to exclude ESRD facilities owned by dialysis organizations that provide only home dialysis services from participation in the Model. The ETC Model is designed to test the effectiveness of the Model's payment adjustments at improving or maintaining quality and reducing costs through increased provision of home dialysis and transplants throughout the dialysis market as a whole, including among ESRD facilities and dialysis organizations that currently provide only home dialysis. Excluding ESRD facilities and dialysis organizations that do not offer in-center dialysis could discourage new entrants to the dialysis market who use innovative care models that do not include in-center dialysis. Discouraging this type of innovation could limit the availability of home dialysis overall.

Comment: A commenter supported the proposal to include non-physician practitioners in the definition of Managing Clinician for the purposes of the Model, as this recognizes the care provided by other clinicians, including nurse practitioners, who manage dialysis patients.

Response: We appreciate the commenters' feedback and support.

Comment: Several commenters stated that they support CMS's proposal to require participation in the ETC Model by ESRD facilities and Managing Clinicians located in Selected Geographic Areas.

Response: We appreciate the commenters' feedback and support.

Comment: Many commenters opposed requiring ESRD facilities and Managing Clinicians to participate in the ETC Model. Several commenters asserted that requiring participation by approximately half of the country does not constitute a model test, but rather a substantive change to Medicare payment policy. Some commenters stated that this exceeds the scope of the Innovation Center's authority. Some commenters stated that, the scope and mandatory nature of the Model, coupled with the downward payment adjustments, constitute an overall payment reduction for ESRD facilities and Managing Clinicians, which will cause unintended consequences, including market consolidation, decrease in availability of services, and disruption of patient care.

Response: We do not believe that the size, scope, and duration of the Model constitute a substantive change to Medicare payment policy, as the model test is limited in duration and is not a permanent change to the Medicare program. We also believe that both section 1115A of the Act and the Secretary's existing authority to operate the Medicare program authorize the ETC Model as we have proposed and are finalizing it.

Section 1115A of the Act authorizes the Secretary to test payment and service delivery models expected to reduce Medicare costs while preserving or enhancing care quality. The statute does not require that models be voluntary, but rather gives the Secretary broad discretion to design and test models that meet certain requirements as to spending and quality. Although section 1115A(b) of the Act describes a number of payment and service delivery models that the Secretary may choose to test, the Secretary is not limited to those models. Rather, models to be tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. Here, the ETC Model addresses a defined population (FFS Medicare beneficiaries with ESRD) for which there are potentially avoidable expenditures (arising from less than optimal modality selection). For the reasons described elsewhere in this final rule, we have determined that it is necessary to test this Model among varying types of ESRD facilities and Managing Clinicians that may not have chosen to voluntarily participate in another kidney care model, such as the CEC Model or KCC Model.

As noted elsewhere in this final rule, we are currently testing a number of voluntary kidney models. We have designed the ETC Model to require participation by ESRD facilities and Managing Clinicians in order to avoid the selection bias inherent to any model in which providers and suppliers may choose whether to participate. As discussed in the proposed rule and previously in this final rule, such a design will enable us to obtain a representative sample, to detect a change in the rate of transplantation under the ETC Model, and to better assess the effect of the Model's interventions on ETC Participants against a contemporaneous comparison group. Under the ETC Model, we will have tested and evaluated such a model across a wide range of ESRD facilities and Managing Clinicians. We believe it is important to gain knowledge from a variety of perspectives in considering whether and which models merit expansion (including on a nationwide basis). Thus, the ETC Model meets the criteria required for an initial model test.

Moreover, the Secretary has the authority to establish regulations to carry out the administration of Medicare. Specifically, the Secretary has

authority under both sections 1102 and 1871 of the Act to implement regulations as necessary to administer Medicare, including testing this payment and service delivery model. We note that, while the ETC Model will be a model, and not a permanent feature of the Medicare program, the Model will test different methods for delivering and paying for services under the Medicare program, which the Secretary has the clear authority to regulate. The proposed rule went into great detail about the proposed provisions of the proposed ETC Model, enabling the public to fully understand how the proposed model was designed and could apply to affected providers and suppliers.

We also note that this is a new model, not an expansion of an existing model. As permitted by section 1115A of the Act, we are testing the ETC Model within Selected Geographic Areas. The fact that the Model will require the participation of certain ESRD facilities and Managing Clinicians does not mean it is not an initial model test. If the ETC Model is successful such that it meets the statutory requirements for expansion, and the Secretary determines that expansion is warranted, we would undertake further rulemaking to expand the duration and the scope of the Model, as required by section 1115A(c) of the Act.

We appreciate the concerns from commenters about the potential impact of the Model on patient care, the structure of the dialysis market, and the availability of dialysis services. We do not expect the Model will result in adverse results such as market consolidation, decrease in availability of services, or disruption of patient care. In contrast, CMS believes that the Model will have the opposite effects. The payment adjustments in the Model are designed to incentivize innovative care delivery methods that focus on expanding access to renal replacement therapies other than in center hemodialysis, that are associated with better clinical outcomes for patients. However, we intend to monitor the impact of the Model closely, as described in section IV.C.10.a of this final rule. In the event that adverse outcomes such as these arise, CMS would modify or terminate the Model accordingly.

Comment: Several commenters stated that previous mandatory models have been of smaller size, and a commenter stated that CMS has cancelled proposed mandatory models in the past, due to further analysis, feedback that mandatory participation would have negative impact on CMS's flexibility to design and test other models, and the possibility of reduction of participation in other voluntary models. Several commenters asserted that the use of mandatory models undermines the creation of and participation in voluntary models.

Response: CMS believes that it is important to test both the mandatory ETC Model and the voluntary KCC Model at the same time, as both of these models test different frameworks. The solicitation for applicants for the KCC Model for PY 1 was completed on January 22, 2020. CMS is satisfied with the number of applications that were submitted. We believe that we will have sufficient participation to be able to test the different options in the KCC Model. Though previous mandatory models tested by the Innovation Center may have been smaller or cancelled in the past, we believe that requiring participation by ESRD facilities and Managing Clinicians in the ETC Model is necessary to achieve the level of model participation needed to detect changes in the rates of dialysis modality choice and for the power calculations discussed in this section of this final rule. As discussed in section IV.C.3.b of this final rule, we are decreasing the size of the Model. This decrease from 50% of HRRs in the country to 30% of HRRs in the country brings the size of the Model more in line with other mandatory models.

Comment: A commenter stated that they agree that the Innovation Center has the authority to proceed with mandatory initiatives, and they support the testing of mandatory models established through the rulemaking process.

Response: We appreciate this feedback and support from the commenter.

Comment: Several commenters stated that CMS should test this model on a voluntary basis. A commenter stated that ESRD facilities and Managing Clinicians located in Comparison Geographic Areas should be allowed to opt in to the ETC Model.

Response: We appreciate this feedback. However, as stated previously in this final rule, we considered using a voluntary design for the Model, but we concluded that we do not believe we can adequately test this Model on a voluntary or opt in basis. Specifically, we do not believe that if the Model were voluntary we would have a sufficient number and diversity of ESRD facilities and Managing Clinicians to conduct a robust test. Additionally, allowing ESRD facilities and Managing Clinicians located in Comparison Geographic Areas to opt-in to the ETC Model could skew the model test through selection effects. We assume that only ESRD facilities and Managing Clinicians who already have high rates of home dialysis and transplantation would opt in to participation. This behavior would produce the appearance of artificially high performance among ETC Participants, because any observed increase in performance could be due to selection effects rather than change in performance related to the Model's payment adjustments. This behavior would also remove high performers from the benchmarking group, which would lower benchmarks for ETC Participants, and therefore not provide as great an incentive for ETC Participants to improve their performance under the Model.

After considering public comments, we are finalizing the provisions regarding mandatory participation in the Model in our regulations at § 512.325(a) as proposed. We are also finalizing the definition of Selected Geographic Area(s) in our regulations at § 512.310, as proposed, with a technical change to capitalize ''Selected Geographic Area(s)'' in the final rule, rather than use ''selected geographic area(s)'' as we did in the proposed rule. In addition, we are finalizing the definitions of ESRD facility in our regulations at § 512.310, as proposed. We are finalizing the definition of Managing Clinician in our regulation at § 512.310 with modification. Specifically, we made a technical change to capitalize ''Managing Clinician'' in the final rule. Additionally, we have added new language to our regulation to clarify that Managing Clinicians will be identified by an National Provider Identifier (NPI), because an NPI uniquely identifies individual clinicians regardless of the location the Managing Clinician furnishes a particular service, which is necessary for purposes of attributing services to each individual Managing Clinician, as described further in section IV.C.5.b.(2).(b) of this final rule.

b. Selected Geographic Areas

We proposed to use an ESRD facility's or Managing Clinician's location in Selected Geographic Areas, randomly selected by CMS, as the mechanism for selecting ETC Participants. We stated in the proposed rule that we believe that geographic areas provide the best means to establish the group of providers and suppliers selected for participation in the Model and the group of providers and suppliers not selected for participation in the Model to answer the primary evaluation questions described in the proposed rule and section IV.C.11

of this final rule. Specifically, by using geographic areas as the unit for randomized selection, we will be able to study the impact of the Model on program costs and quality of care, both overall and between ESRD facilities and Managing Clinicians selected for participation in the Model and those ESRD facilities and Managing Clinicians not selected for participation in the Model.

To improve the statistical power of the Model's evaluation, we noted in the proposed rule our aim of including in the Model approximately 50 percent of adult ESRD Beneficiaries. To achieve this goal, we proposed to assign all geographic areas, specifically HRRs, into one of two categories: Selected Geographic Areas (those geographic areas for which ESRD facilities and Managing Clinicians located in the area would be selected for participation in the ETC Model and would be subject to the Model's Medicare payment adjustments for ESRD care); and Comparison Geographic Areas (those geographic areas for which ESRD facilities and Managing Clinicians located in the area would not be selected for participation in the ETC Model and thus would be subject to customary Medicare payment for ESRD care). Given the national scope of the major stakeholders in the dialysis market and the magnitude of the payment adjustments proposed for this Model, as stated in the proposed rule, we believe a broad geographic distribution of participants would be necessary to effectively test the impact of the proposed payment adjustments.

We proposed to use HRRs as the geographic unit of selection for selecting ETC Participants. An HRR is a unit of analysis created by the Dartmouth Atlas Project to distinguish the referral patterns to tertiary care for Medicare beneficiaries, and is composed of groups of zip codes. The Dartmouth Atlas Project data source is publicly available at *https://www.dartmouthatlas.org/.* Therefore, we proposed to define the term ''HRRs'' to mean the regional markets for tertiary medical care derived from Medicare claims data as defined by the Dartmouth Atlas Project at *https://www.dartmouthatlas.org.*

With 306 HRRs in the U.S., we noted in the proposed rule that we believe there will be a sufficient number of HRRs to support random selection and improve statistical power of the proposed Model's evaluation. As noted in the proposed rule, we conducted power calculations for the outcomes of home dialysis and kidney and kidney-pancreas transplant utilization. For home dialysis, the CMS Office of the Actuary (OACT) forecasted an average increase of 1.5 percentage points per year. With a current home dialysis rate of 8.6 percent,[147] this represents an increase of 18 percent. To detect an effect size of this magnitude with 80 percent power and an alpha of 0.05, we would need few HRRs included in the intervention group. However, for transplants, which are rare events, a substantial number of HRRs would be needed to detect changes. OACT did not assume any change in its main projections but estimated that an additional 2,360 transplants would occur over the course of the proposed Model due to a lower discard rate for deceased donor organs. With 20,161 transplants currently conducted on an annual basis,[148] this represents an 11.7 percent increase over 5 years. To detect an effect size of this magnitude with 80 percent power and an alpha of 0.05, we would need approximately 153 HRRs in the intervention group, which represents 50 percent of the 306 HRRs in the US. As noted in the proposed rule, we believe random selection with a large sample of units, such as the 306 HRRs, would safeguard against uneven distributions of factors among Selected Geographic Areas and Comparison Geographic Areas, such as urban or rural markets, dominance of for-profit dialysis organizations, and dense population areas with greater access to transplant centers.

In the proposed rule, we considered using Core Based Statistical Areas (CBSAs) or Metropolitan Statistical Areas (MSAs) as the geographic unit of selection. However, as we noted in the proposed rule, neither CBSAs nor MSAs include rural areas and, due to the nature of dialysis treatment, we believe inclusion of rural providers and suppliers is vital to testing the Model. Specifically, as a significant proportion of beneficiaries receiving dialysis live in rural areas and receive dialysis treatment from providers and suppliers located in rural areas, we believe using a geographic unit of selection that does not include rural areas would limit the generalizability of the model findings to this population.

In the proposed rule, we also considered using counties or states as the geographic unit of selection. However, as noted in the proposed rule, we determined that counties would be too small and therefore too operationally challenging to use for this purpose, both due to the high number of counties and the relatively small size of counties such that a substantial number of Managing Clinicians practice in multiple counties. We also determined that states would be too heterogeneous in population size, and that using states could confound the evaluation of the Model due to potential variation in state-level regulations relating to ESRD care. Additionally, the use of counties or states could introduce confounding spillover effects, such as where ESRD Beneficiaries receive care from a Managing Clinician in a county or state selected for the Model and dialyze in a county or state not selected for the Model, thus mitigating the effect of the Model's incentives on the beneficiary's overall care. As we noted in the proposed rule, HRRs are derived from Medicare data based on hospital referral patterns, which are correlated with dialysis and transplant referral patterns and which would therefore mitigate potential spillover effects of this nature.

We proposed to establish the Selected Geographic Areas by selecting a random sample of 50 percent of HRRs in all 50 states and the District of Columbia, stratified by region. Regional stratification would use the four Census-defined geographic regions: Northeast, South, Midwest, and West. Information about Census-defined geographic regions is available at *https://www2.census.gov/geo/pdfs/maps-data/maps/reference/usus_regdiv.pdf.*[149] As proposed, the stratification would control for regional patterns in practice variation. If an HRR spans two or more Census-defined geographic regions, the HRR would be assigned to the region in which the HRR's associated state is located. For example, the Rapid City HRR centered in Rapid City, South Dakota, contains zip codes located in South Dakota and Nebraska, which are in the Midwest Census Region, and zip codes located in Montana and Wyoming, which are in the West Census Region. For the purposes of the regional stratification, we would consider the Rapid City HRR and all zip codes therein to be in the Midwest region, as its affiliated state, South Dakota, is in the Midwest region.

We proposed that the U.S. Territories, as that term is defined in section II of the proposed rule and of this final rule, would be excluded from selection, as HRRs are not constructed to include these areas.

[147] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

[148] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 6: Transplantation. *https://www.usrds.org/2018/view/v2_06.aspx.*

[149] This URL has been updated relative to the URL included in the proposed rule.

In addition, outside of the randomization, we proposed that all HRRs for which at least 20 percent of the component zip codes are located in Maryland would be selected for participation in the ETC Model, in conjunction with the Maryland Total Cost of Care (TCOC) Model currently being tested in Maryland. These HRRs would not be included in the randomization process previously described. We stated in the proposed rule that CMS believes that the automatic inclusion of ESRD facilities and Managing Clinicians in these HRRs as participants in the ETC Model would be necessary because, while the Maryland TCOC Model includes incentives to lower the Medicare TCOC in the state, including state accountability for meeting certain Medicare TCOC targets, as well as global budget payments that hold Maryland hospitals accountable for the Medicare TCOC, there currently is no direct mechanism to lower the cost of care for ESRD Beneficiaries specifically under the Maryland TCOC Model. As noted in the proposed rule, we believe that adding Maryland-based ESRD facilities and Managing Clinicians as participants in the ETC Model will assist the state of Maryland and hospitals located in that state to meet the Medicare TCOC targets established under the Maryland TCOC Model.

We proposed that all HRRs that are not Selected Geographic Areas would be referred to as ''Comparison Geographic Area(s).'' We proposed that Comparison Geographic Areas would be used for the purposes of constructing performance benchmarks (as discussed in the proposed rule and in section IV.C.5.d of this final rule), and for the Model evaluation (as discussed in the proposed rule and in section IV.C.11 of this final rule).

The following is a summary of the comments received on Selected Geographic Areas, including the size and scope of the Model, geographic units used for Selected Geographic Areas, and the inclusion or exclusion of certain geographic areas in the Model, and our responses.

Comment: Multiple commenters opposed our proposal to require participation in the ETC Model by ESRD facilities and Managing Clinicians located in 50 percent of the 306 HRRs in the country because doing so would require significant change to the infrastructure of ETC Participants and to the care delivery system nationally. Commenters stated that the change in payments under the Model implemented over the proposed geographic area within the timeframe proposed for the Model could lead to unintended consequences and disruption in care, and several commenters stated that this would harm smaller health care providers, in particular. A commenter stated that this national impact would undermine the integrity of the model test.

Response: We appreciate the feedback from commenters raising concerns around the impact of the proposed scope of the model test on health care providers and beneficiaries. We acknowledge that the scope and timeframe for implementing the Model will require changes on the part of ETC Participants, which may take time to implement. As discussed previously in this final rule, we believe we have addressed commenters' concerns regarding the time needed to make these changes by delaying the Model start date to January 1, 2021. We further believe we have addressed the commenters' concerns regarding the potential for unintended consequences through the benchmarking and scoring methodology (described in section IV.C.5.d of this final rule) and have addressed the commenters' concerns regarding smaller health care providers through the low volume exclusions from the PPA (described in section IV.C.5.f of this final rule). We do not believe that the scope of the ETC Model harms the integrity of the model test. Rather, as discussed in the proposed rule and previously in this final rule, we designed the Model based on power calculations about the scope of participation necessary for CMS to be able to evaluate whether the Model increased the rate of transplants. However, as described in section IV.C.5 of this final rule, we have modified the Model to assess ETC Participant performance on the transplant rate, which includes both the transplant waitlist rate and living donor transplant rate. As such, we have revised the scope of the Model based on power calculations about the level of participation necessary for CMS to be able to evaluate whether the Model increased the rate of transplant waitlisting, living donor transplants, and the rate of home dialysis, as described in section IV.C.5 of this final rule. We discuss our plan for conducting the Model's evaluation in section IV.C.11 of this final rule.

Comment: Several commenters stated that implementing the Model with this proposed geographic scope would constitute a permanent change in Medicare policy, rather than a model test.

Response: We disagree that this Model would constitute a permanent change in Medicare policy. Section 1115A of the Act authorizes the Secretary to test payment and service delivery models intended to reduce Medicare costs while preserving or improving care quality. The ETC Model would be a model tested under this authority, and not a permanent feature of the Medicare program.

Comment: Several commenters expressed concern that requiring participation by ESRD facilities and Managing Clinicians located in 50 percent of the 306 HRRs in the U.S. is beyond the level of participation necessary to evaluate the Model. Several commenters suggested reducing the geographic scope of the Model to 20 percent, 25 percent, or no larger than 25 percent of HRRs in the country. Several commenters suggested starting the Model with a smaller geographic scope, and increasing the scope in subsequent years if the Model is successful.

Response: We appreciate the commenters' feedback. In response to comments, and because we will now evaluate changes to transplant waitlisting, including beneficiaries who receive living donor transplantation we conducted a revised power calculation. We performed the revised power calculation to determine the minimum sample size of ETC Participants and Managing Clinicians and ESRD facilities located in Comparison Geographic Areas necessary to produce robust and reliable results. Our assumptions included a two percentage point increase to the transplant waitlist rate, which is currently 16%. To detect an effect size of this magnitude with 80 percent power and an alpha of 0.05, we would need approximately 30 percent of the 306 HRRs in the US to minimize the risk of false positive and false negative results. This number of HRRs will also be sufficient to detect a one and one-half percent change in home dialysis. As a result, we are finalizing our proposal to require participation in the Model by ESRD facilities and Managing Clinicians located in 30 percent of the HRRs in the country.

Comment: A few commenters noted that the proposed geographic scope of the Model may lead to a spillover effect for ESRD facilities located in the Comparison Geographic Areas given that ownership of ESRD facilities can span across HRRs in Selected Geographic Areas and Comparison Geographic Areas.

Response: We share the commenters' concern that the impact of the model test may extend to the Model's Comparison Geographic Areas through common facility ownership and this may influence our evaluation of the

Model. We plan to examine the variation in the outcome measures prior to and during the model intervention for facilities with common ownership, and if necessary, consider modifications to the Model in future notice-and-comment rulemaking.

Comment: A commenter supported randomizing geographic areas to select ETC Participants. Several commenters opposed randomization of geographic areas as the mechanism for selecting ETC Participants. Several commenters noted that the method proposed for randomization would not sufficiently account for non-random differences between HRRs or ESRD facilities. A few commenters suggested that CMS use covariate-based constrained randomization for purposes of selecting model participants because the commenters claimed that this approach would ensure comparability across treatment and control groups and allow for a smaller model.

Response: We appreciate the comments on the proposed randomization method. As we noted in the proposed rule and previously in this final rule, our proposal to stratify by region would help control for regional patterns in practice variation. We also believe that stratification will help ensure that ETC Participants are geographically dispersed across the country and do not find it necessary to use covariate-based constrained randomization for purposes of selecting model participants, as suggested by some of the commenters. In addition, with the evaluation approach that will be used, we can account for known, measurable differences between ETC Participants in Selected Geographic Areas and those ESRD facilities and Managing Clinicians located in the Comparison Geographic Areas through rigorous statistical methods. Specifically, as we outlined in the proposed rule, the evaluator would match Managing Clinicians and ESRD facilities located in Comparison Geographic Areas with Managing Clinicians and ESRD facilities that are located in Selected Geographic Areas (that is, ETC Participants) using propensity scores or other accepted statistical techniques.

Comment: Several commenters stated that randomization cannot ensure that 50 percent of ESRD Beneficiaries are included in the Model.

Response: While the aim stated in the proposed rule was to include approximately 50 percent of adult beneficiaries with ESRD in the Model, as described in the proposed rule, our determination regarding the size of the geographic area necessary to test the Model is based around the number of HRRs in which ESRD facilities and Managing Clinicians would be required to participate in the Model, not the proportion of individual beneficiaries included in the model test. The same holds true for this final rule; our determination regarding the size of the geographic area necessary to test the Model is based around the number of HRRs in which ESRD facilities and Managing Clinicians are required to participate in the Model, rather than the proportion of individual beneficiaries included in the model test. We are therefore finalizing the randomization method, as proposed.

Comment: A commenter stated that CMS should select regions where home dialysis and transplant rates are particularly low to focus resources on areas with the most need.

Response: As stated in the proposed rule and previously in this final rule, the intent of the model test is to determine whether adjusting the current Medicare FFS payments for dialysis and dialysis-related services would incentivize ESRD facilities and Managing Clinicians to work with their patients to achieve increased rates of home dialysis utilization and kidney transplantation and, as a result, reduce Medicare expenditures while improving or maintaining quality of care. If we were to select ETC Participants from only those geographic areas that had particularly high or particularly low rates of home dialysis or transplants, as the commenter suggested, we would not be able to determine if the Model's payment adjustments would have the same effect nationally.

Comment: Several commenters opposed the use of geographic areas to select model participants. These commenters stated that, due to the national nature of the dialysis market, selecting ESRD facilities for participation based on their location could change the nature of the dialysis market for the entire country or create unintended consequences for the dialysis market nationally. In particular, commenters stated that the Model could make national dialysis companies provide different levels of care to patients in Selected Geographic Areas than in Comparison Geographic Areas and delay the implementation of best practices nationally, or divert resources from Comparison Geographic Areas to Selected Geographic Areas.

Response: We appreciate the feedback from commenters about the national nature of segments of the dialysis market and how this may interact with our proposal to select ETC Participants based on geographic areas. We acknowledge the possibility that national dialysis providers will behave differently, in terms of resource allocation or adoption of best practices in Selected Geographic Areas versus Comparison Geographic Areas, or that they will adopt best practices nationally resulting in broader changes to dialysis provision. However, we believe that, for dialysis providers that operate nationally, either outcome would be true regardless of what mechanism we use to select ESRD facilities for model participation. As described in section IV.C.10.a of this final rule, we will monitor for unintended consequences that arise as a result of the Model.

Comment: Several commenters recommended that CMS should select individual participants, rather than selecting participants based on geographic location.

Response: We did not propose selecting individual participants because we believe that this approach would not work for this Model. A design feature of the Model is aligning the incentives for key dialysis providers, namely Managing Clinicians and ESRD facilities, to support beneficiaries in choosing alternative renal replacement modalities. Managing Clinicians refer ESRD Beneficiaries to multiple ESRD facilities, and ESRD facilities furnish dialysis to beneficiaries under the care of multiple Managing Clinicians. By selecting ETC Participants based on location, we are increasing the likelihood that, for any given ESRD Beneficiary, both the beneficiary's Managing Clinician and ESRD facility are participants in the Model.

Comment: Several commenters recommended that CMS release the Selected Geographic Areas with the proposed rule to allow for public comment or for potential model participants to have sufficient time to prepare for participation. A commenter stated that while they understand that CMS has withheld information about Selected Geographic Areas to assure that CMS receives stakeholder feedback from the entire nation, ETC Participants should have no fewer than 90 days' notice prior to implementation to prepare for participation in the Model.

Response: We appreciate the commenters' suggestions about releasing information about Selected Geographic Areas in advance of the start of the Model, and the need for ETC Participants to have sufficient time to prepare for participation in the Model. We did not provide information about the specific Selected Geographic Areas in the proposed rule because, as the commenters noted, we wanted to ensure that we received feedback from the

public generally, not just those stakeholders located in Selected Geographic Areas. CMS is posting a list of Selected Geographic Areas on the Innovation Center website concurrent with the release of this final rule, thus notifying the public and ETC Participants of the Selected Geographic Areas more than 90 days in advance of the start of the Model on January 1, 2021.

Comment: Commenters expressed concerns about how the method for randomly selecting participating HRRs will interact with the benchmarking methodology using data from Comparison Geographic Areas. Commenters stated that random selection does not address other covariates that impact home dialysis and transplant rates, including current rates of home dialysis and transplantation, urbanicity, population density, percentage of dual-eligible beneficiaries, and the availability of transplant centers. Commenters stated that, if balance on these covariates is not observed, model participants could be unfairly compared to ESRD facilities and Managing Clinicians located in Comparison Geographic Areas that face different factors that contribute to home dialysis and transplant rates.

Response: We appreciate the commenters' concern that underlying regional variation in home dialysis and transplant rates may mean that ETC Participants and ESRD facilities and Managing Clinicians located in Comparison Geographic Areas will face varying factors that affect their rates of home dialysis and transplants. However, as we noted in the proposed rule and earlier in this final rule, our proposal to stratify by region would help control for regional patterns in practice variation. We also believe that inclusion of improvement scoring in the scoring methodology, described in the proposed rule and in section IV.C.5.d. of this final rule, which awards points based on an ETC Participant's improvement against its own past performance, will help compensate for any underlying regional variation in these factors.

Comment: Several commenters stated that, due to the national nature of the dialysis market, large dialysis companies will have ESRD facilities located in both Selected Geographic Areas and in the Comparison Geographic Areas used for benchmarking under the ETC Model. These commenters stated that dialysis companies could face incentives to either not improve on or not maintain current home dialysis and transplant performance in ESRD facilities located in Comparison Geographic Areas to attempt to keep benchmarks low, to improve relative performance for their ESRD facilities located in Selected Geographic Areas.

Response: We appreciate the feedback from commenters about the potential for dialysis organizations operating in both Selected Geographic Areas and Comparison Geographic Areas to manipulate the Model's benchmarks. However, we believe that the achievement benchmarking methodology, described in the proposed rule and in section IV.C.5.d of this final rule, mitigates this risk. First, the proposed achievement benchmarks would use only data from home dialysis and transplant rates among ESRD facilities and Managing Clinicians located in Comparison Geographic Areas. Because we will construct these benchmarks using 12 months of data beginning 18 months before the start of the MY and ending 6 months before the start of the MY, the time periods for determining achievement benchmarks for MY1 and MY2 occurred primarily before the proposal or finalization of the rule to implement the Model. For MY3, the proposed achievement benchmarks would include 6 months of data from before the Model and 6 months of data after the Model began. Only in MY4 would all data used to construct the achievement benchmarks be from after the Model began. It would therefore be difficult for dialysis organizations to alter their past performance in order to manipulate these achievement benchmarks for the initial years of the Model. Additionally, we stated in the proposed rule that it is our intent to increase achievement benchmarks above the rates observed in Comparison Geographic Areas for future MYs through subsequent rulemaking. For these subsequent MYs, we are considering an approach under which achievement benchmarks would not be tied to performance in Comparison Geographic Areas, so there would not be an opportunity for LDOs to manipulate the achievement benchmarks by changing their performance in Comparison Geographic Areas if this approach is finalized.

Comment: Several commenters stated that HRRs may not be reflective of how dialysis care is delivered, how organ transplants are allocated, or referral patterns between Managing Clinicians and ESRD facilities. Commenters pointed out that HRRs are designed to capture patterns of care in hospitals for Medicare beneficiaries, but may not be reflective of other segments of the health care market, including dialysis services. These commenters further stated that, as a result of this misalignment, using HRRs may have unintended consequences. A commenter stated that the misalignment between dialysis company markets and HRRs could create a situation where ESRD facilities owned by a dialysis organization with a centralized home dialysis facility are selected to participate in the Model but the affiliated home dialysis facility is not selected to participate, which would not accurately reflect the provision of home dialysis by that company in that area. Other commenters stated that beneficiaries or ETC Participants may move between HRRs, or may seek or provide care in multiple HRRs.

Response: We appreciate commenters' concerns about the relationship between the geographic distribution of providers and suppliers involved in the provision of services to ESRD Beneficiaries and the geographic unit of selection used in the ETC Model. Providing care to ESRD Beneficiaries involves multiple parts of the health care system—including ESRD facilities and dialysis organizations, as well as Managing Clinicians and the practices in which they operate—each of which furnishes care in a unique geographic area or set of geographic areas. Because there are so many overlapping geographies served by these providers and suppliers, it is unlikely that there is one type of geographic unit that would align perfectly, such that no dialysis organization market is in both Selected Geographic Areas and Comparison Geographic Areas, or that no Managing Clinician sees patients in both Selected Geographic Areas and Comparison Geographic Areas. We continue to believe that HRRs are the most appropriate geographic unit of selection for the Model, for the reasons described in the proposed rule and elsewhere in this section of the final rule. Also, we believe that the aggregation methodology used in assessing ETC Participant performance (described in section IV.C.5.c.(4) of this final rule) addresses concerns about individual ETC Participant performance assessment in relation to geography. We acknowledge that ETC Participants may move between HRRs or provide care in multiple HRRs, and we do not believe that this harms the model test. It is commonplace for participants to move into and out of Innovation Center models on occasion, and this movement generally does not harm model evaluations. As to the movement of ESRD Beneficiaries, because the level at which performance is being assessed is the ETC Participant, not the beneficiary, and attribution of ESRD Beneficiaries to ETC Participants occurs in units of one

month, we do not believe that beneficiaries moving between HRRs will impact the model test.

Comment: Several commenters suggested using different geographic units to select ETC Participants, including CBSAs. A commenter supported using CBSAs instead of HRRs because CBSAs are well understood by health care providers. Other commenters opposed using CBSAs instead of HRRs for several reasons, including that CBSAs are smaller than HRRs and would therefore exacerbate divisions of participants and beneficiaries because the likelihood of a beneficiary being attributed to a participating ESRD facility and non-participating Managing Clinician (and vice versa) would increase, and that CBSAs do not include rural counties and CMS did not propose a method for associating rural counties with CBSAs. Others suggested alternative geographic units for selecting ETC Participants. A commenter suggested that CMS use regions that align with market areas for other payers, such as Medicare Advantage plans and other private payers, to prevent ETC Participants from having to ask other clinicians (such as primary care providers.) to provide different levels of care to ESRD patients based on participation in the Model. That commenter also suggested that CMS use a variety of geographic units to select participants similar to the method used in the design of the Civil Justice Reform Act experiments in the 1990s, in particular that CMS select participants in those states that have expressed interest in and wish to implement regulatory changes in conjunction with the Model, as states play a regulatory role in the provision of dialysis care. A commenter suggested using the ESRD Networks as the geographic units to select ETC Participants, as the ESRD Networks have longstanding relationships with dialysis and transplant programs, personnel, and patients, and could support participants to achieve the goals of the Model. A commenter suggested incorporating Donation Service Areas (DSAs) into the geographic unit selection process.

Response: We appreciate the feedback from commenters about the use of alternative geographic units to select ETC Participants. We acknowledge that there are a variety of types of geographic units we could use to select ETC Participants, and that there are benefits and challenges associated with each option. We continue to believe that HRRs are the most appropriate unit of geographic selection for this Model, for the reasons described in the proposed rule and elsewhere in this section of the final rule.

Comment: A commenter supported our proposal to select for participation all HRRs for which at least 20 percent of the component zip codes are located in Maryland, outside of the randomization, in conjunction with the Maryland TCOC Model currently being tested in Maryland. A commenter opposed including these Maryland HRRs, or any other states participating in Innovation Center models, outside of the randomization, as states are large geographic units and the commenter opposes the size of the Model.

Response: We appreciate the feedback from commenters about the inclusion of HRRs predominantly located in Maryland. We do not believe that including these HRRs outside of the randomization harms the randomization, or represents a significant increase in the size of the Model. We are therefore finalizing this policy as proposed.

Comment: Several commenters stated that they support the proposed exclusion of the U.S. Territories from the Selected Geographic Areas under the ETC Model.

Response: We appreciate the feedback and support from the commenters.

After considering public comments, we are finalizing our proposed provisions on Selected Geographic Areas in our regulations at § 512.325(b), with modification. We are modifying the proportion of HRRs randomly selected for inclusion in the Model as Selected Geographic Areas from 50 percent to 30 percent. We are finalizing the definition of Selected Geographic Area(s) as proposed with the technical change to capitalize the term ''Selected Geographic Area(s)'' in the final rule. We are also finalizing as proposed the definition of hospital referral regions (HRRs), and we are clarifying that we will use the 2017 HRRs for the duration of the ETC Model. HRRs are recalculated periodically to reflect changes in patterns of care over time. At the time of publication of the proposed rule, the 2017 HRRs are the most current available. We are also finalizing as proposed the definition of Comparison Geographic Area(s), with the technical change to capitalize the term ''Comparison Geographic Area(s)'' in the final rule. We are codifying these definitions in our regulations at § 512.310.

c. Participant Selection for the ETC Model

We proposed to define ''ETC Participant'' as an ESRD facility or Managing Clinician that is required to participate in the ETC Model pursuant to § 512.325(a), which describes the selection of model participants based on their location within a Selected Geographic Area, as described in the proposed rule and previously in this final rule. In addition, we noted in the proposed rule that the definition of ''model participant,'' as defined in section II of this final rule, would include an ETC Participant.

The following is a summary of the comments received on providers and suppliers included as ETC Participants and our responses.

Comment: Several commenters stated that the ETC Model should include transplant providers as participants, including transplant centers, transplant physicians, transplant surgeons, OPOs, donor hospitals, and other transplant providers in order to achieve the Model's focus on increasing rates of kidney transplantation. Commenters asserted that transplant providers hold more control over the transplant process than Managing Clinicians and ESRD facilities, so including them in the Model's payment adjustments would be necessary for or would increase the likelihood of Model success.

Response: We appreciate the suggestions from commenters about including transplant providers in the Model. We agree that transplant providers are central to increasing transplant rates. However, we do not believe that it is necessary to include transplant providers as participants receiving payment adjustments in this Model. First, the ETC Model is designed to test the effectiveness of a particular set of policy interventions, namely adjusting certain Medicare payments for Managing Clinicians and ESRD facilities to increase rates of home dialysis and kidney transplants. As noted previously in this final rule, we selected Managing Clinicians and ESRD facilities as participants in this Model because we believe these two groups of health care providers have the most direct relationship with ESRD Beneficiaries. Second, CMS and HHS are undertaking other activities targeting the availability of organs for transplantation. These efforts include the ETC Learning Collaborative described in section IV.C.12 of this final rule, which includes transplant centers and OPOs. As previously noted, HHS published a proposed rule in the **Federal Register** on the December 23, 2019, entitled ''Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization[s]'' (84 FR 70628). This proposed rule would,

among other things, update the OPO Conditions for Coverage to support higher donation rates and reduce discard rates of viable organs. The Health Resources and Services Administration (HRSA) also published a proposed rule in the **Federal Register** on December 20, 2019, entitled ''Removing Financial Disincentives to Living Organ Donation'' (84 FR 70139) to remove financial barriers to organ donation by expanding the scope of reimbursable expenses incurred by living organ donors to include lost wages and childcare and elder-care expenses incurred by a primary care giver. We believe that the increased volume of beneficiaries on the transplant waitlist driven by the payment adjustments in the ETC Model, together with the increased organ availability from other HHS and CMS efforts and the ETC Learning Collaborative, will serve as an incentive for transplant providers to support increasing rates of transplantation. As discussed in section IV.C.5.c.(2) of this final rule, it is our intent to observe organ availability.

After considering public comments, we are finalizing our proposed definition of ETC Participant without modification, and codifying this definition in our regulations at § 512.310.

(1) ESRD Facilities

We proposed that all Medicare-certified ESRD facilities located in a Selected Geographic Area would be required to participate in the ETC Model. We proposed to determine ESRD facility location based on the zip code of the practice location address listed in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). We considered using the zip code of the mailing address listed in PECOS. However, we concluded that mailing address is a less reliable indicator of where a facility is physically located than the practice location address, as facilities may receive mail at a different location than where they are physically located.

The following is a summary of the comments received on required participation for all ESRD facilities located in Selected Geographic Areas and our responses.

Comment: Several commenters suggested that CMS exclude certain ESRD facilities from selection for participation in the ETC Model. In particular, these commenters stated that ESRD facilities owned by small dialysis organizations would face substantial hardship and financial risk if selected for participation. Several of these commenters specifically recommended that ESRD facilities owned in whole or in part by a dialysis organization owning 35 or fewer ESRD facilities should be excluded from the Model, while another commenter recommended that ESRD facilities owned by these smaller dialysis organizations be allowed to opt in to the Model on a voluntary basis. A commenter recommended that CMS exclude dialysis organizations with fewer than 100 patients in a market area. A commenter suggested that no more than 25 percent of a dialysis organization's ESRD facilities should be included in the Model, while another commenter suggested that any health care provider that would have more than 10 percent of all of their treatments subject to the Model's payment adjustments should be excluded from the Model. A commenter recommended that ESRD facilities that decide that it is not logical or possible for them to offer home dialysis should be allowed to opt out of participation in the Model.

Response: The Model was designed to test the proposed payment adjustments for all types of ESRD facilities nationally, including those owned by both large and small dialysis organizations. To determine if payment adjustments can achieve the Model's goals of increasing rates of home dialysis utilization and kidney transplantation and, as a result, improving or maintaining the quality of care while reducing Medicare expenditures among all types of ESRD facilities, we need to test the model with ESRD facilities owned by all types of dialysis organizations. Additionally, while we include all ESRD facilities in the HDPA, as described in the proposed rule and in section IV.C.5.e.(1) of this final rule, the Model excludes certain ESRD facilities that fall below the low volume threshold from the application of the PPA. We believe that this approach balances the need to include all types of ESRD facilities in the model test with the need to increase statistical reliability and to exclude low-volume ESRD facilities from the PPA, which is the only downside financial risk included in the Model. We do not believe that it is appropriate to allow ESRD facilities to opt in or out of the Model for the purposes of the model test, as this would exacerbate potential selection effects.

Comment: Several commenters recommended that CMS adopt requirements around what types of dialysis an ESRD facility, or its parent dialysis organization, must provide in order to be selected for participation in the Model. Some commenters stated that only ESRD facilities that are currently certified to provide home dialysis should be selected for participation, to preserve the quality of care associated with centralization of home dialysis, to avoid unintended adverse outcomes, and/or to avoid penalizing ESRD facilities that cannot become certified to provide home dialysis in a timely manner. Several commenters stated that the Model should exclude from participation those ESRD facilities that are owned by dialysis organizations that own only ESRD facilities that provide home dialysis or that provide home dialysis only in a Selected Geographic Area to avoid ''cherry picking'' by home dialysis-only organizations, resulting in unfair comparisons in the PPA benchmarking methodology.

Response: We do not believe that it is necessary to exclude ESRD facilities that do not currently provide home dialysis services from the Model, nor do we believe that it is necessary to exclude ESRD facilities owned by dialysis organizations that provide only home dialysis. The ETC Model is designed to test the effectiveness of the Model's payment adjustments at improving or maintaining quality and reducing costs through increased provision of home dialysis and transplants on the dialysis market as a whole, including ESRD facilities new to the provision of home dialysis, as well as new entrants to the dialysis market who offer innovative approaches to dialysis provision that do not include in-center dialysis. Excluding these ESRD facilities from the model test could limit the Model's ability to increase provision of home dialysis services by these dialysis providers by discouraging new entrants to the market who may employ innovative approaches to home dialysis.

After considering public comments, we are finalizing our proposal in our regulation at § 512.325(a) to require all Medicare-certified ESRD facilities located in a Selected Geographic Area to participate in the Model, without modification.

(2) Managing Clinicians

We proposed that all Medicare-enrolled Managing Clinicians located in a Selected Geographic Area would be required to participate in the ETC Model. We proposed identifying the Managing Clinician's location based on the zip code of the practice location address listed in PECOS. If a Managing Clinician has multiple practice location addresses listed in PECOS, we proposed to use the practice location through which the Managing Clinician bills the plurality of his or her MCP claims. In the proposed rule, we considered using

the zip code of the mailing address listed in PECOS. However, as noted in the proposed rule, we determined that mailing address is a less reliable indicator of where a clinician physically practices than the practice location address, as clinicians may receive mail at a different location from where they physically practice.

The following is a summary of the comments received on required participation for all Managing Clinicians located in Selected Geographic Areas and our responses.

Comment: A commenter asked for clarification as to whether individual Managing Clinicians would be selected for participation based on their location or if practices with Managing Clinicians would be selected for participation based on their location.

Response: Managing Clinicians will be selected individually based on their location and not the practice location. However, as described in the proposed rule and in section IV.C.5.c.(4) of this final rule, the performance of Managing Clinicians that bill through the same practice TIN will be aggregated to the practice level for purposes of determining the PPA.

Comment: A commenter recommended that CMS not determine a Managing Clinician's location based on where he or she provides the plurality of his or her MCP claims. The commenter stated that this could create misalignment between incentives for Managing Clinicians and ESRD facilities if a Managing Clinician has patients who dialyze at ESRD facilities that are ETC Participants as well as at ESRD facilities located in Comparison Geographic Areas, and therefore CMS should select Managing Clinicians based on the location where dialysis services are provided to their patients.

Response: We recognize that Managing Clinicians provide dialysis management services included in the MCP to ESRD Beneficiaries that dialyze at multiple ESRD facilities, and that in some cases, this may mean that a Managing Clinician may have ESRD Beneficiaries who dialyze at ESRD facilities that are ETC Participants and ESRD Beneficiaries that dialyze at ESRD facilities located in Comparison Geographic Areas. However, selecting Managing Clinicians based on where their attributed beneficiaries dialyze would not solve this issue, as a Managing Clinician could still provide dialysis management services to ESRD Beneficiaries who dialyze at ESRD facilities that are ETC Participants and at ESRD facilities that are located in Comparison Geographic Areas. Also, we believe that the commenter's suggested selection method would be more complex, and would make it more difficult for Managing Clinicians to understand whether they are ETC Participants in real time, as beneficiary attribution occurs after each MY has ended.

After considering public comments, we are finalizing our proposal in our regulation at § 512.325(a) to require all Medicare-enrolled Managing Clinicians located in a Selected Geographic Area to participate in the ETC Model, without modification.

4. Home Dialysis Payment Adjustment

We proposed to positively adjust payments for home dialysis and home dialysis-related services billed by ETC Participants for claims with claim through dates during the first three CYs of the ETC Model (CY 2021–CY 2023). We stated that the HDPA would provide an up-front positive incentive for ETC Participants to support ESRD Beneficiaries in choosing home dialysis. The HDPA would complement the PPA, described in the proposed rule and section IV.C.5 of this final rule, which under our proposal would begin in mid-CY 2021 and increase in magnitude over the duration of the Model; as such we proposed that the HDPA would decrease over time as the magnitude of the PPA increases. There would be two types of HDPAs: The Clinician HDPA and the Facility HDPA. We proposed to define the ''Clinician HDPA'' as the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant for the Managing Clinician's home dialysis claims, as described in § 512.345 (Payments Subject to the Clinician HDPA) and § 512.350 (Schedule of Home Dialysis Payment Adjustments). We proposed to define the ''Facility HDPA'' as the payment adjustment to the Adjusted ESRD PPS per Treatment Base Rate (discussed in section IV.B of this final rule) for an ESRD facility that is an ETC Participant for the ESRD facility's home dialysis claims, as described in § 512.340 (Payments Subject to the Facility HDPA) and § 512.350 (Schedule of Home Dialysis Payment Adjustments). We proposed to define the ''HDPA'' as either the Facility HDPA or the Clinician HDPA. As we noted in the proposed rule, we do not believe that an analogous payment adjustment is necessary for increasing kidney transplant rates during the initial years of the ETC Model. Rather, instead of creating a payment adjustment, we proposed to implement the ETC Learning Collaborative that focuses on disseminating best practices to increase the supply of deceased donor kidneys available for transplant. For a description of the learning collaborative, see section IV.C.12 of this final rule.

The following is a summary of the comments received on the HDPA and our responses.

Comment: A commenter expressed support for the proposed HDPA because it would enable the increased use of home dialysis for appropriate ESRD Beneficiaries. Another commenter expressed concern that, while CMS recognized that the initial transition period onto dialysis is important for supporting ESRD Beneficiaries in selecting home dialysis, the proposed HDPA is tied to claims submitted for home dialysis, and would thus provide the largest benefit to ESRD facilities and Managing Clinicians that already have the infrastructure in place to support increased use of home dialysis. A commenter expressed opposition to providing the HDPA to ESRD facilities, given that, in the commenter's view, ESRD facilities already have an incentive to furnish home dialysis services over in-center dialysis services. According to the commenter, the profit margin for home dialysis is generally higher than or equal to in-center dialysis for ESRD facilities, but the returns on capital are substantially higher when providing home dialysis services, as fewer fixed assets are required to furnish home dialysis services than in-center dialysis.

Response: We thank the commenters for their feedback. CMS recognizes that by tying the HDPA to home dialysis and home dialysis-related claims, ETC Participants who furnish higher numbers of home dialysis and home dialysis-related services at the outset of the Model will receive more HDPA payments under the Model. However, this does not detract from the incentives to increase rates of home dialysis created by the HDPA, particularly in combination with the PPA, and CMS believes the proposed HDPA is an appropriate means to incentivize the increased provision of home dialysis and home dialysis-related services while also rewarding those who are already furnishing high rates of home dialysis and home dialysis-related services. CMS disagrees with the commenter's suggestion to eliminate the Facility HDPA. The commenter's statement that ESRD facilities currently have a greater incentive to provide home dialysis over in-center dialysis is directly contradicted by the data on relative rates of in-center and home dialysis described in the proposed rule and previously in this final rule. The overwhelming majority of ESRD Beneficiaries, including ESRD Beneficiaries for whom Medicare is a

secondary payer, currently receive in-center dialysis rather than home dialysis.

Comment: A commenter recommended that CMS apply the HDPA to payments for devices and procedures related to creation of vascular access for dialysis, and reduce payments for interventions, such as angioplasty and stenting, which are performed when a vascular means of access becomes clogged.

Response: It is not clear whether the commenter was suggesting that CMS adjust payments for vascular access device and procedures to supplement or supplant our proposed payment adjustments to claims for home dialysis and home dialysis-related services. Either way, if ETC Participants use devices and procedures related to creating vascular access for dialysis, and the ESRD Beneficiaries who acquire vascular access then receive home dialysis or home dialysis-related services, Medicare payments for those home dialysis and home dialysis-related services will be adjusted by the HDPA. Moreover, vascular access, while an important consideration for beneficiaries on dialysis, is not the focus of this Model.

Comment: A commenter opined that the payment adjustments proposed for the ETC Model are reminiscent of the ''bonus-and-penalty payment methodology'' used in the Premier Hospital Quality Incentive Demonstration (''Premier''), launched by CMS in 2003, which the commenter described as unsophisticated compared to more recent payment methodologies used in Innovation Center models. The commenter further noted that Premier did not yield improved patient outcomes.

Response: CMS disagrees with the commenter's comparison between Premier and the ETC Model. In Premier, CMS offered high achieving participants either a 1 percent or 2 percent positive adjustment on certain claims, and did not incorporate downside risk. While the HDPA may resemble the Premier payment adjustment, under the ETC Model the HDPA will be applied concurrently with the PPA, which provides both upward and downward adjustments to certain payments, and at a notably larger magnitude than the payment adjustments under Premier.

After considering public comments, we are finalizing our general proposal regarding the HDPA, as proposed. We are also finalizing the proposed definitions for the Home Dialysis Payment Adjustment (HDPA), Clinician Home Dialysis Payment Adjustment (Clinician HDPA), and Facility Home Dialysis Payment Adjustment (Facility HDPA) in our regulation at § 512.300 without modification, other than the technical change to capitalize every word of each of these terms (for example, in the proposed rule, we proposed to define ''Home dialysis payment adjustment,'' but in this final rule we are defining the term ''Home Dialysis Payment Adjustment'').

a. Payments Subject to the HDPA

We proposed that the HDPA would apply to all ETC Participants for those payments described in the proposed rule and in sections IV.C.4.b and IV.C.4.c of this final rule, according to the schedule described in the proposed rule and section IV.C.4.d of this final rule. We solicited comment on our proposal to apply the HDPA with respect to all ETC Participants, without exceptions.

We also proposed that the HDPA would apply to claims where Medicare is the secondary payer for coverage under section 1862(b)(1)(C) of the Act. We explained that when a beneficiary eligible for coverage under an employee group health plan becomes eligible for Medicare because he or she has developed ESRD, there is a 30-month coordination period during which the beneficiary's group health plan remains the primary payer if the beneficiary was previously insured. During this time, Medicare is the secondary payer for these beneficiaries. We proposed to apply the HDPA to Medicare as secondary payer claims because the initial transition period onto dialysis is important for supporting beneficiaries in selecting home dialysis, as beneficiaries who begin dialysis at home are more likely to remain on a home modality. As we noted in the proposed rule, the HDPA would adjust the Medicare payment rate for the initial claim, and then the standard Medicare Secondary Payer calculation and payment rules would apply, possibly leading to an adjustment to the Medicare Secondary Payer amount. We sought comment on the proposal to apply the HDPA to Medicare as secondary payer claims.

The following is a summary of the comments received on payments subject to the HDPA and our proposal to apply the HDPA to claims where Medicare is a secondary payer, and our responses.

Comment: A commenter expressed support for CMS's proposal to apply the HDPA to all ETC Participants, reasoning that the HDPA incentivizes an increase in home dialysis rates, which aligns with the Model's goals. Another commenter recommended that CMS apply the HDPA to all ESRD providers.

Response: We thank the commenters for their feedback. We agree that CMS's proposal to apply the HDPA to all ETC Participants aligns with the Model's goals by incentivizing an increase in home dialysis rates, which we expect to improve or maintain quality while reducing costs. Regarding the commenter's recommendation that CMS apply the HDPA to all ESRD providers, we are finalizing our proposal to apply the HDPA only to ETC Participants to allow us to compare the rates of home dialysis between ETC Participants (who are subject to the HDPA) and ESRD facilities and Managing Clinicians located in Comparison Geographic Areas (who are not subject to the HDPA) for purposes of evaluating whether the HDPA statistically impacts the provision of home dialysis.

Comment: A commenter expressed strong support for CMS's proposal to apply the HDPA to claims where Medicare is the secondary payer.

Response: We thank the commenter for the feedback and support.

After considering public comments, we are finalizing our general proposals regarding payments subject to the HDPA, without modification.

b. Facility HDPA

For ESRD facilities that are ETC Participants, we proposed to adjust Medicare payments under the ESRD PPS for home dialysis services by the HDPA according to the schedule described in the proposed rule and section IV.C.4.d of this final rule. As noted in the proposed rule and previously in this final rule, under the ESRD PPS, a single per treatment payment is made to an ESRD facility for all renal dialysis services, which includes home dialysis services, furnished to beneficiaries. This payment is subject to a number of adjustments, including patient-level adjustments, facility-level adjustments, and, when applicable, a training adjustment add-on for home and self-dialysis modalities, an outlier payment, and the TDAPA. We explained in the proposed rule that, at that time, the formula for determining the final ESRD PPS per treatment payment amount was as follows:

*Final ESRD PPS Per Treatment Payment Amount = (Adjusted ESRD PPS Base Rate + Training Add On + TDAPA) * ESRD QIP Factor + Outlier Payment * ESRD QIP Factor*

We proposed to apply the Facility HDPA to the Adjusted ESRD PPS per Treatment Base Rate on claims submitted for home dialysis services. For purposes of the ETC Model, we proposed to define the ''Adjusted ESRD

PPS per Treatment Base Rate'' as the per treatment payment amount as defined in 42 CFR 413.230, including patient-level adjustments and facility-level adjustments, and excluding any applicable training adjustment add-on payment amount, outlier payment amount, and TDAPA amount. We stated in the proposed rule that the proposed formula for determining the final ESRD PPS per treatment payment amount with the Facility HDPA would be as follows:

*Final Per Treatment Payment Amount with Facility HDPA = ((Adjusted ESRD PPS per Treatment Base Rate * Facility HDPA) + Training Add On + TDAPA) * ESRD QIP Factor + Outlier Payment * ESRD QIP Factor*

In the proposed rule, we considered adjusting the full ESRD PPS per treatment payment amount by the Facility HDPA, including any applicable training adjustment add-on payment amount, outlier payment amount, and TDAPA. However, we concluded that adjusting these additional payment amounts was not necessary to create the financial incentives we seek to test under the proposed ETC Model. We sought comment on our proposed definition of Adjusted ESRD PPS per Treatment Base Rate, and the implications of excluding from the definition the adjustments and payment amounts previously listed, such that those amounts would not be adjusted by the Facility HDPA under the ETC Model.

As discussed previously in section IV.B.1 of this final rule, after we published the proposed rule for the ETC Model, CMS established a new payment adjustment under the ESRD PPS called the TPNIES, which could apply to certain claims as soon as CY 2021. The TPNIES is part of the calculation of the ESRD PPS per treatment payment amount under 42 CFR 413.230 and, like the TDAPA, is applied after the facility-level and patient-level adjustments. We discuss the implications of this change for the Facility HDPA later in this section of the final rule.

In the proposed rule, we proposed in § 512.340 to apply the Facility HDPA to the Adjusted ESRD PPS per Treatment Base Rate on claim lines with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, and with condition codes 74, 75, 76, or 80, when the claim is submitted by an ESRD facility that is an ETC Participant with a claim through date during a CY subject to adjustment, as described in the proposed rule and section IV.C.4.d of this final rule, where the beneficiary is age 18 or older during the entire month of the claim. We explained that facility code 7 (the second digit of Type of Bill) paired with type of care code 2 (the third digit of Type of Bill), indicates that the claim occurred at a clinic or hospital-based ESRD facility. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. We stated in the proposed rule that condition codes 74 and 75 indicate billing for a patient who received dialysis services at home, and condition code 80 indicates billing for a patient who received dialysis services at home and the patient's home is a nursing facility. Condition code 76 indicates billing for a patient who dialyzed at home but received back-up dialysis in a facility. We noted in the proposed rule that, taken together, we believed these condition codes capture home dialysis services furnished by ESRD facilities, and therefore were the codes we proposed to use to identify those payments subject to the Facility HDPA. We sought comment on this proposed provision.

As further described in the proposed rule and in section IV.C.7.a of this final rule, we also proposed that the Facility HDPA would not affect beneficiary cost sharing. Beneficiary cost sharing instead would be based on the amount that would have been paid under the ESRD PPS absent the Facility HDPA.

The following is a summary of the comments received on the Facility HDPA and our responses.

Comment: Many commenters recommended that CMS adjust the home and self-dialysis training add-on payment adjustment under the ESRD PPS by the Facility HDPA. One such commenter opined that the training add-on payment adjustment is directly related to the Model's goal of shifting beneficiaries to home dialysis modalities. A commenter recommended that CMS adjust the TDAPA by the Facility HDPA, asserting that new renal dialysis drugs and biological products pending FDA approval that could be furnished to beneficiaries receiving home dialysis services may be found to better support implementation of home dialysis delivery services. A commenter expressed support for CMS's proposal to exclude the outlier payment from the definition of the Adjusted ESRD PPS per Treatment Base Rate.

Response: We thank the commenters for their feedback. As we stated in the proposed rule, we believe adjusting the training add-on payment adjustment amount and the TDAPA amount by the Facility HDPA is not necessary to create the financial incentives we seek to test under the ETC Model. Regarding the commenter's suggestion that CMS apply the Facility HDPA to the training add-on payment adjustment, while we agree with the commenter that beneficiary training is necessary prior to initiating home dialysis, CMS believes that adjusting the Adjusted ESRD PPS per Treatment Base Rate by the Facility HDPA for claims submitted for home dialysis will provide a sufficient financial incentive to shift beneficiaries to home dialysis. Regarding the commenter's suggestion that CMS should apply the Facility HDPA to the TDAPA, the commenter discussed drugs for which drug sponsors are seeking FDA approval. CMS does not find it appropriate to change its proposed application of the Facility HDPA in anticipation of certain renal dialysis drugs that may or may not be approved by the FDA. Further, even if these drugs were already approved or become approved by the FDA during the Model, that would not change CMS's position, as the Model is not focused on drug innovation or designed to encourage pharmaceutical companies to create and release more drugs. Rather, the Model is designed to increase rates of home dialysis and transplantation.

While we are not modifying the proposed application of the Facility HDPA, we are updating the formula for calculating the final ESRD PPS per treatment payment amount with the Facility HDPA to reflect the addition of the TPNIES. Because CMS would apply the TPNIES in the calculation of the per treatment payment amount after the application of the patient-level adjustments and facility-level adjustments, in the same manner as the TDAPA, the TPNIES does not alter the proposed application of the Facility HDPA. We had proposed to apply the Facility HDPA to the Adjusted ESRD PPS per Treatment Base Rate, meaning the per treatment payment amount as defined in 42 CFR 413.230, including patient-level adjustments and facility-level adjustments and excluding any applicable training adjustment add-on payment amount, outlier payment amount, and TDAPA amount. To take into account the TPNIES payment adjustment that could apply beginning in CY2021, we are finalizing the formula for determining the final ESRD PPS per treatment payment amount with the Facility HDPA, with the TPNIES as follows:

*Final Per Treatment Payment Amount with Facility HDPA = ((Adjusted ESRD PPS per Treatment Base Rate * Facility HDPA) + Training Add On + TDAPA + TPNIES) * ESRD*

*QIP Factor + Outlier Payment * ESRD QIP Factor*

Comment: A commenter expressed general support for CMS's proposed approach for identifying home dialysis services for the purposes of applying the Facility HDPA, but recommended that CMS also apply the Facility HDPA to claims with condition code 73. The commenter asserted that for beneficiaries who qualify for Medicare based on ESRD diagnosis, CMS considers Medicare coverage to begin when a beneficiary participates in a home dialysis training program offered by a Medicare-approved training facility, and ESRD facilities report such home dialysis training using condition code 73 on claims. Other commenters similarly suggested that CMS apply the Facility HDPA to claims for home dialysis-related services with condition code 73.

Response: We thank the commenters for their feedback. CMS understands that condition code 73 relates to training a beneficiary on home dialysis, and that one way CMS determines the start of Medicare coverage for an ESRD Beneficiary is when an ESRD facility bills Medicare using condition code 73 for that beneficiary. However, under the ETC Model, CMS seeks to adjust payments for and incentivize the provision of home dialysis services, and not home dialysis training *per se.* CMS recognizes that training is necessary for a beneficiary to succeed in home dialysis; however, adjusting payments for claims that include condition code 73 may encourage impermissible ''gaming'' wherein ETC Participants train all beneficiaries on home dialysis, regardless of whether the ETC Participant believes home dialysis is the most appropriate modality for the beneficiary. In such a case, CMS would be compensating ETC Participants for simply training beneficiaries, rather than for starting and maintaining trained Beneficiaries on home dialysis. Further, any home dialysis claim submitted for an ESRD Beneficiary after the claim containing condition code 73 would be adjusted by the Facility HDPA, providing a robust enough incentive to ETC Participants to increase the provision of home dialysis services.

Comment: A commenter expressed support for CMS's proposal that the Facility HDPA would not affect beneficiary cost sharing.

Response: We thank the commenter for the feedback and support.

After considering public comments, we are finalizing our proposed provisions on payments subject to the Facility HDPA with modification. Specifically, we are codifying in our regulation at § 512.340 that we will adjust the Adjusted ESRD PPS per Treatment Base Rate by the Facility HDPA for claim lines with Type of Bill 072X and with condition codes 74 or 76 where the claim is submitted by an ESRD facility that is an ETC Participant with a claim service date during a calendar year subject to adjustment as described in § 512.350, where the beneficiary is at least 18 years old before the first day of the month. We are modifying which date associated with the claim we are using to determine if the claim occurred during the applicable MY. Whereas we proposed using the claim through date, we are finalizing using the date of service on the claim, to align with Medicare claims processing standards. Specifically, while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service. Thus, we must use the claim date of service to identify the MY in which the service was furnished. In addition, while we had proposed to apply the Facility HDPA only to claims for which the beneficiary was at least 18 years old for the entire month of the claim, in the final rule, we are changing the language to state that the beneficiary must be at least 18 years of age ''before the first day of the month,'' which is easier for CMS to operationalize and has the same practical effect (that is, a beneficiary who is at least 18 years old before the first date of a month will be at least 18 years old for that entire month). While we proposed to apply the Facility HDPA to claims with condition code 75, we have since learned that this condition code is no longer valid and therefore will be removed for the final rule. Additionally, in this final rule, we will not apply the Facility HDPA to claims with condition code 80, as we had proposed, because condition code 80 indicates billing for a patient who received dialysis services at home and the patient's home is a nursing facility. As described in greater detail in section IV.C.5.b.(1) of this final rule, we are excluding beneficiaries who reside in or receive dialysis services in a SNF or nursing facility from attribution to ETC Participants for purposes of calculating the PPA. We will exclude home dialysis claims for these beneficiaries from the application of the Facility HDPA for the same reason. We are finalizing the definition of Adjusted ESRD PPS per Treatment Base Rate in our regulation at § 512.310 with one modification to reflect that the Adjusted ESRD PPS per Treatment Base Rate calculation excludes any applicable TPNIES amount, with a technical change to capitalize every word in the term ''Adjusted ESRD PPS per Treatment Base Rate.''

c. Clinician HDPA

For Managing Clinicians that are ETC Participants, we proposed to adjust the MCP by the Clinician HDPA when billed for home dialysis services. We proposed to define the ''MCP'' as the monthly capitated payment made for each ESRD Beneficiary to cover all routine professional services related to treatment of the patient's renal condition furnished by a physician or non-physician practitioner as specified in 42 CFR 414.314. We considered adjusting all Managing Clinician claims for services furnished to ESRD Beneficiaries, including those not for dialysis management services. However, as described in the proposed rule, we concluded that adjusting claims for services other than dialysis management was not necessary to create the financial incentives we seek to test under the ETC Model.

We proposed to specify in our regulation at § 512.345 that we would adjust the amount otherwise paid under Part B with respect to MCP claims by the Clinician HDPA when the claim is submitted by a Managing Clinician who is an ETC Participant. MCP claims would be identified by claim lines with CPT® codes 90965 or 90966. We would adjust MCP claims with a claim through date during a CY subject to adjustment, as described in the proposed rule and section IV.C.4.d of this final rule, where the beneficiary is 18 years or older for the entire month of the claim. CPT® code 90965 is for ESRD-related services for home dialysis per full month for patients 12–19 years of age. CPT® code 90966 is for ESRD-related services for home dialysis per full month for patients 20 years of age and older. These two codes are used to bill the MCP for patients age 18 and older who dialyze at home, and therefore are the codes we proposed to use to identify those payments subject to the HDPA. As noted in the proposed rule and previously in this final rule, we proposed to adjust the amount otherwise paid under Part B by the Clinician HDPA so that beneficiary cost sharing would not be affected by the application of the Clinician HDPA. The Clinician HDPA would apply only to the amount otherwise paid for the MCP absent the Clinician HDPA.

The following is a summary of the comments received on the Clinician HDPA and our responses.

Comment: Two commenters expressed support for our proposal that

the Managing Clinician HDPA would not affect beneficiary cost sharing. One such commenter reasoned that beneficiaries included in the Model should not be financially harmed or experience perverse incentives to obtain care not resulting in optimal patient health outcomes. Another commenter expressed concern that CMS did not explain in the proposed rule how the HDPA would impact beneficiary co-insurance.

Response: We thank the commenters for their feedback. As we noted in the proposed rule, the Clinician HDPA is applied to the Part B paid amount. Beneficiary cost sharing (for example, beneficiary coinsurance) is not subject to the HDPA adjustment.

Comment: A commenter suggested that, during the Model, CMS increase the payment amount for physicians' services for patients in training for self-dialysis.

Response: We thank the commenter for this feedback. CMS disagrees with the commenter's suggestion that CMS increase the PFS payment amount for services furnished to patients in training for self-dialysis, as (1) the Model uses percentages for its payment adjustments to give each ETC Participant a percentage (rather than flat-dollar) increase or decrease in payment, and (2) CMS has modified its proposal to include self-dialysis services for purposes of calculating the home dialysis rate, as described in section IV.C.5.c.(1) of this final rule.

After considering public comments, we are finalizing our proposals on the application of the Clinician HDPA to MCP claims with modifications. Specifically, we are codifying in our regulation at § 512.345 that we will adjust the amount that is otherwise paid under Medicare Part B with respect to MCP claims, identified by claim lines with CPT® codes 90965 or 90966, by the Clinician HDPA when the claim is submitted by a Managing Clinician who is an ETC Participant and with a claim service date during a calendar year subject to adjustment described in § 512.350, where the beneficiary is at least 18 years old before the first day of the month. As noted elsewhere, we are modifying which date associated with the claim we are using to determine if the claim occurred during the applicable MY. Whereas we proposed using the claim through date, we are finalizing using the date of service on the claim, to align with Medicare claims processing standards. Specifically, while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service. Thus, we must use the claim date of service to identify the MY in which the service was furnished. In addition, while we had proposed to apply the Clinician HDPA only to claims for which the beneficiary was at least 18 years old for the entire month of the claim, in the final rule, we are changing the language to state that the beneficiary must be at least 18 years ''before the first day of the month,'' which is easier for CMS to operationalize and has the same practical effect (that is, a beneficiary who is at least 18 years old before the first date of a month will be at least 18 years old for that entire month). Finally, we are finalizing the definition of Monthly capitation payment (MCP), as proposed, in our regulation at § 512.310.

d. HDPA Schedule and Magnitude

We proposed to specify in our regulations at § 512.350 that the magnitude of the HDPA would decrease over the years of the ETC Model test, as the magnitude of the PPA increases. In this way, we would transition from providing additional financial incentives to support the provision of home dialysis through the HDPA in the initial three CYs of the ETC Model, to holding ETC Participants accountable for attaining the outcomes that the Model is designed to achieve via the PPA. In the proposed rule, we considered alternative durations of the HDPA, including limiting the HDPA to one year such that there would be no overlap between the HPDA and the PPA, or extending the HDPA for the entire duration of the Model. However, we did not elect to propose these approaches in the proposed rule. We explained that if the HDPA applied for only the first year of the Model, there would be a six-month gap between the end of the HDPA (December 31, 2020) and the start of the first PPA period (July 1, 2021), during which there would be no model-related payment adjustment. If the HDPA applied for the duration of the Model, there would be two sets of incentives in effect: A process-based incentive from the HDPA and an outcomes-based incentive from the home dialysis component of the PPA. As we explained in the proposed rule, while we believe that the time-limited overlap between the two payment adjustments is acceptable to smoothly transition ETC Participants from process-based incentives to outcomes-based incentives, we do not believe this structure is beneficial to the Model test over the long term.

We proposed the payment adjustment schedule in Table 11:

TABLE 11: PROPOSED HDPA SCHEDULE

	CY 2020	CY 2021	CY 2022
Magnitude of Payment Adjustment	+3%	+2%	+1%

Under this proposed schedule, the HDPA would no longer apply to claims submitted by ETC Participants with claim through dates on or after January 1, 2023. We sought input from the public about the proposed magnitude and duration of the proposed HDPA.

The following is a summary of the comments received on the proposed HDPA schedule and magnitude and our responses.

Comment: Several commenters recommended that we continue to apply the HDPA beyond the first 3 years of the Model, and some suggested that we continue to apply the HDPA for the entire duration of the Model. A commenter recommended that the period during which the HDPA is applied be increased from 3 years to 4 years. Several commenters expressed concern regarding the proposal to reduce the magnitude of the HDPA after the first year, and otherwise taper down the magnitude of the HDPA over the course of the first three years of the Model. Commenters also expressed concern regarding the proposal to apply the HDPA during only the first three

years of the Model. Several commenters expressed concern that building up the infrastructure necessary to increase the provision of home dialysis will take time, and that it would be more appropriate to apply the HDPA to claims submitted by ETC Participants for more years of the Model. Some commenters explained that the sources of delay and difficulty in establishing or building upon a home dialysis program include: Capital investments; hiring staff, particularly dialysis nurses who are in short supply across the nation; receiving local zoning and building permits; and obtaining federal and state regulatory approval. Commenters expressed concern that going through the required processes and obtaining the appropriate equipment and staffing can easily take a year or more, at which time the magnitude of the HDPA will have already decreased.

Response: Regarding the comments recommending that CMS extend the duration of time during which the HDPA would be applied, CMS indicated in the proposed rule that applying the HDPA for the duration of the Model would create an overlap between a payment adjustment that is process-based, the HDPA, and another that is outcomes-based, the PPA, that would not be beneficial to the Model test over the long-term. Applying the HDPA for another year would similarly not be beneficial to the Model over the long-term. The Model is designed to more heavily emphasize, in the beginning of the Model, the process of building up necessary infrastructure to provide more home dialysis services, and to more heavily emphasize, in later years of the Model, the outcomes of increased home dialysis and transplants. CMS recognizes that building the necessary infrastructure will take time, and that is why CMS proposed to apply the HDPA for the first three years of the Model. CMS believes that three years is more than enough time to take all necessary steps to increase utilization of home dialysis.

Comment: A commenter recommended that CMS wait to apply the HDPA to claims submitted by an ETC Participant until after a patient has been on home dialysis for three months. The same commenter expressed concern that ETC Participants will start patients on home dialysis who will not do well on home dialysis so that the ETC Participants could potentially receive a short-term increase in payment via the application of the HDPA.

Response: While CMS appreciates the commenter's suggestion that CMS wait to apply the HDPA to claims submitted by an ETC Participant until the beneficiary has been on home dialysis for 3 months, CMS believes it is important to apply the HDPA sooner so as to better position ETC Participants to immediately begin making investments to increase the provision of home dialysis to beneficiaries for whom this modality is clinically appropriate. CMS also appreciates the commenter's concern over the possibility of ETC Participants gaming the HDPA when the HDPA applies immediately and not after a particular ESRD Beneficiary has been on home dialysis for a certain amount of time, but CMS believes the overall payment methodology under the Model eliminates a gaming incentive of this nature. Part of the calculation for the PPA derives from the ETC Participant showing improvement in its home dialysis rate in a given year. An ETC Participant will need to increase its beneficiary population receiving home dialysis in a sustainable fashion for its data to reflect an improvement, creating an incentive for ETC Participants to identify suitable candidates for home dialysis and to keep such candidates on home dialysis over the course of months and years, as appropriate.

Comment: Some commenters expressed general support for the magnitude of the HDPA as proposed. A few commenters expressed agreement with the idea that payment incentives have a role in achieving higher value care for kidney patients. One such commenter noted that rates of PD have increased due to aligning the reimbursement for in-center dialysis with home-based modalities. Similarly, another such commenter noted that ESRD facilities have proven remarkably responsive to policy changes that are tied to payment adjustments, such as the ESRD PPS and ESRD QIP initiatives. That same commenter expressed a belief that the payment adjustments under the ETC Model are far milder than the ESRD PPS and QIP initiatives, and expressed confidence that Managing Clinicians and ESRD facilities that are ETC Participants will quickly adopt new treatment and process innovations to maximize their performance within the Model.

Response: We thank the commenters for the feedback and support. We also appreciate the comment regarding the increase in the provision of PD, but note that the ESRD PPS base payment rate is modality neutral, and that the identified increase in rates of PD could be explained by a higher profit margin for providing PD over HD, and not because the Medicare payment is higher.

Comment: A commenter expressed support for the proposed magnitude of the HDPA, but expressed concern that the uptake of home dialysis may be slower than CMS anticipates, and thus suggested that CMS consider implementing a performance benchmark that an ETC Participant must reach before CMS lowers the magnitude of that ETC Participant's HDPA. The same commenter also recommended that the duration of the HDPA should be different for LDOs versus non-LDOs, such that the HDPA would apply to claims submitted by non-LDOs for a longer period of time than for claims submitted by LDOs, or that the magnitude of the HDPA applied to claims submitted by non-LDOs would taper down more slowly than it would for the LDOs. Several commenters expressed concern that the Facility HDPA and Clinician HDPA adjustments are too low to adequately incentivize behavioral change.

Response: We appreciate the commenters' feedback. CMS does not believe it would be beneficial to the Model to require a performance benchmark for an ETC Participant to reach before CMS decreases the magnitude of the Participant's HDPA, as the intent of the HDPA is to incentivize investments in home dialysis in the early years of the Model. In later years, such incentives would be created by the application of the PPA. CMS also disagrees with the recommendation that CMS differentiate the duration or magnitude of the HDPA between LDOs and non-LDOs, as such a distinction fails to consider differences in current home dialysis service provision across LDOs and non-LDOs. CMS believes that the HDPA and PPA, in combination, provide an equally strong incentive to LDOs and non-LDOs alike toward establishing or building out home dialysis programs. Further, to the extent that the HDPA will result in a greater revenue increase to LDOs over non-LDOs early in the Model, such a disparity is appropriate given the larger volume of patients that LDOs, by definition, serve. An ESRD facility furnishing services to a larger volume of patients will require a larger investment in infrastructure compared to an ESRD facility furnishing services to a smaller volume of patients. CMS further believes that the magnitude of the Facility HDPA and Clinician HDPA, especially when coupled with the respective PPAs, are adequate to incentivize ETC Participants to create or build out their home dialysis programs.

Comment: Many commenters noted that establishing a home dialysis program or building upon an existing program requires hiring and training staff, particularly dialysis nurses, who several commenters noted are in short

supply; securing additional space and equipment; establishing training protocols for patients; undergoing a survey and certification process (depending on the State); obtaining zoning and building permits; and obtaining federal and State regulatory approval. Commenters stated that the magnitude of the HDPA is not large enough to cover these significant up-front costs. Other commenters expressed concern that the HDPA would prove inadequate to help small and independent ESRD facilities increase their provision of home dialysis, as such facilities often have low margins and fewer resources than LDOs. A commenter expressed concern that the HDPA would favor chain ESRD facilities with several ESRD facilities within close proximity who can hire one dialysis nurse to cover multiple ESRD facilities, and will lead smaller health care providers to sell their facility to large chain ESRD facilities, causing further consolidation. Still other commenters expressed concern that CMS did not attempt to quantify the investment required by ESRD facilities and Managing Clinicians to establish or build upon home dialysis programs, which those commenters believed should have informed the proposed magnitude and duration of the HDPA. A commenter expressed concern that CMS did not indicate, in the proposed rule, that the HDPA as proposed would be adequate to allow ETC Participants to increase their capacity to provide home dialysis services.

Response: CMS believes that providing positive payment adjustments via the HDPA over the first three years of the Model will provide sufficient time for ETC Participants to build out infrastructure to establish or build upon home dialysis programs. CMS recognizes that market realities impose significant barriers to increasing capacity to offer home dialysis programs, which is exactly why CMS proposed to apply the HDPA. While CMS cannot easily affect the supply of dialysis nurses or the number of vendors in the home dialysis market, it can provide ETC Participants with positive payment adjustments through the HDPA to help overcome these market obstacles. Regarding the commenter's concern about chain ESRD facilities that have several clinics in close proximity being able to hire one nurse to cover multiple ESRD facilities, such ESRD facilities would have that advantage regardless of the payment adjustments made under this Model. The ETC payment methodology does not create or increase this advantage that chain ESRD facilities have over others. Moreover, we believe that non-chain ESRD facilities can innovate their business practices to overcome the identified advantage that chain ESRD facilities currently have. For example, non-chain ESRD facilities could hire a part-time nurse rather than a full-time nurse, or collaborate with other nearby non-chain ESRD facilities to contract with a nurse to mimic the approach that the commenter anticipates chain ESRD facilities will take. Regarding the comments expressing concern that CMS did not quantify the investment required by ESRD facilities and Managing Clinicians to establish or build upon home dialysis programs, CMS could not have adequately quantified such investments for all ETC Participants. ESRD facilities and Managing Clinicians are heterogeneous, and costs will differ greatly among ESRD facilities and Managing Clinicians. Regional differences in cost, differing patient population sizes, differing relationships with community partners, and differences in margins, funding, and business models make it impossible for CMS to accurately identify the cost of creating or building upon a home dialysis program for each ESRD facility or Managing Clinician. The HDPA will provide ETC Participants with upfront revenue that the ETC Participant can use to increase provision of home dialysis.

Comment: Several commenters expressed concern that the Clinician HDPA, as proposed, is too small in amount to effectively address the current gap in reimbursement between providing in-center dialysis compared to home dialysis. Several commenters expressed concern that even with the 3 percent HDPA, Managing Clinicians are still paid more under current Medicare rules for providing four or more in-center dialysis treatments a month than for providing home dialysis in a month. Noting that CMS acknowledged in the proposed rule that current Medicare payment rates and mechanisms may create a disincentive to prescribe and furnish home dialysis, the commenters suggested the HDPA for Managing Clinicians should be set at a magnitude such that the Clinician HDPA plus the MCP for home dialysis exceeds the current MCP for four or more in-center dialysis visits in a given month. The same commenters recommended that following the end of the proposed HDPA period, CMS should include a payment adjustment to the MCP that equalizes the MCP for home dialysis and the MCP for four or more in-center visits. A commenter stated that the proposed Clinician HDPA of 3 percent still leaves the payment amount for home dialysis services below the in-center MCP payment for four or more visits during a month.

Response: CMS recognizes that for physicians, the MCP for in-center dialysis is currently higher than the MCP for home dialysis. However, CMS firmly believes that moving beneficiaries to home dialysis will ultimately be cost saving for ETC Participants by the end of the model period and that the Clinician HDPA adjustments, as proposed, are sufficiently large to encourage ETC Participants create or build out home dialysis programs to realize those long term savings. The infrastructure and equipment necessary for providing home dialysis may be expensive up-front, but once the infrastructure and equipment have been acquired, home dialysis will be less costly for the ETC Participant to provide compared to providing four or more in-center dialysis sessions. Even though the Clinician HDPA is not large enough to make payment for providing home dialysis equal to or higher than payment for providing four or more in-center dialysis sessions, it is large enough to sufficiently lessen the up-front costs of establishing or building out home dialysis capability and allow the ETC Participant to realize the benefits associated with moving appropriate ESRD Beneficiaries away from in-center services to home dialysis. For ETC Participants, these benefits may include: Reduced labor costs and capital depreciation associated with reduced provision of in-center services; the capacity to increase the total number of patients served at any given time and overall given that fewer patients will use in-center space, which can only accommodate so many patients at any one time, allowing the ETC Participant to more rapidly expand the patient population it serves; and generally decreased operating costs in the medium- and long-run. For ESRD Beneficiaries, the benefits may include reduced or eliminated commuting to ESRD facilities for treatment, greater involvement in the ESRD Beneficiary's own treatment, and generally greater autonomy.

Comment: Several commenters recommended that the HDPA be increased in magnitude. Some of these commenters recommended that the magnitude of the HDPA be increased significantly. Some commenters suggested certain specific amounts for the HDPA. A few commenters recommended that the magnitude of the HDPA be increased to 3–5 percent.

Other commenters suggested that the magnitude of the HDPA stay at 3 percent for all three years it is applied, or that it remain at 3 percent for the duration of the Model. Another commenter recommended that the HDPA be maintained at 3 percent for all three years, but alternatively suggested that the magnitude of the HDPA start at 1 percent in year one, increase to 2 percent in year 2, and to 3 percent in year three. Another commenter more generally suggested that the HDPA be established at a set amount for every year of the Model and not be tapered down in magnitude, as proposed. Some commenters expressed concern that the HDPA would be too small to make an impact on home dialysis rates when combined with the PPA, given that the PPA could impose a large downward adjustment on certain payments for ETC Participants.

Response: CMS does not believe the magnitude of the HDPA needs to be increased. Increasing the HDPA by any amount, including maintaining the HDPA at 3 percent for two additional years or for the duration of the Model, would serve to undermine the Model's emphasis on improving outcomes. CMS believes that the proposed magnitude of the HDPA will be adequate to make an impact on home dialysis rates notwithstanding the PPA, and that increasing the magnitude of the HDPA beyond what was proposed would undercut the focus on outcomes under the Model.

After considering public comments, we are finalizing our proposed provisions on the HDPA schedule and magnitude, with one modification. Specifically, in order to accommodate the start date for the payment adjustments under the ETC Model finalized in our regulations at § 512.320, we are codifying in our regulations at § 512.350 that CMS adjusts the payments specified in § 512.340 by the Facility HDPA and that CMS adjusts the payments specified in § 512.345 by the Clinician HDPA according to the schedule in Table 11.a:

TABLE 11.a: HDPA SCHEDULE

	Calendar Year 2021	Calendar Year 2022	Calendar Year 2023
Magnitude of Payment Adjustment	+3%	+2%	+1%

5. Performance Payment Adjustment

We proposed to adjust payment for claims for dialysis services and dialysis-related services submitted by ETC Participants based on each ETC Participant's Modality Performance Score (MPS), calculated as described in the proposed rule and section IV.C.5.d of this final rule. We proposed to define the ''Modality Performance Score (MPS)'' as the numeric performance score calculated for each ETC Participant based on the ETC Participant's home dialysis rate and transplant rate, as described in § 512.370(d) (Modality Performance Score), which is used to determine the amount of the ETC Participant's PPA, as described in § 512.380 (PPA Amounts and Schedule). We sought comment on the composition of the MPS, particularly the inclusion of the transplant rate in the MPS.

We proposed that there would be two types of PPAs: The Clinician PPA and the Facility PPA. We proposed to define the ''Clinician PPA'' as the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant based on the Managing Clinician's MPS, as described in our regulations at § 512.375(b) (Payments Subject to Adjustment) and § 512.380 (PPA Amounts and Schedule). We proposed to define the ''Facility PPA'' as the payment adjustment to the Adjusted ESRD PPS per Treatment Base Rate for an ESRD facility that is an ETC Participant based on the ESRD facility's MPS, as described in § 512.375(a) (Payments Subject to Adjustment) and § 512.380 (PPA Amounts and Schedule). We proposed to define the ''PPA'' as either the Facility PPA or the Clinician PPA.

The following is a summary of the comments received on the calculation of the proposed PPA, and in particular the inclusion of the transplant rate in the MPS used to calculate the PPA, and our responses.

Comment: Several commenters expressed concern about the level of control ETC Participants have over transplants. Commenters expressed concern that the average waitlist stay for a patient is around 4.6 years, and therefore ETC Participants may not be able to receive credit for a transplant that results from getting a beneficiary on the transplant waitlist given the Model's duration. A commenter recommended that we delay the inclusion of the transplant rate in the calculation of the PPA until there are system-wide improvements in the availability of organs for transplant, the transplant rate is redesigned to enhance patient protections, and the Model explicitly accounts for regional variation in transplant rates. Several commenters recommended that CMS use transplant waitlisting instead of actual transplant rates in calculating the PPA, noting that ESRD facilities and Managing Clinicians have influence over waitlisting rates, but not over the actual transplant rates. Some commenters suggested that CMS simply eliminate the transplant rate from the PPA calculation. Some commenters suggested that though organ supply is outside of the control of ESRD facilities and managing clinicians, there are other aspects of the process that can and should be in their control such as how they educate patients and families about living donation and how effectively they interact with transplant centers. They remarked that there is an opportunity for ESRD facilities and managing clinicians to increase care coordination and patient education with respect to living donor transplantation. A commenter expressed concern about the calculation of the MPS, asserting that the proposed home dialysis rate and transplant rate calculations, risk adjustments, reliability adjustments, and comparison benchmarks seem complex and would make it difficult for ETC Participants to monitor, gauge, and ultimately improve performance.

Response: We thank the commenters for their feedback. CMS believes that using a performance measure related to transplants to determine, in part, an ETC Participant's PPA is vital to incent meaningful behavior change. While CMS does recognize that ETC Participants, as ESRD facilities and Managing Clinicians, do not have control over every step of the transplant process, CMS continues to believe it is appropriate to include a transplant

component in the MPS calculation used to determine the PPA. As the health care providers that ESRD beneficiaries see most frequently, ETC Participants play a pivotal role in the transplant process, including: Educating beneficiaries about their transplant options, including living donation; helping beneficiaries navigate the transplant process, including helping beneficiaries understand the process; providing referrals for care necessary to meet clinical transplant requirements, and referrals for transplant waitlisting; and coordinating care during the transplant process.

Based on feedback from commenters, however, CMS is drawing a distinction between living donor transplants, which are not subject to the same supply constraints brought up by commenters, and deceased donor transplants, which currently have a more limited supply. For the living donation process, CMS recognizes the important role that ETC Participants have in helping inform and support their patients in the living donor process, and will therefore retain the living donor transplant rate in the transplant rate calculation.

In contrast, CMS recognizes that the current process for deceased donor organ allocation and the current shortage of available deceased donor kidneys makes it difficult to hold ETC Participants accountable for the rate of deceased donor kidney transplants at this time. The proposed rule calculated the transplant rate by adding together all transplants, including pre-emptive transplants. However, based on feedback from commenters the rate of deceased donor transplants will not be a part of the transplant rate calculation. The transplant rate will still include living donor transplants, including preemptive transplants, but we replaced the deceased donor transplants in the transplant rate calculation with the transplant waitlist rate because CMS also recognizes that ESRD facilities and Managing Clinicians play an essential role in supporting beneficiaries in selecting transplantation and referring beneficiaries to a transplant waitlist, and are well-positioned to work with OPOs and transplant centers to further increase transplant waitlisting. The ETC Model is designed in part to encourage health care providers to form these relationships. The ETC Learning Collaborative, described in section IV.C.13 of this final rule, is designed to facilitate these relationships as part of the dissemination of best practices to increase organ recovery and utilization. We therefore agree with commenters that it is appropriate to hold ETC Participants accountable for transplant waitlisting while implementing other policies to increase the supply of available deceased donor kidneys. These modifications to the transplant component of the MPS calculation is further discussed in section IV.C.5.c.(2) of this final rule.

CMS recognizes that 88.5% of all deceased donor kidney transplants occurred among patients who had been on the waitlist for less than five years. Given that the ETC Model will last over 5 years, the average Medicare beneficiary placed on a waitlist in the first year is expected to receive a transplant by the end of the Model. Accordingly, CMS may consider incorporating a transplant rate into the PPA calculation for later years of the Model through subsequent rulemaking.

Comment: Commenters expressed a desire for other stakeholders like OPOs to also be held financially accountable for transplant rates under the Model if CMS is going to proceed with holding ETC Participants financially accountable for actual transplants. One such commenter expressed concern that ETC Participants may be unfairly disadvantaged if a transplant program does not put higher risk patients referred by the ETC Participant on the transplant waitlist that other transplant programs might accept.

Response: As discussed in response to the preceding comment and as described in section IV.C.5.d of this final rule, we will not be holding ETC Participants accountable for deceased donor transplants under the ETC Model. Rather, we will use a transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate for purposes of the transplant component of the MPS. Regarding the concern that ETC Participants may be unfairly disadvantaged if a transplant program does not put higher risk patients referred by ETC Participants on the transplant waitlist that other transplant programs might accept, CMS acknowledges that transplant programs have different criteria for accepting patients on transplant waitlists. ETC Participants can work with transplant programs in their respective communities to encourage the acceptance of a particular ESRD Beneficiary on the waitlist. ETC Participants could also recommend that their patients register with a particular transplant program that accepts patients with their levels of risk. ETC Participants can also support ESRD Beneficiaries pursuing living donor transplants by educating beneficiaries about their transplant options, including living donation; helping beneficiaries navigate the transplant process, including helping beneficiaries understand the process; providing referrals for care necessary to meet clinical transplant requirements, and referrals for transplant waitlisting; and coordinating care during the transplant process.

Comment: Some commenters recommended that CMS create a blended home dialysis-transplant measure for determining an ETC Participant's PPA. For example, one commenter suggested using a composite endpoint, where home dialysis and transplantation are measured in one rate, rather than two separate rates, using the same numerator and denominator. Another commenter suggested including an appropriate patient acuity measure and measures that assess social determinants of health and unmet social needs in calculating the home dialysis and transplant rates and issuing the PPA.

Response: We appreciate the commenter's suggestion that we create a blended home dialysis and transplant rate to determine an ETC Participant's PPA and recognize that some ETC Participants may excel at supporting beneficiaries in selecting one alternative to in-center HD and not the other. However, we believe it is important that ESRD Beneficiaries receive the support they need to select either home dialysis or transplantation, regardless of the ETC Participant from which they receive dialysis care. As such, we believe it is important to assess ETC Participant performance on the home dialysis rate and transplant rate separately, rather than using a blended approach.

Comment: A commenter recommended that CMS provide an increased payment to dialysis providers for transplants as part of the ETC Model, similar to the transplant bonus payment in the KCC Model.

Response: CMS disagrees with the commenter's suggestion to provide ETC Participants with a bonus payment for transplants, as ETC Participants can receive such a bonus by participating concurrently in the KCC Model.

Comment: A commenter suggested that CMS adjust payment to ESRD facilities using performance data on quality measures that facilities have publicly reported for a period of time because that would allow stakeholders to assess the reliability and validity of the measures, as well as the proposed scoring methodology, and to identify any potential unintended consequences that may be occurring.

Response: CMS disagrees with the comment regarding deriving performance-based quality adjustments

for ESRD facilities under the ETC Model from previously publicly reported measures. CMS understands the commenter's assertion that measures that have been in use for some time and have been publicly reported demonstrate reliability, validity, and transparency to stakeholders. However, the home dialysis rate and transplant rate used in the ETC Model are part of the model test, and have been constructed solely for the purposes of the model test. For the purposes of testing this Model, we do not believe that it is necessary for these rates to have been publicly reported in advance of the Model. As described in section IV.C.10 of this final rule, we will monitor for unintended consequences and make modifications to the Model, including the home dialysis rate and transplant rate, if necessary, through subsequent rulemaking.

Comment: Many commenters recommended that CMS use validated measures that are endorsed by the National Quality Forum (NQF).

Response: We appreciate the feedback from commenters that CMS should use NQF-endorsed measures to measure ETC Participant performance under the Model. We note that, at present, there are no NQF-endorsed measures for rates of home dialysis, kidney transplants, or inclusion on the kidney transplant waitlist. However, we believe that it is appropriate to use the rates constructed specifically for the purposes of this Model, as our intent is to measure the impact of the Model's payment adjustments on the rates of home dialysis and transplants. Given the tailored nature of the home dialysis and transplant rates and the lack of extant alternatives, we believe it is appropriate to use these rates for this Model.

Comment: A commenter recommended that CMS add shared decision-making measures (that is, measures demonstrating that a patient and clinician made treatment decisions together based on what is best for the patient), such as the Decision Conflict Scale or those shared decision-making measures in NQF's *National Quality Partners Playbook™ Shared Decision Making in Healthcare*. The same commenter noted that the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey for In-Center Hemodialysis (ICH CAHPS) [150] includes questions related to home modality options and transplantation, but does not include shared-decision making questions and is limited to beneficiaries using in-center dialysis. The same commenter therefore also suggested using decision-making tools for the ESRD population, such as the Empowering Patients on Choices for Renal Replacement Therapy (EPOCH). Some commenters offered to work with CMS to construct a shared-decision making measure to supplement the proposed home dialysis rate and transplant rate to assess the performance of ETC Participants under the Model and would also protect a beneficiary's choice and patient protections.

Response: CMS appreciates the feedback to include measures of shared decision making so that beneficiaries have a choice in dialysis treatment modality. CMS believes that the informational material required to be posted in the facility, described in § 512.330(a), addresses the need for beneficiaries to be educated about the Model and the beneficiary protections described in section II of this final rule adequately protect beneficiaries' freedom of choice. While education regarding treatment modality is important, CMS will not adopt this recommendation as it does not fit with the Model's goals of adjusting payments in order to improve or maintain quality while reducing costs through increased rates of home dialysis use, ultimately, and kidney transplants.

Comment: A commenter recommended that CMS define a pathway of supportive care services and allow beneficiaries enrolled in the pathway be included in calculation of the proposed home dialysis rate and transplant rate. According to the commenter, supportive care services include medical management, defined as planned, holistic, person-centered care such as interventions to delay progression of kidney disease and minimize risk of adverse events or complications; shared decision making; active symptom management; detailed communication including advance care planning; psychological support; as well as social and family support. The same commenter similarly recommended that CMS explicitly acknowledge, in the final rule, the need for supportive care services for seriously ill beneficiaries with CKD Stage IV, CKD Stage V, and ESRD.

Response: We agree with the commenter that supportive care services are important for seriously ill beneficiaries with CKD Stage IV, CKD Stage V, and ESRD. CMS also appreciates the commenter's recommendation that CMS define a pathway of supportive care services and allow beneficiaries enrolled in such pathway to count toward the calculation of the home dialysis and transplant rates. However, this Model is designed to improve or maintain quality while decreasing costs by creating incentives for Managing Clinicians and ESRD facilities to increase rates of home dialysis and transplants. We believe that the proposed rates, with the modifications described elsewhere in this final rule, best accomplish this goal. Further, to the extent that supportive care services result in beneficiaries initiating home dialysis, receiving a living donor transplant, or being included on the kidney transplant waitlist, their use will be indirectly counted towards the calculation of the home dialysis rate or the transplant rate, respectively.

Comment: A commenter recommended that CMS include kidney transplants with any other organ, and not just with pancreas.

Response: We appreciate the commenter's feedback. We are clarifying that, in referring to a kidney transplant in the proposed rule, we intended to refer to kidney transplants alone or in conjunction with any other organ transplant. By referring to both kidney transplants and kidney-pancreas transplants, our intent was not to exclude kidney transplants in conjunction with organs other than the pancreas. Accordingly, we are defining the term ''kidney transplant'' in our regulations at § 512.310 to mean the a kidney transplant, alone or in conjunction with any other organ. Accordingly, the transplant waitlist rate calculation included in the transplant rate will include ESRD Beneficiaries listed on a waitlist for any kind of kidney transplant, and the living donor transplant rate calculation included in the transplant rate will include beneficiaries who receive any kind of kidney transplant from a living donor.

Comment: A commenter expressed concern about a proposed measure in ESRD QIP—the Percentage of Prevalent Patients Waitlisted Measure—that, if finalized, may subject an ETC Participant to a second source of negative payment adjustment.

Response: We note that CMS finalized the adoption of the PPPW measure in the CY 2019 ESRD PPS final rule (83 FR 57008). We appreciate the commenter's concern that ESRD facilities that are ETC Participants will receive more than one payment adjustment based on transplant waitlisting. However, we believe that the adjustments under the ESRD QIP and the ETC Model are sufficiently different, in construction, payment adjustment scope and magnitude, and purpose, to support the overlap.

[150] CAHPS® is a registered trademark of the Agency for Health Research and Quality, U.S. Department of Health and Human Services.

After considering public comments, we are finalizing our general proposals for the Performance Payment Adjustment, with certain modifications. Specific provisions and modifications are described in the following sections of this final rule. We received no public comment on our proposed definitions of the Performance Payment Adjustment (PPA), Facility Performance Payment Adjustment (Facility PPA), or Clinician Performance Payment Adjustment (Clinician PPA). As such, we are finalizing these definitions in our regulation at § 512.310 as proposed. We received no public comment on our proposed definition of the Modality Performance Score (MPS), and are finalizing this definition in our regulation at § 512.310 with modification to correct an error in an internal cross-reference. Specifically, the proposed definition of MPS referred to § 512.310(a) of our regulations, but we had meant to refer to the MPS calculation in § 512.310(d). We are adding a definition for ''kidney transplant waitlist'' to our regulations at § 512.310, for the reasons described in section IV.C.5.c(2) of this final rule.

a. Annual Schedule of Performance Assessment and PPA

We proposed to assess ETC Participant performance on the home dialysis rate and the transplant rate, described in the proposed rule and in sections IV.C.5.c.1 and IV.C.5.c.2, respectively, of this final rule, and to make corresponding payment adjustments according to the proposed schedule described later. We proposed in § 512.355(a) that we would assess the home dialysis rate and transplant rate for each ETC Participant during each of the Measurement Years, which would include 12 months of performance data. For the ETC Model, we proposed to define ''Measurement Year (MY)'' as the 12-month period for which achievement and improvement on the home dialysis rate and transplant rate are assessed for the purpose of calculating the ETC Participant's MPS and corresponding PPA. Further, we proposed in § 512.355(b) that we would adjust payments for ETC Participants by the PPA during each of the PPA periods, each of which would correspond to a Measurement Year. We proposed to define ''Performance Payment Adjustment Period (PPA Period)'' as the 6-month period during which a PPA is applied pursuant to § 512.380 (PPA Amounts and Schedule). Each MY included in the ETC Model and its corresponding PPA Period would be specified in § 512.355(c) (Measurement Years and Performance Payment Adjustment Periods).

Under our proposal, each MY would overlap with the subsequent MY, if any, for a period of 6 months, as ETC Participant performance would be assessed and payment adjustments would be updated by CMS on a rolling basis. As we noted in the proposed rule, we believe that this method of making rolling performance assessments balances two important factors: The need for sufficient data to produce reliable estimates of performance, and the effectiveness of incentives that are proximate to the period for which performance is assessed. Beginning with MY2, there would be a 6-month period of overlap between a MY and the previous MY. For example, MY1 would begin January 1, 2020, and would run through December 31, 2020; and MY2 would begin 6 months later, running from July 1, 2020, through June 30, 2021. Each MY would have a corresponding PPA Period, which would begin 6 months after the conclusion of the MY.

Table 12, we proposed the following schedule of MYs and PPA Periods:

TABLE 12: PROPOSED ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS

	Measurement Year (MY)		Performance Payment Adjustment (PPA) Period	
Beginning CY 2020	MY1	1/1/2020 through 12/31/2020	PPA Period 1	7/1/2021 through 12/31/2021
	MY2	7/1/2020 through 6/30/2021	PPA Period 2	1/1/2022 through 6/30/2022
Beginning CY 2021	MY3	1/1/2021 through 12/31/2021	PPA Period 3	7/1/2022 through 12/31/2022
	MY4	7/1/2021 through 6/30/2022	PPA Period 4	1/1/2023 through 6/30/2023
Beginning CY 2022	MY5	1/1/2022 through 12/31/2022	PPA Period 5	7/1/2023 through 12/31/2023
	MY6	7/1/2022 through 6/30/2023	PPA Period 6	1/1/2024 through 6/30/2024
Beginning CY 2023	MY7	1/1/2023 through 12/31/2023	PPA Period 7	7/1/2024 through 12/31/2024
	MY8	7/1/2023 through 6/30/2024	PPA Period 8	1/1/2025 through 6/30/2025
Beginning CY 2024	MY9	1/1/2024 through 12/31/2024	PPA Period 9	7/1/2025 through 12/31/2025
	MY10	7/1/2024 through 6/30/2025	PPA Period 10	1/1/2026 through 6/30/2026

We received no public comment on our proposed schedule of performance assessment and PPA. We are finalizing the proposed provisions with modification to reflect the start date of the model, January 1, 2021, as described elsewhere in this final rule. Specifically, we are codifying at § 512.355 that the PPA will be applied based on the schedule of MYs and PPA Periods in Table 12.a, to accommodate the start date for the payment adjustments under the ETC Model finalized in our regulations at § 512.320. As such, we are finalizing the definition of MY as the 12-month period for which achievement and improvement on the home dialysis rate and transplant rate are assessed for the purpose of calculating the ETC Participant's MPS and corresponding PPA. Each MY included in the ETC Model and its corresponding PPA Period are specified in § 512.355(c). We are finalizing the definition of Performance Payment Adjustment Period (PPA Period), as proposed.

TABLE 12.a: ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS

	Measurement Year (MY)	Performance Payment Adjustment (PPA) Period
Beginning CY 2021	MY 1 – 1/1/2021 through 12/31/2021	PPA Period 1 – 7/1/2022 through 12/31/2022
	MY 2 – 7/1/2021 through 6/30/2022	PPA Period 2 – 1/1/2023 through 6/30/2023
Beginning CY 2022	MY 3 – 1/1/2022 through 12/31/2022	PPA Period 3 – 7/1/2023 through 12/31/2023
	MY 4 – 7/1/2022 through 6/30/2023	PPA Period 4 – 1/1/2024 through 6/30/2024
Beginning CY 2023	MY 5 – 1/1/2023 through 12/31/2023	PPA Period 5 – 7/1/2024 through 12/31/2024
	MY 6 – 7/1/2023 through 6/30/2024	PPA Period 6 – 1/1/2025 through 6/30/2025
Beginning CY 2024	MY 7 – 1/1/2024 through 12/31/2024	PPA Period 7 – 7/1/2025 through 12/31/2025
	MY 8 – 7/1/2024 through 6/30/2025	PPA Period 8 – 1/1/2026 through 6/30/2026
Beginning CY 2025	MY 9 – 1/1/2025 through 12/31/2025	PPA Period 9 – 7/1/2026 through 12/31/2026
	MY 10 – 7/1/2025 through 6/30/2026	PPA Period 10 – 1/1/2027 through 6/30/2027

b. Beneficiary Population and Attribution

We proposed that, in order to assess the home dialysis rate and transplant rate for ETC Participants, ESRD Beneficiaries would be attributed to participating ESRD facilities and to participating Managing Clinicians. For purposes of the ETC Model, we proposed to define ''ESRD Beneficiary'' as a beneficiary receiving dialysis or other services for end-stage renal disease, up to and including the month in which he or she receives a kidney or kidney-pancreas transplant. As we noted in the proposed rule, this would include beneficiaries who are on dialysis for treatment of ESRD, as well as beneficiaries who were on dialysis for treatment of ESRD and received a kidney or kidney-pancreas transplant up to and including the month in which they received their transplant.

Also, we proposed to attribute pre-emptive transplant beneficiaries to Managing Clinicians for purposes of calculating the transplant rate, specifically. We proposed to define a ''pre-emptive transplant beneficiary'' as a Medicare beneficiary who received a kidney or kidney-pancreas transplant prior to beginning dialysis. We stated that this definition would be mutually exclusive of the proposed definition of an ESRD Beneficiary, as a pre-emptive transplant beneficiary receives a kidney or kidney-pancreas transplant prior to initiating dialysis and therefore is not an ESRD Beneficiary. In the proposed rule, we considered defining this concept as pre-emptive transplant recipients, as there are patients who receive pre-emptive transplants who are not Medicare beneficiaries, but who would have become eligible for Medicare if they did not receive a pre-emptive transplant and progressed to ESRD, requiring dialysis. We noted that this definition would more accurately reflect the total number of transplants occurring in the population of patients who could receive pre-emptive transplants, and including these additional patients who receive pre-emptive transplants in the calculation of the transplant rate could better incentivize Managing Clinicians to support kidney transplants via the Clinician PPA. Due to data limitations about patients who are not Medicare beneficiaries, however, we concluded that we could not include patients who received pre-emptive transplants but were not Medicare beneficiaries in the construction of the transplant rate. Therefore, we proposed to limit the definition of pre-emptive transplant beneficiary to include Medicare beneficiaries only.

We proposed to attribute ESRD Beneficiaries and pre-emptive transplant beneficiaries, where applicable, to ETC Participants for each month of each MY, and we further proposed that such attribution would be made after the end of each MY. In the proposed rule, we considered attributing beneficiaries to participating ESRD facilities and Managing Clinicians for the entire MY; however, as noted in the proposed rule, we believe monthly attribution would more accurately capture the care relationship between beneficiaries and their ESRD providers and suppliers. As ETC Participant

behavior and care relationships with beneficiaries may change as a result of the ETC Model, we stated in the proposed rule that we believe that the level of precision associated with monthly attribution of beneficiaries would better support the ETC Model's design. Under our proposal, an ESRD Beneficiary may be attributed to multiple ESRD facilities and Managing Clinicians in one MY, but would be attributed to only one ESRD facility and one Managing Clinician for a given month during the MY. As we stated in the proposed rule, we believe that conducting attribution retrospectively, after the completion of the MY, would better align with the design of the PPA in the ETC Model. We invited public comment on the proposal to attribute beneficiaries on a monthly basis after the end of the relevant MY.

In the proposed rule, we considered conducting attribution prospectively, before the beginning of the MY. However, we concluded that prospective attribution would not be appropriate given the nature of ESRD and the ESRD Beneficiary population. CKD is a progressive illness, with patients moving from late stage CKD to ESRD—requiring dialysis or a transplant—throughout the course of the year. As noted in the proposed rule, we therefore believe prospective attribution would functionally exclude incident beneficiaries new to dialysis from inclusion in the home dialysis and transplant rates of ETC Participants until the following MY. Additionally, we stated our belief that prospective attribution would not work well for the particular design of this Model. In particular, we noted in the proposed rule that, because the PPA would be determined based on home dialysis and transplant rates during the MY, limiting attribution to beneficiaries with whom the ETC Participant had a care relationship prior to the MY would not accurately capture what occurred during the MY. As we stated in the proposed rule, we believe that conducting attribution retrospectively, after the completion of the MY, would better align with the design of the PPA in the ETC Model. We invited public comment on the proposal to attribute beneficiaries on a monthly basis after the end of the relevant MY.

We proposed to provide ETC Participants lists of their attributed beneficiaries after attribution has occurred, after the end of the MY. In the proposed rule, we considered providing lists in advance of the MY, or on a more frequent basis. However, we determined that, since we would be conducting attribution after the conclusion of the MY, prospective lists of attributed beneficiaries that attempted to simulate which beneficiaries would be attributed to a participant during the MY would be potentially misleading. Additionally, we noted in the proposed rule that, as the calculation of the home dialysis rate and transplant rate among attributed beneficiaries would be conducted only once every 6 months due to overlapping MYs, we believe providing lists after the MY would provide ETC Participants sufficient information about their attributed beneficiary populations to understand the basis of their rates of home dialysis and transplants.

The following is a summary of the comments received on beneficiary attribution and our responses.

Comment: A commenter agreed that using retrospective attribution is an appropriate approach for beneficiary attribution in a fee for service model. Another commenter agreed with using pre-emptive transplantation for beneficiary attribution.

Response: We thank the commenters for their feedback and support. CMS will use retrospective beneficiary attribution as proposed. However, as described elsewhere in this final rule, we will use the transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate, rather than the transplant rate as proposed, to assess ETC Participant performance under the Model. Because the living donor transplant rate calculation will include only pre-emptive transplants from living donors, rather than all pre-emptive transplants, we will only attribute beneficiaries who received pre-emptive transplants from living donors prior to beginning dialysis (defined as pre-emptive living donor transplant (LDT) beneficiaries) to Managing Clinicians.

After considering public comments, we are finalizing our proposed provisions on beneficiary attribution, with modification. Specifically, we are codifying in our regulations at § 512.360(a) that CMS will attribute ESRD Beneficiaries to ETC Participants for each month of each MY for the purposes of assessing an ETC Participant's performance on the home dialysis rate and transplant rate during that MY. We also are codifying in our regulations at § 512.360(a) that an ESRD Beneficiary can be attributed to only one ESRD facility and only one Managing Clinician for a given month during a given MY, and that attribution takes place at the end of the MY. We are codifying in our regulations at § 512.310 the definition of ESRD Beneficiary as proposed, with modification to clarify that a beneficiary who has received a transplant will be considered to be an ESRD Beneficiary if the beneficiary either has a non-AKI dialysis or MCP claim at least 12 months after the beneficiary's latest transplant date, or has a non-AKI dialysis or MCP claim less than 12 months after the beneficiary's latest transplant date and has a kidney transplant failure diagnosis code documented in any Medicare claim. We are making this clarification because, while beneficiaries are excluded from the ESRD Beneficiary definition beginning the month after the beneficiary receives a kidney transplant, it was our intent that any beneficiary receiving dialysis or other services for ESRD would be considered an ESRD Beneficiary, subject to the exclusions described elsewhere in this final rule. As modified, this definition makes clear that beneficiaries who have already received a kidney transplant in the past will be eligible for attribution to ETC Participants once they restart dialysis or other services for ESRD.

We are modifying several beneficiary attribution provisions in order to address the modification to the transplant rate to include the transplant waitlist rate and the living donor transplant rate, as described in section IV.C.5 of this final rule. We are finalizing the definition of ''living donor transplant (LDT) Beneficiary'' as an ESRD Beneficiary who received a kidney transplant from a living donor. We are also replacing the term ''Pre-emptive transplant beneficiary'' with the term ''Pre-emptive LDT Beneficiary,'' which we define a beneficiary who received a kidney transplant from a living donor prior to beginning dialysis. We are modifying the attribution of pre-emptive transplant beneficiaries to Managing Clinicians in § 512.360(a), to apply solely to Pre-emptive LDT Beneficiaries and solely for purposes of assessing the Managing Clinician's performance on the living donor transplant rate, in accordance to the change from the proposed transplant rate to a transplant rate that includes the living donor transplant rate described elsewhere in this final rule.

(1) Beneficiary Exclusions

We proposed to exclude certain categories of beneficiaries from attribution to ETC Participants, consistent with other CMS models and programs for purposes of calculating the PPA. Specifically, we proposed to exclude an ESRD Beneficiary or a pre-emptive transplant beneficiary if, at any point during the month, the beneficiary:

- Is not enrolled in Medicare Part B, because Medicare Part B pays for the majority of ESRD-related items and

services, for which Part B claims are necessary for evaluation of the Model.

- Is enrolled in Medicare Advantage, a cost plan, or other Medicare managed care plans, because these plans have different payment structures than Medicare Parts A and B and do not use FFS billing.
- Does not reside in the United States, because it is more difficult to track and assess the care furnished to beneficiaries who might have received care outside of the U.S.
- Is younger than age 18 at any point in the month, because beneficiaries under age 18 are more likely to have ESRD from rare medical conditions that have different needs and costs associated with them than the typical ESRD Beneficiary.
- Has elected hospice, because hospice care generally indicates cessation of dialysis treatment and curative care.
- Is receiving any dialysis for acute kidney injury (AKI) because renal dialysis services for AKI differ in care and costs from a typical ESRD Beneficiary who is not receiving care for AKI. AKI is usually a temporary loss of kidney function. If the kidney injury becomes permanent, such that the beneficiary is undergoing maintenance dialysis, then the beneficiary would be eligible for attribution.
- Has a diagnosis of dementia because conducting dialysis at home may present an undue challenge for beneficiaries with dementia, and such beneficiaries also may not prove to be appropriate candidates for transplant.

In the proposed rule, we considered excluding beneficiaries from attribution for the purposes of calculating the home dialysis rate whose advanced age (for example, ages 70 and older) could make home dialysis inappropriate; however, we did not ascertain a consensus in the literature that supported any specific age cut-off. In the proposed rule, we also considered excluding beneficiaries with housing insecurity from attribution for the purposes of calculating the home dialysis rate, but did not find an objective way to measure housing instability.

The following is a summary of the comments received on beneficiary exclusions from attribution to ETC Participants and our responses.

Comment: Some commenters suggested that CMS not exclude any categories of beneficiaries from attribution to ETC Participants under the Model, allowing the Model to be as inclusive as possible to beneficiaries, despite the beneficiaries' medical conditions or age. A commenter stated that, after searching peer-reviewed literature and clinical guidelines, the commenter did not find obvious exclusion criteria for home dialysis patients. Another commenter suggested that if a beneficiary is able to receive a transplant or dialyze at home, despite being on the exclusion list, CMS should still include that beneficiary in the numerator and denominator for the ETC Participant, in order to give the ETC Participant credit for all transplants and home dialysis treatments.

Response: CMS appreciates this feedback regarding our proposed beneficiary exclusion criteria under the Model. Like one of the commenters noted, the literature and clinical guidelines do not have clear exclusions for home dialysis beneficiaries. However, our proposed exclusions were intended to exclude from attribution to ETC Participants those categories of beneficiaries more likely to be inappropriate candidates for home dialysis and/or transplant in order to track Managing Clinicians' and ESRD facilities' ability to provide appropriate care to patients who can, in fact, safely have the opportunity to receive a kidney transplant or home dialysis. Although an otherwise excluded beneficiary that receives home dialysis, receives a LDT, or is placed on the transplant waitlist could be placed in the numerator and the denominator, in aggregate, we believe that these exclusions are appropriate for the reasons described in the proposed rule and previously in this final rule and will apply them in attributing ESRD Beneficiaries to ETC Participants under the Model.

Comment: Commenters supported our proposal to exclude from attribution to ETC Participants those beneficiaries who are not enrolled in Medicare Part B or who do not reside in the United States. A commenter agreed with our proposed exclusion for patients enrolled in Medicare Advantage; however, one physician group suggested attributing beneficiaries with Medicare Advantage plans to ETC Participants in order to appropriately assess the risk pool for the ETC Model since ESRD Beneficiaries may begin enrolling in Medicare Advantage plans beginning in 2021.

Response: CMS appreciates the feedback and support. After considering the public comments, we are finalizing our proposal to exclude beneficiaries not enrolled in Medicare Part B, enrolled in Medicare Advantage or other managed plans, and those not residing in the United States from attribution to ETC Participants under the Model. With respect to the commenter's suggestion that CMS attribute Medicare Advantage beneficiaries to ETC Participants, the ETC Model is a Medicare FFS model and Medicare Advantage plans have different payment structures than Medicare Parts A and B and do not use FFS billing. Including these beneficiaries in the Model's financial calculations could create unintended consequences for ETC Participants and may complicate our evaluation of the Model.

Comment: Multiple commenters recommended that CMS exclude beneficiaries from attribution to ETC Participants based on factors such as socioeconomic status, homelessness, housing instability, lack of transportation, and lack of caregiver or social support. One of those commenters listed other International Classification of Diseases, 10th Revision (ICD–10) codes that address the issues of social determinations of health around housing economic insecurity, specifically ICD–10 codes Z59.1, Z59.7, Z59.8, and Z59.9. Another commenter suggested using the homelessness ICD–10 code Z59.0 for purposes of implementing exclusions specific to homelessness, though the commenter acknowledged that this code may be underutilized. Another commenter suggested excluding dual eligible beneficiaries from attribution to ETC Participants as this group generally represents a population with lower socioeconomic status.

Response: CMS agrees that housing insecurity, transportation issues, and other social determinants of health affect patient choice of renal replacement modality. We also appreciate the few comments mentioning the ICD–10 codes that could be used to identify homelessness and other social determinants of health. However, we also agree with the commenter who stated that the homelessness ICD–10 code Z59.0 is underutilized, and we believe that adopting an exclusion for homelessness based on this code could be subject to gaming, such that this code would not be an objective measure for housing insecurity. CMS also believes that the other codes of Z59.1, Z59.7, Z59.8, and Z59.9 could be subject to gaming. Accordingly, we are not adopting the commenters' suggestions to use these codes for purposes of the Model. However, CMS will assess the use of these and other codes for purposes of adding any additional beneficiary exclusions from attribution to ETC Participants based on socioeconomic status, homelessness, or other social determinants of health through future rulemaking.

Comment: Several commenters appreciated our proposal to exclude pediatric ESRD Beneficiaries from

attribution to ETC Participants due to the unique medical needs of this population. A commenter expressed concern about of the lack of quality measures for this small population of patients and suggested implementing different pediatric payment reimbursements for traditional Medicare payment for the pediatric renal beneficiaries.

Response: CMS acknowledges the importance of kidney health in the pediatric population, including the need for quality measures specific to this population, and believe that other HHS initiatives outside of the ETC Model, such as Kidney X and the broader Advancing American Kidney Health Initiative, may address this need. Comments related to provider reimbursement in the Medicare program generally are outside the scope of this final rule.

Comment: Several commenters supported excluding beneficiaries from attribution to ETC Participants due to old age. These commenters suggested excluding beneficiaries over the ages of 65, 70, or 75 from the calculation of either the transplant rate, home dialysis rate, or both, since these patients often do not receive a kidney transplant or have limited access to the caregiver support required for home dialysis. A few commenters recommended that CMS not exclude beneficiaries from attribution to ETC Participants due to age, particularly due to the aging population, and instead stressed the importance of other factors to determine a beneficiary's exclusion under the Model, such as functional status and clinical contradictions for home dialysis and kidney transplantation in order to align with a beneficiary's treatment choice and suitable care.

Response: CMS appreciates the comments on possible beneficiary exclusions due to age but notes that there is no objective scientific evidence to tie old age to incompatibility with home dialysis. Moreover, we believe an age restriction would undermine the Model's focus on providing beneficiaries the opportunity to select home dialysis. Therefore, CMS will not restrict beneficiary attribution due to age. However, as described in section § 512.365(c) of this final rule, we are finalizing our proposal to exclude beneficiaries over the age of 75 from the numerator and the denominator of the transplant rate calculation since these patients usually are not candidates for transplants.

Additionally, we decline to adopt the commenters' recommendations that CMS establish exclusions based on functional status and clinical contraindications because clinical guidelines for home dialysis or transplant beneficiaries do not have such exclusions. Moreover, the beneficiary attribution exclusions finalized in our regulations at § 512.360(b) are intended to address common contraindications for home dialysis and kidney transplant while allowing the maximum number of beneficiaries to benefit from the opportunity to select the renal replacement modality of their choice.

Comment: Several commenters supported our proposal to exclude beneficiaries with AKI from attribution to ETC Participants. A commenter requested clarification on how an AKI diagnosis in one month will affect the application of this exclusion for subsequent months for attribution to ETC Participants.

Response: We thank the commenters for their feedback and support and clarify that receipt of dialysis services for an AKI diagnosis in one month makes a beneficiary ineligible for attribution to an ETC Participant for that month, but if the AKI does not resolve and/or transitions to ESRD, the beneficiary will become eligible for attribution in a subsequent month. CMS acknowledges that patient health status may change over time.

Comment: Many commenters identified possible additional beneficiary exclusions due to clinical contradictions that prevent patients from meeting the clinical criteria for home dialysis or transplant. Examples included: Severe diabetic neuropathy or congestive heart failure, recent vascular disease, significant physical disability (Karnofsky Score <40 percent), cardiomyopathy with EF<20 percent, severe pulmonary or cardiovascular issues, cirrhosis, documented recent cardiac surgery, severe morbid obesity (BMI>50), documented status that a patient is unsuitable for a transplant or home dialysis, active infection, medication non-compliance, uncontrolled psychiatric illness or substance abuse, or blindness. Several commenters also recommended certain exclusion criteria specific to home dialysis, including: Recent abdominal surgery, abdominal abscess, peritoneal scarring or failed PD attempts, blindness or impaired vision, irritable bowel syndrome, and diabetic gastroparesis. If these beneficiaries are not excluded from attribution, commenters urged CMS to include these more seriously ill populations in the risk adjustment and PPA in order appropriately compare group benchmarks, align beneficiaries, and provide the ideal care in the ideal setting for these beneficiaries.

Response: CMS appreciates the suggestions from commenters regarding clinical contradictions for home dialysis and kidney transplantation. CMS has responded to comments and concerns related to risk adjustment for seriously ill populations in section IV.C.5.d (*Benchmarking and scoring*) and section IV.C.5.c.(3) (*Risk Adjustment*) of this final rule. CMS believes the beneficiary exclusions in proposed § 512.360(b), with the modifications described elsewhere in this final rule, address common clinical contraindications for home dialysis and kidney transplantation. AKI involves short term use of dialysis, making home dialysis impractical and transplant unnecessary, and as such, the AKI exclusion exists because the Model tests incentives specific to chronic dialysis services. Beneficiaries diagnosed with dementia or who reside in or receive dialysis in a skilled nursing facility (SNF) or nursing facility may not be suitable candidates for both home dialysis or transplantation. The exclusions still provide suitable incentives for ETC Participants to support the greatest number of ESRD Beneficiaries in receiving home dialysis or being added to the kidney transplant waitlist with the ultimate goal of receiving a kidney transplant. We also note that many of the clinical contraindications suggested by commenters for home dialysis are in fact potential contraindications for PD, and are not contraindications for HHD. Adding a large number of beneficiary exclusion criteria would run counter to the Model's focus on increasing the utilization of home dialysis and transplants for ESRD Beneficiaries, and adopting exclusions based on documentation of clinical condition could be subject to gaming.

Comment: Multiple commenters recommended that CMS exclude from attribution to ETC Participants those beneficiaries with cancer, including those diagnosed with recent solid organ malignancy and patients currently receiving related treatment, as cancer is a contraindication for transplantation candidacy and may result in variable dialysis use, in which a beneficiary's ESRD treatment modality may change frequently based on adjustments in cancer treatment such as chemotherapy timing and dosage. Some commenters stated that home dialysis may be inappropriate for beneficiaries with cancer due to complex needs, need for a caregiver, and challenging care coordination and thus these patients often prefer receiving dialysis in the same setting, suggesting that these patients may prefer in-center dialysis.

Response: CMS appreciates the suggestion to exclude beneficiaries with a diagnosis of cancer and acknowledges commenters' concerns of treatment appropriateness. While CMS understands the burden of cancer for both caregivers and beneficiaries, this exclusion would not advance the Model test because it would not result in the greatest number of ESRD Beneficiaries in receiving home dialysis or being added to the kidney transplant waitlist with the ultimate aim of receiving a kidney transplant. Moreover, there are no clear exclusion criteria for home dialysis for beneficiaries with any cancer diagnosis, and it is CMS's belief that these beneficiaries often are not automatically ineligible for transplantation. CMS would like to encourage ETC Participants to provide home dialysis and transplantation for as many beneficiaries that would benefit from these care modalities.

Comment: Multiple commenters supported our proposed exclusion of beneficiaries with a diagnosis of dementia. Some of these commenters who supported excluding beneficiaries with a diagnosis of dementia suggested modifying our proposal to nonetheless include beneficiaries with a diagnosis of mild dementia to allow health professionals to determine the appropriateness of home dialysis for the patient, especially for patients with access to assisted home dialysis programs.

Response: CMS appreciates the commenters' suggestion that CMS attribute beneficiaries with a diagnosis of mild dementia to ETC Participants in order to preserve clinical judgement. While CMS understands that beneficiaries with mild dementia may be covered by the exclusion criteria, and thus be excluded from attribution to ETC Participants, we clarify that in order to objectively identify patients with dementia, as described in greater detail later in this final rule, we will use the most current Hierarchical Condition Category (HCC) model codes that assess dementia, and note that there is no objective way to track dementia progression or deterioration. HCC dementia codes that specify ''without behavioral disturbance'' cannot objectively track progression of dementia.

Comment: Multiple commenters recommended that CMS exclude from attribution to ETC Participants those beneficiaries who reside in group homes or nursing homes, pointing out that SNFs construct an in-center dialysis facility inside the nursing facility and that once beneficiaries are discharged from the SNF, they most often transition back to in-center dialysis. A few commenters suggested altering the exclusion for beneficiaries by including beneficiaries diagnosed with dementia who reside in a SNF or are treated for AKI at a SNF, as SNFs provide a safer alternative than home dialysis for such beneficiaries needing dialysis.

Response: CMS appreciates the feedback recommending that CMS exclude from attribution to ETC Participants those beneficiaries residing in SNFs and nursing facilities. We share the commenters' concerns about dialysis provided in SNFs, particularly around the misalignment of dialysis utilization in SNFs and nursing facilities with the Model's focus on promoting beneficiary choice of treatment modality. In addition, CMS is concerned that the population of beneficiaries who reside in SNFs and nursing facilities is particularly frail, including beneficiaries diagnosed with dementia, and therefore may not be appropriate candidates for home dialysis. Accordingly, we believe that attributing these ESRD Beneficiaries to ETC Participants would not advance the Model goals of improving or maintaining quality while reducing cost by increasing home dialysis rates and transplant rates with the ultimate aim of receiving a kidney transplant. As such, CMS will exclude all beneficiaries residing in or receiving dialysis in a SNF or nursing facility from attribution to ETC Participants under the Model. We also recognize that some beneficiaries may benefit from the level of care in a SNF or nursing facility, such as beneficiaries with dementia. Dementia beneficiaries are excluded from the attribution to ETC Participants. Including beneficiaries residing in SNFs and nursing facilities does not align with the Model's goals of increase home dialysis in a beneficiaries' home.

Comment: A few commenters supported our proposed exclusion of beneficiaries who have elected hospice from attribution to ETC Participants since hospice care generally indicates cessation of dialysis treatment and dialysis care. A couple of commenters recommended not excluding beneficiaries who have elected hospice for purposes of calculating the home dialysis rate specifically, since PD is less costly than in-center HD and offers patients treatment options.

Response: We appreciate the feedback from commenters. While we appreciate the commenters' recommendation to include beneficiaries who have elected hospice in the Model's attribution methodology, we do not believe that doing so would offer more treatment choices to beneficiaries because in general, hospice care focuses on palliative care in a beneficiary's final phase of life rather than dialysis services. We agree with the commenters who suggested excluding beneficiaries who elect hospice since hospice care is by definition time limited and indicates that the beneficiary is close to the end of life.

Comment: A few commenters suggested excluding beneficiaries who choose palliative care for their renal care modality. One of these commenters suggested tracking these more seriously ill beneficiaries differently from the healthier ESRD population and rewarding medical management for these patients receiving any type of ESRD care, including those not utilizing dialysis and instead receiving palliative or hospice care.

Response: CMS appreciates the feedback to exclude beneficiaries choosing supportive care. CMS will exclude beneficiaries who have elected hospice; however, we believe rewarding medical management of hospice beneficiaries is outside the scope of the Model and addressed in other HHS and CMS initiatives, such as the Medicare Care Choices Model.

Comment: A commenter agreed with our proposals to attribute beneficiaries to ETC Participants on a monthly basis and not exclude beneficiaries with Medicare as a secondary payer from attribution. However, the commenter suggested that we provide beneficiary attribution data to ETC Participants on a more frequent basis.

Response: CMS appreciates the feedback and support. Beneficiary attribution will occur on a monthly basis. However, attribution will occur after the MY is over. Thus, while CMS will endeavor to provide attribution data to ETC Participants on a timely basis, these data will be provided only after the MY is over. CMS believes providing accurate beneficiary attribution data is vital to ETC participants. Because the MYs overlap, beneficiary attribution data for one MY will be available during the fourth quarter of the following MY, which will provide the most accurate information within a reasonable amount of time.

After considering public comments, we are finalizing our proposed provisions regarding the exclusion of certain categories of beneficiaries from attribution to ETC Participants with modification. CMS will use the claim service date for purposes of the general attribution criteria described in § 512.360. However, Managing Clinicians and ESRD Facilities utilize different billing requirements and forms. For consistency with these billing requirements and forms, CMS

will use the claim service date at the claim line through date to attribute beneficiaries to Managing Clinicians and will use the claim service date at the claim header through date to attribute beneficiaries to ESRD Facilities.

In addition, in this final rule, we are modifying our proposed exclusions from attribution for ESRD Beneficiaries with a diagnosis of dementia to clarify that such diagnosis must be made at any point during the month or the preceding 12 months, as identified using the most recent dementia criteria at the time of beneficiary attribution, defined using the dementia-related codes from the Hierarchical Condition Category (HCC) Risk Adjustment Model ICD–10–CM Mappings. We will use the HCC Risk Adjustment Model because it includes all objectively related dementia diagnosis codes. A 13-month lookback period, which includes the entire month in question plus the preceding 12 months lookback period for the dementia exclusion aligns with the periodicity with which the HCC Risk Adjustment Model codes are updated, and will ensure that CMS has sufficient data to identify a dementia diagnosis, while also ensuring that any such diagnoses are still relevant and current for the beneficiary. For reference, the 2020 Midyear Final ICD–10–CM Mappings are found at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/Risk2020.*

In addition, we are modifying our exclusion for beneficiaries younger than 18 years of age to state that a beneficiary will be excluded from attribution to an ETC Participant if he or she is younger than 18 years old before the first day of the month of the claim service date. We will identify the beneficiary's age on the first day of the month (rather than for the entire month), as it is easier for CMS to operationalize and has the same practical effect (that is, a beneficiary who is at least 18 years old before the first date of a month will be at least 18 years old for that entire month). In addition, because we will be assessing ETC Participant performance on the transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate in response to public comments, we have removed references to pre-emptive transplant beneficiaries from our regulation at § 512.360(b), and replaced them with references to Pre-emptive LDT Beneficiaries, where appropriate.

In sum, we are codifying in our regulation at § 512.360(b) that ESRD Beneficiaries that fall in the enumerated categories, with the modifications described, will be excluded from attribution to ETC Participants for a month for the purposes of calculating the transplant rate and home dialysis rate under the Model. In addition, based on public comments, we are also excluding beneficiaries from attribution for any month in which they receive dialysis in or reside in a SNF or nursing facility.

(2) Attribution Services

(a) Attribution to ESRD Facilities

We proposed that, to be attributed to an ESRD facility for a month, an ESRD Beneficiary must have received renal dialysis services, other than renal dialysis services for AKI, during the month from the ESRD facility. Because it is possible that a single ESRD Beneficiary receives dialysis treatment from more than one ESRD facility during a month, we further proposed that ESRD Beneficiaries would be attributed to an ESRD facility for a given month based on the ESRD facility at which the ESRD Beneficiary received the plurality of his or her dialysis treatments in that month. As we noted in the proposed rule, we believe the plurality rule would provide a sufficient standard for attribution because it ensures that ESRD Beneficiaries would be attributed to an ESRD facility when they receive more renal dialysis services from that ESRD facility than from any other ESRD facility. In the event that an ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month, we proposed that the ESRD Beneficiary would be attributed to the ESRD facility at which the beneficiary received the earliest dialysis treatment that month.

We proposed that we would identify dialysis claims as those with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, and that have a claim through date during the month for which attribution is being determined. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. Facility code 7 paired with type of care code 2 indicates that the claim occurred at a clinic or hospital based ESRD facility.

In the proposed rule we considered, in the alternative, attributing ESRD Beneficiaries to the ESRD facility at which they had their first dialysis treatment for which a claim was submitted in a given month. However, we determined that using the plurality of claims rather than earliest claim better identifies the ESRD facility that has the most substantial care relationship with the ESRD Beneficiary in question for the given month. For example, using the earliest claim approach could result in attributing a beneficiary that received dialysis treatments from Facility A once during a given month and dialysis treatments from Facility B at all other times during that month to Facility A, even though Facility B is the facility where the beneficiary received most of his or her dialysis treatments that month. As noted in the proposed rule, we would, however, plan to use the earliest date of service in the event that two or more ESRD facilities have furnished the same amount of services to a beneficiary because, as between two or more facilities that performed the same number of dialysis treatments for the beneficiary during a month, the facility that furnished services to the beneficiary first may have established the beneficiary's care plan and therefore is the one more likely to have the most significant treatment relationship with the beneficiary.

In the proposed rule we also considered using a minimum number of treatments at an ESRD facility for purposes of ESRD Beneficiary attribution. However, we determined that, because we are attributing ESRD Beneficiaries on a month-by-month basis, the plurality of treatments method would be more appropriate because it would result in a greater number of ESRD Beneficiaries attributed to the ESRD facilities where they receive care, which may enhance the viability of the ETC Model test. In the proposed rule we also considered including a minimum duration that an ESRD Beneficiary must be on dialysis before the beneficiary can be attributed to an ESRD facility. We determined that this approach was not suitable for this model test, however, as a key factor that influences whether or not a beneficiary chooses to dialyze at home is if the beneficiary begins dialysis at home, rather than in-center. Requiring a minimum duration on dialysis would exclude these early months of dialysis treatment from attribution, which may be key to a beneficiary's modality choice, and would therefore run counter to the intent of the ETC Model.

We proposed that CMS would not attribute pre-emptive transplant beneficiaries to ESRD facilities because beneficiaries who receive pre-emptive transplants do so before they have initiated dialysis and thus do not have a care relationship with the ESRD facility.

The following is a summary of the comments received on ESRD

Beneficiary attribution to ESRD facilities and our responses.

Comment: A commenter recommended that CMS exclude from attribution to an ESRD facility those ESRD Beneficiaries who have three or more dialysis treatments in another ESRD facility for that month. The commenter instead suggested that CMS attribute an ESRD Beneficiary to the ESRD facility at which the ESRD Beneficiary received the most treatments, which the commenter referenced as the ESRD Beneficiary's ''home facility.''

Response: As noted in the proposed rule, we believe that the plurality of dialysis treatments approach for attributing ESRD Beneficiaries to ESRD facilities provides a sufficient standard for attribution because it ensures that ESRD Beneficiaries will be attributed to an ESRD facility that has the primary responsibility for the beneficiary's renal dialysis services.

After considering public comments, we are finalizing our proposed provisions on the services used to attribute ESRD Beneficiaries to ESRD facilities with modification. Specifically, we are codifying in our regulations at § 512.360(c)(1) that ESRD Beneficiaries will be attributed to an ESRD facility for a given month based on the ESRD facility at which the ESRD Beneficiary received the plurality of his or her dialysis services in that month, other than renal dialysis services for AKI, based on claims with claim service date at the claim header date during that month with Type of Bill 072X. We are modifying the regulation text to clarify that an ESRD Beneficiary would not be attributed to an ESRD facility if the beneficiary is excluded from attribution based on the criteria specified in our regulations at § 512.360(b), described elsewhere in this final rule. We are modifying which date associated with the claim we are using to determine if the claim occurred during the applicable PPA Period. Whereas we proposed using the claim through date, we are finalizing using the date of service on the claim, to align with Medicare claims processing standards. We are making this change because while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service, requiring us to use claim date of service to identify the PPA Period in which the service was furnished. We are also codifying in our regulation at § 512.360(c)(1) that, in the event that an ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month, the ESRD Beneficiary will be attributed to the ESRD facility at which the beneficiary received the earliest dialysis treatment that month, as proposed. We clarify that this policy for attributing ESRD Beneficiaries who have received an equal number of dialysis treatments from two or more ESRD facilities would apply regardless of whether the ESRD facility is an ETC Participant or an ESRD facility located in a Comparison Geographic Area. As described elsewhere in this final rule, we have modified our proposal to attribute pre-emptive transplant beneficiaries to Managing Clinicians such that we will attribute only pre-emptive LDT beneficiaries. We therefore modified our regulation at § 512.360(c)(1) to clarify that CMS does not attribute pre-emptive LDT beneficiaries to ESRD facilities.

(b) Attribution to Managing Clinicians

We proposed that, for Managing Clinicians, an ESRD Beneficiary would be attributed to the Managing Clinician who submitted an MCP claim with a claim through date in a given month for certain services furnished to the ESRD Beneficiary. Per the conditions for billing the MCP, the MCP can only be billed once per month for a given beneficiary.[151] Therefore, as noted in the proposed rule, we believe there is no need to create a decision rule for attributing ESRD Beneficiaries to a Managing Clinician for a given month if there are multiple MCP claims that month, as that should never happen. We proposed that, for purposes of ESRD Beneficiary attribution to Managing Clinicians, we would include MCP claims with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD-related services furnished monthly, and indicate beneficiary age (12–19, or 20 years of age and older) and the number of face-to-face visits with a physician or other qualified health care professional per month (1, 2–3, 4 or more). CPT® codes 90965 and 90966 are for ESRD-related services for home dialysis per full month, and indicate the age of the beneficiary (12–19, or 20 years of age and older). We explained in the proposed rule that, taken together, these are all the CPT® codes that are used to bill the MCP that include beneficiaries 18 years old or older, including patients who dialyze at home and patients who dialyze in-center.

Additionally, for the transplant rate for Managing Clinicians, we proposed to attribute pre-emptive transplant beneficiaries to Managing Clinicians. Because pre-emptive transplant beneficiaries have not started dialysis at the time of their transplant, we explained we would not be able to attribute them to Managing Clinicians based on MCP claims, as we would for ESRD Beneficiaries. Rather, we proposed that pre-emptive transplant beneficiaries would be attributed to a Managing Clinician based on the Managing Clinician with whom the beneficiary had the most services between the start of the MY and the month in which the beneficiary received the transplant, and that the pre-emptive transplant beneficiary would be attributed to the Managing Clinician for all months between the start of the MY and the month in which the beneficiary received the transplant. In the proposed rule we considered attributing pre-emptive transplant beneficiaries on a month-by-month basis, mirroring the month-by-month attribution of ESRD Beneficiaries. However, we concluded that this approach would under-attribute beneficiary months to the denominator. Unlike ESRD Beneficiaries who see their Managing Clinician every month for dialysis management, pre-emptive transplant beneficiaries generally do not see a Managing Clinician every month because they have not started dialysis. However, that does not mean that an ongoing care relationship does not exist between the pre-emptive transplant beneficiary and the Managing Clinician in a month with no claim.

The following is a summary of the comments received on beneficiary attribution to Managing Clinicians and our responses.

Comment: A commenter stated that some complex patients have two nephrologists managing their care and suggested that both of these Managing Clinicians should receive attribution in these scenarios. Another commenter suggested that pre-emptive transplant beneficiaries be attributed to the Managing Clinician who initiated the referral to the transplant center to allow ''proactive management.'' Other commenters stressed the importance of educating beneficiaries on renal replacement modality options and the shared decision-making process in order to empower beneficiaries to select from among the available treatment choices and suggested that CMS attribute beneficiaries to ESRD facilities and Managing Clinicians that, through extensive education, time, and effort, refer ESRD Beneficiaries to facilities that offer home dialysis. Many of these same commenters suggested attribution based

[151] Medicare Claims Processing Manual, Chapter 8; *https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104.c08.pdf.*

on the Managing Clinician who educated the beneficiary on treatment modality instead of the Managing Clinician providing a certain dialysis-related service.

Response: CMS appreciates the feedback from the commenters about beneficiary attribution to Managing Clinicians. While CMS acknowledges that two or more Managing Clinicians may manage care for a given ESRD Beneficiary, for the purposes of this Model, we believe that attribution to one Managing Clinician is most appropriate because generally only one MCP is billed for a given ESRD Beneficiary during a month, even if multiple Managing Clinicians are involved in beneficiary's care. In addition, if the ESRD Beneficiary receives care from one or more other clinicians within the practice of the Managing Clinician to whom the ESRD Beneficiary is attributed, the care furnished to that ESRD Beneficiary will be considered in assessing the performance for all such clinicians under the aggregation methodology described elsewhere in section IV of this final rule. Additionally, while we appreciate feedback about the attribution of pre-emptive transplant beneficiaries, we do not believe that attributing pre-emptive transplant beneficiaries to the Managing Clinician who refers them to the transplant center is appropriate for the Model. As described elsewhere in this final rule, we are now only attributing Pre-emptive LDT Beneficiaries to Managing Clinicians given the change to the calculation of the transplant rate. Attributing these Pre-emptive LDT Beneficiaries to Managing Clinicians based on who refers a Pre-emptive LDT Beneficiary to a transplant center may not identify the Managing Clinician primarily responsible for supporting the beneficiary through the living donor transplant process. Rather, we believe that the main care relationship between Pre-emptive LDT Beneficiary and Managing Clinician is more accurately identified using the methodology included in this final rule.

After considering public comments, we are finalizing our proposed provisions on the services used to attribute beneficiaries to Managing Clinicians, with modification. We are finalizing in our regulation at § 512.360(c)(2) that we will attribute ESRD Beneficiaries to the Managing Clinician who bills an MCP for services furnished to the beneficiary claim service date at the claim line through date during the entire month in question, and that such claims will be identified by CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. We stated in the proposed rule that there is no need to create a decision rule for attributing ESRD Beneficiaries to a Managing Clinician for a given month because the full month MCP CPT® codes can only be billed once per month for a given beneficiary. However, we found a very small number of instances where the full month MCP code was billed by multiple Managing Clinicians for a given beneficiary. To address the rare case that an MCP is billed in a single month by more than one Managing Clinician, we also added new text to our regulation at § 512.360(c)(2) to clarify that, in cases where more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary with a claim service date at the claim line through date in a month, the ESRD Beneficiary will be attributed to the Managing Clinician associated with the earliest claim service date at the claim line through date that month. In cases where more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary for the same earliest claim service date at the claim line through date for that month, the ESRD Beneficiary will be randomly attributed to one of these Managing Clinicians.

In addition, we are modifying our proposed method for attributing pre-emptive transplant beneficiaries to Managing Clinicians. As described in section IV.C.5 of this final rule, the transplant rate calculation will include only living donor transplants, rather than all kidney transplants including those received from deceased donors. As such, we are modifying pre-emptive transplant beneficiary attribution to Managing Clinicians in § 512.360(c)(2) of our regulation to include only Pre-emptive LDT Beneficiaries, rather than all beneficiaries who receive a kidney transplant prior to beginning dialysis, including from deceased donors. Consistent with our approach for attributing pre-emptive transplant beneficiaries to Managing Clinicians, we are finalizing that a Pre-emptive LDT Beneficiary will be attributed to the Managing Clinician with whom the beneficiary had the most claims between the start of the MY and the month of the transplant. We are also finalizing that, in the event that no Managing Clinician had the plurality of claims for a given Pre-emptive LDT Beneficiary, such that multiple Managing Clinicians each had the same number of claims for that beneficiary during the MY, that beneficiary will be attributed to the Managing Clinician with the latest claim service date at the claim line through date for the beneficiary, up to and including the month of the transplant. If more than one of these Managing Clinicians has the latest claim service date at the claim line through date for that beneficiary, the Pre-emptive LDT Beneficiary will be randomly attributed to one of those Managing Clinicians.

In addition, we are modifying which date associated with the claim we are using to determine if the claim occurred during the applicable PPA Period. Whereas we proposed using the claim through date, we are finalizing using the date of service on the claim, to align with Medicare claims processing standards. We are making this change because while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service, requiring us to use claim date of service to identify the PPA Period in which the service occurred. We have revised § 512.360(c)(2) of this final rule accordingly.

c. Performance Measurement

We proposed to calculate the home dialysis and transplant rates for ESRD facilities and Managing Clinicians using Medicare claims data and Medicare administrative data about beneficiaries, providers, and suppliers. We noted in the proposed rule that Medicare administrative data refers to non-claims data that Medicare uses as part of regular operations. This includes information about beneficiaries, such as enrollment information, eligibility information, and demographic information. Medicare administrative data also refers to information about Medicare-enrolled providers and suppliers, including Medicare enrollment and eligibility information, practice and facility information, and Medicare billing information. For the transplant rate calculations, we also proposed to use data from the Scientific Registry of Transplant Recipients (SRTR), which contains comprehensive information about transplants that occur in the U.S., to identify transplants among attributed beneficiaries for inclusion in the numerator about the occurrence of kidney and kidney-pancreas transplants. In the proposed rule, we considered requiring ETC Participants to report on their home dialysis and transplant rates, as this would give ETC Participants more transparency into their rates. However, as noted in the proposed rule, we believe basing the rates on claims data, supplemented with Medicare administrative data about beneficiary

enrollment and transplant registry data about transplant occurrences, will ensure there is no new reporting burden on ETC Participants. Additionally, using these existing data sources would be more cost effective for CMS, as it would not require the construction and maintenance of a new reporting portal, or changes to an existing reporting portal to support this data collection.

We solicited comment on our proposed use of claims data, Medicare beneficiary enrollment data, and transplant registry data to calculate the home dialysis rate and transplant rate. The following is a summary of the comments received and our responses.

Comment: A commenter supported our proposal to use Medicare claims data and Medicare administrative data for purposes of calculating the home dialysis rate and the transplant rate, and our proposal to use data from the SRTR for purposes of calculating the transplant rate.

Response: We appreciate the feedback and support from the commenter. As described in the proposed rule, we proposed to use these existing data sources to avoid imposing an administrative burden on ETC Participants.

After considering public comments, we are finalizing our proposed provisions on the sources of data used for measuring the performance of ETC Participants under the Model with modification. Specifically, as the transplant rate calculation will include only living donor transplants, rather than all kidney transplants including those received from deceased donors, we are modifying our regulation at § 512.365(a) to refer to Pre-emptive LDT Beneficiaries rather than pre-emptive transplant beneficiaries.

(1) Home Dialysis Rate

We proposed to define ''home dialysis rate'' as the rate of ESRD Beneficiaries attributed to the ETC Participant who dialyzed at home during the relevant MY, as described in § 512.365(b) (Home Dialysis Rate). We proposed to construct the home dialysis rate for ETC Participants that are ESRD facilities as described in the proposed rule and section IV.C.5.c.1.a of this final rule and for ETC Participants who are Managing Clinicians as described in the proposed rule and section IV.C.5.c.1.b of this final rule. We described in the proposed rule and describe later in this final rule our proposed plan for risk adjusting and reliability adjusting these rates.

The following is a summary of the comments received on the home dialysis rate and our responses.

Comment: Multiple commenters stated that it is important to protect patient choice of treatment modality, which may depend on the beneficiary's financial resources, housing, social support, and personal preference even after proper education on all possible ESRD treatment choices. These commenters recommended that CMS consider revising the home dialysis rate to include shared-decision making measures that take into account the treatment modality most clinically and socially appropriate for the beneficiary.

Response: We agree with commenters that it is important to protect patient choice of treatment modality, but disagree that a shared decision measure should be included in the home dialysis rate calculation due to possible gaming and lack of shared decision making measures specific to home dialysis.

Comment: A few commenters suggested including ESRD Beneficiaries enrolled in Medicare Advantage plans in the numerator of the home dialysis rate calculation, with one of those commenters explaining that these beneficiaries often utilize in-center self-care dialysis. According to the commenters, adding these beneficiaries, presumably to the numerator of the home dialysis rate calculation, could mitigate risks that Managing Clinicians have for these more serious, medically complex beneficiaries for whom in-center self-care dialysis is a safer option than home dialysis.

Response: Consistent with the beneficiary exclusions from attribution codified in our regulations at § 512.360(b), we will not include ESRD Beneficiaries enrolled in Medicare Advantage in the calculation of the home dialysis rate because the ETC Model is not a test of the Medicare Advantage program or payment. Specifically, the ETC Model is designed as a test within Medicare FFS, which excludes Medicare Advantage enrollees from attribution to ETC Participants for purposes of the Model's financial calculations, including the PPA. As such, it would be inappropriate to include beneficiaries enrolled in Medicare Advantage in the construction of the home dialysis rate.

Comment: Several commenters recommended that we exclude beneficiaries residing in or receiving dialysis in a SNF or nursing facility from our calculation of the home dialysis rate. Some commenters clarified that beneficiaries often reside in a nursing facility or utilize a SNF as a more permanent residence, and as such, the dialysis received in a SNF more resembles in-center dialysis. A commenter suggested that we apply the exclusion only to the denominator of the home dialysis rate such that such beneficiaries would be included in the numerator if they received home dialysis. A commenter recommended classifying SNFs, inpatient rehabilitation facilities, and long-term care hospitals (LTCH) as a home dialysis site for patients that receive on-site dialysis at one of the respective locations.

Multiple commenters supported the inclusion of beneficiaries who dialyze at SNFs in the calculation of the home dialysis rate, with some commenters pointing out that ESRD facilities may provide dialysis services to SNF residents within an approved home training and support modality in cases where beneficiaries, such as those with AKI or dementia, may have better quality of life when receiving dialysis in a SNF.

Response: We appreciate these comments, and share the commenters' concerns about including beneficiaries residing in or receiving dialysis in a SNF or nursing facility in the home dialysis rate calculations. We disagree with commenters that support including these beneficiaries in the home dialysis rate. As described previously in section IV.B.1 of this final rule, in our regulations at § 512.360(b), we are excluding beneficiaries who are residing in or receiving dialysis services in SNFs and nursing facilities from attribution to ETC Participations for purposes of the PPA calculation generally for the reasons described in section IV.B.1.

After considering public comments, we are finalizing our general proposal regarding the home dialysis rate as proposed. We are also finalizing the definition of the home dialysis rate as proposed without modification in our regulation at § 512.310. Specific provisions regarding the home dialysis rate calculation for ESRD facilities and Managing Clinicians are detailed in the following sections of this final rule.

(a) Home Dialysis Rate for ESRD Facilities

We proposed that the denominator of the home dialysis rate for ESRD facilities would be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator would be composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. We would identify months during which an attributed ESRD Beneficiary received maintenance

dialysis based on claims, specifically claims with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2. Facility code 7 paired with type of care code 2, indicates that the claim occurred at a clinic or hospital based ESRD facility, and the Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities.

We proposed that the numerator of the home dialysis rate for ESRD facilities would be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home. Home dialysis treatment beneficiary years included in the numerator would be composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. We would identify maintenance dialysis at home months based on claims, specifically claims with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, with condition codes 74, 75, 76, or 80. Facility code 7 paired with type of care code 2, indicates that the claim occurred at a clinic or hospital based ESRD facility. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. We stated in the proposed rule that condition codes 74 and 75 indicate billing for a patient who received dialysis services at home, and condition code 80 indicates billing for a patient who received dialysis services at home and the patient's home is a nursing facility. Condition code 76 indicates billing for a patient who dialyzes at home but received back-up dialysis in a facility. As noted in the proposed rule, taken together, we believe these condition codes capture home dialysis services furnished by ESRD facilities. Information used to calculate the ESRD facility home dialysis rate includes Medicare claims data and Medicare administrative data.

In the proposed rule, we considered including beneficiaries whose dialysis modality is self-dialysis or temporary PD furnished in the ESRD facility at a transitional care unit in the numerator, given that these modalities align with one of the overarching goals of the proposed ETC Model, to increase beneficiary choice regarding ESRD treatment modality. However, we concluded that these modalities lack clear definitions in the literature and delivery of care for these modalities is billed through the same codes as in-center HD, making it impossible for CMS to identify the relevant claims.

The following is a summary of the comments received on the home dialysis rate calculation for ESRD facilities and our responses.

Comment: Some commenters agreed with the primary construction of the home dialysis rate, as proposed. Other commenters argued that condition codes of 74, 75, 76, and 80 provide little predictive value. Many commenters stated that self-dialysis should be included in the home dialysis rate numerator, particularly for patients who may be more seriously ill and for whom self-care in-center dialysis is a better treatment modality. CMS received a letter from a coalition of 26 stakeholders including nephrologists, ESRD facilities, patients, and manufacturers, which recommended that self-dialysis should be included in the numerator for home dialysis rate calculation for ESRD facilities. The coalition's letter also urged that the definition of self-dialysis be further clarified beyond what is already present in 42 CFR 494.10 and recommended that CMS identify self-dialysis using condition code 72, since self-care in-center dialysis is tracked through this code. Other commenters similarly suggested a broader definition for self-care dialysis or suggested that CMS use the commenters' ESRD facilities' criteria for establishing a patient as ''self-care'', such as a patient setting up the machine without assistance or pulling the needle at the end of treatment. A commenter suggested treating homeless beneficiaries receiving self-dialysis in-center as a home dialysis patient for purposes of calculating the home dialysis rate, since these patients do not have the option of dialyzing at home.

Response: CMS appreciates the commenters' suggestions for identifying self-care in-center dialysis patients. We agree with commenter feedback that self-dialysis can be identified with condition code 72. We also appreciate that self-dialysis may serve as a way to provide a gradual transition from in-center dialysis to home dialysis, allowing patients to become comfortable with conducting dialysis under medical supervision. We considered including beneficiaries whose treatment modality is self-dialysis in the numerator of the home dialysis rate in the proposed rule, pointing out that it was consistent with the overarching goals of the ETC Model and helped to promote beneficiary choice of treatment modalities. Our concern in the proposed rule was that there was not a clear, universally accepted definition of self-care dialysis in the literature or a clear way for CMS to identify these claims. However, commenters pointed out that there is an already defined condition code under the ESRD PPS for self-dialysis. Therefore, we are finalizing the home dialysis rate numerator for ESRD facilities to include self-dialysis, as identified by condition code 72, at one half of the value of home dialysis. We believe this policy will effectively balance the benefits of self-dialysis and its ability to help beneficiaries transition to home dialysis with the recognition that self-dialysis is not home dialysis and does not have all of the same benefits. Specifically, each beneficiary month for which an attributed beneficiary receives self-dialysis will contribute one half month to the numerator.

Comment: Several commenters suggested including beneficiaries who have received home dialysis training, as identified by claims with condition code 73, in the numerator of the home dialysis rate calculation for ESRD facilities. Other commenters suggested that CMS include in the numerator beneficiaries who have received re-training treatment (as identified by conditions code 87 and full care in unit (as identified by condition code 71), when used in combination with the Revenue Code 0831 (urgent start PD) to encourage transitions to home dialysis as well as to capture patients who require abdominal surgery and hope to transition back to home dialysis. A commenter suggested that we allow at least 90 days to classify patients under these PD condition codes before including these beneficiaries in the numerator of the home dialysis rate calculation to take into account delays of PD use for various health reasons that would not negatively affect ETC Participants.

Response: We appreciate the feedback from the commenters, and recognize the importance of home dialysis training, as well as retraining and full care in unit. We believe that including beneficiaries who have received these services in the numerator of the home dialysis rate for ESRD facilities is not necessary to create the financial incentives we seek to test under the proposed ETC Model and that training incentives are captured through training add-on payment adjustment for home dialysis under the ESRD PPS.

After considering public comments, we are finalizing our proposed provisions on the calculation of the home dialysis rate for ESRD facilities, with modifications. Specifically, we are codifying in our regulation at § 512.365(b)(1) that the denominator of the home dialysis rate for ESRD facilities will be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the

MY, as proposed. We are codifying in our regulation at § 512.365(b)(1) that the numerator of the home dialysis rate for ESRD facilities will be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home, as identified by claims with Type of Bill 072X, with condition codes 74 or 76. While we proposed to include claims with condition code 75, we are no longer including these claims because we have since learned that this condition code is no longer valid. Additionally, in this final rule, we will not include claims with condition code 80, as proposed, because condition code 80 indicates billing for a patient who received dialysis services at home and the patient's home is a SNF or nursing facility, and we are excluding beneficiaries residing in or receiving dialysis in a SNF or nursing facility from attribution to ETC Participants for purposes of the PPA calculation generally, as described elsewhere in this final rule. We are further modifying this proposal to also include one half of the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis via self-dialysis, as identified by claims with Type of Bill 072X and condition code 72, and are clarifying that self-dialysis treatment beneficiary years included in the numerator are those months in which attributed ESRD Beneficiaries received self-dialysis in-center, such that one beneficiary year is comprised of 12 beneficiary months. Of note, we have removed references to the risk adjustment methodology as we are not finalizing the proposed risk adjustment methodology for the home dialysis rate for ESRD facilities, as described in section IV.C.5.c.(3) of this final rule. We are also modifying references to the proposed reliability adjustment methodology and are replacing them with references to the aggregation methodology for the home dialysis rate for ESRD facilities, as described in section IV.C.5.c.(4) of this final rule.

(b) Home Dialysis Rate for Managing Clinicians

We proposed that the denominator of the home dialysis rate for Managing Clinicians would be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator would be composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. We noted that we would identify maintenance dialysis months based on claims, specifically claims with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD-related services furnished monthly, and indicate beneficiary age (12–19 years of age or 20 years of age and older) and the number of face-to-face visits with a physician or other qualified health care professional per month (1, 2–3, 4 or more). CPT® codes 90965 and 90966 are for ESRD related services for home dialysis per full month, and indicate the age of the beneficiary (12–19 years of age or 20 years of age and older). Taken together, these codes are used to bill the MCP for beneficiaries aged 18 or older, including patients who dialyze at home and patients who dialyze in-center.

As proposed, the numerator for the home dialysis rate for Managing Clinicians would be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home. Home dialysis treatment beneficiary years included in the numerator would be composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. We would identify maintenance dialysis at home months based on claims, specifically claims with CPT® codes 90965 or 90966. CPT® code 90965 is for ESRD related services for home dialysis per full month for patients 12–19 years of age. CPT® code 90966 is for ESRD related services for home dialysis per full month for patients 20 years of age and older. These two codes are used to bill the MCP for beneficiaries aged 18 and older who dialyze at home. Information used to calculate the Managing Clinician home dialysis rate includes Medicare claims data and Medicare administrative data.

In the proposed rule, we considered including beneficiaries whose dialysis modality is self-dialysis or temporary PD furnished in the ESRD facility at a transitional care unit in the numerator, given that these modalities align with one of the overarching goals of the proposed ETC Model, to increase beneficiary choice regarding ESRD treatment modality. However, we noted in the proposed rule that these modalities lack clear definitions in the literature and delivery of care for these modalities is billed through the same codes as in-center HD, making it impossible for CMS to identify the relevant claims.

The following is a summary of the comments received on the home dialysis rate calculation for Managing Clinicians and our responses.

Comment: Many commenters suggested including self-care in-center dialysis patients in the numerator of the home dialysis rate calculation for ESRD facilities using condition code 72, and one of these commenters suggested removing these patients from the denominator of the home dialysis rate calculation so that these patients do not count against the ESRD facilities or Managing Clinicians. CMS received a letter from a coalition of 26 stakeholders including nephrologists, dialysis facilities, patients, and manufacturers urging that the definition of self-dialysis be further clarified beyond what is already present in 42 CFR 494.10 and that self-dialysis should be included in the numerator for the ETC Model and be monitored using condition code 72 since self-care in-center dialysis is tracked through this code.

Response: CMS appreciates the commenters' suggestions for identifying self-care in-center dialysis patients. We agree with commenter feedback that self-dialysis can be identified with condition code 72. We also appreciate that self-dialysis may serve as a way to provide a gradual transition from in-center dialysis to home dialysis, allowing patients to become comfortable with conducting dialysis under medical supervision. We considered including self-dialysis in the numerator of the proposed rule, pointing out that it was consistent with the overarching goals of the ETC Model and helped to promote beneficiary choice of treatment modalities. The concern we expressed in the proposed rule was that there was not a clear, consistent definition of self-dialysis in the literature or a clear way for CMS to identify these claims. However, comments from stakeholders point out that there is an already defined claim code in the ESRD PPS and a clear definition in federal law at 42 CFR 494.10.

After considering public comments, we are finalizing our proposed provisions on the home dialysis rate calculation for Managing Clinicians, with modification. Specifically, we are codifying in our regulation at § 512.365(b)(2) that the denominator of the home dialysis rate for Managing Clinicians will be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY, as proposed. We are codifying in our regulation at § 512.365(b)(2) that the numerator of the home dialysis rate for

Managing Clinicians will be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home, as identified by CPT® codes 90965 or 90966; however, we are modifying this proposal to also include one half of the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis via self-dialysis. Specifically, each beneficiary month for which an attributed beneficiary receives self-dialysis will contribute one half month to the numerator. Self-dialysis treatment beneficiary years included in the numerator are composed of those months during which an attributed ESRD Beneficiary received self-dialysis in center, such that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed ESRD Beneficiary received self-dialysis will be identified by claims with Type of Bill 072X, with condition code 72. We are using condition code 72 because self-dialysis cannot be identified using CPT® codes submitted by Managing Clinicians. We are making this change for consistency with the modifications made to the home dialysis rate calculation for ERSD facilities in response to comments, and similarly believe this policy change, as applied to the home dialysis rate for Managing Clinicians, will effectively balance the benefits of self-dialysis and its ability to help beneficiaries transition to home dialysis with the recognition that it is not home dialysis and does not have all of the same benefits. Of note, we have removed references to the risk adjustment methodology because we are not finalizing the proposed risk adjustment methodology for the home dialysis rate for Managing Clinicians, as described in section IV.C.5.c.(3) of this final rule. We are also modifying references to the proposed reliability adjustment methodology and are replacing them with references to the aggregation methodology for the home dialysis rate for Managing Clinicians, as described in section IV.C.5.c.(4) of this final rule.

(2) Transplant Rate

We proposed to define the ''transplant rate'' as the rate of ESRD Beneficiaries and, if applicable, pre-emptive transplant beneficiaries attributed to the ETC Participant who received a kidney or kidney-pancreas transplant during the MY, as described in proposed § 512.365(c) (Transplant Rate). We proposed to construct the transplant rate for ETC Participants that are ESRD facilities as described in the proposed rule and section IV.C.5.c.(2)(a) of this final rule, and for ETC Participants who are Managing Clinicians as described in the proposed rule and section IV.C.5.c.(2)(b) of this final rule.

For purposes of constructing the transplant rate, we proposed two transplant rate-specific beneficiary exclusions. Specifically, we proposed to exclude an attributed beneficiary from the transplant rate calculations for any months during which the beneficiary was 75 years of age or older at any point during the month, and for any months in which the beneficiary was in a SNF at any point during the month. We proposed these additional exclusions to recognize that, while these beneficiaries can be candidates for home dialysis, they are generally not considered candidates for transplantation. As we noted in the proposed rule, these exclusions would be similar to the exclusions used in the PPPW measure that has been adopted by the ESRD QIP. We sought comment on the proposal to exclude from the transplant rate beneficiaries aged 75 or older and beneficiaries in SNFs. The transplant rate calculations would also exclude beneficiaries who elected hospice, as we proposed to exclude beneficiaries who have elected hospice from attribution generally under the ETC Model and therefore they would be excluded from the calculation of both the transplant rate and the home dialysis rate.

In the proposed rule, we considered using rates of transplant waitlisting rather than the actual transplant rate. However, for the ETC Model, we proposed to test the effectiveness of the Model's incentives on outcomes, rather than on processes. We stated in the proposed rule that the relevant outcome for purposes of the ETC Model is the receipt of a kidney or kidney-pancreas transplant, not getting on and remaining on the kidney transplant waitlist. While we acknowledged in the proposed rule that getting a beneficiary on the transplant waitlist is more directly influenced by the ESRD facility and/or the Managing Clinician than the beneficiary actually receiving the transplant, we stated that we believed that ESRD facilities and Managing Clinicians are well positioned to assist beneficiaries through the transplant process, and we wanted to incentivize this focus. We also acknowledged in the proposed rule that transplant waitlist measures do not capture living donation, which is an additional path to a successful kidney transplant, and ESRD facilities and Managing Clinicians may support this process. Details about the PPPW Clinical Measure can be found in the CY 2019 ESRD PPS final rule (83 FR 56922, 57003–08). We solicited comment on our proposal to not test the effectiveness of the Model's incentives on increasing the number of patients added to the kidney transplant waitlist. Additionally, we solicited comment on an alternative transplant waitlist measure that would also capture living donation.

We proposed using one year of data, from an MY, to construct the transplant rate to align with the construction of the home dialysis rate. However, we noted that because transplants are rare events for statistical purposes, we may not have sufficient statistical power to detect meaningful variation using only one year of performance information at the ETC Participant level. In order to ensure that we would have sufficient statistical power to detect meaningful variation in performance, in the proposed rule we also considered the alternative of using 2, 3, or 4 years of data, corresponding with the MY plus the calendar year or years immediately prior to the MY, to construct the transplant rate. However, we wanted to avoid adjusting ETC Participant payment based on performance that occurred prior to the implementation of the ETC Model, if finalized, and concluded that the proposed reliability adjustment aggregation methodology, described in the proposed rule and section IV.C.5.c.(4) of this final rule, would compensate for any lack of statistical power, and would therefore eliminate the need to include data from calendar years prior to the MY in order to produce a reliable and valid transplant rate. We discuss later in this final rule our proposal for risk adjusting and reliability adjusting these rates.

The following is a summary of the comments received on the use of the transplant rate and the alternatives considered, and our responses.

Comment: Several commenters agreed with CMS's proposal to use transplantation to assess ESRD facility performance on the transplant rate since transplantation generally provides the best outcomes for patients and promotes collaboration for transplant efforts. Some of these same commenters suggested that increasing the number of patients on the transplant waitlist may not correlate with an increase in transplantation rates. Instead of the transplant rate, some commenters suggested a focus on patient education around treatment modality choices or the transplant process. However, multiple other commenters stated that they are concerned that complexities outside of health care providers' and patients' control, including policy

barriers, lack of available organs, which is often due to the way deceased organs are procured, long waitlist times, patient choice, and the lack of a clinical fit for transplant do not support the proposed methodology to assess ETC Participant performance based on a transplant rate. Some commenters instead suggested using the PPPW measure and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) measure, but pointed out that the SWR does not include pre-emptive transplants in its data and that the PPPW measures prevalence of beneficiaries on the waitlist, which includes beneficiaries who have been on the waitlist for a long duration and may not account for other barriers to transplantation.

Response: CMS appreciates this feedback. In the proposed rule, we specifically solicited comment on our proposal not to test the effectiveness of the Model's incentives on increasing the number of patients added to the transplant waitlist. We appreciate commenters concerns that certain factors that impact the transplant rate are beyond the control of the ETC Participant, particularly regarding the supply of deceased donor organs available for transplantation. While we believe that other efforts intended to increase the supply of deceased donor organs, including the ETC Learning Collaborative (described in section IV.C.12 of this final rule) and extending the Kidney Disease Education benefit to multiple provider types (described in section IV.C.7.b of this final rule) will help to address this concern, we also acknowledge that these efforts will take time to produce results. As such, we are modifying our proposed transplant rate and will instead use a transplant rate that is calculated as the sum of the transplant waitlist rate and the living donor transplant rate for purposes of the PPA calculation under the Model. This policy change aligns with suggestions from commenters that, particularly in light of the current shortage of deceased donor organs for transplant, a transplant waitlist rate is more within the control of the ETC Participant. This approach will allow the changes made by the proposed rule issued December 23, 2019 entitled Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement (CMS–3380–P) and the proposed rule published December 20, 2019 entitled Removing Financial Disincentives to Living Organ Donation, if finalized, as well as the ETC Learning Collaborative under the Model time to have an effect on deceased donor organ supply before holding ETC Participants accountable for their performance on the transplant rate that includes deceased donor organ transplants. It is our intent to observe the supply of deceased donor organs available for transplantation. Any change to the composition of the transplant rate to include the rate of deceased donor kidney transplants for the purposes of the PPA calculation under the Model would be established through future rulemaking.

We also sought comment on an alternative transplant waitlist measure that would capture living donation, which is an alternative path to a successful kidney transplant. We did not receive any suggestions of alternative measures of transplant waitlisting that would capture living donation. However, we wanted to recognize the important role that ETC Participants, as ESRD facilities and Managing Clinicians, can play in increasing the rates of living donor kidney transplants outside the transplant waitlist process and are keeping living donor transplants in the transplant rate calculation alongside the transplant waitlist rate, instead of deceased donor transplants as was in the proposed rule. We define the ''living donor transplant rate'' as the rate of ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries attributed to the ETC Participant who received a kidney transplant from a living donor during the MY.

To accommodate this change, we are modifying the definition of the ''transplant rate'' as the sum of the transplant waitlist rate and the living donor transplant rate. We define the ''transplant waitlist rate'' as the rate of ESRD Beneficiaries attributed to the ETC Participant who were on the kidney transplant waitlist during the MY, as described in § 512.365(c)(1)(i) and § 512.365(c)(2)(i). We acknowledge that there are existing transplant waitlist measures, including the PPPW and SWR identified by commenters. However, we believe that constructing a transplant waitlist rate specific to the ETC Model is the best approach. The transplant waitlist rate for the ETC Model is similar in concept to the PPPW but uses the attribution methodology specific to the ETC Model. As noted previously in this final rule, we may seek to modify the ETC Model in the future to use a transplant rate that includes deceased donor transplants, and would do so through subsequent rulemaking. In the final rule, we are clarifying that CMS will obtain data about the kidney transplant waitlist from SRTR, which maintains all transplant waitlists.

Comment: Several commenters recommended that we exclude beneficiaries in SNFs from our calculation of the transplant rate. Other commenters stated that CMS should factor the longevity of the organ transplant into the transplant rate. A commenter stated that CMS should add in beneficiaries who have received a transplant into the denominator of the transplant rate calculation. Several commenters suggesting removing from the denominator of the transplant rate calculation those beneficiaries who are ineligible for transplant.

Response: CMS appreciates the feedback. CMS is now excluding ESRD Beneficiaries who reside in or receive dialysis at a SNF or nursing home facility from attribution to ETC Participants for purposes of calculating the PPA, as described in section IV.C.5.b.(1) of this final rule, and therefore these beneficiaries will be excluded from the calculation of the transplant rate well as the home dialysis rate. We believe that the beneficiary attribution exclusions as well as not including beneficiaries over the age of 75 in the transplant rate calculation remove the majority of beneficiaries who are ineligible for transplantation from the denominator of the transplant rate. In addition, because we are modifying our proposal and will use the transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate rather than the transplant rate including deceased donor transplants, the longevity of the organs is no longer a relevant consideration. If the transplant rate originally proposed is adopted for later years of the Model through subsequent rulemaking, CMS may consider incorporating organ longevity as part of the transplant rate and/or altering the denominator of the transplant rate calculation in a manner suggested by the commenters, and would solicit public comment on such a change through a future notice of proposed rulemaking. We also note that organ longevity is a consideration for the KCC Model, which is testing the efficacy of payment incentives on post-transplant care via a kidney transplant bonus. Through this kidney transplant bonus, CMS aims to test the impact of making a payment reward to model participants for each aligned beneficiary who receives a kidney transplant. This kidney transplant bonus payment would be made in each of the three years following the transplant in which the transplant remains successful, meaning the beneficiary does not return to dialysis.

In terms of the recommendation that CMS add in beneficiaries who have received a transplant into the denominator of the transplant rate calculation, as described elsewhere in this final rule, CMS is modifying the definition of ESRD Beneficiary to clarify that a beneficiary who has received a kidney transplant would be considered an ESRD Beneficiary (and therefore included in the denominator of the transplant waitlist rate and the living donor transplant rate) if the beneficiary either: (1) Has a dialysis or MCP claim at least 12 months after the beneficiary's latest transplant date; or (2) has a dialysis or MCP claim less than 12 months after the beneficiary's latest transplant date that includes a kidney transplant failure diagnosis code documented in any Medicare claim. These beneficiaries also would be included in the numerator of the transplant waitlist rate if the beneficiary is added to the kidney transplant waitlist, and in the numerator of the living donor transplant rate if the beneficiary received a transplant from a living donor.

After considering public comments, we are finalizing our general proposal on the transplant rate, with modifications. Specifically, in response to comments received, we are replacing the transplant rate we had proposed to use for purposes of calculating the PPA with the transplant rate calculated as the sum of the living donor transplant rate that had been included as part of the original transplant rate calculation and the transplant waitlist rate on which we had solicited comments. In addition, we are not finalizing the definition of transplant rate as proposed. Rather, in our regulation at § 512.310, we are modifying the definition of ''transplant rate'' to mean the sum of the transplant waitlist rate and the living donor transplant rate. We are defining the term ''transplant waitlist rate'' to mean the rate of ESRD Beneficiaries attributed to the ETC Participant who were on the kidney transplant waitlist during the MY, as described in § 512.365(c). We are also defining the term ''living donor transplant rate'' to mean the rate of ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries attributed to the ETC Participant who received a kidney transplant from a living donor during the MY.

(a) Transplant Rate for ESRD Facilities

For ESRD facilities, we proposed that the denominator for the transplant rate would be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY, subject to the aforementioned exclusions. Dialysis treatment beneficiary years included in the denominator would be composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home or in an ESRD facility, such that 1 beneficiary year would be comprised of 12 attributed beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis would be identified by claims with Type of Bill 072X. We explained in the proposed rule that Facility code 7 paired with type of care code 2, indicates that the claim occurred at a clinic or hospital based ESRD facility. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. However, in order to effectuate the exclusions previously described, we would exclude claims for attributed ESRD Beneficiaries who were 75 years of age or older at any point during the month or were in a SNF at any point during the month.

We proposed that the numerator for the transplant rate for ESRD facilities would be the total number of attributed beneficiaries who received a kidney transplant or a kidney-pancreas transplant during the MY. We would identify kidney and kidney-pancreas transplants using Medicare claims data, Medicare administrative data, and SRTR data. For Medicare claims data, we would use claims with Medicare Severity Diagnosis Related Groups (MS–DRGs) 008 (simultaneous pancreas-kidney transplant) and 652 (kidney transplant); and claims with ICD–10 procedure codes 0TY00Z0 (transplantation of right kidney, allogeneic, open approach), 0TY00Z1 (transplantation of right kidney, syngeneic, open approach), 0TY00Z2 (transplantation of right kidney, zooplastic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplastic, open approach). Because kidney-pancreas transplants are billed by including an ICD–10 procedure code for the type of kidney transplant and a separate ICD–10 procedure code for the type of pancreas transplant, in the proposed rule we determined that we would not need to include additional ICD–10 codes to capture kidney-pancreas transplants beyond the ICD–10 codes for kidney transplants listed. We proposed that we would supplement Medicare claims data on kidney and kidney-pancreas transplants with information from the SRTR Database and Medicare administrative data about the occurrence of kidney and kidney-pancreas transplants not identified through claims. If a beneficiary who receives a transplant during a MY returns to dialysis during the same MY, the beneficiary would remain in the numerator.

In the proposed rule, we also considered constructing the numerator for the ESRD facility transplant rate such that the number of attributed beneficiaries who received transplants during a MY would remain in the numerator for every MY after the transplant during which the transplanted beneficiary does not return to dialysis, for the duration of the proposed ETC Model. Keeping attributed beneficiaries who received transplants in a MY in the numerator for MYs subsequent to the MY in which the transplant occurs would acknowledge the significant efforts made by ESRD facilities to successfully assist beneficiaries through the transplant process. However, as noted in the proposed rule, we believe this approach would artificially inflate transplant rates in later years of the Model and disproportionately disadvantage new ESRD facilities who begin providing care to ESRD Beneficiaries in later years of the Model. In the proposed rule we concluded that this potential for artificially inflated rates and the disadvantage that would result for new ESRD facilities outweighed the advantage of accruing transplants over time.

The following is a summary of the comments received on the proposed transplant rate for ESRD facilities and our responses.

Comment: Multiple commenters mentioned that ESRD facilities can control only evaluation and referral of patients to transplant centers. A commenter suggested that ETC Participants be required to refer any patient with an Estimated Post Transplant Survival (EPTS) Score of 75 percent or below to receive a transplant evaluation.

Response: We appreciate the feedback from the commenters. As described in section IV.C.5 of this final rule, we appreciate the complexity of the transplant process, including the number of transplant providers involved and the different roles they play. For this reason, we are modifying our proposal and will instead use a transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate for purposes of calculating the Facility PPA. As the health care providers that ESRD beneficiaries see most frequently, ESRD

facilities play a pivotal role in the living donor and transplant waitlist process, including: Educating beneficiaries about their transplant options, including living donation; helping beneficiaries navigate the transplant process, including helping beneficiaries understand the process; providing referrals for care necessary to meet clinical transplant requirements, and referrals for transplant waitlisting; and coordinating care during the transplant process.

As noted previously in this final rule, we may seek to modify the ETC Model through subsequent rulemaking to use a transplant rate that incorporates the rate of deceased donor transplants.

After considering public comments, we are finalizing our proposed provisions on the transplant rate for ESRD facilities in our regulations at § 512.365(c)(1), with modifications. Specifically, in response to comments received, the transplant rate for ESRD facilities is calculated as the sum of the transplant waitlist rate for ESRD facilities and the living donor transplant rate for ESRD facilities. As was the case with the proposed transplant rate for ESRD facilities, the denominator for the transplant waitlist rate for ESRD facilities and the living donor transplant rate for ESRD facilities is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home or in an ESRD facility, such that 1 beneficiary year is comprised of 12 attributed beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X. Beneficiaries who are 75 years of age or older at any point during the month are excluded from the denominator. Because beneficiaries who reside in SNFs or nursing facilities are now excluded from attribution to ETC Participants for purposes of the PPA calculation in general, it is not necessary to specifically exclude beneficiaries who were in a SNF from the transplant waitlist rate denominator, as we had proposed to do for purposes of the transplant rate.

The numerator for the transplant waitlist rate for ESRD facilities is the number of beneficiary years for which attributed ESRD Beneficiaries were on the kidney transplant waitlist during the MY. As noted previously, we are clarifying in this final rule that CMS will obtain transplant waitlist data from SRTR, which maintains data on all transplant waitlists.

The denominator for the living donor transplant rate for ESRD facilities will be calculated in the same manner as the denominator for the transplant waitlist rate finalized for ESRD facilities. The numerator for the living donor transplant rate for ESRD facilities is the total number of attributed beneficiary years for LDT Beneficiaries during the MY. Beneficiary years for LDT Beneficiaries included in the numerator are composed of the number of months from the beginning of the MY up to and including the month of the transplant for LDT Beneficiaries attributed to the ESRD facility during the month of the transplant. This method of determining the number of months associated with a LDT mirrors the method for determining beneficiary attribution for pre-emptive transplant beneficiaries included in the proposed rule and for determining beneficiary attribution for Pre-emptive LDT Beneficiaries as described in section IV.C.5.b.(2)(b) of this final rule. This method is necessary in order to transform a singular event, in particular receipt of a living donor transplant, into a number of beneficiary months such that the numerators for the transplant waitlist rate and the living donor transplant rate can be combined into the transplant rate. CMS will obtain living donor transplant data from SRTR, which maintains data on all transplant, including living donor transplants, and from Medicare claims. We would identify kidney transplants using Medicare claims and administrative data, and SRTR data. As was the case in the proposed rule, to identify kidney transplants using Medicare claims data, we will use claims with Medicare Severity Diagnosis Related Groups (MS–DRGs) 008 (simultaneous pancreas-kidney transplant) and 652 (kidney transplant); and claims with ICD–10 procedure codes 0TY00Z0 (transplantation of right kidney, allogeneic, open approach), 0TY00Z1 (transplantation of right kidney, syngeneic, open approach), 0TY00Z2 (transplantation of right kidney, zooplastic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplastic, open approach) We are also defining LDT Beneficiary in our regulations at § 512.310 to mean an ESRD Beneficiary who received a kidney transplant from a living donor during the MY.

Of note, we are modifying references to the proposed reliability adjustment methodology and are replacing them with references to the aggregation methodology for the transplant rate for ESRD facilities, as described in section IV.C.5.c.(4) of this final rule.

(b) Transplant Rate for Managing Clinicians

As we noted in the proposed rule, whereas ESRD facilities provide care to beneficiaries only once they have begun dialysis, Managing Clinicians provide care for beneficiaries before they begin dialysis. Therefore, we proposed to use a numerator and denominator for the transplant rate for Managing Clinicians that would include pre-emptive transplant beneficiaries, that is, beneficiaries who receive transplants before beginning dialysis, in addition to ESRD Beneficiaries. In this construction, a pre-emptive transplant beneficiary would be included in the numerator for the Managing Clinician as a transplant and in the denominator for the Managing Clinician for the number of months from the beginning of the MY up to and including the month of the transplant. In the proposed rule, we considered including pre-emptive transplants during the MY among attributed pre-emptive transplant beneficiaries in the numerator, to acknowledge Managing Clinician efforts in assisting ESRD Beneficiaries with pre-emptive transplants, without including them in the denominator. However, we concluded that this would disproportionately favor pre-emptive transplants in the construction of the rate. We sought comment on the proposed inclusion of pre-emptive transplants in both the numerator and the denominator for the Managing Clinician transplant rate calculation.

We proposed that the denominator for the transplant rate for Managing Clinicians would be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY, plus the total number of attributed beneficiary years for pre-emptive transplant beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator would be composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis would be identified based on claims, specifically claims with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD related services monthly, and

indicate beneficiary age (12–19 or 20 years of age or older) and the number of face-to-face visits with a physician or other qualified health care professional per month (1, 2–3, 4 or more). CPT® codes 90965 and 90966 are for ESRD related services for home dialysis per full month, and indicate the age of the beneficiary (12–19 or 20 years of age or older). Taken together, these codes are used to bill the MCP, including patients who dialyze at home and patients who dialyze in-center. However, in order to effectuate the exclusions previously described, we proposed to exclude claims for attributed ESRD Beneficiaries who were 75 years of age or older at any point during the month or were in a SNF at any point during the month.

For pre-emptive transplant beneficiaries, attributed beneficiary years included in the denominator would be composed of those months during which a pre-emptive transplant beneficiary is attributed to the Managing Clinician, between the start of the MY and the month of the transplant. In the proposed rule we recognized that including pre-emptive transplant beneficiary years in the denominator may create a bias in favor of pre-emptive transplants occurring at the beginning of the MY, which may influence Managing Clinician behavior. As pre-emptive transplant beneficiaries only contribute months to the denominator from the start of the MY to the month of the transplant, the earlier in the MY the transplant occurs, the fewer months are included in the denominator, and the higher the Managing Clinician's transplant rate. However, as noted in the proposed rule, we believed that the potential for this bias to impact Managing Clinician behavior is small due to the complexity of scheduling in the pre-emptive transplant process (such as surgeon availability, donor and recipient schedules, etc.).

We proposed that the numerator for the transplant rate for Managing Clinicians would be the number of attributed ESRD Beneficiaries who received a kidney transplant or a kidney-pancreas transplant during the MY, plus the number of pre-emptive transplant beneficiaries attributed to the Managing Clinician for the MY. We proposed to identify kidney and kidney-pancreas transplants using Medicare claims data, Medicare administrative data, and SRTR data. For Medicare claims data, we would use claims with Medicare Severity Diagnosis Related Groups (MS–DRGs) 008 (simultaneous pancreas-kidney transplant) and 652 (kidney transplant); and claims with ICD–10 procedure codes 0TY00Z0 (transplantation of right kidney, allogeneic, open approach), 0TY00Z1 (transplantation of right kidney, syngeneic, open approach), 0TY00Z2 (transplantation of right kidney, zooplastic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplastic, open approach). Because kidney-pancreas transplants are billed by including an ICD–10 procedure code for the type of kidney transplant and a separate ICD–10 procedure code for the type of pancreas transplant, we concluded that we would not need to include additional ICD–10 codes to capture kidney-pancreas transplants beyond the ICD–10 codes for kidney transplants listed. We proposed that we would supplement Medicare claims data on kidney and kidney-pancreas transplants with information from the SRTR Database and Medicare administrative data about the occurrence of kidney and kidney-pancreas transplants not identified through claims. We stated that if a beneficiary who receives a transplant during an MY returns to dialysis during the same MY, the beneficiary would remain in the numerator, to acknowledge the efforts of the Managing Clinician in facilitating the transplant but also to hold the Managing Clinician harmless for transplant failure, which may be outside of the Managing Clinician's control.

In the proposed rule we also considered constructing the numerator for the Managing Clinician transplant rate such that the number of attributed beneficiaries who received transplants during a MY would remain in the numerator for every MY after the transplant for which the transplanted beneficiary does not return to dialysis, for the duration of the ETC Model. Keeping transplants in the numerator for MYs subsequent to the MY in which the transplant occurs would acknowledge the significant efforts made by Managing Clinicians to successfully assist beneficiaries through the transplant process. However, as noted in the proposed rule, we believed this approach would artificially inflate transplant rates in later years of the Model and disproportionately disadvantage new Managing Clinicians who begin providing care to ESRD Beneficiaries in later years of the Model. We concluded that this potential for artificially inflated rates and the disadvantage that would result for new ESRD facilities outweighed the advantage of accruing transplants over time.

The following is a summary of the comments received on the proposed transplant rate for Managing Clinicians and our responses.

Comment: We received one comment recommending that CMS include claims for beneficiaries who have received a transplant in the numerator of the transplant rate for Managing Clinicians, even for the MYs after the transplant, to give Managing Clinicians credit for helping to manage patient care and improve post-transplant outcomes for these beneficiaries.

Response: We appreciate the feedback from the commenter. As we are modifying the transplant portion of the MPS used in calculating the PPA to use the transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate, instead of the transplant rate as proposed, we do not believe it would be appropriate to include beneficiaries in the transplant waitlist rate calculation post-transplant, as there would generally be no need for Managing Clinicians to add these beneficiaries to a transplant waitlist. We also do not believe it would be necessary to include post-transplant LDT Beneficiaries or Pre-emptive LDT Beneficiaries in the living donor transplant rate beyond the MYs in which the transplant occurs, as the focus of the rate is whether or not a transplant occurred, not what occurs post-transplant. However, if we modify the MPS calculation to use a transplant rate that includes deceased donor transplants or a similar measure for future MYs through subsequent rulemaking, we may consider proposing to incorporate post-transplant outcomes through such subsequent rulemaking.

After considering public comments, we are finalizing our proposed provisions on the transplant rate for Managing Clinicians in our regulation at § 512.356(c)(2), with modification. The transplant rate for Managing Clinicians is calculated as the sum of the transplant waitlist rate for Managing Clinicians and the living donor transplant rate for Managing Clinicians. The denominator for the transplant waitlist rate for Managing Clinicians is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. As was the case with the proposed transplant rate for Managing Clinicians, dialysis treatment beneficiary years included in the denominator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home or in an ESRD facility, such that 1 beneficiary year is

comprised of 12 attributed beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified based on claims, specifically claims with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. Beneficiaries who are 75 years of age or older at any point during the month are excluded from the denominator. Because beneficiaries who reside in or receive dialysis in SNFs or nursing facilities during the month are now excluded from attribution in general, we are also excluding beneficiaries who were residing in or receiving dialysis a skilled nursing facility or nursing home facility from the transplant waitlist rate denominator. Of note, the denominator for the Managing Clinician transplant waitlist rate does not include attributed Pre-emptive LDT Beneficiaries, as these beneficiaries do not have to be on the transplant waitlist to receive their transplant because living donor organs are not allocated through the transplant waitlist.

The numerator for the transplant waitlist rate for Managing Clinicians is the number of beneficiary years for which attributed ESRD Beneficiaries were on the kidney transplant waitlist during the MY. We are clarifying in this final rule that CMS will identify months during which an attributed ESRD beneficiary was on the kidney transplant waitlist using data from the SRTR database, which maintains data on all transplant waitlists.

The denominator for the living donor transplant rate for Managing Clinicians is the sum of total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY and the total number of attributed beneficiary years for attributed Pre-emptive LDT Beneficiaries during the MY. We define a Pre-emptive LDT Beneficiary in our regulations at § 512.310 as a beneficiary who received a pre-emptive kidney transplant from a living donor during the MY. Including Pre-emptive LDT Beneficiaries in the living donor transplant rate denominator for Managing Clinicians follows the same reasoning and method as described in the proposed rule for including pre-emptive transplant beneficiaries in the transplant rate for Managing Clinicians. That is, whereas ESRD facilities provide care to beneficiaries only once they have begun dialysis, Managing Clinicians provide care for beneficiaries before they begin dialysis. However, the construction of the denominator for the living donor transplant rate differs from the proposed construction of the denominator for the proposed transplant rate because the living donor transplant rate includes only pre-emptive transplants that came from living donors. As such, the denominator for the living donor transplant rate for Managing Clinicians does not include beneficiaries who received a pre-emptive transplant from a deceased donor. Dialysis treatment beneficiary years included in the denominator of the living donor transplant rate for Managing Clinicians are the same as those included in the denominator of the transplant waitlist rate, as described above. As was the case for preemptive transplant beneficiary years in the proposed rule, pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to the Managing Clinician, between the start of the MY and up to and including the month of the transplant. The numerator for the living donor transplant rate for Managing Clinicians is the total number of attributed beneficiary years for LDT Beneficiaries during the MY plus the total number of attributed beneficiary years for Pre-emptive LDT Beneficiaries during the MY. Beneficiary years for LDT Beneficiaries included in the numerator are composed of the number of months from the beginning of the MY up to and including the month of the transplant for LDT Beneficiaries attributed to the Managing Clinician during the month of the transplant. As described above in regards to the living donor transplant rate for ESRD facilities, this method is necessary in order to transform a singular event, in particular a living donor transplant, into a number of beneficiary months such that the numerators for the transplant waitlist rate and the living donor transplant rate can be combined into the transplant rate. As with the denominator for the living donor transplant rate for Managing Clinicians, pre-emptive LDT beneficiary years included in the numerator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to the Managing Clinician, between the start of the MY and up to and including the month of the transplant.

CMS will obtain transplant waitlist data from SRTR, which maintains status data for all transplant waitlists and transplants, including living donor transplants. CMS will obtain living donor transplant data from SRTR, which contains comprehensive information about transplants that occur in the U.S., as well as from Medicare claims. Of note, we are modifying references to the proposed reliability adjustment methodology and are replacing them with references to the aggregation methodology for the transplant rate for Managing Clinicians, as described in section IV.C.5.c.(4) of this final rule.

(3) Risk Adjustment

In order to account for underlying variation in the population of beneficiaries attributed to participating ESRD facilities and Managing Clinicians, we proposed that CMS would risk adjust both the home dialysis rate and the transplant rate.

For the home dialysis rate, we proposed to use the most recent final risk score for the beneficiary, calculated using the CMS–HCC (Hierarchical Condition Category) ESRD Dialysis Model used for risk adjusting payment in the Medicare Advantage program, to risk adjust the home dialysis rate under the proposed ETC Model. As noted in the proposed rule, internal analyses completed by CMS show that lower HCC risk scores are associated with beneficiaries on home dialysis than with beneficiaries on in-center HD. The risk adjustment methodology we proposed for the ETC Model home dialysis rate would account for ESRD facilities and Managing Clinicians with a population that is relatively sicker than the general Medicare population. As we explained in the proposed rule, the CMS–HCC risk adjustment models were developed for the Medicare Advantage program and use a Medicare beneficiary's medical conditions and demographic information to predict Medicare expenditures for the next year. In the Medicare Advantage context, the per-person capitation amount paid to each Medicare Advantage plan is adjusted using a risk score calculated using the CMS–HCC Models.[152] We proposed to use the most recent final risk score calculated for the beneficiary that is available at the time of the calculation of ESRD facility and Managing Clinician home dialysis rates to risk adjust the ETC Model home dialysis rate for that MY and corresponding PPA Period.

In the proposed rule, we summarized at a high level how the CMS–HCC Models are developed and used in risk adjusting payment to Medicare Advantage plans.

We explained that CMS proposes and adopts the CMS–HCC ESRD Dialysis Model for risk adjusting payments to Medicare Advantage organizations for a particular payment year through the Advance Notice and Rate Announcement for the Medicare

[152] CMS. Report to Congress: Risk adjustment in Medicare Advantage. December 2018; *cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf.*

Advantage program.[153] This happens the year before the payment year begins, meaning that the CMS–HCC ESRD Dialysis Model used to risk adjust payments for 2020 was adopted and announced in April 2019. However, CMS does not calculate final risk scores for a particular payment year until several months after the close of the payment year.

We explained in the proposed rule that using risk scores developed using the CMS–HCC ESRD Dialysis Model to risk adjust the ETC Model home dialysis rate would be appropriate as it can be more difficult to transition sicker beneficiaries to home dialysis, and risk adjusting the home dialysis rate using risk scores calculated using the CMS–HCC ESRD Dialysis Model would account for the relative sickness of the population of ESRD Beneficiaries attributed to each ETC Participant relative to the national benchmark. We also stated that use of these final risk scores for the ETC Model would mean use of the same methodology and the same coefficients for the relevant HCCs as the CMS–HCC ESRD Dialysis Model used for the prior Medicare Advantage payment year. The CMS–HCC ESRD Dialysis Model includes the risk factors outlined in § 422.308(c)(1) and (c)(2)(ii), so those risk factors would be used in risk adjustment for the ETC Model. Under our proposal, the risk scores used for the ETC Model would also be adjusted with the same coding pattern and normalization factors that are adopted for the CMS–HCC ESRD Dialysis Model for the relevant year but, for the ETC Model, we did not propose to use a frailty adjustment (for example, outlined in § 422.308(c)(4)) as is used in the Medicare Advantage program for certain special needs plans.

In the proposed rule, we also considered not applying a risk adjustment methodology to the ETC Model home dialysis rate in recognition of the limitations of existing risk adjustment methodologies to account for housing instability, which is a key factor preventing utilization of home dialysis. However, we concluded that not risk adjusting the home dialysis rate would disproportionately disadvantage ETC Participants that provide care to sicker beneficiaries. We also stated that we considered creating a custom risk-adjustment methodology for the ETC Model based on certain factors found in the literature to affect rates of home dialysis, but said that we believed that the HCC system currently in use in the Medicare Advantage program would be sufficient for the purposes of this Model, without the effort required to develop a new methodology.

We proposed that the risk-adjustment methodologies for the home dialysis rate and transplant rate would be applied independently. In the proposed rule we also considered using the same risk adjustment strategy for both rates, but recognized that the risk factors that may impact the ability of an ESRD Beneficiary to successfully dialyze at home are different from the risk factors that may impact the ability of an ESRD Beneficiary or pre-emptive transplant beneficiary to receive a kidney transplant. We further noted that, even in the Medicare Advantage program, a different CMS–HCC Model is used for beneficiaries who have received a transplant and stated our belief that the benefit of separate risk adjustment methodologies would outweigh the additional complexity. For the transplant rate, we noted in the proposed rule that we wanted to use a risk adjustment methodology that aligns with a risk adjustment methodology with which ESRD facilities and Managing Clinicians are likely to be familiar and that similarly would not require development of a new and unfamiliar methodology. In the proposed rule we noted that we believe that the methodology used for purposes of risk adjusting the PPPW satisfies these criteria and would be appropriate to apply in risk adjusting the transplant rate. Specifically, we proposed that the ESRD facility and Managing Clinician transplant rates would be risk adjusted for beneficiary age, using the similar age categories, with corresponding risk coefficients, used for purposes of the PPPW measure described earlier (83 FR 57004).

Although age alone is not a contraindication to transplantation, we stated in the proposed rule that older patients are likely to have more comorbidities and generally be more frail, thus making them potentially less suitable candidates for transplantation, and therefore some may be appropriately excluded from waitlisting for transplantation. The risk adjustment model for the PPPW contains risk coefficients specific to each of the following age categories of beneficiaries (with age computed on the last day of each reporting month): Under 15; 15–55; 56–70; and 71–74. Given that the ETC Model would exclude beneficiaries under 18 from the attribution methodology used for purposes of calculating the transplant rates, we proposed to use the risk coefficients calculated for the PPPW for the populations aged 18–55, 56–70, and 71–74, with age computed on the last day of each month of the MY. Transplant rates for ESRD facilities and Managing Clinicians would be adjusted to account for the relative percentage of the population of beneficiaries attributed to each ETC Participant in each age category relative to the national age distribution of beneficiaries not excluded from attribution. Further information on the risk adjustment model used for purposes of the PPPW can be found in the PPPW Methodology Report (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Report-for-Percentage-of-Prevalent-Patients-Waitlisted.pdf*).

In the proposed rule, we stated that we had considered using the risk adjustment methodology used in the Standardized Waitlist Ratio available online at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Report-for-Standardized-First-Kidney-Transplant-Waitlist-Ratio-for-Incident-Dialysis-Facilities.pdf* for risk adjusting the ETC Model transplant rate. However, we decided not to as this measure is focused only on incident beneficiaries in their first year of dialysis, rather than the broader population of beneficiaries that would be included in the ETC Model.

In the proposed rule we also considered using the CMS–HCC ESRD Transplant Model for risk adjusting the ETC Model transplant rate. However, we decided not to as the model is focused on costs once a beneficiary receives a transplant, rather than the beneficiary's suitability for receiving a transplant.

The following is a summary of the comments received on the risk adjustment methodology for the home dialysis rate, the risk adjustment methodology for the transplant rate, and our responses.

Comment: We received several comments urging CMS to not use the CMS ESRD–HCC Risk Score methodology for risk adjusting the home dialysis rate as proposed. Many commenters commented that although there is a correlation between healthier beneficiaries and home dialysis utilization, the relationship is not causative, nor is beneficiary health status the most important factor

[153] For example, CMS, Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter, January 30, 2019. *cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf* and CMS, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2019; *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

affecting home dialysis uptake rates. Other commenters commented that the CMS ESRD–HCC Risk Score methodology is built using fee for services data to project Medicare Advantage spending, not relative levels of illness; the commenters also pointed out that a beneficiary whose risk score is twice that of another is not necessarily half as likely to be an effective candidate for home dialysis. Commenters also raised concerns that this proposed methodology was not transparent as ESRD facilities and Managing Clinicians do not necessarily receive the CMS ESRD–HCC risk score information for their patients. One dialysis company noted in its comments that the CMS ESRD–HCC risk score methodology has a different methodology for beneficiaries who are new to the Medicare program and that the HCC risk scores may be less predictive for this population given the increased rates of home dialysis utilization among beneficiaries who are new to dialysis.

Response: After receiving comments on the proposed rule, we performed an additional analysis that showed a correlation between lower CMS–HCC risk scores and an increased likelihood to receive home dialysis as opposed to in-center dialysis. The average CMS–HCC risk score for a beneficiary receiving home dialysis is 0.9, while the average CMS–HCC risk score for a beneficiary receiving in-center hemodialysis is 1.03, and this difference is statistically significant with a p-value of .02. However, the same analysis done by CMS after receiving comments on the proposed rule showed that, although the difference in CMS–HCC risk scores between these two populations is statistically significant, CMS–HCC risk scores have an explanatory ability of only 1.5 percent for determining whether a beneficiary will receive home dialysis rather than in-center dialysis, and vice versa. Based on the low explanatory power of the CMS–HCC risk score in predicting whether a beneficiary will receive home dialysis, together with the other issues with the proposed risk-adjustment methodology raised by the commentators, we do not believe that there is a significant value in risk adjusting the home dialysis rate based on this proposed methodology, and therefore we are not finalizing this approach. We are instead finalizing the home dialysis rate calculation without a risk-adjustment methodology and we seek input from commenters about risk adjustment methodologies to be proposed in future rulemaking. We recognize that in the proposed rule, we stated that we believed that not risk adjusting the home dialysis rate would disproportionately disadvantage ETC Participants that provide care to sicker beneficiaries. However, our subsequent analysis indicated that although there is a statistically significant correlation between beneficiary risk scores and propensity for home dialysis, the relationship had very little explanatory power, meaning that we do not believe our proposed risk adjustment methodology will help to address this issue. We intend to monitor for whether the lack of a risk-adjustment methodology for the home dialysis rate has any negative consequences for ETC Participants and ESRD Beneficiaries and may modify the ETC Model to add a risk-adjustment methodology for calculation to the home dialysis rate through subsequent rulemaking.

Comment: Many commenters recommended that CMS consider using socioeconomic factors for purposes of risk adjusting the home dialysis rate, as these factors can preclude beneficiaries from being appropriate candidates for home dialysis. The commenters asserted that beneficiaries suffering from housing insecurity or homelessness are not good candidates for the home dialysis modality and that peritonitis, an infection of the perineum that can result from PD and prevents beneficiaries from being able to continue receiving PD is more common among socially disadvantaged groups. Commenters had several suggestions as to which socioeconomic factors CMS could use to risk-adjust the home dialysis rate, including using dual eligibility status as a proxy for socioeconomic status, using the ZIP code or the ZIP+4 based on the location of the beneficiary or the ESRD facility, using Z-codes in ICD–10 to track socioeconomic status or homelessness, looking at the urban/rural divide, using presence on the kidney transplant waitlist as a proxy for health status, or setting up a standardized ratio measure based on projected rates of transplants.

Three separate commenters—including a dialysis company, a patient advocacy group, and a nephrology practice—each independently recommended that CMS use the risk adjustment methodology from the Hospital Readmissions Reduction Program, as laid out in the FY 2018 IPPS final rule [154] (82 FR 37990, 38221 (August 14, 2017)) in order to risk-adjust the home dialysis rate for socioeconomic factors.

[154] *https://www.govinfo.gov/content/pkg/FR-2017-08-14/pdf/2017-16434.pdf.*

Response: We thank the commenters for their recommendations and believe that risk adjusting the home dialysis rate based on socioeconomic factors may have merit. However, risk adjusting the home dialysis rate based on socioeconomic factors would represent a significant departure from the risk adjustment methodology outlined in the proposed rule. Accordingly, we are not finalizing a risk-adjustment methodology based on socioeconomic factors at this time. As described previously in this final rule, we are finalizing the home dialysis rate calculation without a risk adjustment methodology. We seek input from the public on how to construct a risk adjustment methodology for the home dialysis rate that could account for socioeconomic factors, like the one from the Hospital Readmissions Reduction Program, to inform any future rulemaking on this topic.

Comment: We received several comments critiquing the risk adjustment methodology from the PPPW measure we proposed to apply to the transplant rate. A commenter raised issues with the methodology, pointing out that it was not NQF endorsed and that it risk adjusts by age in a way that has abrupt cut points, rather than using age as a continuous variable.

Response: We continue to believe that the risk adjustment methodology for the PPPW measure is appropriate to use for the transplant waitlist rate, which we are finalizing as part of the transplant rate. We extensively tested the PPPW measure, including its risk adjustment methodology, before we adopted that measure for the ESRD QIP, and our rationale supporting the use of a similar risk adjustment methodology for the transplant waitlist rate is consistent with the rationale that supports our use of that methodology for the ESRD QIP. The specific design of the risk adjustment methodology for the PPPW measure, including the cut points, is designed to best fit the transplant waitlist data in the PPPW measure. Though it is not an NQF-endorsed measure, this is a measure currently used by CMS and we believe the methodology to be sound.

Comment: Some commenters asserted that the proposed risk adjustment methodology for the transplant rate should also include other factors related to the transplant process, including diagnoses of malignancy, cardiac surgery, or other comorbidities that could prevent a beneficiary from being a transplant candidate. Other commenters urged CMS to consider other factors related to transplant eligibility or to recognize different levels

of access to kidneys in different geographies.

Response: CMS believes that by modifying the transplant rate to remove deceased donor organ transplants, as described previously in this final rule, we do not need to risk adjust the transplant rate for these specific issues around organ supply that may affect access to kidneys, in particular deceased donor organs, in different geographies. In addition, though there are disparaties in the transplant process, CMS also decided not to include other factors in risk adjusting the transplant waitlist rate to align with the risk adjustment methodology for the PPPW measure, which also did not include these factors. Additionally, we believe that the exclusions from beneficiary attribution to ETC Participants described in section IV.C.5.b.(1) of this final rule sufficiently account for relevant contraindications to transplant and that additional risk adjustment for these factors is not necessary.

After considering public comments, we are finalizing our proposed provisions for risk adjusting the home dialysis rate and the transplant rate, with modifications. Specifically, in response to the methodological concerns highlighted by commenters regarding our proposed methodology for risk adjusting the home dialysis rate and subsequent analysis conducted by CMS, we are finalizing the home dialysis rate calculation without a risk adjustment methodology. CMS may add a risk adjustment methodology to the home dialysis rate calculation, taking into account the comments received and any additional feedback received from the public, in future rulemaking. We are finalizing in our regulation at § 512.365(d) that the transplant waitlist rate portion of the transplant rate will be risk adjusted based on beneficiary age with separate risk coefficients for the following age categories of beneficiaries, with age computed on the last day of each month of the MY: 18 to 55; 56 to 70; and 71 to 74. We are also finalizing in our regulation at § 512.365(d) that the transplant waitlist rate portion of the transplant rate will be adjusted to account for the relative percentage of the population of beneficiaries attributed to the ETC Participant in each age category relative to the national age distribution of beneficiaries not excluded from attribution. The living donor transplant rate portion of the transplant rate will not be risk adjusted due to small sample sizes.

(4) Reliability Adjustments and Aggregation

In order to overcome low reliability of the home dialysis rate and transplant rate related to small numbers of beneficiaries attributed to individual ETC Participants, we proposed to employ a reliability adjustment. Under this approach, we proposed using statistical modeling to make reliability adjustments such that the home dialysis rate and the transplant rate would produce reliable estimates for all ETC Participants, regardless of the number of beneficiaries for whom they provide care. We also proposed this approach to improve comparisons between ETC Participants and those ESRD facilities and Managing Clinicians not selected for participation in the Model for purposes of achievement benchmarking and scoring, described in the proposed rule and section IV.C.5.d of this final rule. The proposed reliability adjustment approach would create a weighted average between the individual ETC Participant's home dialysis rate and transplant rate and the home dialysis rate and transplant rate among the ETC Participant's aggregation group (previously described), with the relative weights of the two components based on the statistical reliability of the individual ETC Participant's home dialysis rate and transplant rate, as applicable. For example, if an ETC Participant's home dialysis rate has high statistical reliability, then the ETC Participant's individual home dialysis rate would contribute a large portion of the ETC Participant's reliability-adjusted home dialysis rate and the aggregation group's home dialysis rate would contribute a small portion of the ETC Participant's reliability-adjusted home dialysis rate. We currently employ this technique in a variety of settings, including the measures used in creating hospital ratings for Hospital Compare. We explained in the proposed rule that the advantage of using this approach is that we could use one method to produce comparable performance rates for ESRD facilities and Managing Clinicians across the size spectrum. We also noted that the disadvantage of using this approach is that reliability adjusted performance rankings do not necessarily reflect absolute or observed performance, and may be difficult to interpret directly. We stated that we believed this approach balanced the need for individualized performance assessment and incentives with the importance of reliably assessing the performance of each ETC Participant.

For Managing Clinicians, we proposed that the performance on these measures would be first aggregated up to the practice level, as identified by the practice Taxpayer Identification Number (TIN) for Managing Clinicians who are in a group practice, and at the individual National Provider Identifier (NPI) level for Managing Clinicians who are not in a group practice, that is, solo practitioners. We proposed to define ''TIN'' as a Federal taxpayer identification number or employer identification number as defined by the Internal Revenue Service in 26 CFR 301.6109–1. We proposed to define ''NPI'' as the standard unique health identifier used by health care providers for billing payers assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162. We proposed these definitions because they are used elsewhere by the Medicare program (see 42 CFR 414.502). Performance would then be aggregated to the aggregation group level. We proposed that the aggregation group for Managing Clinicians, once aggregated to the group practice or solo practitioner level, as applicable, would be all Managing Clinicians within the HRR in which the group practice is located (for group practices) or the Managing Clinician's HRR (for solo practitioners).

For ESRD facilities, we proposed that the individual unit would be the ESRD facility. We proposed to define a ''Subsidiary ESRD facility'' as an ESRD facility owned in whole or in part by another legal entity. We proposed this definition in recognition of the structure of the dialysis market, as described in this rule. We proposed that the aggregation group for Subsidiary ESRD facilities would be all ESRD facilities located within the ESRD facility's HRR owned in whole or in part by the same company, and that ESRD facilities that are not Subsidiary ESRD facilities would be in an aggregation group with all other ESRD facilities located within the same HRR (with the exception of those ESRD facilities that are Subsidiary ESRD facilities).

We sought input on our proposal to use reliability adjustments to address reliability issues related to small numbers, as well as on our proposed aggregation groups for conducting the reliability adjustment for ESRD facilities and Managing Clinicians that are ETC Participants.

In the proposed rule, we acknowledged that for some segments of the dialysis market, companies operating ESRD facilities may operate specific ESRD facilities that focus on home dialysis, which furnish home dialysis services to all patients receiving home dialysis through that company in a given area. Therefore, assessing home

dialysis rates at the individual ESRD facility level may not accurately reflect access to home dialysis for beneficiaries receiving care from a specific company in the area. In the proposed rule, we stated that we believed that the reliability adjustment approach would help to address this concern, because the construction of the reliability adjustment for Subsidiary ESRD facilities would aggregate to the company level within a given HRR and thus incorporate this dynamic. In the proposed rule, we considered using a single aggregated home dialysis rate for all ESRD facilities owned in whole or in part by the same company within a given HRR to account for this market dynamic. However, in the proposed rule we stated that producing individual ESRD facility rates and reliability adjusting individual ESRD facility scores would be necessary to incentivize ESRD facilities within the same company in the same HRR to provide the same level of care to all of their attributed beneficiaries.

The following is a summary of the comments received on the proposed reliability adjustment and aggregation methodologies and our responses.

Comment: We received comments that our proposed reliability adjustment lacked transparency and was difficult to understand. Commenters noted that there was not sufficient detail for them to assess the potential impacts of the proposed policy.

Response: We appreciate the feedback from commenters about the proposed reliability adjustment. In response to these comments, we are not finalizing the proposed reliability adjustment policy. CMS no longer believes that the reliability adjustment is necessary for Managing Clinicians or for ESRD facilities in light of the changes to the aggregation policies described in this section of this final rule, under which the performance of Managing Clinicians will be assessed at the practice level, if applicable, and the performance of ESRD facilities will be assessed at the aggregation group level instead of at the individual facility level. In addition, as discussed in section IV.C.5.f of this final rule, we have increased the low-volume threshold relative to the low-volume threshold outlined in the proposed rule, which will remove greater numbers of the smallest ETC Participants from the application of the PPA, further increasing the statistical reliability of the rates used as part of the PPA calculation.

Comment: We received comments in support of our proposal to aggregate performance on the home dialysis rate and transplant rate for Managing Clinicians in a group practice at the TIN level. We also received comments recommending that performance for a Managing Clinician should be assessed only based on the performance of other Managing Clinicians with whom the Managing Clinician shares a business relationship.

Response: We appreciate the commenters' support and are finalizing our proposal to assess the performance of Managing Clinicians in a group practice at the TIN level and to assess the performance of Managing Clinicians who are not in a group practice, that is, solo practitioners at the NPI level. However, we no longer plan to further aggregate performance for Managing Clinicians up to the HRR level, as proposed. Based on comments received, we recognize that it is most appropriate to aggregate performance for Managing Clinicians only for Managing Clinicians practicing under a common group practice (as identified by a TIN), and that the performance of solo practitioner Managing Clinicians should not be aggregated with that of any other Managing Clinicians. Specifically, we do not believe the Managing Clinician should be held accountable for the performance of Managing Clinicians in unaffiliated practices at the HRR level because of their lack of business relationships.

Comment: We received multiple comments objecting to our proposed aggregation methodology for ESRD facilities, pointing out that dialysis companies often concentrate their home dialysis patients at certain regional centers that solely focus on home dialysis. Additionally, we received comments that requiring a home dialysis program to be built at each ESRD facility would be duplicative and would not necessarily improve patient care. We also received comments that ESRD Beneficiaries who receive treatment from ESRD facilities that are ETC Participants may receive home dialysis services from a home dialysis facility that is owned in whole or in part by the same dialysis company, but that is not necessarily within the same HRR as the ESRD facility.

Response: Based on comments received from the public, we believe that the nature of the dialysis market means that assessing home dialysis rates at the individual ESRD facility level may not accurately reflect access to home dialysis through that company in a given area. Our intent is to ensure that home dialysis is available to every ESRD Beneficiary, not necessarily at every individual ESRD facility. In order to better align with market dynamics, we will assess ESRD facility performance at the aggregation group level, rather than at the facility level. However, as proposed, the aggregation group for a Subsidiary ESRD facility will include only those ESRD facilities owned in whole or in part by the same company located in the same HRR. Based off of our analyses, CMS found rare instances of typographical errors for facility information in PECOS. We will address these inconsistencies by identifying those ESRD facilities owned in whole or in part by the same company using the Chain TIN and Chain Name from PECOS with adjustments made for any mismatches arising from typographical errors in those fields in PECOS using CrownWEB and other CMS data sources.

While we understand the commenters' concerns that dialysis companies may operate across multiple HRRs, as described in sections IV.C.5.3.b and IV.C.5.3.c.(1) of this final rule, we believe HRRs are the best representation of patterns of care and, unlike other geographic units of selection considered in the proposed rule, also include rural areas. Additionally, CMS does not have sufficient information regarding the location of home dialysis facilities relative to other Subsidiary ESRD facilities of the same dialysis companies in order to make informed aggregation decisions on that basis (also, these arrangements are likely subject to change). Moreover, tailoring ESRD facility aggregation based on each dialysis company's corporate structure would be difficult to administer for CMS and could be subject to gaming by the dialysis companies.

Comment: We received multiple comments in support of our proposal that the aggregation group for Subsidiary ESRD Facilities should be all ESRD facilities located within the ESRD facility's HRR owned in whole or in part by the same company. Additionally, we received comments suggesting that all ESRD facilities located in the same HRR should receive a single combined score regardless of their ownership status.

Response: We appreciate comments supporting our proposal that the aggregation group for Subsidiary ESRD facilities would be all ESRD facilities owned in whole or in part by the same company within an HRR. We believe this is a fair approach that allows the performance for ESRD facilities to be assessed based solely on the performance of facilities that are owned in whole or in part by the same company, rather than facilities that may be owned by different companies. Additionally, we see the benefits of grouping ESRD facilities within the

same HRR, as the boundaries of the HRRs reflect referral patterns and because an ESRD facility is more likely to refer patients for home dialysis and other services to an ESRD facility located in the same geographic area than to an ESRD facility located farther away.

Comment: We received a comment recommending that CMS create a virtual group for small or low-volume ESRD facilities with a smaller presence in the specific HRR to aggregate performance.

Response: We appreciate this recommendation but do not believe that creating a virtual group will be necessary to improve the reliability of the home dialysis rates and transplant rates for low-volume ESRD facilities. In addition to the operational complexities that implementing a virtual group would present for CMS, we believe that the increased low-volume threshold described in section IV.C.5.f. of this final rule will help to improve the statistical reliability of the home dialysis rates and transplant rates for small ESRD facilities, while ensuring a viable model test.

After considering public comments, we are finalizing our proposed provisions for reliability adjustment and aggregation of the home dialysis rate and transplant rate, with modifications. Specifically, we are removing the reliability adjustment for both ESRD facilities and Managing Clinicians. Additionally, we are codifying in our regulation at § 512.365(e)(2) that a Managing Clinician's performance on the home dialysis rate and transplant rate will be aggregated to the Managing Clinician's aggregation group, which is identified at the TIN level for Managing Clinicians in a group practice and at the individual NPI level for Managing Clinicians who are solo practitioners. We are not finalizing our proposal to further aggregate Managing Clinician performance with all other Managing Clinicians located within the HRR. Additionally, in § 512.365(e)(1), we are finalizing our proposal that ESRD facilities' home dialysis rate and transplant rate will be aggregated to the ESRD facility's aggregation group, which is defined as all ESRD facilities owned in whole or in part by the same company within an HRR for a Subsidiary ESRD facility. As discussed previously in this final rule rule, CMS is finalizing its proposal to use PECOS to verify the correct zip code of the ESRD facility location for purposes of selecting ESRD facilities for participation in the Model. However, CMS received public comments regarding our proposed aggregation policy suggesting that CMS use resources in addition to PECOS to correctly identify ESRD facilities. Subsequent CMS analyses also found rare instances of typographical errors for facility information in PECOS. In response, we are modifying our policy in this final rule such that Subsidiary ESRD facilities will be identified using the Chain TIN and Chain Name from PECOS and that CMS will use other CMS data sources, including CrownWEB, to identify and correct any mismatches arising from typographical errors in those fields in PECOS. CMS may notify ESRD facilities of their status as a Subsidiary ESRD Facility and, if applicable, the other Subsidiary ESRD Facilities with which CMS has identified a common ownership relationship during the MY to allow ESRD facilities the opportunity to confirm and provide feedback before CMS calculates the PPA for that MY. We are also modifying our aggregation approach for ESRD facilities that are not Subsidiary ESRD facilities, such that these ESRD facilities will not be aggregated with other facilities located within the HRR in which the facility is located or otherwise. We are also finalizing the Taxpayer Identification Number (TIN), National Provider Identifier (NPI), and Subsidiary ESRD facility definitions, as proposed, in our regulation at § 512.310.

d. Benchmarking and Scoring

We proposed calculating two types of benchmarks for rates of home dialysis and transplants against which to assess ETC Participant performance in MY1 and MY2 (both of which would begin in CY 2020). Under our proposal, risk-adjusted and reliability-adjusted ETC Participant performance for the home dialysis rate and the transplant rate would be assessed against these benchmarks on both achievement and improvement at the ETC Participant level.

The first set of benchmarks would be used in calculating an achievement score for the ETC Participant on both the home dialysis rate and the transplant rate. This set of benchmarks would be constructed based on historical rates of home dialysis and transplants in Comparison Geographic Areas. We proposed constructing the benchmarks using 12 months of data, beginning 18 months before the start of the MY and ending 6 months before the start of the MY, to allow time for claims run-out and calculation. We proposed to refer to this period of time as the ''benchmark year.'' We proposed using data from ESRD facilities and Managing Clinicians located in Comparison Geographic Areas to construct these benchmarks. In the proposed rule, we alternatively considered using national performance rates to construct these benchmarks. However, in order to prevent the impact of the model intervention altering benchmarks for subsequent MYs, we decided against this alternative in the proposed rule. We proposed to calculate the home dialysis rate and transplant rate benchmarks for ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year using the same methodologies that we use to calculate the home dialysis rate and transplant rate for ESRD facilities and Managing Clinicians located in Selected Geographic Areas during the MYs. We stated our intent to establish the benchmarking methodology for future MYs through subsequent rulemaking.

As stated in the proposed rule, our intent in future MYs is to increase achievement benchmarks among ETC Participants above the rates observed in Comparison Geographic Areas. By MY9 and MY10, in order to receive the maximum achievement score, as noted in the proposed rule, we were considering that an ETC Participant would have to have a combined home dialysis rate and transplant rate equivalent to 80 percent of attributed beneficiaries dialyzing at home and/or having received a transplant. We sought public comment on our intent to increase achievement benchmarks over the duration of the Model.

The second set of benchmarks would be used in calculating an improvement score for the ETC Participant on both the home dialysis rate and the transplant rate. This set of benchmarks would be constructed based on historical rates of home dialysis and transplants by the ETC Participant during the Benchmark Year. We proposed to calculate the improvement score by comparing MY performance on the home dialysis rate and transplant rate against past ETC Participant performance to acknowledge efforts made in practice transformation to improve rates of home dialysis and transplants. However, we proposed that an ETC Participant could not attain the highest scoring level through improvement scoring. Specifically, while an ETC Participant could earn an achievement score of up to 2 points for the transplant rate and the home dialysis rate, the maximum possible improvement score is 1.5 points for each of the rates. We explained that this policy would be consistent with other CMS programs and initiatives employing similar improvement scoring methodologies, including the CEC Model.

In the proposed rule, we considered not including improvement scoring for the first two MYs, as this would mean assessing improvement in the MY against ETC Participant performance before the ETC Model would begin. However, as noted in the proposed rule, we believe that including improvement scoring for the first two MYs is appropriate, as it acknowledges performance improvement gains while participating in the ETC Model. We sought input on the use of improvement scoring in assessing ETC Participant performance for the first two MYs. Table 13 details the proposed scoring methodology for assessment of MY1 and MY2 achievement scores and improvement scores on the home dialysis rate and transplant rate.

TABLE 13: PROPOSED SCORING METHODOLOGY FOR ASSESSMENT OF MEASUREMENT YEARS 1 AND 2 ACHIEVEMENT SCORES AND IMPROVEMENT SCORES ON THE HOME DIALYSIS RATE AND TRANSPLANT RATE

Achievement Score Scale for MYs 1 and 2	Points	Improvement Score Scale for MYs 1 and 2
90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	2	Not a scoring option
75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	1.5	Greater than 10 percent improvement relative to Benchmark Year rate
50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	1	Greater than 5 percent improvement relative to Benchmark Year rate
30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	0.5	Greater than 0 percent improvement relative to Benchmark Year rate
<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	0	Less than or equal to Benchmark Year rate

Under our proposal, the ETC Participant would receive the higher of the achievement score or improvement score for the home dialysis rate and the higher of the achievement score or improvement score for the transplant rate, which would be combined to produce the ETC Participant's Modality Performance Score (MPS). We proposed the following formula for determining the MPS:

MPS = 2 × (The higher of the home dialysis rate achievement or improvement score) + (The higher of the transplant rate achievement or improvement score)

We proposed that the home dialysis rate score would constitute two thirds of the MPS, and that the transplant rate score would constitute one third of the MPS. In the proposed rule, we considered making the home dialysis rate score and the transplant rate score equal components of the MPS, to emphasize the importance of both home dialysis and transplants as alternative renal replacement therapy modalities. However, we recognized that transplant rates may be more difficult for ETC Participants to improve than home dialysis rates, due to the limited supply of organs and the number of other providers and suppliers that are part of the transplant process but are not included as participants in the ETC Model. For this reason, we proposed that the home dialysis rate component take a greater weight than the transplant rate component of the MPS.

The following is a summary of the comments received on the proposed benchmarking and scoring methodology and our responses.

Comment: Several commenters opposed our proposal to use a comparative or percentile based methodology for purposes of calculating the achievement benchmarks. According to some of these commenters, this comparative approach would not accurately reflect ETC Participant performance or the care being provided. Some of these commenters stated that this comparative approach serves only as a way for CMS to ensure Model savings, as some ETC Participants' performance would fall below the achievement benchmarks, resulting in a negative payment adjustment. A commenter opined that the percentile based achievement scoring approach would not be operational at the ESRD facility level because, based on the commenter's analysis, there would be no differentiation in home dialysis rates for the three lowest scoring groups. This comment was cited by several other commenters.

Response: We disagree that using a comparative approach for calculating achievement benchmarks, percentile-based or otherwise, does not reflect ETC Participant performance or the care being provided. On the contrary, comparative benchmarks reflect the performance of the ETC Participant relative to their peers. We also disagree that a comparative approach serves only

as a way to ensure Model savings for two reasons. First, because achievement benchmarks are constructed based on performance of those not selected for participation in the Model, it is possible that many ETC Participants will meet or exceed the level of performance necessary to not receive a negative adjustment through achievement scoring alone. Second, the use of improvement scoring alongside achievement scoring means that ETC Participants can avoid negative payment adjustments through improvement alone, regardless of their performance in relation to the achievement benchmarks. We disagree with the commenter's analysis suggesting that there would be no differentiation between the lowest three benchmark groups if home dialysis rates were assessed at the ESRD facility level based on our analyses of claims data conducted in the development of this final rule. Specifically, our analyses indicated that after the application of the aggregation group methodology to the performance of ESRD facilities located in Selected Geographic Areas, there is differentiation in the home dialysis rates among ESRD facilities at or below the 50th percentile of benchmark rates for Comparison Geographic Areas, which corresponds with the lowest three groups used for purposes of assessing an ESRD facility's achievement score. We also note that, as proposed, we will calculate the benchmarks for the home dialysis rate and the transplant rate for ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year using the same methodologies that we use to calculate the home dialysis rate and transplant rates for ESRD facilities and Managing Clinicians located in Selected Geographic Areas during the MYs. Accordingly, we will be aggregating Subsidiary ESRD facilities with all ESRD facilities owned in whole or in part by the same dialysis organization located in the same HRR when constructing the benchmarks, as described in section IV.C.5.c.(4) of this final rule.

Comment: A commenter supported our proposal to use Comparison Geographic Areas to create achievement benchmarks, and concurred with CMS's decision not to use national performance rates to construct these benchmarks because the model design adequately controls for any spillover effects due to the national nature of the dialysis market.

Response: We appreciate the feedback and support from the commenter and agree that the model design adequately controls for any spillover effects due to the national nature of the dialysis market.

Comment: Several commenters opposed the construction of achievement benchmarks based on rates in Comparison Geographic Areas, for the following reasons. First, several of these commenters pointed out that, due to the national nature of the dialysis market, dialysis companies operating nationally may implement practices that improve rates nationwide, not just in Selected Geographic Areas, so achievement benchmarks based on rates in Comparison Geographic Areas would not remain constant over time. Second, one of these commenters stated that basing achievement benchmarks on Comparison Geographic Areas when dialysis organizations have ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas creates an incentive for those dialysis organizations to lower rates of home dialysis and transplants in Comparison Geographic Areas to improve the performance of their locations that are ETC Participants.

A commenter recommended that CMS monitor the rates of home dialysis and transplants between Selected Geographic Areas and Comparison Geographic Areas to determine whether the Model is resulting in unintended consequences—including market consolidation, manipulation of achievement benchmarks, declining rates of home dialysis or transplant in Comparison Geographic Areas, or adverse patient outcomes—due to the distribution of LDOs in both Selected Geographic Areas and Comparison Geographic Areas. A commenter recommended that the use of Comparison Geographic Areas for achievement benchmarks be contingent on achieving statistical balance on certain covariates that may impact rates of home dialysis and transplantation between Selected Geographic Areas and Comparison Geographic Areas, to avoid making inappropriate comparisons between the two.

Response: We anticipate that rates for home dialysis, transplant waitlisting, and living donor transplants will change in Selected Geographic Areas, and may change in Comparison Geographic Areas, over the course of the Model. As stated in the proposed rule and in section IV.C.5.d of this final rule, we intend to establish a different method for establishing achievement benchmarks for future years of the Model through subsequent rulemaking. We expect that this method would not be based solely based on rates in Comparison Geographic Areas, and would be designed to incentivize improved performance in Selected Geographic Areas. We believe that this approach would mitigate concerns that dialysis organizations operating ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas may exert influence on achievement benchmarks by altering the provision of home dialysis or transplant services in Comparison Geographic Areas. As described in section IV.C.10 of this final rule, we intend to monitor for unintended consequences, such as those enumerated by commenters, and to make adjustments to the Model through subsequent rulemaking should such unintended consequences arise. We appreciate the suggestion that we check for balance on certain covariates that may impact rates of home dialysis and transplantation between Selected Geographic Areas and Comparison Geographic Areas. However, we believe that our policy of establishing Selected Geographic Areas by stratified randomization of a sufficiently large number of HRRs adequately accounts for underlying variation.

Comment: A commenter recommended calculating achievement benchmarks separately for each Selected Geographic Area, or including a geographic adjustment factor in the achievement benchmark calculation, to account for regional variation in rates. A commenter recommended that CMS create achievement benchmarks for each Selected Geographic Area for the transplant rate, to account for historical variation in the availability of organs and rates of transplantation across the country. Another commenter opined that achievement benchmarks for home dialysis rates should not be the same nationally because there may be underlying factors that vary across the country that impact patient preference for home dialysis. A commenter opposed constructing benchmarks specific to each Selected Geographic Area, opining that this would be overly complicated.

Response: We appreciate the commenters' recommendations that we calculate more regionally specific achievement benchmarks. However, we agree with the commenter that stated that calculating achievement benchmarks specific to each Selected Geographic Area would be overly complicated, and we also believe that this approach would perpetuate regional differences in home dialysis and transplant rates that are not beneficial for beneficiaries. Accordingly, we are finalizing our proposal to establish a single achievement benchmark for each MY based on rates of home dialysis, transplant waitlisting, and living donor

transplants in the Comparison Geographic Areas.

Comment: A commenter stated that any changes to the organ allocation system, such as those under consideration by the Organ Procurement and Transplant Network (OPTN), may make achievement benchmarks for transplant rates based on historical performance in Comparison Geographic Areas an inappropriate comparison for purposes of assessing current transplant rates due to intervening changes in organ availability by region.

Response: We appreciate the feedback from this commenter. As described in section IV.C.5.c.(2) of this rule, we are modifying the transplant rate used to assess ETC Participant performance such that it no longer includes deceased donor transplants. As such, we do not believe that changes to the organ allocation system will impact performance benchmark construction, as these changes do not directly impact transplant waitlisting or living donation. Additionally, as discussed in the proposed rule and previously in this final rule, we intend to make changes to the achievement benchmarking approach for future MYs through subsequent rulemaking, including to set benchmarks that are not dependent on historical rates of transplants in Comparison Geographic Areas. We will take this comment into consideration as we consider any such future changes, to ensure that any changes in the organ allocation system will not disproportionately impact the achievement benchmarks used in future MYs.

Comment: A commenter recommended that CMS establish achievement benchmarks that are not based on Comparison Geographic Areas.

Response: We appreciate the input from the commenter. We continue to believe that using Comparison Geographic Areas to establish achievement benchmarks for the initial years of the Model is appropriate. However, we will consider this input about establishing achievement benchmarks that are not based on Comparison Geographic Areas if we make changes to the achievement benchmarking methodology for future years of the Model through subsequent rulemaking.

Comment: Several commenters opposed our stated intent to increase achievement benchmarks for future MYs through subsequent rulemaking. Some commenters opined that this approach lacks transparency, unfairly penalizes ETC Participants by changing the target over time, and undermines ETC Participant success in the Model. Several commenters expressed concern that CMS would adjust the benchmarking methodology for future MYs to achieve Model savings rather than to accurately reflect ETC Participant performance and incentivize ETC Participants to achieve the Model's goals of improving or maintaining quality and reducing costs by increasing rates of home dialysis and transplantation. Several commenters recommended that CMS maintain the benchmarking methodology proposed for MY1 and MY2 for the duration of the Model. Several commenters stated that CMS should establish the benchmarking methodology for all MYs before the Model begins to give ETC Participants the opportunity to plan accordingly.

Response: We appreciate the commenters' concerns about the need for transparency and for ETC Participants to be successful in the Model. However, we believe that our approach would be transparent, as any changes to the achievement benchmarking methodology for subsequent MYs would be established through notice and comment rulemaking. While we do not intend to maintain the benchmarking methodology we are finalizing now through the duration of the Model, as we expect that this methodology would not provide a sufficient incentive for ETC Participants to raise home dialysis and transplant rates at a rate faster than would occur absent the Model, we do acknowledge that finalizing our proposal to apply this methodology only for MY1 and MY2 would create some uncertainty about the benchmarking methodology for MYs immediately following MY2. For this reason, we are specifying that we will continue to use the achievement benchmarking methodology we proposed and are finalizing for MY1 and MY2 for future MYs if subsequent rulemaking cannot be completed with sufficient notice in advance of those MYs.

Comment: Several commenters expressed support for setting ambitious goals for home dialysis and transplant rates, and stated that higher rates of home dialysis and transplantation are achievable. A commenter who expressed such support recommended lowering our goal for future MYs from a combined home dialysis rate and transplant rate equivalent to 80 percent of attributed beneficiaries dialyzing at home and/or having received a transplant to 50 percent, which they suggested was still ambitious but more attainable for ETC Participants. Another commenter recommended that our goal for future MYs should be reduced to a more attainable level in consultation with the kidney community.

Response: We appreciate this feedback from the commenters and the support for setting ambitious goals. While we did not codify these goals in the final rule, we anticipate that we will codify more ambitious achievement goals in subsequent rulemaking. We appreciate the commenter's concern about setting the achievement goal at 80 percent, as well as the suggestion of using 50 percent as the goal. We will take these comments into consideration as we consider any future changes to the achievement benchmark methodology.

Comment: Multiple commenters expressed opposition to the goal of having 80 percent of attributed beneficiaries dialyzing at home and/or receiving a kidney or kidney-pancreas transplant. Commenters stated that there is not empirical or clinical evidence that the 80 percent goal is achievable or desirable in the U.S., or within the timeframe of the Model. Several commenters stated that this goal would lead to inappropriate pressure on beneficiaries to select home dialysis, when home dialysis may not be their preferred form of renal replacement therapy. A commenter stated that this goal would ensure that ETC Participants are not successful in future MYs. A commenter pointed out that the Regulatory Impact Analysis for the proposed ETC Model projected a conservative growth rate in home dialysis and no growth in transplantation, which contradicts the 80 percent goal. A commenter pointed out that without significant increases in organ availability, it would not be possible for ETC Participants to achieve increases in the transplant rate over the duration of the Model necessary to achieve the 80 percent goal. A commenter stated that CMS should raise achievement benchmarks over the duration of the Model at a rate that is reasonable in relation to historic performance.

Response: We clarify that, as described in the proposed rule, the 80 percent goal would be the target for receiving the highest payment adjustment in the final MYs of the Model. However, any changes to the achievement benchmark methodologies for the later MYs of the Model would be made through subsequent rulemaking. We appreciate this feedback from commenters about the feasibility of the goal we are considering for MY9 and MY10 and will take these comments into consideration as we consider any future changes to the achievement benchmark methodology.

Comment: A commenter stated that CMS should propose all benchmarks through notice and comment rulemaking. A commenter suggested that the achievement benchmarks not be communicated to ETC Participants in advance of the MY to which they apply, in order to avoid a ''performance floor'' effect in which ETC Participants aim to meet only the minimum necessary performance.

Response: We proposed the achievement benchmark methodology for the initial MYs of the Model in the proposed rule, which we are finalizing with modification in this final rule, and will establish any changes to these benchmarking methodologies through notice and comment rulemaking. However, in order to provide achievement benchmarks for each MY that reflect changing rates of home dialysis and transplant in a timely manner, we do not intend to propose the benchmarks themselves through rulemaking. Rather, we will use the methodologies finalized through rulemaking to calculate the applicable achievement benchmark in advance of each MY. We do not believe that it would be fair to ETC Participants not to announce achievement benchmarks in advance of the period to which those benchmarks apply and therefore decline to adopt the commenter's suggestion that benchmarks should not be communicated to participants in advance of the MY.

Comment: A commenter stated that CMS should consider geographic and socioeconomic factors that impact home dialysis and transplant rates when establishing achievement benchmarks.

Response: We appreciate the feedback from the commenter, and recognize that there is variation in rates of home dialysis and transplantation by region and by socioeconomic status. Were we to make adjustments to account for these factors, we would do so in the risk adjustment methodology for the home dialysis rate and transplant rate, rather than by adjusting the achievement benchmarks for each ETC Participant such that we would be able to provide one set of general achievement benchmarks rather than achievement benchmarks specific to particular regions or populations. In section IV.C.5.c.(3) of this final rule, we discuss the risk adjustment methodology for the ETC Model.

Comment: Several commenters supported the proposed inclusion of improvement scoring, but opposed our proposal that ETC Participants cannot obtain full points on the basis of improvement scoring. Several commenters stated that it would be inappropriate to limit ETC Participants' ability to achieve the highest score based on improvement scoring, particularly because the proposed achievement benchmarks would not account for regional variation in home dialysis rates and transplant rates. A commenter pointed out that ETC Participants that improve significantly on the home dialysis rate may nonetheless not receive an upward payment adjustment if their home dialysis rates are below the 50th percentile achievement benchmark or their transplant rates are not above the 50th percentile achievement benchmark. Several commenters recommended changing the improvement scoring methodology to provide greater recognition of improvement over time. In particular, commenters recommended that improvement greater than 10 percent be awarded two points.

Response: We appreciate the feedback from these commenters, and acknowledge the importance of incentivizing improvement over time. However, as stated in the proposed rule and previously in this final rule, we proposed not to award full points for improvement for consistency with other CMS programs and initiatives employing similar improvement scoring methodologies. The ETC Model is designed to focus on outcomes. While improvement is laudable and deserving of recognition through improvement scoring, awarding maximum points for improvement scoring is inconsistent with the Model's focus. As such, we will award full points for achievement scoring only.

Comment: A commenter raised concerns that the proposed construction of the MPS places greater weight on home dialysis rates, and therefore gives ETC Participants a greater incentive to improve rates of home dialysis than transplantation rates, when the goal of the Model should be to ensure that all appropriate ESRD Beneficiaries receive transplants. A commenter stated that the proposed approach for weighting home dialysis rates and transplant rates in calculating the MPS penalizes small ESRD facilities that cannot develop and maintain home dialysis programs. A commenter stated that, given how little control ESRD facilities have over who receives a kidney transplant, the inclusion of the transplant rate as one third of the MPS does not accurately reflect dialysis provider efforts or performance.

Response: We appreciate the feedback from commenters on the relative weights of the home dialysis portion and the transplant portion of the MPS. We disagree that the goal of the Model should be to ensure that all appropriate ESRD Beneficiaries receive transplants, as the stated goal is to maintain or improve quality and reduce Medicare expenditures through increased rates of home dialysis and transplants. As we stated in the proposed rule, we considered making the home dialysis rate score and the transplant rate score equal components of the MPS, to emphasize the importance of both home dialysis and transplants as alternative renal replacement therapy modalities. However, we recognized that transplant rates may be more difficult for ETC Participants to improve than home dialysis rates, due to the limited supply of organs and the number of other providers and suppliers that are part of the transplant process. The transplant portion of the MPS is now based on performance on the transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate, as described in sections IV.C.5 and IV.C.5.c.(2) of this final rule, which addresses the commenter's concern that the transplant rate does not accurately reflect ESRD facility performance due to factors outside of their control, given that the main limiting factor is the availability of deceased donor organs. Despite this change to the transplant portion of the MPS, we continue to believe that the transplant waitlist and living donor processes involve similar challenges for ETC Participants as the transplant process overall, including the number of other providers and suppliers that are part of the transplant process. Therefore, we continue to believe that it is appropriate that the home dialysis rate constitute two thirds of the MPS and that the transplant rate constitute one third of the MPS.

Comment: Several commenters recommended that CMS use the benchmarking and scoring methodology used by the ESRD QIP for purposes of the MPS calculation. These commenters stated that ESRD facilities are familiar with these methodologies, and that using them in this Model would make the two initiatives more consistent with each other. A commenter recommended that CMS adapt the quality benchmarking and scoring methodology used by the CEC Model for purposes of the MPS calculation under the Model.

Response: While we acknowledge that ESRD facilities are familiar with the ESRD QIP benchmarking and scoring methodologies, we do not believe these methodologies are well suited to this Model. The ETC Model is designed to test the ability of the Model's payment adjustments to improve or maintain

quality while reducing costs through increased rates of home dialysis and transplantation. The benchmarking methodology for the ETC Model must be designed with this goal in mind. While the ESRD QIP performance standard setting methodology substitutes performance standards from previous years if those performance standards are higher than the performance standards that would otherwise apply, it does not ensure escalating performance standards over time. Rather, the ESRD QIP performance standard setting methodology ensures that performance standards do not decrease over time. As stated in the proposed rule and elsewhere in this final rule, we may consider increasing the achievement benchmarks used under this Model for future MYs. Any such changes would be made through future rulemaking. While we may consider increasing the performance standards, we do not intend to adopt a policy to specifically prevent that achievement benchmarks do not decrease. Additionally, Managing Clinicians are not subject to the ESRD QIP, and therefore may not be familiar with the ESRD QIP methodology. We believe it is important to maintain consistency within the ETC Model for the two types of ETC Participants—namely ESRD facilities and Managing Clinicians. We point out that we are using the same benchmarking and scoring methodology as the one used by the CEC Model for scoring quality performance.

After considering public comments, we are finalizing our proposed provisions on the benchmarking and scoring methodology in our regulation at § 512.370(a), with modification. Specifically, while we proposed to apply our proposed achievement benchmark policy only for MY1 and MY2, in response to public comments, we will apply the achievement benchmarking methodology we are finalizing in this final rule for MY1 (January 1, 2021 to December 31, 2021) and MY2 (July 1, 2021 to June 30, 2022), and for subsequent MYs, if not first modified by subsequent rulemaking. We are also finalizing our proposal to define the ''Benchmark Year'' as the 12-month period of data that begins 18 months prior to the start of a given MY from which data is used to construct benchmarks against which to score an ETC Participants achievement and improvement on the home dialysis rate and transplant rate for the purpose of calculating the ETC Participant's MPS in our regulation at § 512.310. In addition, we are making a technical change to capitalize the term ''Benchmark Year'' in the final rule.

e. Performance Payment Adjustments

We proposed that CMS would make upward and downward adjustments to payments for claims for dialysis and dialysis-related services, described in the proposed rule and in section IV.C.5.e of this final rule, submitted by each ETC Participant with a claim through date during the applicable PPA period based on the ETC Participant's PPA. We proposed that the magnitude of the potential positive and negative payment adjustments would increase over the PPA Periods of the ETC Model. The magnitude of the PPAs were designed to be comparable to the MIPS payment adjustment factors for MIPS eligible clinicians, as described in the proposed rule and in sections IV.C.5.e.(1) and IV.C.5.e.(2) of this final rule. Specifically, the PPAs were designed to be substantial enough to incentivize appropriate behavior without overly harming ETC Participants through reduced payments. The payment adjustments proposed for the ETC Model would start at the same 5 percent level in 2020 as the MIPS payment adjustment at 42 CFR 414.1405(c). As discussed in the proposed rule, the PPAs proposed for the ETC Model were also designed to increase over time and to be asymmetrical—with larger negative adjustments than positive adjustments—in order to create stronger financial incentives.

As we noted in the proposed rule, CMS believes that downside risk is a critical component of this Model in order to create strong incentives for behavioral change among ETC Participants. We proposed that the negative adjustments would be greater for ESRD facilities than for Managing Clinicians, in recognition of the ESRD facilities' larger size and ability to bear downside financial risk relative to individual clinicians. As noted in the proposed rule, we believe that the exclusion of ESRD facilities that fall below the low-volume threshold described in the proposed rule and in section IV.C.5.f.(1) of this final rule would ensure that only those ESRD facilities with the financial capacity to bear downside risk would be subject to application of the Facility PPA.

The following is a summary of the comments received on the proposed PPA and our responses.

Comment: A commenter expressed support for our proposal to subject Managing Clinicians to less downside risk than ESRD facilities. A commenter recommended that CMS not apply a negative PPA to ESRD facility home dialysis treatments, even if an ESRD facility earns a negative PPA. The same commenter recommended that CMS remove negative payment adjustments from the Model altogether, and instead create upside financial incentives for the more than 50 percent of ESRD facilities that currently do not offer home dialysis. Another commenter recommended that CMS apply any negative PPA amount only to in-center treatment payments, and not to home dialysis treatment or home training payments.

Response: We thank the commenters for their feedback. CMS believes that negatively adjusting home dialysis claims is appropriate when an ETC Participant earns a negative PPA, just as CMS believes it is appropriate to positively adjust home dialysis claims when an ETC Participant earns a positive PPA. As discussed in the proposed rule, the PPA is designed to be substantial enough to provide an incentive robust enough to spur positive behavior change without overly harming ETC Participants through reduced payments.

CMS disagrees that eliminating the negative payment adjustment or subjecting ESRD facilities that currently do not furnish home dialysis to upside financial incentives only would be appropriate given the goals of the Model. Specifically, CMS intends for the ETC Model to both encourage ESRD facilities who do not currently offer home dialysis to establish home dialysis programs, and for ESRD facilities who currently do offer home dialysis to increase the provision of these services. The proposed PPA accomplishes this goal by holding all ESRD facilities accountable for their rates of home dialysis, which CMS believes provides a powerful incentive to establish successful home dialysis programs. We further believe that imposing the HDPA only, or a similar upside financial incentive, to ESRD facilities that do not currently provide home dialysis would not provide a strong enough incentive to create the behavior change CMS seeks in implementing this Model.

In addition, CMS believes that negatively adjusting claims for in-center dialysis only would not produce a sufficient incentive to encourage the behavior change that the Model is designed to produce.

Comment: Many commenters expressed concerns about our proposal to apply significant downside risk for MY1, reasoning that ETC Participants would not have sufficient time to build out a clinical model and the necessary infrastructure to establish or build upon

a home dialysis program before being subject to downside financial risk for their rates of home dialysis. Several commenters recommended that CMS delay implementing the PPA for one year. Other commenters recommended that CMS delay implementing the PPA for two years. Those commenters recommending that the PPA be delayed asserted that such a change would allow more time for ETC Participants to receive positive adjustments from the HDPA and ensure that ETC Participants would have access to performance data before being subjected to downside risk. Other commenters asserted that delaying the implementation of the PPA would better allow ETC Participants to build infrastructure, gather necessary resources and equipment, and spread out the potential for financial losses, without risking closure of ESRD facilities and possibly limiting patients' access to care, particularly in urban and rural areas where ESRD facility margins are low and housing instability rates are high. Some commenters recommended that CMS delay implementing downside risk related to transplant until CMS can learn from the many comments submitted in response to the request for information in the CY 2020 Hospital Outpatient Prospective Payment System proposed rule (84 FR 39398) related to OPOs and transplant centers (84 FR 39597).

Response: CMS believes that applying downside financial risk via the PPA, as proposed, is more appropriate than the alternatives suggested by the commenters. CMS believes it is important to apply downside risk at the beginning of the Model to create strong incentives for behavior change. As described in the proposed rule and earlier in this final rule, CMS carefully considered the timeline for applying the HDPA and the PPA, and CMS continues to believe that the proposed schedules of each optimally balances the timing and magnitude of the process-based incentive, the HDPA, with the outcome-based incentive, the PPA. Further, the PPA starts at its lowest point while the HDPA starts at its highest point, which gives ETC Participants the time to build out their clinical models and necessary infrastructure to establish or build upon their home dialysis programs. While CMS understands the commenters' view that delays in the application of the PPA would allow ETC Participants more time to take all steps necessary to increase provision of home dialysis, CMS intends for the ETC Model to incent behavior change, and CMS continues to believe that the proposed PPA and HDPA schedule best accomplishes that goal.

Regarding the comments that CMS can learn from the comments submitted in response to the request for information in the CY 2020 Hospital Outpatient Prospective Payment System proposed rule (84 FR 39398) related to OPOs and transplant centers (84 FR 39597), CMS will not change the PPA policy in this final rule based on those comments, but those comments may inform future policy changes under the Model.

Comment: A commenter that supported a delay in implementing downside financial risk under the Model recommended that CMS implement a transplant bonus to incentivize ETC Participants and other stakeholders to implement new programs and processes needed to support transplant rate growth.

Response: CMS disagrees with the recommendation to implement a transplant bonus in the ETC Model. CMS believes that the PPA sufficiently rewards high performing ETC Participants for successfully increasing their transplant waitlisting rate and living donor transplant rate, which may ultimately result in higher rates of kidney transplants. Further, ETC Participants may simultaneously participate in the KCC Model, which includes a kidney transplant bonus payment. It is likely that at least some ETC Participants will also participate in the KCC Model, such that implementing a kidney transplant bonus payment under the ETC Model would present the risk of ''double paying'' ETC Participants for successful transplants. In addition, using distinct payment methodologies in the KCC Model, which has a kidney transplant bonus payment, and the ETC Model, which does not, will better allow CMS to determine the effectiveness of a transplant bonus in incentivizing support and care for beneficiaries through the kidney transplant process, including after transplantation, as CMS will be able to test the effects of different payment methodologies under the two models as well as the effects of overlapping incentives.

Comment: A commenter expressed support for the ETC Model's two-sided risk structure. Another commenter expressed general support for both the Clinician PPA and Facility PPA.

Response: We appreciate the feedback and support from the commenters.

Comment: Several commenters expressed concern that the PPA could have unintended consequences, including ESRD facility closure, reduced patient choice, reduced quality of care for beneficiaries, and/or beneficiaries who receive in-center dialysis being required to travel longer distances to receive treatment. Some of these commenters articulated specific reasons why they expected the PPA would result in such unintended consequences, such as smaller entities needing to expend substantial capital to prepare for the Model, hire nephrology nurses, build or expand training space, and increase administrative capabilities. A few of these commenters expressed concern that the PPA could lead to facility closures for small, independent, and/or rural ESRD facilities, which the commenters suggested are less able than LDOs to absorb financial losses that may result from the application of the PPA. A commenter expressed concern that the PPA would destabilize the Medicare ESRD benefit, which the commenter asserted is already underfunded. Some commenters expressed concern that potential for downside risk due to the application of the PPA would incentivize ETC Participants to push ESRD Beneficiaries to home dialysis modalities even when it is not clinically or socially appropriate. One such commenter identified housing insecurity and social isolation as social factors that may make a beneficiary ill-suited for home dialysis, and recommended that CMS consider social and clinical factors in determining the magnitude of an ESRD facility's PPA.

Response: CMS disagrees with the comments expressing concern that the PPA will cause ESRD facility closure, reduce patient choice, reduce quality of care, and/or force ESRD Beneficiaries to travel longer distances to receive treatment. The Model aims to increase choice by addressing a notable lack of home dialysis provision, and thus increase ESRD Beneficiary choice among renal replacement modalities and, in many cases, eliminate the commutes ESRD Beneficiaries must currently make to receive treatment in center. CMS also disagrees with comments expressing concern that the PPA will especially harm small, independent, and/or rural ESRD facilities, as opposed to LDOs, since the PPA uses percentages rather than absolute figures in making its adjustments. While LDOs are larger and, as a result, may be better able to absorb financial losses, an LDO and a non-LDO who perform equally poorly will face proportionate reductions in Medicare reimbursement under the Model, and vice versa. Moreover, even if the proposed PPA would have the unintended consequences cited by commenters, as discussed later in this

final rule, CMS is finalizing a reduction in the magnitude of the Clinician PPA and Facility PPA in response to the comments received. CMS also disagrees that the proposed PPA would incent ETC Participants to push ESRD Beneficiaries into clinically or socially inappropriate modalities. CMS believes that ESRD facilities and Managing Clinicians alike will continue to act in their patients' best interest, and will respond to the Model's financial incentives, including the PPA, with positive behavior change and creativity in appropriately increasing beneficiary access to home dialysis while being mindful of social issues, such as social isolation.

Comment: A few commenters expressed concern that the proposed PPA appeared to be designed to reduce Medicare payments to ESRD facilities and Managing Clinicians over the duration of the Model. One such commenter expressed opposition to using the ETC Model to cut Medicare payments, reasoning that ETC Participants would need to make increased investments to achieve the delivery system reform that CMS envisions, which would be more difficult with less money. A few commenters recommended that CMS proceed with a budget-neutral or budget-saving model. One such commenter recommended that a budget-neutral or budget-saving model could provide positive incentives and resources for ESRD facilities to increase their provision of home dialysis and transplant-related services, while reducing the total cost of care to Medicare in the long run by generating savings through improved care quality. Other commenters recommended that CMS eliminate the downside risk in the proposed PPA and provide only bonus payments. A few commenters expressed concern that the proposed PPA was set arbitrarily or without a rationale for its magnitude, and/or that CMS failed to provide an articulated and substantial defense of the magnitude of the PPA under the Model. One such commenter characterized the PPA as reducing Medicare payments to ESRD facilities and Managing Clinicians every year, even if those ESRD facilities and Managing Clinicians improve their performance.

Response: Congress established the Innovation Center to design and test innovative payment and service delivery models, like this ETC Model, that are expected to reduce Medicare expenditures while preserving or enhancing the quality of care. While CMS understands the commenters' concerns that moving toward more home dialysis therapy may require investments on the part of ETC Participants, the Model provides higher payments to those ETC Participants who produce results. Regarding the commenters' suggestion that CMS proceed with a budget-neutral or budget-saving model, CMS expects the ETC Model will be a budget-saving model. Specifically, CMS anticipates that the Model will reduce Medicare expenditures, and will likely generate long-term cost savings by reducing the total costs of care, just as the commenter suggested. Regarding the rationale for the magnitude of the PPAs, CMS proposed the magnitude of the Facility PPA and Clinician PPA after careful consideration, hoping to provide a robust incentive to drive significant behavior change among ETC Participants without causing harm to beneficiaries. As described later in this final rule, CMS is reducing the magnitude of the PPAs in response to comments received, which should lessen the concerns expressed by commenters that the PPA will impose too much downside risk on ETC Participants. Finally, CMS disagrees with the comments recommending that CMS either eliminate the downside risk of the PPA but keep the upward adjustment or simply eliminate the PPA altogether. The PPA, by providing meaningful downside risk, represents the most important incentive in the Model for encouraging ESRD facilities and Managing Clinicians to increase the volume of home dialysis services and transplants.

Comment: Several commenters expressed concern over the proposed magnitude of the PPA, especially the magnitude of the potential downward adjustments from the PPA. Some commenters recommended that CMS reduce the magnitude of the PPA as compared to what was proposed. A commenter recommended that CMS reduce the downward payment adjustments for the initial MYs to encourage ETC Participants to commit resources and make early investments in infrastructure needed to succeed in the Model. A commenter recommended that CMS modify the PPA such that potential upward adjustments exceed potential downward adjustments. Another commenter expressed concern over the proposed magnitude of the negative PPA adjustment given the commenter's belief that the home dialysis rate and transplant rate measures are often unrelated to providers' and suppliers' actual rates of performance. Other commenters offered more concrete alternatives. A commenter recommended that CMS reduce the Facility PPA adjustments from +10 percent and −13 percent for MY9 and MY10 to +2.75 percent and −3.25 percent for MY9 and MY10, reasoning that these lower margins are similar to those used in ESRD QIP, which the commenter believed has been successful in driving behavior. Other commenters similarly urged CMS to align the magnitude of the PPA adjustments to that seen in the ESRD QIP. Two commenters recommended that the negative PPA adjustment be limited to a maximum of −2 percent, one of whom viewed as aligning with the ESRD QIP, and other commenters expressed a belief that the −2 percent penalty from the ESRD QIP has produced results. One of these two commenters also recommended that this reduction to the negative PPA adjustment could be accompanied by a corresponding reduction in the positive PPA adjustment. Another commenter recommended that CMS implement a payment methodology similar to that used in the ESRD QIP, wherein attainment and improvement would be determined using a method like that used in the ERSD QIP rather than based on performance relative to Comparison Geographic Areas or the ETC Participant's own historical performance.

Response: CMS understands the commenters' concern about the magnitude of the PPA, and specifically the downside risk of the PPA. After taking into consideration these comments, CMS also agrees that the proposed magnitudes of the Facility PPA and Clinician PPA were higher than necessary to achieve the Model's goals. However, CMS believes that they were not much higher than necessary. Thus, while CMS is reducing the magnitude of the PPAs in response to comments received, which should lessen the concerns expressed by commenters that the PPA will impose too much downside risk on ETC Participants, CMS declines to adopt the specific alternatives suggested by the commenters. First, CMS notes that the PPA adjustments are structured differently from the ESRD QIP adjustments in that an ETC Participant can receive a positive PPA, whereas the ESRD QIP adjustments do not offer the possibility of a positive adjustment to facilities (which are the only entities that can participate in the program). Second, commenters' recommendations that CMS reduce the magnitude of the PPA adjustments to as low as +2.75 percent/−3.25 percent (or lower) would not provide the level of incentive to

increase home dialysis and transplant rates that CMS sees as necessary to effectuate meaningful behavior change. The PPA amounts that CMS is finalizing in this rule optimally balance CMS's interests in achieving the Model's goals while not imposing too much financial risk on ETC Participants. The PPA amounts begin at around the same level of the payment adjustments under MIPS (which, for 2020, generally are +/−5 percent subject to a scaling factor), and then gradually increase in magnitude over time. CMS believes that generally following the MIPS payment adjustment amounts in PPA Period 1 of the ETC Model will provide an initial incentive amount that some ETC Participants have become accustomed to under MIPS, and thus which should be manageable, before the magnitude of the PPA gradually increases. The financial risk imposed on ETC Participants by the PPA will be incremental given this gradual increase, and will eventually provide a stronger incentive than that currently offered under MIPS or the ESRD QIP program, but without asking ETC Participants to take on the same level of risk they might under another model tested under section 1115A of the Act, such as the KCC Model. For example, under the CMS Kidney Care First (KCF) option of the KCC Model, KCF Participants that perform poorly in terms of quality and utilization may receive a downward adjustment of up to 20 percent to certain payments under the model.

Comment: Several commenters recommended that CMS redesign the PPA such that the ETC Model is an Advanced APM. Another commenter who recommended that CMS eliminate the PPA altogether reasoned that nephrologists who are MIPS eligible clinicians already participate in MIPS, which subjects those nephrologists to positive or negative payment adjustments based on performance, and that unless the ETC Model is redesigned to qualify as an Advanced APM, such nephrologists will be subjected to two uncoordinated pay-for-performance initiatives. Two commenters recommended that CMS exempt Managing Clinicians participating in the ETC Model from MIPS.

Response: We appreciate the recommendations from the commenters, but we decline to adopt either. We received many comments expressing concern about the magnitude of the PPA, and nearly as many comments recommending that we reduce the magnitude, especially the negative magnitude, of the PPA. We have responded to those comments by modifying the proposed PPA such that its magnitude is reduced, and we find this change to be most appropriate in light of the comments received globally. Modifying this Model to be an Advanced APM would require that we subject ETC Participants to significant downside risk starting in MY1, which we believe would put many ETC Participants in a difficult financial position. Instead, we believe that adjusting payments by the HDPA only during the first two MYs and then introducing the PPA adjustments is the most appropriate design given the Model's articulated goals and the comments received. Regarding the recommendation that CMS exempt Managing Clinicians who are ETC Participants from MIPS, it is not clear that the Innovation Center has the authority to categorically exempt any eligible clinicians, including Managing Clinicians as that term is defined for purposes of this Model, from MIPS. Moreover, even if CMS had the authority to exempt Managing Clinicians from MIPS, CMS believes this would undermine MIPS. MIPS provides important incentives based on, among other things, performance on quality and cost measures that this Model does not. This Model is not intended to replace MIPS, but instead to place emphasis on increasing rates of home dialysis and transplants.

After reviewing public comments, we are finalizing our general proposals regarding the Performance Payment Adjustment, with modifications. CMS will modify the proposed schedule for the Facility PPA and Clinician PPA in our regulation at § 512.380 in accordance with the revised start date for the payment adjustments under the ETC Model, described in section IV.C.1 of this final rule. In addition, after reviewing the comments regarding the proposed magnitude of the PPA amounts, we are reducing the magnitude of the PPA amounts. Specifically, relative to the magnitude of the PPA amounts described in the proposed rule, CMS is reducing the magnitude of the maximum PPA amounts each PPA period by 2 percent. We chose to reduce the PPA amounts by 2 percentages points in response to commenter feedback that the proposed PPA amounts were too high, and to more closely align the finalized PPA amounts with the payment adjustments under MIPS, which generally will be +/−7% in 2021 and +/−9% in 2022, subject to a scaling factor. The specific final magnitudes of the Facility PPA and the Managing Clinician PPA are discussed in sections IV.C.5.e.(1) and IV.C.5.e.(2) of this final rule.

(1) Facility PPA

For ESRD facilities that are ETC Participants, as described in proposed § 512.325(a) (Selected Participants), we proposed to adjust certain payments for renal dialysis services by the Facility PPA. Specifically, we would adjust the Adjusted ESRD PPS per Treatment Base Rate for claim lines with Type of Bill 072x, where the type of facility code is 7 and the type of care code is 2, and for which the beneficiary is 18 or older for the entire month and where the claim through date is during the applicable PPA Period as described in proposed § 512.355(c) (Measurement Years and Performance Payment Adjustment Periods). We explained in the proposed rule that facility code 7 paired with type of care code 2 indicates that the claim occurred at a clinic or hospital based ESRD facility. Type of Bill 072X therefore captures all renal dialysis services furnished at or through ESRD facilities. As with the HDPA, we proposed to apply the Facility PPA to claims where Medicare is the secondary payer.

We proposed that the formula for determining the final ESRD PPS per treatment payment amount with the Facility PPA would be as follows:

*Final ESRD PPS Per Treatment Payment Amount with PPA = ((Adjusted ESRD PPS per Treatment Base Rate * Facility PPA) + Training Add On + TDAPA) * ESRD QIP Factor + Outlier Payment * ESRD QIP Factor*

We further proposed that, for time periods and claim lines for which both the Facility HDPA and the Facility PPA apply, the formula for determining the final ESRD PPS per treatment payment amount would be as follows:

Final ESRD PPS Per Treatment Payment Amount with PPA and HDPA = ((Adjusted ESRD PPS per Treatment Base Rate (Facility HDPA + Facility PPA)) + Training Add On + TDAPA) * ESRD QIP Factor + Outlier Payment * ESRD QIP Factor*

As discussed previously in sections II.B.1 and IV.C.4.b of this final rule, after we published the proposed rule for the ETC Model, CMS established a new payment adjustment under the ESRD PPS called the TPNIES, which could apply to certain claims as soon as CY 2021. The TPNIES is part of the calculation of the ESRD PPS per treatment payment amount under 42 CFR 413.230 and, like the TDAPA, is applied after the facility-level and patient-level adjustments. We discuss the implications of this change for the Facility PPA later in this section of the final rule.

Table 14 depicts the proposed amounts and schedule for the Facility PPA over the ETC Model's PPA periods, which we proposed to codify in proposed § 512.380.

TABLE 14: PROPOSED FACILITY PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE

		Performance Payment Adjustment Period				
	MPS	1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Facility Performance Payment Adjustment	≤ 6	+5.0%	+6.0%	+7.0%	+8.0%	+10.0%
	≤ 5	+2.5%	+3.0%	+3.5%	+4.0%	+5.0%
	≤ 3.5	0.0%	0.0%	0.0%	0.0%	0.0%
	≤ 2	-4.0%	-4.5%	-5.0%	-6.0%	-6.5%
	≤ .5	-8.0%	-9.0%	-10.0%	-12.0%	-13.0%

Also, as we described in the proposed rule and in section IV.C.7.a of this final rule, we proposed that the Facility PPA would not affect beneficiary cost sharing. Beneficiary cost sharing would instead be based on the amount that would have been paid under the ESRD PPS absent the Facility PPA.

The following is a summary of the comments received on the proposed Facility PPA and our responses.

Comment: A few commenters expressed support for the proposal to apply the Facility PPA to claims where Medicare is the secondary payer.

Response: We appreciate this feedback and support from the commenters.

Comment: A few commenters recommended that CMS include condition code 73 in the types of claims adjusted by the Facility PPA, as condition code 73 corresponds to home dialysis training.

Response: We thank the commenters for their feedback. As noted previously in this final rule, condition code 73 is related to training a beneficiary on home dialysis and the inclusion of this code on a claim is one way in which CMS determines the start of Medicare coverage for an ESRD Beneficiary. CMS believes it is unnecessary and inappropriate to include condition code 73 in the payments adjusted by the PPA. First, as noted previously in this final rule, under the ETC Model, CMS seeks to adjust payments for and incentivize the provision of home dialysis services, and not home dialysis training *per se,* and adjusting payments for claims that include condition code 73 may encourage ''gaming'' wherein ETC Participants train all beneficiaries on home dialysis, regardless of whether the ETC Participant believes home dialysis is the most appropriate modality for the beneficiary. Second, we note that any dialysis claim submitted for an ESRD Beneficiary after the claim containing condition code 73 would be adjusted by the Facility PPA, providing a robust enough incentive to ETC Participants to increase the provision of home dialysis services. Further, if CMS were to adjust claims containing condition code 73 by the Facility PPA and an ESRD facility received a negative Facility PPA, the ESRD facility would face a disincentive to train ESRD Beneficiaries on home dialysis. CMS therefore believes it is most appropriate to exclude claims with condition code 73 from the payments adjusted by the Facility PPA.

Comment: A commenter expressed support for the proposal that the Facility PPA would not affect beneficiary cost sharing, reasoning that beneficiaries included in the Model should not be financially harmed or be discouraged from obtaining care necessary to obtain optimal patient health outcomes. A commenter expressed concern that CMS did not explain in the proposed rule how the PPA would impact ESRD Beneficiary co-insurance.

Response: We thank the commenters for their feedback and support. In the proposed rule, we indicated that the PPA would not affect beneficiary cost sharing. We clarify that cost sharing refers to both the deductible and beneficiary co-insurance. As described in the proposed rule, beneficiary cost sharing would instead be based on the amount that would have been paid under the ESRD PPS absent the Facility PPA.

In addition, we are clarifying that the formula for calculating the final ESRD PPS per treatment payment amount with the Facility PPA will reflect the addition of the TPNIES. Because CMS would apply the TPNIES in the calculation of the per treatment payment amount after the application of the patient-level adjustments and facility-level adjustments, in the same manner as the TDAPA, the TPNIES does not alter the proposed application of the Facility PPA. We had proposed to adjust the Adjusted ESRD PPS per Treatment Base Rate, meaning the per treatment payment amount as defined in § 413.230, including patient-level adjustments and facility-level adjustments and excluding any applicable training adjustment add-on payment amount, outlier payment amount, and TDAPA amount, by the Facility PPA. We are revising the formula for determining the final ESRD PPS per treatment payment amount with the Facility PPA alone and the Facility PPA and Facility HDPA to reflect the addition of the TPNIES be as follows:

*Final ESRD PPS Per Treatment Payment Amount with PPA = ((Adjusted ESRD PPS per Treatment Base Rate * Facility PPA)) + Training Add On + TDAPA + TPNIES) * ESRD QIP Factor + Outlier Payment * ESRD QIP Factor*

Final ESRD PPS Per Treatment Payment Amount with PPA and HDPA = ((Adjusted ESRD PPS per Treatment Base Rate (Facility HDPA + Facility PPA)) + Training Add On + TDAPA + TPNIES) * ESRD QIP Factor + Outlier Payment * ESRD QIP Factor*

We note that, under our regulations at § 512.355, the PPA will not apply to any

claims until the first PPA Period, which starts on July 1, 2022.

After considering public comments, we are finalizing our proposed provisions for the Facility PPA, with modification. Specifically, we are modifying the magnitude of the Facility PPA for each MPS and each PPA Period relative to what we proposed, as described in Table 14.a, and codifying the modified Facility PPA in Table 1 to our regulation at § 512.380. We are finalizing in our regulation at § 512.375(a) that the PPA will adjust the Adjusted ESRD PPS per Treatment Base Rate, as proposed, as well as that the PPA will apply only to claims for beneficiaries 18 years of age or older. While we had proposed to apply the PPA only to claims for which the beneficiary was 18 years of age or older for the entire month of the claim, in the final rule we are modifying the language to state that the beneficiary must be age 18 or older ''before the first day of the month,'' which is easier for CMS to operationalize and has the same practical effect (that is, a beneficiary who is at least 18 years old before the first date of a month will be at least 18 years old for that entire month). We are also modifying which date associated with the claim we are using to determine if the claim occurred during the applicable PPA Period. Whereas we proposed using the claim through date, we are finalizing using the date of service on the claim, to align with Medicare claims processing standards. Specifically, while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service. Thus, we must use the claim date of service to identify the PPA Period in which the service was furnished. We are also modifying the definition of Adjusted ESRD PPS per Treatment Base Rate in our regulation at § 512.310 to reflect that it excludes any applicable TPNIES amount, as discussed previously in section IV.C.4.a and this section of the final rule.

TABLE 14a: FACILITY PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE

		Performance Payment Adjustment Period				
	MPS	1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Facility Performance Payment Adjustment	≤ 6	+4.0%	+5.0%	+6.0%	+7.0%	+8.0%
	≤ 5	+2.0%	+2.5%	+3.0%	+3.5%	+4.0%
	≤ 3.5	0%	0%	0%	0%	0%
	≤ 2	-2.5%	-3.0%	-3.5%	-4.5%	-5.0%
	≤ .5	-5.0%	-6.0%	-7.0%	-9.0%	-10.0%

(2) Clinician PPA

For Managing Clinicians that are ETC Participants, as described in proposed § 512.325(a) (Selected Participants), we proposed to adjust payments for managing dialysis beneficiaries by the Clinician PPA. Specifically, we would adjust the amount otherwise paid under Part B with respect to the MCP claims on claim lines with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, by the Clinician PPA when the claim is submitted by an ETC Participant who is a Managing Clinician and the beneficiary is 18 or older for the entire month and where the claim through date is during the applicable PPA Period as described in proposed § 512.355(c) (Measurement Years and Performance Payment Adjustment Periods). We explained in the proposed rule that CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD-related services furnished monthly, and indicate beneficiary age (12–19 or 20 years of age or older) and the number of face-to-face visits with a physician or other qualified health care professional per month (1, 2–3, 4 or more). CPT® codes 90965 and 90966 are for ESRD-related services for home dialysis per full month, and indicate the age of the beneficiary (12–19 or 20 years of age or older). Taken together, these codes are used to bill the MCP for ESRD-related services furnished to beneficiaries age 18 and older, including patients who dialyze at home and patients who dialyze in-center. As with the HDPA, we proposed to apply the Clinician PPA to claims where Medicare is the secondary payer.

Table 15 depicts the proposed amounts and schedule for the Clinician PPA over the ETC Model's PPA periods, which we proposed to codify in proposed § 512.380.

TABLE 15: PROPOSED CLINICIAN PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE

	MPS	Performance Payment Adjustment Period				
		1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Clinician Performance Payment Adjustment	≤ 6	+5.0%	+6.0%	+7.0%	+8.0%	+10.0%
	≤ 5	+2.5%	+3.0%	+3.5%	+4.0%	+5.0%
	≤ 3.5	0.0%	0.0%	0.0%	0.0%	0.0%
	≤ 2	-3.0%	-3.5%	-4.0%	-4.5%	-5.5%
	≤ .5	-6.0%	-7.0%	-8.0%	-9.0%	-11.0%

We proposed to adjust the amount otherwise paid under Part B by the Clinician PPA so that beneficiary cost sharing would not be affected by the application of the Clinician PPA. The Clinician PPA would apply only to the amount otherwise paid for the MCP absent the Clinician PPA.

The following is a summary of the comments received on the proposed Clinician PPA and our responses.

Comment: A commenter expressed support for CMS's proposal to apply the Clinician PPA to claims where Medicare is the secondary payer.

Response: We thank the commenter for the feedback and support.

After considering public comments, we are finalizing our proposed provisions for the Clinician PPA, with modification. Specifically, we are modifying the amounts of the Clinician PPA from those proposed, to reduce the magnitude of the Clinician PPA for each MPS and PPA Period relative to what we proposed, as described in Table 15.a, and codifying the modified Clinician PPA in Table 2 to our regulation at § 512.380. We are finalizing that the Clinician PPA will adjust the amount otherwise paid for the MCP as proposed, as well as that the Clinician PPA will only apply to claims for beneficiaries 18 years of age or older. While we had proposed to apply the Clinician PPA only to claims for which the beneficiary was 18 years of age or older during the entire month of the claim, we are changing the language to state that the beneficiary must be at least 18 years of age ''before the first date of the month,'' which is easier for CMS to operationalize and has the same practical effect (that is, a beneficiary who is at least 18 years old on the first date of the month will be at least 18 years old for that entire month). We are modifying which date associated with the claim we are using to determine if the claim occurred during the applicable PPA Period. Whereas we proposed using the claim through date, we are finalizing using the date of service on the claim, to align with Medicare claims processing standards. Specifically, while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service. Thus, we must use the claim service date to identify the PPA Period in which the service was furnished.

TABLE 15.a: CLINICIAN PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE

	MPS	Performance Payment Adjustment Period				
		1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Clinician Performance Payment Adjustment	≤ 6	+4.0%	+5.0%	+6.0%	+7.0%	+8.0%
	≤ 5	+2.0%	+2.5%	+3.0%	+3.5%	+4.0%
	≤ 3.5	0%	0%	0%	0%	0%
	≤ 2	-2.5%	-3.0%	-3.5%	-4.0%	-4.5%
	≤ .5	-5.0%	-6.0%	-7.0%	-8.0%	-9.0%

f. Low-Volume Threshold Exclusions for the PPA

(1) ESRD Facilities

We proposed excluding ETC Participants that are ESRD facilities that have fewer than 11 attributed beneficiary-years during a given MY from the application of the PPA during the corresponding PPA Period. Each beneficiary-year would be equivalent to 12 attributed beneficiary months, where a beneficiary month is one calendar month for which an ESRD Beneficiary is attributed to an ETC Participant using the attribution methodology described in the proposed rule and in section IV.C.5.b of this final rule, meaning that an ESRD facility must have at least 132 total attributed beneficiary months for a MY in order to be subject to the PPA for the corresponding PPA Period. Under our proposal, a beneficiary year could be comprised of attributed beneficiary

months from multiple beneficiaries. We proposed this exclusion threshold to increase statistical reliability and to exclude low-volume ESRD facilities from the application of the Facility PPA. We selected this particular threshold because it is similar to the 11 qualifying patient minimum threshold that the ESRD QIP uses for purposes of scoring certain measures during the performance period. In the proposed rule, we stated that we had considered using the 11 qualifying patients threshold used for purposes of scoring some measures under the ESRD QIP, but due to differences in beneficiary attribution methodologies between the ESRD QIP and the proposed ETC Model, we concluded that using beneficiary-years was more appropriate for purposes of testing the ETC Model, as the rates proposed for the ETC Model are based on beneficiary-years.

We invited public comment on our proposal for excluding ESRD facilities with fewer than 11 attributed beneficiary-years from the application of the PPA during the applicable PPA Period, as well as the alternatives considered.

The following is a summary of the comments received on the proposed low-volume exclusion from the application of the PPA for ESRD facilities and our responses.

Comment: A commenter expressed opposition to the proposed low-volume exclusion for ESRD facilities, opining that CMS's reasons for proposing the low-volume exclusion for ESRD facilities do not outweigh the need to promote home dialysis to patients of low-volume facilities who want such services. The same commenter recommended that instead of a low-volume exclusion for ESRD facilities, CMS should create a mechanism for small and low-volume ESRD facilities to aggregate their performance to a virtual group to strengthen the ability of these ESRD facilities to perform in the Model. The same commenter expressed concern that excluding ESRD facilities from the application of the PPA based on volume alone may not be sufficiently nuanced to account for ESRD facilities that serve an important access need, and thus serve a relatively high volume of ESRD Beneficiaries, but that are unable to bear downside financial risk.

On the other hand, another commenter expressed concern that the proposed low-volume exclusion for ERSD facilities would cover only a small number of ESRD facilities which operate with narrow profit margins or even narrow losses. The same commenter provided data suggesting of the 353 rural ESRD facilities reporting financial losses in 2017, only 64 of these ESRD facilities would be designated as ''low-volume'' under the Model and thus be excluded from the application of the Facility PPA. Another commenter expressed concern that rural ESRD facilities, which often have few insured patients and high numbers of patients with little support at home, will not and cannot perform well in the Model, and may be forced to close, leaving rural beneficiaries without access to care. A commenter recommended that an ESRD facility farther than 20 miles away from the next nearest ESRD facility should not be subjected to negative payment adjustments, but still be able to receive positive payment adjustments, reasoning that if such an ESRD facility performs poorly, it may have to close and cause its patients to travel much farther to receive care. Another commenter suggested that CMS use the ESRD PPS definition of a ''low-volume facility'' and not apply negative PPA adjustments to those ESRD facilities. Another commenter recommended that CMS still apply positive PPA adjustments to ESRD facilities excluded under the low-volume exclusion, but not subject them to negative PPA adjustments.

Another commenter recommended that CMS broaden the proposed low-volume exclusion for ESRD facilities to exclude from the application of the PPA all low-volume and rural ESRD facilities owned by organizations with 35 or fewer ESRD facilities, unless the ESRD facility voluntarily elects to be subject to the PPA, reasoning that low-volume and rural ESRD facilities are disproportionately less likely to offer home dialysis therapy, and that a substantial number of low-volume and rural ESRD facilities are small and independent providers that operate with negative Medicare margins and lack sufficient resources to make the investments necessary to establish a home dialysis program. The same commenter expressed concern that the current low-volume exclusion policy for ESRD facilities is inadequate to protect beneficiary access to care and prevent further market consolidation. Another commenter recommended that CMS provide an exclusion for low-volume ESRD facilities and for Managing Clinicians providing services at low-volume ESRD facilities. The same commenter expressed concern that small and independent facilities that have 12 ESRD Beneficiaries (and thus would not be excluded from the application of the Facility PPA under our proposed low-volume exclusion), all of whom are unable or unwilling to receive home dialysis or a transplant, would be forced to close due to the application of the Facility PPA. The same commenter recommended that CMS make its low-volume exclusion based on an attestation that the ESRD facility is a low-volume facility.

Response: We thank the commenters for their feedback. Regarding the comment that the need to promote home dialysis outweighs the reasons CMS cited for proposing the low-volume exclusion for ESRD facilities, we must underscore that statistical reliability is essential for determining whether the financial incentives offered in this Model can significantly alter the provision of home dialysis. Further, CMS hopes that all ESRD facilities, regardless of participation in the ETC Model, will promote home dialysis and educate their patients regarding all renal replacement modalities, including home dialysis modalities. Moreover, creating a virtual group for small and low-volume ESRD facilities, as suggested by the commenter, would be unduly complex operationally, as described previously in this final rule. We are also concerned that it would be difficult to define virtual groups for purposes of the low-volume threshold for ESRD facilities without inadvertently giving either the virtual group, or those ESRD facilities not in the virtual group, an unfair advantage. In addition, as discussed later in this section of the final rule, CMS will calculate the low-volume threshold for ESRD facilities at the level of the aggregation group (as described in our regulation at § 512.365(e)(1)), under which CMS will aggregate all ESRD facilities that are not Subsidiary ESRD facilities with all other ESRD facilities that are not Subsidiary ESRD facilities located within the same HRR. Because CMS is not aggregating independent or ESRD facilities that are not Subsidiary ESRD facilities, CMS will apply the low-volume threshold exclusion policy to ESRD facilities that are not Subsidiary facilities at the facility level. As described elsewhere in this final rule, an aggregation group pools the performance of several ESRD facilities in a particular HRR and thus strengthen their ability to perform in the Model. Applying the low-volume threshold exclusion policy at the aggregation group level, as discussed below, allows CMS to more precisely exclude ESRD facilities who may be unlikely to perform adequately under the Model due to low historical beneficiary attribution, while bolstering statistical reliability. CMS believes that this policy sufficiently addresses the concerns the

commenter intended to address in recommending the virtual group policy.

While we agree with the commenter that volume alone may not be sufficiently nuanced to account for all ESRD facilities that serve an important access need but are unable to bear downside financial risk, part of CMS's reasoning for pursuing the low-volume exclusion is to bolster statistical reliability, which ultimately benefits ETC Participants. Similarly, even if CMS's proposed low-volume exclusion does not exclude from the application of the PPA all ESRD facilities operating with a near-zero or negative profit margin, (1) CMS reiterates its need to assure statistical reliability in the calculation of the PPA, and (2) the ETC Model offers such ESRD facilities an opportunity to increase revenue through the payment adjustments, depending upon their performance. Similarly, CMS believes that the commenter's concerns about rural ESRD facilities are unfounded, as the home dialysis rate measure captures the percentage of an ESRD facility's ESRD Beneficiaries who use a home dialysis modality. ESRD facilities currently operating with thin profit margins could see those margins grow by investing capital in creating or building upon home dialysis or self-dialysis programs, thus reducing their costs associated with providing dialysis services in-center multiple days a week and potentially earning them a positive PPA or increasing the magnitude of the PPA earned. Similarly, while rural ESRD facilities may have high numbers of patients without support at home, the Model is designed to incent ESRD facilities to consider how to increase access to home dialysis modalities for their ESRD Beneficiaries, and CMS will be including self-dialysis in the home dialysis rate measure, as discussed elsewhere in this final rule. If an ESRD facility has many ESRD Beneficiaries lacking support at home, such an ESRD facility could prioritize training its ESRD Beneficiaries on self-dialysis rather than home dialysis, which would, like home dialysis, give the beneficiaries greater agency in their treatment and help the ESRD facility improve its performance under the Model. CMS believes that the proposed low-volume exclusion, with the modifications described in this section of the final rule, is sufficient to ensure beneficiary access to care and will not result in market consolidation, and that the Model, through the HDPA, will provide ESRD facilities that are not excluded from the application of the PPA with greater financial resources during the initial years of the Model to establish or build upon home dialysis programs, which will help position ESRD facilities to earn a higher PPA. While it is possible that an ESRD facility could have 12 ESRD Beneficiaries, all of whom are not appropriate candidates for either home dialysis or a transplant, CMS finds this situation to be highly unlikely. However, if an ESRD facility found itself in that situation, the ESRD facility could still perform well under the Model by focusing attention on educating its ESRD Beneficiaries on self-dialysis and transplantation, and encouraging and helping its ESRD Beneficiaries to register for a transplant waitlist.

Regarding the comment that CMS should provide an exclusion for low-volume ESRD facilities, this is what we proposed to do; however, we disagree with the alternative low-volume thresholds recommended by the commenters. Regarding the comment suggesting that CMS make its low-volume exclusion for ESRD facilities based on an attestation that the facility is low-volume, CMS is concerned that such a policy would lead to gaming and abuse in the context of this Model. While CMS requires attestations from ESRD facilities that qualify as ''low volume'' under the ESRD PPS, the Model is using a different policy for identifying ''low volume'' than that used under the ESRD PPS, and operational limitations render attestations and subsequent confirmation by CMS or its Medicare Administrative Contractors (MACs), as is done under the ESRD PPS, unsuitable for this Model. CMS also finds its policy for identifying a low-volume ESRD facility under the Model to be more appropriate than the ESRD PPS definition for purposes of the Model, in light of the goals of the Model and CMS's need for statistically reliable data.

CMS also declines to include the commenter's recommended exclusion for ESRD facilities located more than 20 miles away from another ESRD facility at this time. While CMS understands the commenter's concern, an exclusion of this nature could give rise to gaming, insofar as ETC Participants that are newly building spaces for home dialysis training and self-dialysis could strategically position new ESRD facilities more than 20 miles away from other ESRD facilities. Finally, regarding the comment recommending that CMS apply positive PPAs to ESRD facilities otherwise excluded from the application of the PPA, but exclude such facilities from any negative PPAs, CMS believes this would not produce a strong enough financial incentive for such ESRD facilities to improve home dialysis and, ultimately, transplant rates.

After considering public comments, we are finalizing our proposed provisions on the low volume exclusion for ESRD facilities, with modification. Specifically, in an effort to limit the scope of the low-volume exclusion in order to promote modality choice with the need for statistical reliability, CMS is modifying its proposal such that, under the ETC Model, CMS will exclude aggregation groups (as described in our regulation at § 512.365(e)(1)) of ESRD facilities with fewer than 11 attributed ESRD beneficiary years during an MY from the application of the Facility PPA for the corresponding PPA Period. CMS will similarly exclude ESRD facilities that are not Subsidiary ESRD facilities with fewer than 11 attributed ESRD beneficiary years during an MY from the application of the Facility PPA for the corresponding PPA Period. This policy is also consistent with our final policy for assessing ESRD facility performance for purposes of the MPS calculation, which will also occur at the aggregation group level. Because the low-volume threshold determination will generally be made at the aggregation group level (that is, across multiple Subsidiary ESRD facilities), under this final policy, fewer ESRD facilities will be excluded from the application of the Facility PPA as compared to the number that would have been excluded under the policy we proposed. This low-volume exclusion is also narrower than the ESRD PPS definition suggested by the commenter and accordingly better ensures that a greater number of ESRD Beneficiaries will receive the benefit of receiving care from an ESRD facility incentivized by the Model to provide home dialysis services, self-dialysis services, and a robust pathway to transplantation. By contrast, the ESRD PPS definition of ''low-volume facility'' is an ESRD facility that (1) furnished less than 4,000 treatments in each of the three ''cost reporting years . . . preceding the payment year;'' and (2) ''[h]as not opened, closed, or received a new provider number due to a change of ownership'' in the same time period. 42 CFR 413.232(b). This definition captures a larger number of ESRD facilities than does the low-volume facility provision in this final rule.

We are codifying the modified low-volume threshold for ESRD facilities in § 512.385(a) of our regulation.

(2) Managing Clinicians

We proposed excluding ETC Participants that are Managing Clinicians who fall below a specified low-volume threshold during an MY

from the application of the PPA during the corresponding PPA Period. The low-volume exclusion would ensure that we would be adjusting payment based on reliable measurement of Managing Clinician performance. We noted that Managing Clinicians with sufficiently small attributed beneficiary populations may serve unique patient populations, such as children, such that we may not be able to produce statistically reliable transplant rates and home dialysis rates for these Managing Clinicians. We proposed that the low-volume threshold would be set at the bottom five percent of ETC Participants who are Managing Clinicians in terms of the number of beneficiary-years for which the Managing Clinician billed the MCP during the MY. We stated in the proposed rule that we considered using 11 beneficiary-years as the low-volume exclusion for Managing Clinicians, to mirror the proposed exclusion for ESRD facilities. However, we recognized that ESRD facilities and Managing Clinicians are different in that Managing Clinicians are more diverse, as compared to ESRD facilities, in terms of both volume of services furnished to beneficiaries related to receiving dialysis and services furnished that are not related to dialysis. Therefore, we proposed using a percentile-based low-volume exclusion threshold for Managing Clinicians that would help to ensure statistical soundness while recognizing the diversity of the Managing Clinician population. In the proposed rule, we alternatively considered establishing the low-volume threshold based on the bottom five percent of Managing Clinicians who are ETC Participants in the total dollar value of Medicare claims paid. However, as Managing Clinicians are in a variety of specialties and provide a wide range of services that are paid at a variety of rates, we concluded that a dollar-value threshold was not suitable for purposes of this proposed exclusion.

We invited public comment on this proposal for excluding certain Managing Clinicians from the application of the PPA during the applicable PPA Period based on our proposed low volume threshold, as well as the alternatives considered.

The following is a summary of the comments received on the proposed low-volume exclusion from the application of the PPA for Managing Clinicians and our responses.

Comment: A commenter expressed support for the proposed low-volume exclusion for Managing Clinicians. Another commenter expressed support for the proposed low-volume exclusion for Managing Clinicians, but suggested that CMS give otherwise excluded Managing Clinicians the option to opt in to the application of the PPA under Model.

Response: We thank the commenters for their feedback and support. Regarding the commenter's suggestion that CMS allow otherwise excluded Managing Clinicians to opt in to the application of the PPA under the Model, we decline to adopt this recommendation because Managing Clinicians who are ETC Participants must treat at least a minimum volume of ESRD Beneficiaries in order for CMS to produce statistically reliable transplant rates and home dialysis rates for purposes of calculating the Managing Clinicians' MPS and corresponding Clinician PPA. However, CMS determined, after publishing the NPRM, that the policy described in the NPRM would not exclude Managing Clinicians with adequate precision. In other words, our proposed policy would result in CMS applying the PPA to Managing Clinicians who have far fewer attributed beneficiary years than we expected and need for the purpose of achieving statistical reliability. Accordingly, CMS is modifying its proposal for the Managing Clinician low-volume threshold exclusion, as described below.

After considering public comments, we are modifying our proposed provisions on the low volume exclusion for Managing Clinicians. Specifically, we are changing the low-volume threshold for excluding Managing Clinicians from the application of the PPA during the applicable PPA Period from excluding Managing Clinicians in the bottom five percent of ETC Participants who are Managing Clinicians in terms of the number of beneficiary-years for which the Managing Clinicians billed the MCP during the MY, as proposed, to excluding Managing Clinicians in an aggregation group (as described in our regulation at § 512.365(e)(2)) with fewer than 11 attributed ESRD beneficiary-years during an MY. Determining the low-volume threshold for a Managing Clinician at the aggregation group level conforms to changes CMS made to the ESRD facility low-volume exclusion policy, described above, and also is consistent with our final policy for assessing ESRD facility performance for purposes of the MPS calculation, which will also occur at the aggregation group level. CMS is similarly changing its policy from setting the exclusion level at the bottom five percent of ETC Participants who are Managing Clinicians in terms of the number of beneficiary-years to fewer than 11 attributed ESRD beneficiary years. As with the modified low-volume exclusion policy for ESRD facilities described elsewhere in this section of the final rule, this modified low-volume exclusion policy for Managing Clinicians allows CMS to more precisely exclude groups of ETC Participants that have low historical beneficiary attribution from application of the PPA, while bolstering statistical reliability. CMS noted in the proposed rule that ESRD facilities and Managing Clinicians are different, in that Managing Clinicians are more diverse as compared to ESRD facilities, in terms of both volume of services furnished to beneficiaries related to receiving dialysis and services furnished that are not related to dialysis. While CMS still believes this to be true, CMS determined subsequent to publishing the NPRM that the Managing Clinician low-volume threshold exclusion policy described in the NPRM would not precisely exclude Managing Clinicians with too few attributed ESRD beneficiary years to obtain statistical reliability. Accordingly, to obtain statistical reliability, CMS must modify its proposal to set the Managing Clinician low-volume threshold exclusion at 132 attributed ESRD beneficiary months, or 11 attributed ESRD beneficiary years. This modification will result in a higher number of Managing Clinicians being excluded from the Model. Finally, CMS is making the change from considering ''beneficiary-years'' to ''attributed ESRD beneficiary-years'' to conform to the low-volume threshold exclusion for ESRD facilities, as ESRD facilities will not have attributed Pre-emptive LDT Beneficiaries. We are codifying this low-volume exclusion in § 512.385(b) of our regulation.

g. Notification

Per the PPA schedule, we proposed that payment adjustments would be made during the PPA period that begins 6 months after the end of the MY. This 6-month period would allow for 3 months claims run-out to account for lag in claims processing, and for CMS to calculate and validate the MPS and the corresponding PPA for each ETC Participant. After we calculate ETC Participant MPSs and PPAs, we proposed to notify ETC Participants of their attributed beneficiaries, MPSs and corresponding PPAs. We proposed notification of ETC Participants no later than 1 month before the start of the PPA Period in which the PPA would go into effect. As stated in the proposed rule, we believe this notification period balances the need for sufficient claims run-out to ensure accuracy, as well as

sufficient time for MPA and PPA calculation and validation by CMS, with our interest in providing sufficient advanced notification regarding the resulting payment adjustments to ETC Participants.

We proposed to conduct notifications in a form and manner determined by CMS. The following is a summary of the comment received on proposed notifications and our response.

Comment: A commenter expressed concern that providing reports regarding the ETC Participant's attributed beneficiaries, MPS, and PPA for a PPA Period only once per year would be insufficient and would not provide the information necessary for ETC Participants to measure their performance and take corrective action when necessary.

Response: We thank the commenter for the feedback. As described in the proposed rule and previously in this final rule, each PPA Period will be 6 months long and will begin 6 months after the last date of the corresponding MY. As a result, ETC Participants will receive notifications regarding beneficiary attribution, MPS, and PPA twice per year (that is, every six months)—one month prior to each PPA Period. We believe this notification schedule affords CMS the time needed collect data, attribute beneficiaries, calculate the MPS and PPA, validate those calculations, and distribute this information to ETC Participants in accordance with the requirements set forth in this final rule, while protecting the ETC Participant's interest in timely receiving the data, reviewing for suspected errors, and implementing performance improvement strategies for current and subsequent MYs.

After considering the public comment, we are finalizing our proposed notification provision in our regulation at § 512.390(a) without modification.

h. Targeted Review

We noted in the proposed rule that we believe that it would be advisable to provide a process according to which an ETC Participant would be able to dispute errors that it believes to have occurred in the calculation of the MPS. Therefore, we proposed a policy that would permit ETC Participants to contest errors found in their MPS, but not in the ETC Model home dialysis rate calculation methodology, transplant rate calculation methodology, achievement and improvement benchmarking methodology, or MPS calculation methodology. We noted that, if ETC Participants have Medicare FFS claims or decisions they wish to appeal (that is, Medicare FFS issues experienced by the ETC Participant that occur during their participation in the ETC Model that do not involve the calculation of the MPS), then the ETC Participant should continue to use the standard CMS procedures through their MAC. Section 1869 of the Act provides for a process for Medicare beneficiaries, providers, and suppliers to appeal certain claims and decisions made by CMS.

We proposed that ETC Participants would be able to request a targeted review of the calculation of their MPS. ETC Participants would be able to request a targeted review for certain considerations, including, but not limited to, when: The ETC Participant believes an error has occurred in the home dialysis rate or transplant rate used in the calculation of the MPS due to data quality or other issues; or the ETC Participant believes that there are certain errors, such as misapplication of the home dialysis rate or transplant rate benchmark in determining the ETC Participant's achievement score, improvement score, or the selection of the higher score for use in the MPS. We noted in the proposed rule that the targeted review process would be subject to the limitations on administrative and judicial review as previously described. Specifically, an ETC Participant could not use the targeted review process to dispute a determination that is precluded from administrative and judicial review under section 1115A(d)(2) of the Act and our regulation at § 512.170.

To request a targeted review, we proposed that the ETC Participant would provide written notice to CMS of a suspected error in the calculation of their MPS no later than 60 days after we notify ETC Participants of their MPS, or at a later date as specified by CMS. We proposed that this written notice must be submitted in a form and manner specified by CMS. The ETC Participant would be able to include additional information in support of its request for targeted review at the time the request is submitted.

We proposed that we would respond to each request for targeted review submitted in writing in a timely manner, and determine within 60 days of receipt of the request whether a targeted review is warranted. We proposed that we would either accept or deny the request for targeted review, or request additional information from the ETC Participant that we would deem necessary to make such a decision. If we were to request additional information from the ETC Participant, we would require that it be provided and received within 30 days of the request. Non-responsiveness to the request for additional information would potentially result in the closure of the targeted review request. If we were to find, after conducting a targeted review, that there had been an error in the calculation of the ETC Participant's MPS, we would notify the ETC Participant within 30 days of the finding. If the error in the MPS were such that it caused us to apply an incorrect PPA during the PPA Period associated with the incorrect MPS, we would notify the ETC Participant and resolve the payment discrepancy during the next PPA Period following notification of the MPS error. We proposed that decisions based on the targeted review process would be final, and there would be no further review or appeal.

In the proposed rule, we considered compressing the duration of the targeted review process such that it could be completed before the PPA Period for which the MPS in question sets the PPA. However, we stated that we believe that this would be an insufficient amount of time for ETC Participants to review their MPS, consider the possibility of a calculation or data error, request a targeted review, and provide additional information to CMS if requested.

The following is a summary of the comment received on the proposed targeted review process and our response.

Comment: We received one comment that 60 days would be insufficient time for ETC Participants to review their MPS, identify potential errors, and request a targeted review from CMS. The commenter suggested 90 days as an alternative.

Response: We thank the commenter for the feedback. After considering the comment, we will adopt a final policy that ETC Participants must provide written notice to CMS of a suspected error in the calculation of their MPS no later than 90 days after we notify ETC Participants of their MPS, or at a later date as specified by CMS. This modification would be an increase from the 60-day period discussed in the proposed rule.

After considering the public comment received, we are finalizing our targeted review proposal in our regulation at § 512.390(b), with modification. As noted previously in this section of the final rule, we are increasing the amount of time that an ETC Participant will have to request a targeted review from 60 days to 90 days after the ETC Participant is notified of their MPS. We are also modifying the regulatory text at § 512.390(b)(1) to specify that the ETC

Participant may request a targeted review at a later date as specified by CMS to align with the proposed policy as described in the preamble to the proposed rule. In addition, we are modifying the regulatory text at § 512.390(b)(4) of our regulations to clarify that CMS must resolve any resulting discrepancy in payment that arises from the application of an incorrect PPA in a time and manner determined by CMS, as opposed to during the next PPA Period that begins after the notification of the ETC Participant, as we had proposed. We believe this flexibility will allow CMS to more quickly and effectively resolve PPA payment discrepancies than the more specific time frame described in the proposed rule.

6. Overlap With Other Innovation Center Models and CMS Programs

As proposed, the ETC Model would overlap with several other CMS programs and models, and we sought comment on our proposals to account for overlap:

- ESRD Quality Incentive Program (ESRD QIP)—The ESRD QIP reduces payment to a facility under the ESRD PPS for a calendar year by up to 2 percent if the facility does not meet or exceed the total performance score established by CMS for the corresponding ESRD QIP payment year with respect to measures specified for that payment year. We proposed that the ETC Model's Facility HDPA and Facility PPA would be applied prior to the application of the ESRD QIP payment adjustment to the ESRD PPS per treatment payment amount, as we were proposing that the Facility HDPA and the Facility PPA would adjust the Adjusted ESRD PPS per Treatment Base Rate, as previously discussed in the proposed rule and in section IV.C.4.b of this final rule.
- Merit-based Incentive Payment System (MIPS)—Under section 1848(q)(6) of the Act and 42 CFR 414.1405(e), the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) generally apply to the amount otherwise paid under Medicare Part B with respect to covered professional services furnished by a MIPS eligible clinician during the applicable MIPS payment year. We proposed that the Clinician HDPA and the Clinician PPA in the ETC Model would similarly apply to the amount otherwise paid under Medicare Part B, but would occur prior to the application of the MIPS payment adjustment factors. This was designed to ensure that the MIPS payment adjustment factors would still have a significant weight for Managing Clinicians.
- Kidney Care Choices (KCC) Model[155]—The KCC Model is an optional Innovation Center model for nephrologists, dialysis facilities, transplant providers, and other providers and suppliers that will be focused on beneficiaries with CKD and beneficiaries with ESRD. The KCC Model is scheduled to begin with an implementation period for a portion of 2020 and 2021, with the performance period of the model beginning on April 1, 2021, and continuing through December 31, 2023, with the option for the Innovation Center to extend the model by one or two additional performance years.[156] Thus, the KCC Model will have up to nearly five years of financial accountability overlap with the ETC Model beginning April 1, 2021. We proposed that the types of entities eligible to participate in the KCC Model as Kidney Care First (KCF) practices and Kidney Contracting Entities (KCEs) would be permitted to participate in the KCC Model within regions where the ETC Model would be in effect. We stated in the proposed rule that not allowing these entities to participate as KCF practices or KCEs in the KCC Model within the ETC Model's Selected Geographic Areas would limit participation in the KCC Model, and could prevent a sufficient number of KCF practices or KCEs from participating in the KCC Model, such that the KCC Model would not have sufficient participation to be evaluated. We explained that we believed it was important to test both models in order to evaluate payment incentives inside and outside the coordinated care context. As stated in the proposed rule, the ETC Model would allow for a broader scope of test due to its mandatory nature across half the country, while the KCC Model will test the effects on outcomes of higher levels of risk for a self-selected group of participants. We proposed that payment adjustments under the ETC Model would be counted as expenditures for purposes of the KCC Model. We designed both models to include explicit incentives for participants when beneficiaries receive kidney transplants; and we proposed that a participant in both models would be eligible to receive both types of adjustments under the ETC Model (the HDPA and PPA), as well as a kidney transplant bonus payment under the KCC Model. Kidney transplants represent the most desired and cost effective treatment for most beneficiaries with ESRD, but providers and suppliers may currently have insufficient financial incentives to assist beneficiaries through the transplant process because dialysis generally results in higher reimbursement over a more extended period of time than a transplant.[157] As a result, we stated that we believed it would be appropriate to test incentives in both the ETC Model and KCC Model simultaneously to assess their effects on the transplant rate.
- Comprehensive ESRD Care (CEC) Model—The CEC Model is a voluntary model for ESRD dialysis facilities, nephrologists, and other providers and suppliers that focuses on beneficiaries with ESRD. We noted in the proposed rule that the CEC Model will end on December 31, 2020, and therefore, would overlap for one year with the proposed ETC Model, though the models will now only overlap for three months from January 1, 2021 to March 31, 2021 due to the updated timeline for the ETC and CEC Models. We proposed that ETC Participants could be selected from regions where there are participants in the CEC Model. Given the national distribution of CEC ESCOs, we noted in the proposed rule that we do not believe the overlap between the two Models would impact the validity of the ETC Model test, as ESCOs would be equally likely to be located in Selected Geographic Areas as in Comparison Geographic Areas, creating a net neutral effect. We also stated that we do not believe that the proposed ETC Model would significantly affect the CEC Model because the payment incentives under the ETC Model would be smaller in 2020 when the CEC Model is active and because the CEC Model is focused on total cost of care, the majority of which is non-dialysis care. In the proposed rule we noted our belief that not allowing CEC ESCOs to participate in the CEC Model within the ETC Model's Selected Geographic Areas would require either terminating ESCOs that participate in the CEC Model in the

[155] The KCC Model was referred to as the Comprehensive Kidney Care Contracting and Kidney Care First Models in the proposed rule, but has since undergone a rebranding. References in this final rule have been updated to reflect the name of the model in use as of the date of the publication of the final rule.

[156] This timing has been updated from what appeared in the proposed rule to reflect the current anticipated timeline for this model as of the date of publication of this final rule.

[157] Abecassis M, Bartlett ST, Collins AJ, Davis CL, Delmonico FL, Friedewald JJ et al. Kidney transplantation as primary therapy for end-stage renal disease: A National Kidney Foundation/Kidney Disease Outcomes Quality Initiative (NKF/KDOQITM) conference. Clinical Journal of the American Society of Nephrology. 2008;3(2):471–80.

ETC Model's Selected Geographic Areas, which we believe would negatively impact the CEC Model test, or altering ETC Model randomization to exclude regions in which CEC ESCOs are participating in the CEC Model, which we believe would negatively impact the ETC Model by interfering with the proposed randomization.

• All other APMs with Medicare—For other Medicare APMs, such as the Medicare Shared Savings Program or the Next Generation ACO Model, that focus on total cost of care, we proposed that any increase or decrease in program expenditures that is due to the ETC Model would be counted as program expenditures to ensure that the Medicare APM continues to measure the total cost of care to the Medicare program. The Medicare Shared Savings Program regulations include a policy for addressing payments under a model, demonstration, or other time-limited program. Specifically, in conducting payment reconciliation for the Medicare Shared Savings Program, CMS considers ''individually beneficiary identifiable final payments made under a demonstration, pilot, or time limited program'' (see, for example, § 426.610(a)(6)(ii)(B)). In the proposed rule we stated our belief that this existing policy sufficiently addresses overlaps that would arise between the Medicare Shared Savings Program and the proposed ETC Model. We also stated that CMS would review any other models where this form of reconciliation may not be possible and make an assessment as to what changes, if any, may be necessary to account for the effects of testing the ETC Model.

We invited public comments on our proposals to account for overlaps with other CMS programs and models.

The following is a summary of the comments received on overlaps between the ETC Model and other CMS programs and models, and our responses.

Comment: We received several comments urging the Innovation Center to test potential methods to increase home dialysis and transplant rates solely through a voluntary model or coordinated care framework, rather than with the proposed framework of the ETC Model.

Response: We appreciate the feedback. However, as discussed in section IV.C.3.a of this final rule, we believe that both voluntary and mandatory frameworks can be used by the Innovation Center to test models and can accomplish different goals. As described in the proposed rule and previously in section IV.C.3.a of this final rule, for the ETC Model, we believe that a mandatory framework is critical to avoid selection bias and to ensure a broad representation of participants. Concurrent with the ETC Model test, we plan to test the voluntary KCC Model to test the efficacy of coordinated care for beneficiaries with advanced kidney disease.

Comment: We received several comments urging CMS to exclude from the ETC Model beneficiaries aligned to coordinated care models, particularly beneficiaries aligned to participants in the CEC Model or the KCC Model.

Response: We appreciate the feedback; however, we believe that these models are testing different policy questions and that beneficiaries should be aligned or attributed to participants in more than one model if such alignment or attribution is consistent with the methodologies for the models. The CEC and KCC Models are focused around incentives for managing total cost of care and for managing beneficiary care across different providers, while the ETC Model is focused specifically on dialysis modality selection. While both the KCC and ETC Models include financial incentives around kidney transplantation, we believe that the incentives are different enough in structure, including with respect to the entity to whom the incentive payments are made, that both are worth testing. We view this payment overlap between the ETC Model and the KCC Model as similar to how an ESRD facility may both participate in the CEC Model and be subject to payment adjustments under the ESRD PPS based on the facility's performance under the ESRD QIP. Additionally, we are concerned about having a sufficiently large beneficiary population to be able to evaluate the results from the ETC Model if KCC Participants are excluded and are also concerned about a situation where ETC Participants could control whether a beneficiary is aligned to them under the ETC Model by taking steps to ensure that the beneficiary is aligned to an entity participating in either the CEC Model or the KCC Model.

Comment: We received comments urging that any payment adjustments under the ETC Model be excluded from the payment calculations under the Medicare Shared Savings Program or under models tested by the Innovation Center under section 1115A of the Act.

Response: We believe that excluding ETC Model payments from the payment calculations under these other initiatives would compromise the design of these other initiatives, many of which are focused on accountability for the total cost of care. For example, the Medicare Shared Savings Program considers all Medicare Part A and B expenditures, only excluding Inpatient Medical Education and Disproportionate Share Hospital payments, while explicitly including individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program when performing financial calculations under the program (see, for example, 42 CFR 425.601(c)(2)). We view the inclusion of payment adjustments made under the ETC Model as similar to how the payment adjustments for CMS quality programs, like the ESRD QIP, are incorporated into expenditure calculations under the Medicare Shared Savings Program and models tested by the Innovation Center under section 1115A.

Comment: We received a comment urging CMS to adopt quality measures around home dialysis and kidney transplants under the ESRD QIP, rather than testing the separate ETC Model.

Response: CMS is proposing to implement these payment adjustments in the ETC Model rather than the ESRD QIP because it is our intention to apply these incentives to Managing Clinicians in addition to ESRD facilities. The incentives in the ESRD QIP program apply to ESRD facilities, and not to Managing Clinicians, yet CMS believes that Managing Clinicians are a key part of supporting beneficiary modality choice and should also face payment incentives to increase utilization of home dialysis and transplants. Additionally, the maximum penalty for the ESRD QIP is 2 percent and we believe that increasing rates of home dialysis and the inclusion of beneficiaries on transplant waitlists are important enough areas to focus on that ETC Participants should have a larger potential downside and the potential for upside for succeeding in improving their rates in these areas.

Comment: We received a comment from a group representing physicians pointing out that Managing Clinicians who are MIPS eligible clinicians are already subject to MIPS and would be subject to a second set of payment adjustments under the ETC Model. They urged that nephrologist payments only be adjusted by MIPS.

Response: The MIPS program was designed to tie payments to quality and cost efficient care, drive improvement in care processes and health outcomes, increase the use of healthcare information, and reduce the cost of care, while the ETC Model has a narrower focus on kidney replacement modality choice. CMS believes that both are important focuses for Managing Clinicians. Accordingly, CMS believes it

is appropriate for Managing Clinicians participating in the ETC Model to have their payments adjusted under both the MIPS program and the ETC Model.

After considering the public comments, we are finalizing the overlaps in policy as proposed without modification.

7. Medicare Program Waivers

We noted in the proposed rule our belief that it was necessary and appropriate to provide additional flexibilities to ETC Participants for purposes of testing the ETC Model. The purpose of such flexibilities would be to give ETC Participants additional access to the tools necessary to ensure ESRD Beneficiaries can select their preferred treatment modality, resulting in better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, suppliers, and beneficiaries.

We proposed to implement these flexibilities using our waiver authority under section 1115A of the Act. Section 1115A(d)(1) of the Act provides authority for the Secretary to waive such requirements of title XVIII of the Act 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. This provision affords broad authority for the Secretary to waive Medicare program requirements as necessary to test models under section 1115A of the Act.

The following is a summary of the comments we received suggesting that CMS issue additional waivers and our responses.

Comment: We received many comments urging CMS to waive other requirements. Many commenters requested CMS to waive requirements similar to those we have indicated that we intend to waive for purposes of testing the voluntary KCC Model, such as the requirements that will be waived for purposes of testing the Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit Enhancement, the Home Health Benefit Enhancement, Telehealth Benefit Enhancement, and Post-Discharge Home Visits Benefit Enhancement under that Model, as well as requirements we have waived for purposes of testing the voluntary Next Generation Accountable Care Organization Model, including the waivers necessary for testing the Care Management Home Visits Benefit Enhancement. A commenter also specifically requested that CMS waive certain telehealth requirements as necessary to test allowing nurses to provide home dialysis visits via telemedicine under the Model.

Another commenter asked CMS to waive back-up arrangement requirements for certifications of home dialysis providers, and instead allow licensed home-dialysis providers to provide back-up hemodialysis in the space licensed for home dialysis. CMS also received a comment requesting to include a waiver to permit advanced practice providers under the general supervision of a Managing Clinician to manage a patient's home dialysis care. A commenter urged CMS include waivers necessary to allow renal dieticians to bill for services of nutrition education under this Model. According to the commenter, nutrition therapy and education provided by a renal dietician can improve the patient's quality of life and delay the progress of kidney disease. We received a comment suggesting that CMS issue a waiver to allow certified dialysis technicians, without the physical presence of a licensed nurse, and clinicians providing remote monitoring to qualify as caregivers who may perform Medicare-covered home dialysis.

Response: We thank all of the commenters for their feedback. The suggested benefit enhancements and other waivers were not included in the proposed rule, and we therefore are not finalizing these benefit enhancements or other waivers suggested by the commenters in this final rule. CMS will take the commenters' feedback into consideration as we consider potential future changes to the model design.

a. Medicare Payment Waivers

In order to make the proposed payment adjustments under the ETC Model, namely the HDPA and PPA discussed in the proposed rule and in sections IV.C.4 and IV.C.5 of this final rule, respectively, we stated in the proposed rule that we believe we would need to waive certain Medicare program rules.

Therefore, in accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act, we proposed to waive requirements of the Act for the ESRD PPS and PFS payment systems only to the extent necessary to make these payment adjustments under this proposed payment model for ETC Participants selected in accordance with CMS's proposed selection methodology. Also, we proposed to waive the requirement in section 1881(h)(1)(A) of the Act that payments otherwise made to a provider of services or a renal dialysis facility under the system under section 1881(b)(14) of the Act for renal dialysis services be reduced by up to 2.0 percent if the provider of services or renal dialysis facility does not meet the requirements of the ESRD QIP for a payment year, as may be necessary solely for purposes of ensuring that the ESRD QIP payment reduction would be applied to ESRD PPS payments that have been adjusted by the HDPA and the PPA. In addition, we proposed that the payment adjustments made under this Model would not change beneficiary cost sharing from the regular Medicare program cost sharing for the related Part B services that were paid for beneficiaries who receive services from ETC Participants. We proposed to make payment adjustments without impacting beneficiary cost sharing because, if beneficiary cost sharing changed as a result of the HDPA and the PPA, this would create a perverse incentive in which beneficiaries would pay less to receive services from ETC Participants with lower rates of home dialysis and transplants, potentially increasing beneficiary interest in receiving care from providers and suppliers performing poorly on the rates the ETC Model intends to improve, which would be contrary to the purpose of the Model.

Therefore, we proposed to waive the requirements of sections 1833(a), 1833(b), 1848(a)(1), 1881(b), and 1881(h)(1)(A) of the Act to the extent that these requirements otherwise would apply to payments made under the ETC Model. We sought comment on our proposed waivers of Medicare payment requirements related to the HDPA and PPA and beneficiary cost sharing.

The following is a summary of the comments we received on the proposed Medicare payment waivers and our responses.

Comment: We received comments supporting our proposal that beneficiary cost-sharing would be unaffected by the HDPA and the PPA.

Response: We thank the commenters for their feedback and support and will finalize this policy as proposed.

Comment: A commenter asked CMS to consider including a waiver for payment modifications for surgeons, hospitals, and surgery centers within the Model to bring reimbursement for PD catheter placement in-line with arteriovenous fistula reimbursement. Additionally, the commenter recommended adding a PD catheter placement diagnosis related group payment to further incentivize surgeons, hospitals, and surgery centers to perform this procedure.

Response: We thank the commenter for these suggestions. This type of waiver was not included in the proposed rule, and we therefore are not finalizing a waiver of this nature in this final rule. Additionally, the

commenter's recommendation to add a PD catheter placement diagnosis related group payment is outside the scope of this rulemaking. CMS will take the commenter's other recommendations into consideration for future potential changes to the model design.

After considering the public comments received, CMS will finalize the Medicare payment waivers, including our policy with respect to beneficiary cost-sharing, as proposed without modification in our regulation at 42 CFR 512.397(a).

b. Waiver of Select KDE Benefit Requirements

We stated in the proposed rule our belief that it is necessary for purposes of testing the ETC Model to waive select requirements of the KDE benefit authorized in section 1861(ggg)(1) of the Act and in the implementing regulation at 42 CFR 410.48. Medicare currently covers up to 6, 1-hour sessions of KDE services for beneficiaries that have Stage IV CKD. While the KDE benefit is designed to educate and inform beneficiaries about the effects of kidney disease, their options for transplantation, dialysis modalities, and vascular access, the uptake of this service has been low at less than 2 percent of eligible patients. As noted in the proposed rule, we believe that the KDE benefit is one of the best tools to promote treatment modalities other than in-center HD and that this waiver is necessary to test ways to increase its utilization from its current low rate as part of the model test.

We proposed to waive the following requirements for ETC Participants billing for KDE services:

- Currently, doctors, physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists (CNSs) are the only clinician types that can furnish and bill for KDE services as required by section 1861(ggg)(2)(A)(i) of the Act and its implementing regulation at 42 CFR 410.48(a) and 42 CFR 410.48(c)(2)(i). However, the payment for KDE is lower than a typical evaluation and management (E/M) visit, so there may be limited financial incentive for these clinician types to conduct the KDE sessions. There are various other types of health care providers that also may be well-suited to educate beneficiaries about kidney disease, such as registered dieticians and nephrology nurses. In its 2015 report on home dialysis, GAO recommended allowing other types of health care providers to perform KDE to increase uptake of the benefit.[158] We proposed to waive the requirement that KDE be performed by a physician, PA, NP or CNS, to allow additional clinical staff such as dietitians and social workers to furnish the service under the direction of a Medicare-enrolled participating Managing Clinician. The staff would not need to be Medicare-enrolled, but would furnish these services incident to the services of a clinician authorized to bill Medicare for KDE services as specified in section 1861(ggg)(2)(B)(i). In the proposed rule, we considered also waiving the requirement under section 1861(ggg)(2)(B) of the Act and the implementing regulation at 42 CFR 410.48(c)(2)(ii) restricting ESRD facilities from billing for KDE directly, but decided not to, as we did not believe it is necessary for testing the Model. Moreover, ESRD facilities are already required to provide information to beneficiaries about their treatment modality options in the ESRD facility conditions for coverage at § 494.70(a)(7); and to develop and implement a plan of care that addresses the patient's modality of care, at § 494.90(a)(7).

- KDE is now covered only for Medicare beneficiaries with Stage IV CKD as required by section 1861(ggg)(1)(A) of the Act and in the implementing regulations at 42 CFR 410.48(b)(1). As we noted in the proposed rule, we understood this prevents many beneficiaries in Stage V of CKD from receiving the benefits of KDE before starting dialysis or pursuing a transplant. In the proposed rule, we hypothesized that beneficiaries with ESRD could also benefit from this education in the first 6 months after an ESRD diagnosis. While CKD Stage V and early ESRD patients' disease may be more advanced and the prospect of dialysis or transplant more certain than for patients with Stage IV CKD, there is still opportunity to improve beneficiary knowledge to ensure the best patient-centered care and outcomes. GAO recommended covering the KDE benefit for beneficiaries with Stage V CKD.[159] We proposed to waive the requirement that KDE is covered only for Stage 4 CKD patients for purposes of testing the ETC Model and to permit beneficiaries with CKD Stage V and those in the first 6 months of receiving an ESRD diagnosis to receive the benefit, when billed by an ETC Participant who is a Managing Clinician.

- Under 42 CFR 410.48(d)(1), at least one of the KDE sessions must be dedicated to management of comorbidities, including delaying the need for dialysis. Because we proposed a waiver that would extend the KDE benefit to beneficiaries with CKD Stage V and ESRD in the first 6 months of diagnosis, this KDE topic may no longer be relevant to patients who are facing a more immediate decision to commence dialysis or arrange for a kidney transplant. We proposed to waive the requirement that KDE include the topic of managing comorbidities and delaying the need for dialysis under the ETC Model, when furnishing KDE to beneficiaries with CKD Stage V and ESRD. We proposed further clarifying, however, that ETC Participants who are Managing Clinicians furnishing KDE (either personally or with clinical staff incident to their services) must still cover this topic if relevant to the beneficiary, for example, if the beneficiary has not yet started dialysis and can still benefit from education regarding delaying dialysis.

- Under 42 CFR 410.48(d)(5)(iii), an outcomes assessment designed to measure beneficiary knowledge about CKD and its treatment must be performed by a qualified clinician during one of the 6 sessions. This requirement presents two challenges; first that it may take away time from a session that could be dedicated exclusively to education, and second that if a beneficiary demonstrates inadequate knowledge, there may not be sufficient time in one session to address all areas in which a beneficiary might need assistance. If the outcomes assessment could be performed by qualified staff during a follow-up visit to the Managing Clinician, there would still be 6 full KDE sessions available to beneficiaries, and we believe there would be more flexibility for the qualified staff to reinforce what the beneficiary learned during the KDE sessions and fill in any gaps. We proposed to maintain the requirement that an outcomes assessment be performed by qualified staff in some manner within one month of the final KDE session, but to waive the requirement that it be conducted within a KDE session.

In the proposed rule, we also considered waiving the co-insurance requirement for the KDE benefit and certain telehealth requirements to allow the KDE benefit to be delivered via telehealth for beneficiaries outside of rural areas and other applicable limitations on telehealth originating sites, but did not believe those waivers

[158] United States Government Accountability Office, 2015.

[159] United States Government Accountability Office, 2015.

were necessary for purposes of testing the Model.

The following is a summary of the comments received on the proposed waivers of select requirements of the KDE benefit for purposes of testing the ETC Model and the alternatives considered and our responses.

Comment: We received several comments, supporting CMS' proposal to waive select requirements of the KDE Benefit for the purposes of testing the ETC Model. However, many commenters asked CMS to further increase the scope of the KDE benefit under the proposed waivers, specifically in order to allow additional clinicians and health care sites provide the KDE benefit, including dieticians, social workers, ambulance providers, home health aides, and other clinicians who work in nursing homes or ESRD facilities. Additionally, a commenter asked CMS not to increase the scope of the KDE benefit to dialysis provider staff, while another requested that CMS issue additional waivers in order to provide more flexibility around the timeframe within which the KDE benefit could be provided. Finally, a commenter expressed concern that the KDE Benefit would permit health care providers to give beneficiaries incomplete information.

Response: We appreciate the commenters' support for our proposals to waive select requirements of the KDE benefit for purposes of testing the ETC Model. While we understand the commenter's interest in increasing even further the types of clinicians and entities that may provide the KDE benefit, we believe that our proposed policy provides the necessary flexibility to test the Model and will finalize the types of clinicians and entities that may provide the KDE benefit as proposed. We also understand the commenter's concern that the proposed waivers of certain KDE Benefit requirements would allow health care providers to give beneficiaries less information than is currently required. However, we proposed to waive the requirement to include managing comorbidities and delaying the need for dialysis as a required topic as part of a KDE session because those topics may not be relevant to beneficiaries with CKD Stage V and ESRD, who will be able to receive the KDE Benefit under the ETC Model. We also will finalize our proposed clarification that ETC Participants who are Managing Clinicians furnishing KDE (either personally or with clinical staff incident to their services) must still cover this topic if relevant to the beneficiary, for example, if the beneficiary has not yet started dialysis and can still benefit from education regarding delaying dialysis.

Comment: We received comments urging CMS to waive additional categories of beneficiary cost sharing in this Model, including cost-sharing for the KDE benefit or home-dialysis treatments.

Response: We thank the commenters for their feedback. While we considered waiving the coinsurance for the KDE benefit, the ETC Model aims to test the use of financial incentives for ETC Participants (namely Managing Clinicians and ESRD facilities), rather than beneficiary incentives, and we are concerned that testing a financial incentive for ETC Participants in conjunction with additional behavioral incentives for beneficiaries could confound the Model test. Specifically, it would be difficult to determine whether the impacts observed in the Model are a result of the Model's financial incentives or beneficiary incentives. Additionally, CMS is concerned that including waivers for additional categories of beneficiary cost-sharing could influence beneficiaries to choose health care providers based on the lower cost of treatment, rather than the quality of care that the health care providers deliver. CMS will take the commenters' recommendations into consideration for future potential changes to the model design.

Comment: We received one comment asking CMS to change payment for KDE to ''per treatment-hour reimbursement'' to incentivize ESRD facilities to educate patients as early as possible for transition to home dialysis. The commenter also suggested that ''highly skilled, 24/7 centralized real-time equipment and clinical telephone support'' must be in place after patients begin dialyzing at home.

Response: We thank the commenter for this feedback. We did not propose to change payment for the KDE benefit in the proposed rule, nor did we propose to require that ''highly skilled, 24/7 centralized real-time equipment and clinical telephone support'' be in place after patients begin dialyzing at home, and we therefore are not finalizing these policies in this final rule. CMS will take the commenter's recommendations into consideration for future potential changes to the model design.

Comment: A commenter recommended the commenter's proprietary tool for patient education programs for home dialysis and asked CMS to require ETC Participants to use this tool in all educational programs related to home dialysis.

Response: While we encourage innovation in both the private and public sectors, CMS is not permitted to endorse any particular product.

After considering the public comments, we are finalizing the proposed waivers of select requirements of the KDE Benefit for purposes of testing the ETC Model, with changes, in our regulation at § 512.397(b). Specifically, we will waive the requirement that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish KDE services to allow KDE services to be provided by clinical staff under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. Our regulation at § 512.397(b) will now list the Supplier and Non-Physician Practitioner types that will be able to furnish and bill for the KDE benefit under this waiver. This list does not exclude any supplier types that would otherwise have been permitted to furnish the KDE benefit. Specifically, the waiver will allow the KDE benefit to be furnished and billed by a physician, as well as a clinical nurse specialist, licensed clinical social worker, nurse practitioner, physician assistant, registered dietician/nutrition professional, and supplier specialty listed as clinic/group practice to test greater use of the KDE benefit. We also will waive the requirement that KDE is covered only for Stage 4 CKD patients to permit beneficiaries with CKD Stage V and those in the first 6 months of starting dialysis to receive the KDE benefit. In the proposed rule, we stated that we would waive this requirement to permit beneficiaries with CKD Stage V and those in the first 6 months of an ESRD diagnosis to receive the KDE benefit. However, we have since determined that using ESRD diagnosis codes to identify beneficiaries in the first 6 months of an ESRD diagnosis in order to determine eligibility for the KDE benefit would be difficult to operationalize due to the potential for delays in reporting of the diagnosis, as well as incomplete reporting of diagnosis codes on Medicare claims. By contrast, CMS can use Medicare claims data to more quickly and accurately identify ESRD Beneficiaries based on the submission of claims for the initiation of dialysis, which is consistent with how Medicare FFS identifies ESRD Beneficiaries generally. We are therefore modifying our regulation at 512.397(b)(2) to permit KDE services to be furnished to beneficiaries in the first 6 months of starting dialysis (rather than the first 6 months of receiving an ESRD diagnosis). Therefore, in the final rule, we will

waive this requirement to permit beneficiaries with CKD Stage IV, CKD Stage V, and those in the first 6 months of dialysis to receive the KDE benefit. Also, as we noted in the preamble to the proposed rule, we clarify that this waiver applies only when claims for such services are billed by an ETC Participant who is a Managing Clinician. We will also waive the requirement that the content of the KDE sessions include the topic of managing comorbidities and delaying the need for dialysis under the ETC Model, when such services are furnished to beneficiaries with CKD Stage V or ESRD. However, we will require that ETC Participants who are Managing Clinicians furnishing KDE (either personally or with clinical staff incident to their services) must still cover this topic if relevant to the beneficiary, for example, if the beneficiary has not yet started dialysis and can still benefit from education regarding delaying dialysis. As proposed, we will waive the requirement that an outcomes assessment designed to measure beneficiary knowledge about CKD and its treatment be performed by qualified staff as part of one of the KDE sessions, provided that such outcomes assessment is performed in some manner within one month of the final KDE session by qualified staff.

8. Compliance With Fraud and Abuse Laws

The authority for the ETC Model is section 1115A of the Act. Under section 1115A(d)(1) of the Act, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and certain provisions of section 1934 as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b). For this Model and consistent with this standard, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the SSA. However, CMS proposed that no fraud and abuse waivers would be issued for this Model. Thus, notwithstanding any other provision of this final regulation, all ETC Participants must comply with all applicable laws and regulations.

The following is a summary of the comments received on compliance with fraud and abuse laws and our responses.

Comment: We received several requests from commenters to include waivers of the physician self-referral law (commonly referred to as the ''Stark law''), Federal Anti-Kickback Statute, and the Beneficiary Inducements Civil Monetary Penalty to provide ETC Participants with the flexibilities found in other models tested under the authority of section 1115A of the Act. Commenters asserted that these fraud and abuse waivers are necessary to improve care coordination, population health management, patient education on home dialysis, and post-transplant care.

Response: We appreciate the commenters' interest in this matter. However, as we stated in the proposed rule (84 FR 34563), no fraud and abuse waivers are being issued for this Model. At this time, we believe that the arrangements contemplated by this Model can be executed in a manner that complies with existing fraud and abuse laws and that fraud and abuse waivers are not necessary to test this Model. Thus, notwithstanding any other provisions of this final regulation, all ETC Participants must comply with all applicable laws and regulations.

9. Beneficiary Protections

As we discussed in the proposed rule and in section IV.C.4.b of this final rule, we proposed to attribute non-excluded ESRD Beneficiaries and, as applicable, pre-emptive transplant beneficiaries to the ETC Participant that furnishes the plurality of the beneficiary's dialysis and other ESRD-related services. Although the ETC Model would not allow ESRD Beneficiaries to opt out of the payment adjustment methodology being applied to the Medicare payments made for their care, the Model would not affect beneficiaries' freedom to choose their dialysis services provider or supplier, meaning that beneficiaries may elect to see any Medicare-enrolled provider or supplier including those selected and not selected to participate in the Model based on geography. In addition, the general beneficiary protections described in the proposed rule and section II.B.2.a.(8) of this final rule would apply to the ETC Model; accordingly, ETC Participants would be prohibited from restricting beneficiary freedom of choice or access to medically necessary covered services, which includes the beneficiary's choice regarding the appropriate modality to receive covered services. ETC Participants also would be prohibited from using or distributing descriptive model materials and activities that are materially inaccurate or misleading. We proposed to prohibit ETC Participants from offering or paying any remuneration to influence a beneficiary's choice of renal replacement modality, unless such remuneration complied with all applicable law. We stated in the proposed rule that we believed this policy is necessary to help ensure that beneficiary modality selection is based on the care of the beneficiary and the beneficiary's needs and preferences, rather than financial or other incentives the beneficiary may have received or been offered.

Furthermore, we explained in the proposed rule, beneficiaries with disabilities who receive care from ETC Participants, including dementia and cognitive impairments, remain protected under Federal disability rights laws including, but not limited to, section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, as amended, and section 1557 of the Patient Protection and Affordable Care Act. These beneficiaries cannot be denied access to home dialysis or kidney transplant due to their disability. We stated that ETC Participants may not apply eligibility criteria for participation in programs, activities, and services that screen out or tend to screen out individuals with disabilities; nor may ETC Participants provide services or benefits to individuals with disabilities through programs that are separate or different, excepting those separate programs that are necessary to ensure that the benefits and services are equally effective.

In addition, as described in the proposed rule and in sections IV.C.4.c and IV.C.5.e.(2) of this final rule, we proposed to apply the Clinician HDPA and the Clinician PPA to the amount otherwise paid under Medicare Part B and furnished by the Managing Clinician during the CY subject to adjustment, which would mean that beneficiary cost sharing would not be affected by the application of the Clinician HDPA and the Clinician PPA. Similarly, as described in the proposed rule and section IV.C.7.a. of this final rule, we proposed to use our waiver authority under section 1115A(d)(1) of the Act to issue certain payment waivers, pursuant to which beneficiaries would be held harmless from any model-specific payment adjustments made to Medicare payments under this Model.

We proposed to specify in our regulations at § 512.330(a) that ETC Participants would be required to prominently display informational materials in each of their offices or facility locations where beneficiaries receive treatment to notify beneficiaries that the ETC Participant is participating in the ETC Model. This notification would serve to inform a beneficiary that his or her provider or supplier is participating in a model that incentivizes the use of home dialysis

and kidney transplants and who to contact if they have questions or concerns. As we stated in the proposed rule, we proposed this notification to further non-speculative government interests including transparency and beneficiary freedom of choice. So as not to be unduly burdensome, we stated in the proposed rule that CMS intends to provide a template for these materials to ETC Participants, which would identify required content that the ETC Participant must not change and places where the ETC Participant may insert its own original content. This template would include information for beneficiaries about how to contact the ESRD Network Organizations with any questions or concerns regarding participation in the ETC Model by their health care provider(s). (The 18 ESRD Network Organizations serve distinct geographical regions and operate under contract to CMS; their responsibilities include oversight of the quality of care to ESRD Beneficiaries, the collection of data to administer the national Medicare ESRD program, and the provision of technical assistance to ESRD providers and patients in areas related to ESRD). We noted in the proposed rule that all other ETC Participant communications with beneficiaries that are descriptive model materials and activities would be subject to the requirements for such materials and activities included in the general provisions, as discussed in the proposed rule and section II.D.3 of this final rule.

The following is a summary of the comments received on the proposed beneficiary protections and our responses.

Comment: We received multiple comments expressing concern that the structure and incentives of the Model could produce unintended consequences that would be contrary to beneficiary freedom of choice and access to medically necessary covered services. Many commenters stressed that the criteria for ESRD Beneficiaries to be excluded from attribution to ETC Participants under the ETC Model, described in § 512.360(b) of the regulatory text, should include an exclusion for patient treatment choice. Additionally, a commenter recommended that beneficiaries be allowed to opt of out the Model. The rationale for these suggestions was that patients could choose other treatment modalities or supportive care due to religious reasons, patients' need or desire to travel for work or leisure, or reliance on inpatient facilities due to other confounding co-morbidities or factors. Several commenters acknowledged that patients may choose other treatment modalities besides home dialysis or transplant despite adequate education on treatment choices. Accordingly, a commenter suggested adding in a quality measure for physician-patient relationship and the shared decision making process.

Response: CMS appreciates the feedback to include additional provisions regarding patient choice in the design of the model, but believes patient choice is adequately protected in the provision to be finalized in our regulation at § 512.120. As applied to the ETC Model, this provision prohibits ETC Participants from inhibiting a beneficiary's freedom to choose the provider and supplier from which they receive care. The ETC Model would not restrict beneficiaries from choosing in-center dialysis as their treatment choice.

We are, however, making certain modifications to our proposed beneficiary notification requirements in light of the comments received. As proposed, each ETC Participant will be required to prominently display informational materials in each of their office or facility locations where beneficiaries receive treatment to notify beneficiaries that the ETC Participant is participating in the ETC Model. Also as proposed, CMS will provide a template for these materials, which will include information for beneficiaries about how to contact the ESRD Network Organizations with any questions or concerns regarding participation in the ETC Model by their health care provider(s). To promote CMS's interest in ensuring that beneficiaries are not mislead into believing that the Model in any way restricts their freedom of choice, the CMS-provided template for the beneficiary notification materials will also include an affirmation of a beneficiary's protections under Medicare, including the freedom to choose his or her provider or supplier and to select the treatment modality of his or her choice. We have revised our regulation at § 512.330(a) to specify that the CMS-provided template for the beneficiary notification will include, without limitation, this information.

Additionally, ETC Participants must continue to make medically necessary covered services available to beneficiaries and cannot target or avoid treating beneficiaries on the basis of their income levels or other factors that would render a beneficiary an at-risk beneficiary as that term is defined for purposes of the Medicare Shared Savings Program, and similarly may not selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the ETC Participant's financial or quality performance in the ETC Model. We address comments related to beneficiary exclusions under section IV.C.B.1 of this final rule. Beneficiaries are not Model participants and while they cannot opt out of the ETC Model's payment methodology, attributed beneficiaries retain all existing beneficiary rights and protections regarding Medicare Parts A and B services, including choice of providers, suppliers and treatment modality.

Comment: We received one comment requesting that we create an Alternative Payment Models Beneficiary Ombudsman to cast a wide net for beneficiary issues.

Response: We disagree that a Beneficiary Ombudsman is necessary for the testing of the ETC Model. As previously noted, beneficiaries are not Model participants and while they cannot opt out of the ETC Model's payment methodology, attributed beneficiaries retain all existing beneficiary rights and protections regarding Medicare Parts A and B services, including choice of providers, suppliers and treatment modality. In addition, as described elsewhere in this final rule, we plan to conduct the monitoring activities described in our regulation at § 512.150 to determine whether the Model is resulting in unintended consequences, including impact on beneficiary choice. We thank the commenter for this feedback and are finalizing the rule without the addition of a Beneficiary Ombudsman.

Comment: We received two comments in support of the beneficiary protection provisions identified in § 512.120 of the proposed rule and their application to the ETC Model. Multiple commenters appreciated CMS proposals to protect beneficiaries' freedom to choose services providers and suppliers by applying the general beneficiary protection provisions identified in § 512.120 to the ETC Model and the proposed requirement for ETC Participants to notify beneficiaries of such participation under proposed § 512.330(a).

Response: We thank the commenters for their feedback and support.

Comment: A commenter recommended that beneficiaries be provided optional assistance in transferring to a provider or supplier not participating in the ETC Model without undue hardship, including assistance with any transportation barriers. Some commenters asked for beneficiaries to have the ability to formally indicate they are not interested in home dialysis or kidney transplantation and, as a result, to be excluded from the home dialysis rate and transplant rate

calculations for purposes of the ETC Model.

Response: We disagree with these recommendations and will finalize the rule without this modification. Nothing in this final rule prohibits a practice from offering beneficiaries the optional assistance described by the commenter, as long as the assistance complies with all applicable laws and regulations, including the Federal anti-kickback statute and the civil monetary penalty provision prohibiting inducements to beneficiaries. To the extent the commenter is advocating that the Secretary waive one or more laws pursuant to section 1115A(d)(1) of the Act to enable the provision of transportation or other assistance, we note that the statutory standard for issuance of such a waiver would not be satisfied because we have determined that offering transportation or other assistance to beneficiaries is not necessary to test the ETC Model. The Model would not affect beneficiaries' freedom to choose their dialysis services provider or supplier, meaning that beneficiaries may elect to see any Medicare-enrolled provider or supplier including those selected and not selected to participate in the Model based on geography. We decline to modify the Model terms to permit beneficiaries to opt out of the Model payment adjustment methodology being applied to the Medicare payments made for their care because their attribution and inclusion are necessary to determine if Model payment adjustments can achieve the Model's goals of increasing rates of home dialysis utilization and kidney transplantation and, as a result, improving or maintaining the quality of care while reducing Medicare expenditures among all types of ESRD facilities and for a full representation of beneficiaries receiving services at those ESRD facilities. In addition, while payment adjustments to the Managing Clinicians and ESRD facilities are being tested under the Model, the health care services available to Beneficiaries likely will not change since the Beneficiary will retain their existing Medicare right to choose their providers and suppliers, as identified in § 512.120 of the final rule. The notification required under § 512.330 will also include an affirmation of the ESRD Beneficiary's protections under Medicare, including the beneficiary's freedom to choose his or her provider or supplier and to select the treatment modality of his or her choice.

Comment: A commenter recommended that we require ETC Participants to inform beneficiaries about all available coverage options and disclose relevant information about payments to patients and insurers.

Response: We disagree that beneficiary notifications beyond those identified in §§ 512.330 and 512.120 of the final rule are necessary for the testing of this Model. As noted in the proposed rule and elsewhere in this final rule, beneficiaries will retain all existing beneficiary rights and protections regarding Medicare Parts A and B services, including choice of providers, suppliers, and treatment modality.

After considering the public comments, we are finalizing the proposed beneficiary notification requirements in our regulation at § 512.330 with modification. In § 512.330(b) of the final rule, we are making a change to the applicability of our regulation at § 512.120(c) (regarding descriptive model materials and activities) to the CMS-provided templates for the informational materials required to be displayed in the office or facilities of ETC Participants where beneficiaries receive treatment described in our regulation at § 512.330(a). In the proposed rule, we had proposed that the entirety of § 512.120(c) would not apply to such CMS-provided materials. However, this was a drafting error. We had intended to refer only to the requirement in 512.120(c)(2), such that the requirement to include the disclaimer that ''The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document'' would not apply to those CMS-provided materials. Because the purpose of these materials is to educate beneficiaries about the Model and because our regulation at § 512.330(a) will permit an ETC Participant to insert its own original content to the CMS-provided templates, where indicated by CMS, we believe that it is important that the other requirements of § 512.120(c) apply to those materials, including the requirement that such materials not be materially inaccurate or misleading, that ETC Participants retain copies of such materials, and that CMS reserve the right to review such materials to determine whether the content added by the ETC Participant is materially inaccurate or misleading. Also, we have revised § 512.330(a) of our regulations to specify that the CMS-provided template for the beneficiary notification will include, without limitation, a notification that the ETC Participant is participating in the ETC Model; instructions on how to contact the ESRD Network Organizations with any questions or concerns about the ETC Participant's participation in the Model; and an affirmation of the ESRD beneficiary's protections under Medicare, including the beneficiary's freedom to choose his or her provider or supplier and to select the treatment modality of his or her choice.

10. Monitoring

a. Monitoring Activities

We proposed that the general provisions relating to monitoring described in the proposed rule and in section II.I of this final rule would apply to ETC Participants, including but not limited to cooperating with the model monitoring activities under § 512.150, granting the government the right to audit under § 512.135(a), and retaining and providing access to records under §§ 512.135(c) and 512.135(b), respectively. CMS would conduct the model monitoring activities in accordance with the proposed § 512.150. We stated in the proposed rule that we believed that we must closely monitor the implementation and outcomes of the ETC Model throughout its duration. As described in the proposed rule, the purpose of monitoring would be to ensure that the Model is implemented safely and appropriately; that ETC Participants comply with all the terms and conditions of the ETC Model; and to protect beneficiaries from potential harms that may result from the activities of an ETC Participant. All monitoring activities under the ETC Model would focus exclusively on Medicare FFS beneficiaries.

Consistent with proposed § 512.150, we proposed that monitoring activities may include documentation requests sent to the ETC Participant; audits of claims data, quality measures, medical records, and other data from the ETC Participant; interviews with members of the staff and leadership of the ETC Participant; interviews with beneficiaries and their caregivers; site visits to the ETC Participant; monitoring quality outcomes and clinical data; and tracking patient complaints and appeals. Specific to the ETC Model, we would use the most recent claims data available to track utilization of certain types of treatments, beneficiary hospitalization and Emergency Department use, and beneficiary referral patterns to make sure the utilization and beneficiary outcomes are in line with the Model's intent. We stated in the

proposed rule that we believe this type of monitoring is important because as ETC Participants adapt to new payment incentives, we want to ensure to the greatest extent possible that the Model is effective and Medicare beneficiaries continue to receive high quality, low cost, and medically appropriate care.

In the proposed rule, we recognized that one of the likely outcomes of this Model would be an increase in utilization of home dialysis. However, in testing payment incentives aimed at increasing utilization of this modality, there may be a risk of inappropriate steering of ESRD Beneficiaries who are unsuitable for home dialysis. As described in the proposed rule and section IV.C.5.b.(1) of this final rule, we proposed to exclude from beneficiary attribution certain categories of beneficiaries not well suited to home dialysis, including beneficiaries with a diagnosis of dementia. We proposed these eligibility criteria to exclude certain categories of beneficiaries from attribution up front so Managing Clinicians and ESRD facilities that are ETC Participants do not attempt or believe that it is wise to attempt to place these particular beneficiaries on home dialysis. In addition, we proposed that CMS would monitor for inappropriate encouragement or recommendations for home dialysis through the proposed monitoring activities. We stated in the proposed rule that instances of inappropriate home dialysis would show up through increases in patient hospitalization, infection, or incidence of peritonitis. For example, multiple incidences of peritonitis would be a good indicator that the patient should not be on PD. If claims data show unusual patterns, we proposed to review a sample of medical records for indicators that a beneficiary was not suited for home dialysis. In the proposed rule, we discussed using patient surveys and interviews to look for instances of coercion on beneficiary choice of modality against beneficiary wishes. If such instances of coercion were found, we stated that we would take one or more remedial action(s) as described at § 512.160 against the ETC Participant and refer the case to CMS for further investigation and/or remedial action.

Additionally, we noted in the proposed rule that we would 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. We stated in the proposed rule that we believe it is important to monitor the transplant and home dialysis trends over a longer period of time to make sure the incentives are not adversely affecting the population of beneficiaries included in the Model.

We also stated in the proposed rule that we would examine the extent of any unintended consequences, including any increase in adverse clinical events such as graft failures, returns to dialysis, peritonitis and other health incidents due to home dialysis, fluctuations in machine and supplies markets, lemon-dropping clinically complex patients, cherry-picking of less clinically complex patients, increase in referrals to home dialysis for patients that are not physically or cognitively able to safely handle the responsibility of dialyzing at home, or an increase in referrals to Comparison Geographic Areas. Specifically, we would monitor the rate at which back-up in-center dialysis (Claim Code 76) and ESRD self-care retraining (Claim Code 87) are used for home dialysis beneficiaries. The use of back-up dialysis for a home dialysis beneficiary can also be an indicator of equipment malfunction. Under the Innovation Center's authority in 42 CFR 403.1110, and built upon in our regulation at § 512.130, we would seek to obtain clinical data for home dialysis patients such as an increase in instances of fever, abnormal bleeding, access point issues, and changes in vitals or weight, from ETC Participants for monitoring purposes and also would use applicable Medicare claims data.

In the proposed rule, we welcomed input about how to best track issues with home dialysis equipment and machines and the format of any proposed documentation for any incidents that occur, and how CMS should share any information about incidents that occur.

For those beneficiaries attributed to ETC Participants who have received a kidney transplant, we proposed to monitor transplant registry data from the SRTR, Medicare claims data available for life of transplant, post-transplant rates of hospitalization and ED visits, infection and rejection rates, and cost of care compared to the beneficiaries who have received a kidney transplant and are not included in the ETC Model test.

We stated in the proposed rule that a key pillar of our monitoring strategy for both transplant, pre-emptive transplant and home dialysis beneficiaries would be stakeholder engagement, and we would continue conversations and relationships with patient-advocate groups and closely monitor patient surveys to uncover any of the unintended consequences listed earlier or others that may be unforeseen. We noted in the proposed rule that we believe beneficiary and/or care partner feedback would be a tremendous asset to help CMS determine and resolve any issues directly affecting beneficiaries.

In addition, we sought comment on how the payment adjustments under the ETC Model may influence delivery-oriented interventions among participating ESRD facilities and Managing Clinicians (for example, increased Managing Clinician knowledge of dialysis modalities, greater patient education, increased investment in equipment and supplies), as well as how the Model's financial incentives may affect the resourcing of these endeavors, and what are the barriers to change. The following is a summary of the comments received on monitoring and our responses.

Comment: We received multiple comments expressing support for our proposed monitoring plan for the ETC Model.

Response: We thank the commenters for their support and are finalizing this monitoring policy for the ETC Model without modification.

Comment: We received multiple comments recommending additional events and conditions for monitoring under the ETC Model. A commenter recommended that we monitor for frequent hospitalizations, patient non-compliance and non-adherence, tracheotomy, patients who have a catheter in certain cases, acute blood loss due to surgical intervention, unknown acute blood loss including gastrointestinal bleeds, heart failure exacerbation, endocarditis, stroke, sepsis, septic shock, surgical procedures (for example, heart surgery, amputations, etc.), active malignancies, diabetic ketoacidosis, Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-susceptible Staphylococcus aureus (MSSA), ulcers (for example, decubitus or foot ulcers), open wounds (for example, bed sores), abscess (stump or other diabetic-related abscess), peri-anal abscess, osteomyelitis, bowel perforation, cardiac arrest, cellulitis, leg and hip fractures, cholecystitis, ulcerative colitis, substance abuse, active lupus, active Polycystic Kidney Disease (PKD), behavioral problems, especially those associated with mental illness diagnosis, bariatric issues, especially those patients with weighing in excess of 500 lbs., and chronic hypertension related to cardiac disease such as cardiomyopathy. Another commenter

recommended that we look for blood stream infections for beneficiaries receiving HHD and peritonitis for beneficiaries receiving PD. Another commenter recommended that we monitor for resource shifting between the Comparison Geographic Areas and Selected Geographic Areas, lemon-dropping and cherry-picking patients who are more likely to receive a transplant, market exits and reduction of in-center chairs in small and low-volume facilities serving a critical need, rates of peritonitis, bloodstream infections in home HD patients, and attrition from home dialysis.

Response: We thank the commenters for their feedback, which will be informative and helpful as we further develop our monitoring strategy for the ETC Model. We note that hospitalizations, infections and peritonitis were identified in the preamble to the proposed rule as items for monitoring and we intend to monitor for these events under the ETC Model.

Comment: A commenter expressed concern that the monitoring approach described in the proposed rule is too vague and requested that CMS provide additional information on our plans to monitor for beneficiary choice and medical appropriateness under the Model.

Response: We thank the commenter for the feedback and are finalizing our monitoring policy for the ETC Model without modification. We disagree with the comment that our monitoring policy for the ETC Model is too vague. In the proposed rule, we provided a list of monitoring activities we would plan to implement in the ETC Model. We identified a number of areas of ETC Model-specific risk and provided specific examples of data, documentation and activities that we would monitor to address that risk. Within a broad outline of monitoring activities described in the regulatory text and preamble of the final rule, we will retain discretion and flexibility as to the specific risks, subject matter, timing, items to be reviewed and mechanics of our monitoring strategy and activities during the model test to be responsive and devote resources to areas of high priority as they become identified. In the proposed rule, we also identified that we may review medical records and clinical data, perform interviews with beneficiaries, caregivers, and ETC Participant leadership and staff, implement surveys, review complaints and appeals, and engage with stakeholders and including patient advocacy groups. We believe these activities will support our monitoring for restrictions on beneficiary choice and medical appropriateness.

Comment: A commenter recommended that we consider whether monitoring could be accomplished through an existing network or survey rather than a separate, model-specific monitoring process and, in the alternative, requested clarification on how the ETC Model monitoring process would align with existing monitoring processes.

Response: As noted in the proposed rule and previously in this final rule, the ETC Model is aimed at increasing utilization of home dialysis and thus may create a risk of inappropriate steering ESRD Beneficiaries who are unsuitable for home dialysis. This unique risk created under this Model requires model-specific monitoring activities, in addition to the existing CMS monitoring processes to protect ESRD Beneficiaries. We thank the commenter for the feedback and are finalizing our proposed monitoring strategy without modification.

Comment: A commenter expressed concern that peritonitis is not included in hospital acquired infection reporting and is not accounted for in hospital payment, and asked that facilities that accept PD patients and place PD catheters be accountable for clinical competency and infections.

Response: We thank the commenter for this feedback and note this specific item is beyond the scope of this rulemaking. The ETC Model, as described in the final rule, would not change or modify hospital quality reporting or payment methodology to account for incidences of peritonitis that occur in their facility or otherwise.

Comment: A commenter expressed concern that our proposed monitoring plan would be too retrospective and would not identify issues quickly enough. The commenter cited the timing for the availability of claims data as an example. In addition, the commenter expressed concern that certain risks are difficult or impossible to identify through claims data, including peritonitis and partner burnout.

Response: We thank the commenter for the feedback. However, we note that in addition to reviewing claims data, we also may review medical records and clinical data, perform interviews with beneficiaries, caregivers, and ETC Participant leadership and staff, implement surveys, review complaints and appeals, and engage with stakeholders including patient advocacy groups. We believe these monitoring strategies will provide us timely feedback and will supplement the information made available through claims data.

After consideration of the public comments, we are finalizing the monitoring policy for the ETC Model as proposed, without modification.

b. Quality Measures

In addition to the monitoring activities discussed previously, we proposed two ESRD facility quality measures for the ETC Model:

- Standardized Mortality Ratio (SMR); NQF #0369—Risk-adjusted standardized mortality ratio of the number of observed deaths to the number of expected deaths for patients at the ESRD facility.
- Standardized Hospitalization Ratio (SHR); NQF #1463—Risk-adjusted standardized hospitalization ratio of the number of observed hospitalizations to the number of expected hospitalizations for patients at the ESRD facility.

We explained in the proposed rule that SMR and SHR measures are currently calculated and displayed on Dialysis Facility Compare, a public reporting tool maintained by CMS. The SHR is also included in the ESRD QIP measure set as a clinical measure on which ESRD facilities' performance is scored.[160] Because data collection and measure reporting are ongoing, there would be no additional burden to ETC Participants to report data on these measures for the ETC Model. We stated in the proposed rule that, although CMS has in a previous rule acknowledged concerns that the SMR might not be adequately risk adjusted (78 FR 72208), we believe this measure is appropriate for purposes of the ETC Model, under which the SMR would not be used for purposes of determining payment. Mortality is a key health care outcome used to assess quality of care in different settings. We noted in the proposed rule that while we recognize that the ESRD population is inherently at high risk for mortality, we believe that mortality rates are susceptible to the quality of care provided by dialysis facilities, and note that the measure is currently being used in the CEC Model. The SMR is NQF endorsed, indicating that it serves as a reliable and valid measure of mortality among ESRD Beneficiaries who receive dialysis at ESRD facilities.

We stated in the proposed rule that we considered including the In-Center Hemodialysis (ICH) CAHPS® survey to monitor beneficiary perceptions of

[160] For the specifications for these measures, see ''CMS ESRD Measures Manual for the 2018 Performance Period/2020 Payment Year'', June 20, 2018, *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/ESRD-Manual-v30.pdf.*

changes in quality of care as a result of the ETC Model. However, the ICH CAHPS survey includes only beneficiaries who receive in-center dialysis. The survey specifically excludes the two beneficiary populations that the ETC Model would focus on, namely beneficiaries who dialyze at home and beneficiaries who receive transplants and, therefore, we did not propose to use this measure for purposes of the ETC Model.

We noted in the proposed rule that we considered including quality measures for Managing Clinicians that are reported by Managing Clinicians for MIPS or other CMS programs. However, whereas all ESRD facilities are subject to the same set of quality measures under the ESRD QIP, there is no analogous source of quality measure data for Managing Clinicians. We stated that Managing Clinicians may be subject to MIPS, or they may be participating in a different CMS program—or an Advanced APM—which has different quality requirements. In addition, most Managing Clinicians participating in MIPS select the quality measures on which they report. Taken together, these factors mean that we would be unable to ensure that all Managing Clinicians in the ETC Model are already reporting on a given quality measure, and therefore would be unable to compare quality performance across all Managing Clinicians without imposing additional burden.

We proposed that the SHR and SMR measures would not be tied to payment under the ETC Model. However, we stated in the proposed rule that we believe that the collection and monitoring of these measures would be important to guard against adverse events or decreases in quality of care that may occur as a result of the performance-based payment adjustments in the ETC Model. We noted that we believe we would be able to observe changes over time in individual ESRD facility level scores on these measures, as well as comparing change over time for ESRD facilities that are ETC Participants against change over time in those that are not ETC Participants. In the aggregate, these measures should capture any increase in adverse events, particularly for patients on home dialysis, as home dialysis patients are included in both the numerators and denominators of these measures. We stated in the proposed rule that home dialysis patients primarily receive care through ESRD facilities, and barring beneficiaries excluded from the measures per the measure specifications, the majority of ESRD Beneficiaries attributed to an ETC Participant would be captured in these measures. These measures also include ESRD Beneficiaries before they receive a kidney transplant; however, beneficiaries post-transplant would not be included, per the measure specifications.

We invited public comment on the proposed quality measures and whether their proposed use would enable CMS to sufficiently monitor for adverse conditions for ESRD Beneficiaries, in combination with the monitoring activities previously described. We also invited other suggestions as to measures that would support monitoring beneficiary health and safety under the Model, while minimizing provider burden.

Additionally, as described in the proposed rule and in section IV.C.6 of this final rule, we proposed that ETC Participants that are ESRD facilities would still be included in the ESRD QIP and required to comply with that program's requirements, including being subject to a sliding scale payment reduction if an ESRD facility's total performance score does not meet or exceed the minimum total performance score specified by CMS for the payment year. We explained that ETC Participants who are Managing Clinicians and are MIPS eligible clinicians would still be subject to MIPS requirements and payment adjustment factors, and those in a MIPS APM would be scored using the APM scoring standard. ETC Participants who are Managing Clinicians and who are in an Advanced APM would still be assessed to determine whether they are Qualifying APM Participants (QPs) who, as such, would earn the APM incentive payment and would not be subject to the MIPS reporting requirements or payment adjustment. We did not propose to waive any of these requirements for purposes of testing the ETC Model.

The following is a summary of the comments received on the quality measures included in the Model and our responses.

Comment: CMS received supportive comments for our proposal to use the two quality measures and not tie them to payment. However, a commenter stated that the measures incentivize increase utilization rather than performance improvement.

Response: CMS appreciates the feedback from these commenters. Both the SMR and the SHR are NQF-endorsed outcome measures for patients who receive dialysis at a given ESRD facility. The measures were chosen for the purpose of monitoring for adverse events that may occur as an unintended consequence of performance-based payment adjustments for home dialysis and transplant. While there are currently no measures of adverse events for beneficiaries who dialyze at home, CMS believes that adverse events at ESRD facilities is a suitable proxy, as the measures include both beneficiaries who dialyze at home and beneficiaries who dialyze in-center for a given ESRD facility.

Comment: We received several comments emphasizing the importance of beneficiary experience and requesting that CMS include a formal measure of beneficiary experience in this Model. A couple comments suggested that CMS develop a CAHPS measure for home dialysis.

Response: CMS considered the inclusion of ICH CAHPS to monitor beneficiary perceptions of change in quality of care as a result of the ETC Model. However, as we stated in the proposed rule, because the ICH CAHPS survey includes only beneficiaries who receive in-center dialysis, and specifically excludes the beneficiary populations that this Model is specifically focused on, namely beneficiaries moving away from in-center hemodialysis to alternative renal replacement therapies, ICH CAHPS does not reach the target beneficiary population. Because there is no equivalent CAHPS or other survey for home dialysis patients, or for post-transplant patients, CMS intends to develop a beneficiary experience measure, similar to the CAHPS survey, that could influence Model payments to participants as early as the third year of the Model. We intend to propose and incorporate a beneficiary experience measure in the ETC Model in the near future.

The Model's evaluation will examine the effect of the ETC Model on such key outcomes as improved quality of care and quality of life. Data collection activities performed for purposes of the evaluation may include patient surveys and beneficiary focus groups.

Comment: Multiple commenters encouraged CMS to add additional quality measures. The commenters suggested measures including: ED utilization; peritonitis in hospital acquired infections; provision of supportive care services; behavioral and mental health; care coordination; safety and reliability; provider engagement; and Advanced Care Plans. In addition, commenters recommended that CMS develop a measure for referrals into the transplantation process as well as hospice. A commenter noted the burden of manual data collection and the impact on patient care.

Response: CMS chose the SMR and SHR measures, essential indicators for the ESRD population, because they are already reported in Dialysis Facility Reports and the ESRD QIP, respectively. These are programs run by CMS/CCSQ that produce dialysis facility-level quality data annually and, therefore, impose no additional administrative burden on ESRD facilities. We appreciate commenters suggestions about other potential quality measures that we could include in the ETC Model that may benefit the patient population. However, we believe that the two quality measures we have included are sufficient for the purposes of monitoring to guard against adverse events or decreases in quality of care that may occur as a result of the performance-based payment adjustments in the Model. All ETC Participants remain subject to other applicable CMS quality programs unless otherwise exempt, so we believe that other potential aspects of quality of care are sufficiently captured and incentivized by those quality programs. In addition, the purpose of the measures is solely for monitoring for adverse events that may occur as an unintended consequence of performance-based payment adjustments for home dialysis and transplant, and will have no impact on the payment adjustments under the ETC Model. Therefore, CMS believes these two measures are adequate and no additional measures are needed at this time.

Comment: CMS received one comment urging CMS to use mortality and hospitalization rates rather than ratios because ratio measures have wide confidence intervals that potentially lead to incorrect information about facility performance being reported. In addition, the commenter recommended that CMS work with NQF to develop social-demographic adjusters.

Response: CMS appreciates the feedback. Both of the proposed measures are NQF-endorsed measures for renal conditions and are already reported through CMS reporting systems, Dialysis Facility Compare for SHR and SMR, and ESRD QIP for SHR. We believe it is appropriate to use the ratio measures for the purposes of the Model because they align with existing CMS programs. Additionally, we do not believe that the statistical features of these ratio measures referenced, namely the wide confidence intervals, contributes to incorrect information about facility performance being reported. These measures are already reported publicly at the facility level through Dialysis Facility Compare and the ESRD QIP, with explanation of the statistical properties of the ratios. Additionally, the measures are being used in the Model for monitoring purposes, and are not intended to convey specific information about individual facility performance to the public.

Comment: A commenter requested that CMS acknowledge that palliative dialysis is a patient-preference option that should not result in penalties under the ESRD QIP.

Response: CMS appreciates the feedback from our stakeholders. However, the comment pertains to the ESRD QIP generally and is therefore not within the scope of this final rule.

Based on the comments received, we are finalizing the quality measures as proposed without modification.

11. Evaluation

As we described in the proposed rule, an evaluation of the ETC Model would be conducted in accordance with section 1115A(b)(4) of the Act, which requires the Secretary to evaluate each model tested by the Innovation Center. We noted in the proposed rule that we believe an independent evaluation of the Model is necessary to understand its impacts of the Model on quality of care and Medicare program expenditures and to share with the public. We would select an independent evaluation contractor to perform this evaluation. As specified in the proposed rule and section II.E of this final rule, all ETC Participants would be required to cooperate with the evaluation.

We stated in the proposed rule that research questions addressed in the evaluation would include, but not be limited to, whether or not the ETC Model results in a higher rate of transplantation and home dialysis, better quality of care and quality of life, and reduced utilization and expenditures for ESRD Beneficiaries in Selected Geographic Areas in relation to Comparison Geographic Areas. The evaluation would also explore qualitatively what changes Managing Clinicians and ESRD facilities implemented in response to the ETC Model, what challenges they faced, and lessons learned to inform future policy developments.

We proposed that the ETC Model evaluation would employ a mixed-methods approach using quantitative and qualitative data to measure both the impact of the Model and implementation effectiveness. The impact analysis would examine the effect of the ETC Model on key outcomes, including improved quality of care and quality of life, and decreased Medicare expenditures and utilization. The implementation component of the evaluation would describe and assess how ETC Participants implement the Model, including barriers to and facilitators of change. We noted in the proposed rule that findings from both the impact analysis and the implementation assessment would be synthesized to provide insight into what worked and why, and to inform the Secretary's potential decision regarding model expansion.

We would use multi-pronged data collection efforts to gather the quantitative and qualitative data needed to understand the context of the Model implemented at participating ESRD facility and Managing Clinician locations and the perspectives of different stakeholders. Data for the analyses would come from sources including, but not limited to, payment and performance data files, administrative transplant registry data, beneficiary focus groups, and interviews with ETC Participants.

As described in the proposed rule, the quantitative impact analysis would compare performance and outcome measures over time, using a difference-in-differences or a similar approach to compare beneficiaries treated by ETC Participants to those treated by ESRD facilities and Managing Clinicians in Comparison Geographic Areas. We would examine both cumulative and year-over-year impacts. The quantitative analyses conducted for the evaluation would take advantage of the mandatory nature of the ETC Model for ESRD facilities and Managing Clinicians located in Selected Geographic Areas.

We explained in the proposed rule that, while the model design would control for the selection bias inherent in voluntary models, a comparison group would still be necessary to determine if any changes in outcomes are due to the ETC Model or to secular trends in CKD and ESRD care. The comparison group would be those Managing Clinicians and ESRD facilities located in Comparison Geographic Areas which would not be subject to the ETC Model payment adjustments. The evaluator would match Managing Clinicians and ESRD facilities located in Comparison Geographic Areas with Managing Clinicians and ESRD facilities that are located in Selected Geographic Areas (that is, ETC Participants) using propensity scores or other accepted statistical techniques. Beneficiaries who receive care from ESRD facilities and Managing Clinicians in these Selected Geographic Areas and Comparison Geographic Areas would be identified using the ETC Model claims-based eligibility criteria, and would be

attributed using the same claims-based beneficiary attribution methods we proposed to use for purposes of calculating the MPS.

We stated in the proposed rule that the evaluation would account for any interaction with other CKD- and ESRD-related initiatives at CMS, such as the ESRD QIP, the CEC Model, and the KCC Model (formerly the CKC Model). For example, the evaluator would look for disparate outcomes that could arise in the ESRD QIP between facilities that are also participating in the ETC Model and facilities that are not participating in the ETC Model and also assess whether performance in the ETC Model varies for Managing Clinicians and ESRD Facilities who are also participating in the CEC or KCC Models.

We invited public comment on our proposed approach related to the evaluation of the ETC Model.

Comment: A commenter noted that CMS did not specify the timing of the ETC Model evaluation.

Response: We thank the commenter for this feedback. The evaluation will be active during and after the Model test period to allow for data collection and analysis. We expect the evaluation will have annual reports covering the assessment of the Model using available data, including a summative report following the conclusion of the model test.

Comment: A commenter recommended that the evaluation take into account any possible negative impacts or lack of impact of the Model. Should the latter occur, the commenter suggested that the Model should be terminated.

Response: We agree with the commenter regarding the need to assess potential negative impacts of the Model. We clarify here that the evaluation will account for potential impacts of the Model including positive, negative, or a lack thereof, in terms of both Medicare expenditures and the quality of care and we would determine the appropriate actions, including potential termination of the Model, based upon an analysis of the evaluation findings.

Comment: A commenter noted that the Model evaluation should measure the impact of concurrent hospice dialysis access; specifically, patient and family experience with care satisfaction and costs at the end of life.

Response: We appreciate this comment suggesting a measure to assess in evaluating the Model. The Model evaluation's questions around quality of care and quality of life and expenditures include questions regarding patient and family experience and costs at the end of life, and we will analyze these questions to the extent feasible.

Comment: Several commenters expressed concern that 50 percent of the 306 HRRs in the US is larger than is necessary to evaluate a change in the transplantation rate as a result of the Model.

Response: As previously noted, we performed a power calculation to determine the minimum sample size of the participant and comparison groups in the Model in order to produce robust and reliable results. We determined from these tests that 30 percent of the HRRs are needed to minimize the risk of false positive and false negative results, and the minimum detectable effect of a two percentage point increase or decrease in the rate of transplant wait listing and a one and one-half percentage point increase or decrease in home dialysis Since this approach provides sufficient statistical power, we are finalizing our evaluation approach as proposed.

12. Learning System

We proposed that in conjunction with the ETC Model, CMS would operate a voluntary learning system focused on increasing the availability of deceased donor kidneys for transplantation. The learning system would work with, regularly convene, and support ETC Participants and other stakeholders required for successful kidney transplantation, such as transplant centers, OPOs, and large donor hospitals. We proposed that these ETC Participants and stakeholders would utilize learning and quality improvement techniques to systematically spread the best practices of highest performers. The application of broad scale learning and other mechanisms for rapid and effective transfer of knowledge within a learning network would also be used. Quality improvement approaches would be employed to improve performance by collecting and analyzing data to identify the highest performers, and to help others to test, adapt and spread the best practices of these high performers throughout the entire national organ recovery system. We stated in the proposed rule that we believed that implementation of the learning system would help to increase the supply of transplantable kidneys, which would help ETC Participants achieve the goals of the Model.

Comment: We received several comments in this area, all supporting CMS's proposal to implement the proposed learning system. A commenter proposed working with the Quality Improvement Organizations (QIOs) to help implement the learning system and branding the learning collaborative as the ''Transplant First'' initiative. Another commenter proposed delaying implementation of the transplant component of the PPA until the learning collaborative has been implemented for multiple years.

Response: We appreciate the commenters' support for the proposed learning system and are finalizing our proposal to implement it as proposed. We plan to refer to the learning system as the ETC Learning Collaborative as it is a part of the ETC Model test and we do not wish to confuse ETC Participants or the public by giving the learning system a name with no clear connection to the Model. We appreciate the suggestion about the QIOs, but we do not believe that QIO involvement is necessary given their other priority areas that they are working on. In terms of the comment recommending that CMS delay implementation of the transplant component of the PPA until the learning collaborative has been implemented for multiple years, while we hope that the ETC Learning Collaborative will be successful at improving utilization of available kidneys, such a delay is not necessary because, as previously described in section IV.C of this final rule, we are now assessing ESRD facilities and Managing Clinicians based on their ability to impact transplant rates calculated as the sum of the transplant waitlist rate and the living donor transplant rate, rather than overall transplant rates including deceased donor transplants, for purposes of the ESRD PPA and Managing Clinician PPA, respectively.

After considering the public comments, we are implementing the learning system under this Model as proposed.

13. Remedial Action

As described in the proposed rule and in section 512.160 of this final rule, the remedial actions outlined in the general provisions in § 512.160 would apply to the ETC Model. Accordingly, if CMS determines that an ETC Participant has engaged in one or more of the actions listed under § 512.160(a) (Grounds for Remedial Action), CMS may take one or more of the remedial actions listed under § 512.160(b).

We did not receive comments on our proposals relating to remedial action in the ETC Model. Therefore, we are finalizing these proposals without modification.

14. Termination of the ETC Model

As described in the proposed rule, the general provisions relating to termination of the Model that CMS proposed in the proposed rule and discussed in section II.J of this final rule would apply to the ETC Model. Consistent with these provisions, in the event we terminate the ETC Model, we would provide written notice to ETC Participants specifying the grounds for termination and the effective date of such termination or ending. As provided by section 1115A(d)(2) of the Act and § 512.170, termination of the Model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

We did not receive comments on the proposals relating to termination of the ETC Model. Therefore, we are finalizing our proposals without modification.

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, evaluation, and expansion of models under section 1115A of the Act. As a result, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget. However, we have summarized the anticipated information collection requirements in section VI.C.4. of this final rule.

VI. Regulatory Impact Analysis

We have examined the impact of this final rule as required by Executive Order 12866 and other laws and Executive Orders, requiring economic analysis of the effects of final rules. 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 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 final rule.

A. Statement of Need

1. Need for the Radiation Oncology (RO) Model

Radiotherapy (RT) services represent a promising area of health care for payment and service delivery reform. First, RT services are furnished in both freestanding radiation therapy centers paid under the Medicare Physician Fee Schedule (PFS) and the Outpatient Prospective Payment System (OPPS). There are site-of-service payment differentials between the OPPS and PFS payment systems, which can result in financial incentives to offer care in one setting over another. Second, as in other health care settings, health care providers are financially incentivized to provide more services to patients because they are paid based on the volume of care they provide, not value. We believe that these incentives are misaligned with evidence-based practice, which is moving toward furnishing fewer radiation treatments for certain cancer types. Third, difficulties in coding and setting payment rates for RT services have led to volatility in Medicare payment for these services under the PFS and increased coding complexity and administrative burden. As part of the RO Model's design, we will examine whether the model leads to higher quality care by encouraging improved adherence to clinical guidelines and by collecting information related to quality performance and clinical practice. The RO Model aims to incentivize RO participants to maintain high quality care with the opportunity to earn back a withheld payment amount through successful quality outcomes and clinical data reporting.

As described in detail in section III.C.8. of this final rule, RO participants are required to collect and submit data on quality measures, clinical data, and patient experience throughout the course of the RO Model, beginning January 1, 2021, with the final data submission ending in 2026.

We refer readers to section III.B. of this final rule for more information on our research and rationale for the RO Model, including summaries of stakeholder comments on this rationale and our response. We refer readers to section III.C for more information on policy-related stakeholder comments, our responses to those comments, and statements of final policy.

2. Need for End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model

Beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. One of CMS' goals in designing the ETC Model is to test ways to incentivize home dialysis and kidney transplants, so as to enhance beneficiary choice of modality for renal replacement therapy, and improve or maintain quality of care while reducing Medicare program expenditures. The substantially higher expenditures, mortality, and hospitalization rates for dialysis patients in the U.S. compared to those for individuals with ESRD in other countries indicate a population with poor clinical outcomes and potentially avoidable expenditures. We anticipate preservation or improvement in quality of care for beneficiaries and reduced expenditures under the ETC Model inasmuch as the Model will create incentives for beneficiaries, along with their families and caregivers, to choose the optimal kidney replacement modality.

In section IV.B of this final rule, we describe how current Medicare payment rules and a deficit in beneficiary education result in a bias toward in-center hemodialysis, which is often not preferred by patients or physicians relative to home dialysis or kidney transplantation. We provide evidence from published literature to support the projection that higher rates of home dialysis and kidney transplants will reduce Medicare expenditures, and, not only enhance beneficiary choice, independence, and quality of life, but also preserve or enhance the quality of care for ESRD beneficiaries.

As described in detail in sections II. and IV. of this final rule, ETC Participants will be subject to payment adjustments under the ESRD Prospective Payment System (ESRD PPS) and Physician Fee Schedule (PFS), as applicable, and will be required to comply with certain requirements, including to cooperate with CMS's monitoring and evaluation activities, for the duration of the ETC Model.

3. Impact of RO Model and ETC Model

In the proposed rule (84 FR 34567), we estimated, as detailed in Table 16A of the proposed rule, a net impact of $260 million in net savings to the Medicare program due to the RO Model from January 1, 2020 through December 31, 2024, with a range of impacts between $50 million and $460 million in net Medicare savings. Alternatively, as detailed in Table 16B of the proposed rule, we estimated a net impact of $250 million in net savings to the Medicare program due to the RO Model from April 1, 2020 through December 31, 2024, with a range of impacts between $40 million and $450 million in net Medicare savings.

As detailed in Table 17 of the proposed rule, we estimated the Medicare program would save a net total of $185 million from the PPA and HDPA, which would be applied under the ETC Model between January 1, 2020 through June 30, 2026. We also stated our expectation that the ETC Model would cost an additional $15 million, resulting from increases in education and training costs. Therefore, we estimated the net impact to Medicare

spending to be $169 million in savings as a result of the ETC Model.

We solicited comment on the assumptions and analysis presented throughout the regulatory impact section of the proposed rule.

Comment: A few commenters stated that the RO Model's estimates of $250-$260 million in savings over a 5-year period are understated. One commenter suggested that total savings would be closer to $320 million over 5 years based on volume and intensity (V&I) calculations of the bundled services per episode, which remain unchanged between the period used for rate setting and when payments are made.

Response: We thank these commenters for expressing their concerns. Policy impact estimates may vary depending on a number of factors. Our estimate reflects a net Medicare Part B financial impact. Therefore, our impact analysis includes changes to Medicare Trust Fund payments and other Medicare financing interaction effects such as changes in Part B Trust Fund revenue, MA capitation rates, APM incentive payments, and the BBA 1999 IPPS Part A deductible cap. Moreover, the impact estimate excluded changes in beneficiary cost sharing liability to the extent it is not shifted to being a Federal outlay by the policy. Our estimate also assumed the V&I of the bundled services per episode remains unchanged between the period used for rate setting and when payments are made. We estimated that if V&I were to decrease by 1.0 percent annually for the bundled services absent the model, then Medicare would reduce net outlays by $50 million ($40 million with an April 1, 2020 start date) between 2020 and 2024. Similarly, if V&I increases by 1.0 percent annually then net outlays would be reduced by $460 million ($450 million with an April 1, 2020 start date) for the projection period. While we noted in the proposed rule that although V&I growth from 2014 through 2017 fell within this 1.0 percent range and did not exhibit a secular trend, actual experiences may vary. We are finalizing a different Model performance period and Model geographic scope than proposed, and have updated assumptions and estimates in VI.C of this final rule.

Based on the finalized policy, we have updated our net estimate of the RO Model impact and now expect a savings of $230 million for Medicare. We have also updated our net estimate of the ETC Model impact and now expect a savings of $23 million for Medicare. We discuss our analysis in greater detail in sections VI.C.1(a) and VI.C.2.a(3) of this final rule.

B. Overall Impact

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

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. As stated previously in this final rule, this final rule triggers these criteria.

C. Anticipated Effects

1. Scale of the Model

As we stated in the proposed rule (84 FR 34569 through 34570), there is no one-size-fits-all approach to designing, implementing, and evaluating models. Each payment and service delivery model tested by the Innovation Center is unique in its goals, and thus its design. Models vary in size in order to accommodate various design features and satisfy a variety of priorities. Decisions made regarding the features and design of the model strongly influence the extent to which the evaluation will be able to accurately assess the effect of a given model test and produce clear and replicable results.

The Innovation Center conducts analyses to determine the ideal number of participants for each model for evaluation purposes. This analysis considers a variety of factors including the target population (for example, Medicare beneficiaries with select medical conditions), model eligibility (for example, beneficiary eligibility criteria for inclusion in the model), participant enrollment strategy (for example, mandatory versus voluntary) and, the need to test effects on subgroups. Model size can also be influenced by the type and size of hypothesized effect on beneficiary outcomes, such as quality of care, or the target level of model savings. The smaller the expected impact a model is hypothesized to achieve, the larger a model needs to be for CMS to have confidence in the observed impacts.

An insufficient number of participants increases the risk that the evaluation will be imprecise in detecting the true effect of a model, potentially leading, for example, to a false negative or false positive result. The goal is to design a model that is sufficiently large to achieve adequate precision but not so large as to waste CMS's limited resources. These decisions affect the quality of evidence CMS is able to present regarding the impacts of a model on quality of care, utilization, and spending.

a. Radiation Oncology (RO) Model

In the case of the RO Model, in the proposed rule we determined the sample size necessary for a minimum estimated savings impact of 3 percent (84 FR 34568). While a savings higher than 3 percent would require a smaller sample size from an evaluation perspective, if we were to reduce the size of the RO Model and if the actual savings are at or just below the 3 percent level, then we would increase the risk of being unable to detect whether the RO Model resulted in savings.

We refer readers to the proposed rule where we proposed that the RO Model would include 40 percent of radiation oncology episodes in eligible geographic areas and our simulation based on this proposal. In section III.C.3.c of this final rule, we finalized our policy to include 30 percent of radiation oncology episodes and a low-volume exception. We performed a simulation based on our finalized policies. Based on this simulation, we expect to have

approximately 500 physician group practices (PGPs) (of which 275 are freestanding radiation therapy centers) and 450 HOPDs furnishing RT services in those simulated selected CBSAs. We further expect the RO Model to include approximately 348,000 episodes, 309,000 beneficiaries, and $5.3 billion in total episode spending of allowed charges over the Model performance period. To determine the number of PGPs, we counted the number of TINs that furnished at least one professional or technical component in 2018 in one of the CBSAs selected for Model participation as recorded in the 2016–2018 episode file. To determine the number of HOPDs, we counted the number of facility CCNs that furnished at least one technical component in 2018 in the CBSAs selected for Model participation as recorded in the 2016–2018 episode file. Similarly, to determine episode count, beneficiary count, and total spending estimates, we drew upon the historical data of RO participants simulated into CBSAs selected for participation. These estimates represent the Model size of 30 percent of RO episodes in eligible geographic areas

b. End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model

The ETC Model will include approximately 30 percent of ESRD beneficiaries, through the ESRD facilities and Managing Clinicians selected for participation in the Model. The Innovation Center will randomly select 30 percent of HRRs, stratified by region, and include separate from randomization all HRRs for which at least 20 percent of the component zip codes are located in Maryland. All ESRD facilities and Managing Clinicians in selected HRRs, referred to as Selected Geographic Areas, will be required to participate in the Model. There are currently 7,196 ESRD facilities and 2,286 Managing Clinicians enrolled in Medicare, distributed across 306 HRRs and providing care for 383,057 ESRD beneficiaries that meet the eligibility criteria for attribution to ETC Participants under the Model. Only approximately 10 percent of beneficiaries on dialysis received home dialysis in 2017. The ETC Model will apply the payment adjustments described in section IV. of this final rule to claims with ''claim service dates'' between January 1, 2021 through June 30, 2027, and over that time period, will randomize 30 percent of the HRRs that the ESRD facilities and Managing Clinicians align with and generate $23 million in net Medicare savings. See Table 2 for an annual breakdown.

c. Aggregate Effects on the Market

As we noted in the proposed rule, there may be spillover effects in the non-Medicare market, or in non-ESRD areas of the Medicare market because of the implementation of these models. Testing changes in Medicare payment policy may have implications for non-Medicare payers. As an example, non-Medicare patients may benefit if participating providers and suppliers introduce system-wide changes that improve the coordination and quality of health care. Other payers may also be developing payment models and may align their payment structures with CMS or may be waiting to utilize results from CMS' evaluations of payment models. Because there is uncertainty whether and how this evidence applies to a test of these new payment models, our analyses assume that spillover effects on non-Medicare payers will not occur, although this assumption is subject to considerable uncertainty. We solicited comments on this assumption and evidence on how this rulemaking would impact non-Medicare payers and patients.

Comment: A couple of commenters expressed concern that the RO Model payment methodology could the impact practices where commercial payers use Medicare rates as a proxy.

Response: As stated in the proposed rule for the RO Model (84 FR 34568), although we assume that spillover effects on non-Medicare payers will not occur, we understand that considerable uncertainty surrounds this assumption. However, no evidence has been found to support this assumption that that the RO Model will impact non-Medicare payers either. In our analyses, we assume growth of FFS Medicare Part B enrollment as projected in the 2018 Medicare Trustees Report. We also assume that providers and suppliers would not change payer mix as a response to the RO Model. However, we hope that, at the end of the RO Model's evaluation, information learned can move Medicare and non-Medicare payment to more accurately and appropriately reimburse high-value RT services.

2. Effects on the Medicare Program

a. Radiation Oncology Model

(1) Overview

Under the current FFS payment system, RT services are paid on a per service basis to both PGPs (including freestanding radiation therapy centers) and HOPDs through the PFS and the OPPS, respectively. The RO Model will be a mandatory model designed to test a prospectively determined episode payment for RT services furnished to Medicare beneficiaries during episodes initiated between January 1, 2021 and December 31, 2025.

The RO Model will test differences in payment from traditional FFS Medicare by paying RO participants two equal lump-sum payments, once at the start of the RO episode and again at the end, for episodes of care. RO episode means the 90-day period that, as set forth in § 512.245, begins on the date of service that a Professional participant or a Dual participant furnishes an initial treatment planning service to an RO beneficiary in a freestanding radiation therapy center or an HOPD, provided that a Technical participant or the same Dual participant furnishes a technical component RT service to the RO beneficiary within 28 days of such RT treatment planning service. RO episodes include all Medicare items and services described in § 512.235 that are furnished to an RO beneficiary described in § 512.215. Once an RO episode is initiated, RO participants will no longer be allowed to separately bill other HCPCS codes or APC codes for activities related to radiation treatment for the RO beneficiary in that RO episode.

For each participating entity, the participant-specific professional episode payment and participant-specific technical episode payment amounts would be determined as described in detail in section III.C.6. of this final rule.

The RO Model is not a total cost of care model. RO participants will still bill traditional FFS Medicare for services not included in the episode payment and, in some instances, for less common cancers not included in the model and other exclusion criteria. A list of cancer types that meet the criteria for inclusion in the RO Model and associated FFS procedure codes are included in section III.C.5. of this final rule.

(2) Data and Methods

Similar to the analysis performed for regulatory impact analysis for the proposed rule (84 FR 34571), a stochastic simulation based on the finalized policies was created to estimate the financial impacts of the RO Model relative to baseline expenditures. The simulation relied upon statistical assumptions derived from retrospectively constructed RT episodes between 2016 and 2018 (updated from the 2015–2017 episodes used in the proposed rule to reflect finalized policy). This information was reviewed and determined to be reasonable for the estimates.

To project baseline expenditures, traditional FFS payment system billing patterns are assumed to continue under current law. Forecasts of the Medicare Part A and Part B deductibles were obtained from the 2019 Medicare Trustees Report and applied to simulated episode payments to estimate interactions of lump sum payments with the HOPD line item cap as described in section 1833(t)(8)(C)(i) of the Act. We assumed that the current relative value units under the PFS and relative payment weights under the OPPS in the updated episode data from 2016 through 2018 would continue into the future, which is consistent with the updates we made for the payment methodology in section III.C.6 of this final rule. Similarly, conversion factors in both the PFS and OPPS were indexed to the appropriate update factors under current law. Payment rate updates to future PFS conversion factors are legislated at 0.25 percent in 2019 and 0.0 percent for 2020 through 2025 under the Medicare Access and CHIP Reauthorization Act of 2015. OPPS conversion factors are updated by the productivity-adjusted inpatient hospital market basket update in our simulation. We forecast that net OPPS updates will outpace the PFS by 3.0 percent on average annually between 2019 and 2025.

(3) Medicare Estimate

Table 1 summarizes the estimated impact of the RO Model. The estimated impact reflects the finalized policies, which are different than some of the proposed rule policies. For instance, we are finalizing policies for reduced discount factors, a smaller Model size of 30 percent of RO episodes in eligible geographic areas, a low volume opt-out option, a stop-loss policy for RO participants with fewer than 60 episodes during 2016–2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of this final rule, and a Model performance period of January 1, 2021 through December 31, 2025. Thus, we are now estimating that on net the Medicare program will save $230 million over the Model performance period. As in the proposed rule, this is the net Medicare Part B impact that includes both Part B premium and Medicare Advantage United States Per Capita Costs (MA USPCC) rate financing interaction effects. This estimate excludes changes in beneficiary cost sharing liability to the extent it is not a Federal outlay under the policy.

On net, we project a lower spending reduction per RO episode and that slightly more RO episodes (2,000 more RO episodes) would be paid through the RO Model. As for the stop-loss policy, it applies only to RO participants with fewer than 60 episodes during 2016–2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of this final rule. Under the stop-loss policy, if payments under the Model resulted in more than 20 percent loss as compared to the amount the RO participant would have received under FFS, then CMS owes the RO participant the amount that exceeds that 20 percent. Recall that RO participants with fewer than 60 episodes during 2016–2018 do not receive a historical experience adjustment. The stop-loss payments for these RO participants were projected under the assumption that similar qualification rates and FFS claims volatility for these eligible providers experienced during 2016–2018 would occur within no-pay claims submitted during the Model test. The RO participants eligible for the stop-loss policy are projected to account for 1.2 percent of the Model episode spending, and we estimate the five-year cost of this policy to be $0.3 million, an immaterial impact on the savings estimate as displayed in Table 1. Revisions to the projected impacts primarily reflect the net effects of changes to the Model start and end dates, refinements to the randomization procedures used for CBSA selection, and a reduction in the proposed discount factors by 0.25 percent.

We project that 83 percent of physician participants (measured by unique NPI) would receive the APM incentive payment under the Quality Payment Program at some point (at least one QP Performance Period) during the model performance period. This assumption is based on applying the 2020 QPP final rule qualification criteria to simulated billing and treatment patterns for each QPP performance year during the RO Model test. Episode-initiating physicians were assumed to form an APM entity with the TIN(s) under which they bill for RT services. For each APM entity, counts of total treated patients and spending for covered physician services under the RO Model were estimated and applied to QPP qualification criteria based on CY2018 provider billing patterns.

As explained in section III.C.9 of this final rule, the APM incentive payment will apply only to the professional episode payment amounts and not the technical episode payment amounts and that APM incentive payments will be paid based on participation in the RO Model during 2021 and 2022. Due to the 2-year lag between the QPP performance and payment periods, these APM incentive payments are therefore assumed to be made during 2023 and 2024.

Complete information regarding the data sources and underlying methodology used to determine amounts for reconciliation were not available at the time of this forecast. In the case of the incomplete payment withhold, we assumed CMS retains payment only in the event that offsetting payment errors were made elsewhere. Past CMS experience in other value-based payment initiatives that included a penalty for not reporting have shown high rates of reporting compliance. Given the limited spending being withheld, scoring criteria, and specified timeframes involved, we assume that quality and patient experience withholds, on net, have a negligible financial impact to CMS.

A key assumption underlying of the impact estimate is that the volume and intensity (V&I) of the bundled services per episode remains unchanged between the period used for rate setting and when payments are made. If V&I were to decrease by 1.0 percent annually for the bundled services absent the RO Model, then we estimate the impact of the RO Model to Medicare spending to be approximately budget neutral between January 1, 2021 and 2025. Similarly if V&I increases by 1.0 percent annually then net outlays would be reduced by $470 million for the projection period. Although V&I growth from 2014 through 2018 fell within this 1.0 percent range and did not exhibit a secular trend, actual experience may differ. Please also note that due to the current public health crisis caused by the COVID–19 virus, the forecasted impacts for the RO Model are subject to an additional level of uncertainty. The duration of the current COVID–19 pandemic, its severity, and the policy measures taken as a response are variables that are significant but unknown at this time. This forecast assumes that Medicare FFS billing and treatment patterns for beneficiaries observed during the 2016–2018 baseline period resume by the start of 2021. To the extent that this assumption does not hold, actual experience may vary significantly.

This table summarizes our estimated impacts of this final rule:

TABLE 1. ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS $) FOR RADIATION ONCOLOGY MODEL (Starting January 1, 2021)

	Year of Model					
	2021	2022	2023	2024	2025	Total*
Net Impact To Medicare Program Spending	-30	-40	-40	-50	-60	-230
Changes to Incurred FFS Spending	-30	-30	-40	-40	-50	-190
Changes to MA Capitation Payments	-20	-20	-30	-30	-40	-130
Part B Premium Revenue Offset	10	10	10	20	20	80
Total APM Incentive Payments	0	0	10	10	0	20
Episode Allowed Charges	990	1,030	1,060	1,100	1,120	5,300
Episode Medicare Payment	770	800	830	860	880	4,130
Total Number of Episodes	67,000	68,000	70,000	71,000	72,000	348,000
Total Number of Beneficiaries	65,000	67,000	68,000	69,000	70,000	309,000

*Negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase.

*Totals may not sum due to rounding and from beneficiaries that have cancer treatment spanning multiple years.

b. ESRD Treatment Choices Model

(1) Overview

Under the ESRD Prospective Payment System (PPS) under Medicare Part B, a single per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. Under the Physician Fee Schedule, medical management of an ESRD beneficiary receiving dialysis by a physician or other practitioner is paid through the MCP. The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in section IV. of this final rule, for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021 to June 20, 2027.

Under the ETC Model, there will be two payment adjustments designed to increase rates of home dialysis and kidney transplants through financial incentives. The HDPA is an upward payment adjustment on certain home dialysis claims for ESRD facilities, as described in §§ 512.340 and 512.350, and to certain home dialysis-related claims for Managing Clinicians, as described in §§ 512.345 and 512.350, during the initial 3 years of the ETC Model.

The PPA is an upward or downward payment adjustment on certain dialysis and dialysis-related claims submitted by ETC Participants, as described in §§ 512.375(a) and 512.380 for ESRD facilities and §§ 512.375(b) and 512.380 for Managing Clinicians, which will apply to claims with claim service dates beginning on July 1, 2022 and increase in magnitude over the duration of the Model. We will assess each ETC Participant's home dialysis rate, as described in § 512.365(b), and ETC Participant's transplant rate, as described in § 512.365(c), for each Measurement Year. The ETC Participant's transplant rate, which is calculated as the sum of the risk adjusted transplant waitlist rate and living donor transplant rate, will be aggregated, as described in 512.365(e), and the ETC Participant's home dialysis rate will be aggregated, as described in § 512.365(e). The ETC Participant will receive a Modality Performance Score (MPS) based on the weighted sum of the higher of the ETC Participant's achievement score or improvement score for the home dialysis rate and the higher of the ETC Participant's achievement score or improvement score for the transplant rate, as described in § 512.370(d). The achievement scores will be calculated in relation to a set of benchmarks based on the historical rates of home dialysis and inclusion on the transplant waitlist among ESRD facilities and Managing Clinicians located in Comparison Geographic Areas. As discussed in the proposed rule and section IV.C.5.d. of this final rule, we intend to increase these benchmarks over time. Any such changes would be made through subsequent notice and comment rulemaking. The improvement score will be calculated in relation to a set of benchmarks based on the ETC Participant's own historical performance. The ETC Participant's MPS for a MY will determine the magnitude of its PPA during the corresponding 6-month PPA Period, which will begin 6 months after the end of the MY. An ETC Participant's MPS will be updated on a rolling basis every 6 months.

The ETC Model will not be a total cost of care model. ETC Participants will still bill FFS Medicare, and items and services not subject to the ETC Model's payment adjustments will continue to be paid as they would in the absence of the Model.

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the Model relative to baseline expenditures. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims and transplant waitlist data reported during 2016 and 2017, the most recent years with complete data available. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary.

The ESRD facilities and Managing Clinicians datasets were restricted to the following eligibility criteria. Beneficiaries must be residing in the United States, 18 years of age or older, and enrolled in Medicare Part B. Beneficiaries enrolled in Medicare Advantage or other cost or Medicare managed care plans, who have elected hospice, receiving dialysis for acute kidney injury (AKI) only, is residing in or receiving dialysis in a skilled nursing facility (SNF) or nursing facility, or has a diagnosis of dementia were excluded. In addition, the HRR was matched to the claim service facility zip code or the rendering physician zip code for ESRD facility and Managing Clinician, respectively.

For the modeling exercise used to estimate changes in payment to

providers and suppliers and the resulting savings to Medicare, OACT maintained the previous method proposed to identify ESRD facilities with common ownership, the low-volume exclusion threshold, and the aggregation assumptions as these proposed changes are unlikely to have a significant impact in terms of our modeling. To clarify OACT's methodology, the ESRD facilities data were aggregated to the CMS Certification Number (CCN) level for beneficiaries on dialysis identified by outpatient claims with Type of Bill 072X to capture all dialysis services furnished at or through ESRD facilities. Beneficiaries receiving home dialysis services were defined as condition codes 74, 75, 76, and 80. Beneficiaries receiving in-center dialysis services were defined using condition codes 71, 72, and 73. For consistency with the exclusion in § 512.385(a), after grouping within each HRR, aggregated ESRD facilities with less than 132 total attributed beneficiary months during a given MY were excluded. When constructing benchmarks, for consistency with the methodology for aggregating performance for purposes of the PPA calculation, we aggregated all ESRD facilities owned in whole or in part by the same dialysis organization located in the same HRR.

The Managing Clinicians' performance data were aggregated to the TIN level (for group practices) and the individual NPI level (for solo practitioners). For purposes of calculating the home dialysis rate, beneficiaries on home dialysis and were identified using outpatient claims with CPT® codes 90965 and 90966. Beneficiaries receiving in-center dialysis were identified by outpatient claims with CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962. Similar to our decision for the ESRD facilities, we did not expect the proposed changes to the low-volume threshold for the Managing Clinicians to have a significant impact on the model's estimate. To clarify, within each HRR, OACT applied a low-volume exclusion to Managing Clinicians in the bottom 5 percent in terms of beneficiary-years for which the Managing Clinician billed the MCP during the year. The aggregation method may vary when the ETC Model is executed.

The Scientific Registry of Transplant Recipients (SRTR) transplant waitlist data were obtained from the Center for Clinical Standards and Quality (CCSQ). To construct the transplant waitlist rate, the numerator was based on per-patient counts and included every addition to the waitlist for a patient in any past year. The waitlist counts for the numerator included waitlists for kidney transplants, alone or with another organ, active and inactive records, multi-organ listings, and patients that have subsequently been removed from the waitlist. The denominator was a unique count of prevalent dialysis patients as of the end of the year. Only patients on dialysis as of December 31st for the selected year were included. Facility attribution was based on the facility the patient was admitted to on the last day of the year.

The effects of the living donor transplants are described in two sections of this RIA. First, we provide a sensitivity estimate in the ''Effects on Kidney Transplantation'' section that includes the impact of living donor transplants. Since the sensitivity estimate is not part of the main model's calculations, the overall savings to Medicare estimate was not impacted. Second, we describe the modified transplant rate that includes two parts, the transplant waitlist rate and the living donor transplant rate in the ''Effects of the Revised Transplant Rate'' section. OACT's conclusion of the modified transplant rate was that the preemptive and living donor transplants are limited in frequency among the Medicare primary payer population; therefore, their inclusion in the transplant waitlist scores is not estimated to significantly impact overall payments under the Model.

The home dialysis score and transplant waitlist score for the PPA were calculated using the following methodology for the ESRD facilities and Managing Clinicians. ETC Participant behavior for each year was simulated by adjusting the ETC Participant's baseline home dialysis (or transplant waitlist) rate for a simulated statistical fluctuation and then summing with the assumed increase in home dialysis (or transplant waitlist) rate multiplied by a randomly generated improvement scalar. The achievement and improvement scores were assigned by comparing the ETC Participant's simulated home dialysis (or transplant waitlist) rate for the MY to the percentile distribution of home dialysis (or transplant waitlist) rates in the prior year. Last, the MPS was calculated using the weighted sum of the higher of the achievement or improvement score for the home dialysis rate and the transplant waitlist rate. The home dialysis rate constituted two-thirds of the MPS, and the transplant waitlist rate one-third of the MPS.

In addition, the waitlist benchmarks were annually inflated by approximately 2 percentage points growth observed during years 2017 through 2019 in the CCSQ data, to project rates of growth. The annual growth rate was from the median transplant waitlist rate across HRR condensed facilities growing from 8 percent in 2017 to 10 percent in 2018 to 13 percent in 2019 (that is, not a growth rate of 1.02 percent per year).

To assess the impact of COVID–19 on the kidney transplant waitlist, we analyzed data from the United Network for Organ Sharing (UNOS).[161] The UNOS data suggest that the number of new patients added to the kidney transplant waitlist steadily decreased between the weeks of March 15, 2020 through May 3, 2020, when between 16 to 81 percent of patients listed on the weekly kidney transplant waitlist became inactive due to COVID–19 precautions. During June and July 2020, the number of new patients added to the kidney transplant waitlist increased to near pre-pandemic levels with an average of less than 4 percent of patients listed as inactive due to COVID–19. Therefore, we assume that the number of new patients added to the waitlist will not decrease as a result of the pandemic and the linear 2 percentage point growth rate for the transplant waitlist calculated using years 2017 through 2019 CCSQ data does not need to be revised to account for COVID–19.

The HDPA calculation required a simplified methodology, with home dialysis and home dialysis-related payments adjusted by decreasing amounts (3, 2, and 1 percent) during each of the first 3 years of the Model.

The Kidney Disease Education (KDE) benefit utilization and cost data were identified by codes G0420 and G0421, to capture face-to-face individual and group training sessions for chronic kidney disease beneficiaries on treatment modalities. The home dialysis training costs for incident beneficiaries on home dialysis for Continuous Ambulatory Peritoneal Dialysis (CAPD) or Continuous Cycler-Assisted Peritoneal Dialysis (CCPD) were defined using CPT® codes 90989 and 90993 for complete and incomplete training sessions, respectively.

Data from calendar year 2017 were used to project baseline expenditures and the traditional FFS payment system billing patterns were assumed to continue under current law.

[161] UNOS. 2020. COVID–19 and Solid Organ Transplants. Transplant and Waitlist Data Visualizations. *https://unos.org/covid/.*

(3) Medicare Estimate—Primary Specification, Assume Rolling Benchmark

Table 2 summarizes the estimated impact of the ETC Model when assuming a rolling benchmark where the achievement benchmarks for each year are set using the average of the home dialysis rates for year *t*-1 and year *t*-2 for the HRRs randomly selected for participation in the ETC Model. We estimate the Medicare program will save a net total of $32 million from the PPA and HDPA between January 1, 2021 and June 30, 2027 less $9 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be $23 million in savings. In Table 2, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results were generated from an average of 500 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag. The projections do not include the Part B premium revenue offset because the payment adjustments under the ETC Model will not affect beneficiary cost-sharing. Any potential effects on Medicare Advantage capitation payments were also excluded from the projections. This approach is consistent with how CMS has previously conveyed the primary Fee-For-Service effects anticipated for an uncertain model without also assessing the potential impact on Medicare Advantage rates.

As anticipated, the expected Medicare program savings were driven by the net effect of the Facility PPA; a reduction in Medicare spending of $57 million over the period from July 1, 2022 through June 30, 2027. In comparison, the net effect of the Clinician PPA was only $1 million in Medicare savings. This estimate was based on an empirical study of historical home dialysis utilization and transplant waitlist rates for Medicare FFS beneficiaries that CMS virtually attributed to ESRD facilities and to Managing Clinicians based on the plurality of associated spending at the beneficiary level. We analyzed the base variation in those facility/practice level measures and simulated the effect of the payment policy assuming providers and suppliers respond by marginally increasing their share of patients utilizing home dialysis. Random variables were used to vary the effectiveness that individual providers and suppliers might show in such progression over time and to simulate the level of year-to-year variation already noted in the base multi-year data that was analyzed. The uncertainty in the projection was illustrated through an alternate scenario assuming that the benchmarks against which ETC Participants are measured were to not be updated as well as a discussion of the 10th and 90th percentiles of the actuarial model output. These sensitivity analyses are described in sections VII.C.2.b.(3)(a) and VII.C.2.b.(3)(b) of this final rule, respectively. KDE sessions on treatment modalities and home dialysis (HD) training for incident dialysis beneficiaries are relatively small outlays and were projected to represent only relatively modest increases in Medicare spending each year.

The key assumptions underlying the impact estimate are that each consolidated ESRD facility or Managing Clinician's share of total maintenance dialysis provided in the home setting was assumed to grow by up to an assumed maximum growth averaging 3 percentage points per year. Factors underlying this assumption about the home dialysis growth rate include: Known limitations that may prevent patients from being able to dialyze at home, such as certain common disease types that make peritoneal dialysis impractical (for example, obesity); current equipment and staffing constraints; and the likelihood that a patient new to maintenance dialysis starts dialysis at home compared to the likelihood that a current dialysis patient who dialyzes in center switches to dialysis at home. The 3 percentage point per year max growth rate will, in effect, move the average market peritoneal dialysis rate (about 10 percent) to the highest market baseline peritoneal dialysis rate (for example, Bend, Oregon HRR at about 25 percent), which we believe is a reasonable upper bound on growth over the duration of the ETC Model for the purposes of this actuarial model.

Consolidated ESRD facilities at the HRR level or Managing Clinicians were assumed to achieve anywhere from zero to 100 percent of such maximum growth in any given year. Thus, the average projected growth for the share of maintenance dialysis provided in the home was 1.5 percentage points per year. Projected forward, this will result in home dialysis ultimately representing approximately 19 percent of overall maintenance dialysis in Selected Geographic Areas by the end of 2027. In contrast, we do not include an official assumption that the overall number of kidney transplants will increase and provide justification for this assumption in section VII.C.2.b.(4). of this final rule. However, as part of the sensitivity analysis for the savings calculations for the model, we lay out different savings scenarios if the incentives under the ETC Model were to cause an increase in living donation and if the ETC Learning Collaborative described in section IV.C.12 of this final rule were to be successful in decreasing the discard rate of deceased donor kidneys and increasing the utilization rate of deceased donor kidneys that have been retrieved.

TABLE 2. ESTIMATES OF MEDICARE PROGRAM SAVINGS (ROUNDED $M) FOR ESRD TREATMENT CHOICES MODEL

	Year of Model							
	2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**6.5 Year Total***
Net Impact to Medicare Spending	13	7	0	-5	-10	-16	-8	**-23**
Overall PPA Net & HDPA	12	5	-2	-7	-12	-18	-10	**-32**
Clinician PPA Downward Adjustment		-1	-2	-3	-3	-4	-2	-15
Clinician PPA Upward Adjustment		1	2	3	3	4	2	14
Clinician PPA Net		0	0	0	0	0	0	-1
Clinician HDPA	1	1	1					3
Facility Downward Adjustment		-9	-20	-24	-33	-42	-23	-151
Facility Upward Adjustment		5	13	17	21	25	13	94
Facility PPA Net		-4	-7	-7	-12	-17	-9	-57
Facility HDPA	10	8	5					23
Total PPA Downward Adjustment		-10	-22	-27	-36	-46	-25	-166
Total PPA Upward Adjustment		6	15	20	24	28	15	108
Total PPA Net		-4	-8	-7	-12	-18	-10	-58
Total HDPA	12	9	5					26
KDE Benefit Costs	0	1	1	1	1	1	1	**3**
HD Training Costs	1	1	1	1	1	1	1	**6**

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The KDE Benefit Costs are less than $1M each year, but are rounded up to $1M to show what years they apply to. Similarly, the HD Training Costs are less than $1M for years 2021-2024, but are rounded up to $1M to indicate that costs were applied those years.

(a) Sensitivity Analysis: Medicare Estimate—Assume Fixed Benchmark for Home Dialysis and Fixed Benchmark for Transplants

An alternative model specification was analyzed where benchmarks remain *fixed* at baseline year 0 over time (results available upon request). Both the rolling and fixed benchmark assumptions projected $12 and $11 million, respectively, in increased overall HDPA Medicare payments to ESRD facilities and Managing Clinicians in the first year of the Model. We project about $1 million in additional HD training add-on payments. This will represent $13 and $12 million in increased Medicare expenditures in the first year of the Model overall. The rolling and fixed specifications of the benchmark also projected the net impact of approximately $7 and $8 million, respectively, in increased Medicare expenditures in the second year of the Model.

The two scenarios diverge after the second year of the Model, with large differences observed in overall net PPA and HDPA savings/losses. Table 2 illustrates that when benchmarks are rolled forward, using the methodology described in section VII.C.2.b.(3). of this final rule, the overall *savings* in PPA net and HDPA increase each year during the 2022–2026 period. Peak savings of $15 million occurs in 2026, followed by a slight deceleration in 2027 to $7 million in savings. In contrast, when benchmark targets are fixed, losses are projected for the net impact to Medicare spending (net of education and training but before administrative cost) in years 2022–2026 of $4, $7, $22, $39, and $26 million, respectively. The fixed benchmark will allow the ESRD facilities and Managing Clinicians to have more favorable achievement and improvement scores over time compared to the rolling benchmark method. In summary, the total of overall net PPA and HDPA from January 1, 2021 through June 30, 2027, with the fixed benchmark, was $102 million in losses, compared to a total of $32 million in savings with the rolling benchmark method. The net impact on Medicare spending for the PPA and HDPA using the fixed benchmark method is $117 million in *losses.*

(b) Sensitivity Analysis: Medicare Estimate—Assume Rolling Benchmark for Home Dialysis and Fixed Benchmark for Transplants in Response to COVID–19

At the time of writing, there were only six months of data available on COVID–19 in the United States. A few recent publications cite advantages of home dialysis in combination with telehealth in comparison to in-center dialysis by reducing the vulnerable ESRD population's exposure to COVID–19. In July 2020, CMS proposed expanding the transitional add-on payment adjustment for new and innovative equipment and supplies, or TPNIES, to include certain capital-related assets that are home dialysis machines, which would make it easier to get them to Medicare beneficiaries. If finalized, this policy would take effect January 1, 2021. Since we have not been able to observe the impact of this rule on potential changes to the home dialysis rates, we propose to keep the benchmark for home dialysis as rolling.

The UNOS data show that after the first wave of COVID–19, the number of new patients being added to the kidney transplant waitlist was approaching pre-pandemic levels by July 2020. Specifically, the number of kidney transplants experienced a slight decline starting April 12, 2020 in response to fewer living donor transplants; however, the overall kidney transplant rate remained stable when comparing the slope for the same dates in 2019. It is unknown how future waves of COVID–19 may affect the kidney transplant waitlist and the transplant rate. To address this uncertainty, we tested the actuarial model by setting the benchmark to be *rolling* for home dialysis and *fixed* for transplants and did not find the model to be sensitive to incremental changes in the transplant

rate because most of the weighting is determined by the home dialysis score.

(c) Sensitivity Analysis: Medicare Savings Estimate—Results for the 10th and 90th Percentiles

Returning to the primary specification used for the Medicare estimate with rolling benchmarks for home dialysis and transplants, we compare the results (available upon request) for the top 10th and 90th percentiles of the 500 individual simulations to the average of all simulation results reported in Table 2. Since the impact on Medicare spending for the ETC Model using the rolling benchmark method is estimated to be in savings rather than losses, the top 10th and 90th percentiles represent the most optimistic and conservative projections, respectively. The overall net PPA and HDPA for the top 10th and 90th percentiles using the rolling benchmark method are $79 million in savings and $7 million in losses (encompassing the mean estimate of $32 million in savings in Table 2).

(4) Effects on Kidney Transplantation

Kidney transplantation is considered the optimal treatment for most ESRD beneficiaries. However, while the PPA includes a one-third weight on the ESRD facilities' or Managing Clinician's transplant rate, calculated as the sum of the transplant waitlist rate and living donor transplant rate, with the ultimate goal of increasing the rate of kidney transplantation including from deceased donors, we decided to not include an assumption that the overall number of kidney transplants will increase. The number of ESRD patients on the kidney transplant waitlist has for many years far exceeded the annual number of transplants performed. Transplantation rates have not increased to meet such demand because of the limited supply of deceased donor kidneys. The United States Renal Data System [162] reported 20,161 kidney transplants in 2016 compared to an ESRD transplant waiting list of over 80,000. Living donor kidney transplantation (LDKT) has actually declined in frequency over the last decade while deceased donor kidney transplantation (DDKT) now represent nearly three out of four transplants as of 2016.

The PPA's transplant incentive will likely increase the share of ESRD beneficiaries who join the transplant waitlist but is unlikely to impact the deceased donor kidney supply limitation. There is evidence that the overall quantity of transplants could be positively impacted by reducing the discard rate for certain DDKT with lower quality, high-Kidney Donor Profile Index (KDPI) organs. However, while such transplantation has been shown to improve the quality of outcomes for patients, kidney transplant centers have reported barriers to their use including a higher cost of providing care in such relatively complex transplant cases relative to Medicare's standard payment. Because the PPA will not impact payment to transplant centers, the ETC Model will not mitigate the barrier to increased marginal kidney transplantations. Furthermore, even to the extent that marginal DDKT were somehow improved because of PPA incentives, evidence also suggests that the impact of DDKT with high-KDPI organs may not reduce overall spending despite improving the quality of outcomes for patients.

It is possible that the ETC Model could generate additional living donor kidney donations for which significant Medicare program savings could be realized. given that the living donor transplant rate is a component of the transplant rate used in calculating the PPA. In addition, additional patient education could lead more beneficiaries to find donors by tapping into resources already available to remove financial disincentives to donors (for example, payment for travel, housing, loss of wages, and post-operative care).[163] [164] The ETC Model does not include a policy to assist with minimizing disincentives to living donors for their kidney donation; however, qualified donors may apply for financial assistance through the National Living Donor Assistance Center (NLDAC), which administers federal funding received from HRSA under the federal Organ Donation Recovery and Improvement Act.[165] All applicants under this Act are means tested, with preference given to recipients and donors who are both below 300 percent of the federal poverty line (FPL). Approved applicants can receive up to $6,000 to cover travel, lodging, meals, and incidental expenses. In 2017, only 8.38 percent of the approximate 6,000 total living kidney donations [166] received NLDAC support, resulting in up to $3 million in paid expenses per year. Additional methods are necessary to decrease financial disincentives for kidney donors and their recipients who exceed the means testing criteria of the NLDAC.

The costs/savings incurred by kidney transplantation vary by donor type. Axelrod et al. (2018) used Medicare claims data with Medicare as the primary payer linked to national registry and hospital cost-accounting data provides evidence for the cost-savings of kidney transplantations by donor type compared to dialysis.[167] The authors estimated ESRD expenditures to be $292,117 over 10 years per beneficiary on dialysis. LDKT was cost-saving at 10 years, reducing expected expenditures for ESRD treatment by 13 percent ($259,119) compared to maintenance dialysis. In contrast, DDKT with low-KDPI organs was cost-equivalent at $297,286 over 10 years compared to dialysis. Last, DDKT with high-KDPI organs resulted in increased spending of $330,576 over 10 years compared to dialysis.

The approximately $33,000 in savings per beneficiary over 10 years for LDKT compared to maintenance dialysis is likely a lower bound since living donation will help reduce the number of beneficiaries under the age of 65 who will be eligible for Medicare enrollment. The lower bound conditional savings can be adjusted to account for additional savings through reduced Medicare enrollment by considering the share of potential new live donations across three main scenarios.

The LDKT expected cost of $259,119 over 10 years per beneficiary projected by Axelrod et al. (2018) assumes Medicare primary payer status. For roughly 25 percent of LDKTs, Medicare can be assumed to be the primary payer regardless of transplant success; therefore, the projected spending need not be adjusted. For the next 25 percent of LDKTs, we assumed the beneficiary is on dialysis and Medicare is the primary payer, but they will eventually leave Medicare enrollment if they had a transplant. We adjusted the expected Medicare spending for these cases downward by 33 percent. This projected a savings of approximately $119,000 over 10 years relative to the baseline spending projection of $292,117 over 10

[162] United States Renal Data System. 2018. ''ADR Reference Table 6 Renal Transplants by Donor Type.''

[163] Salomon DR, Langnas AN, Reed AI, et al. 2015. ''AST/ASTS Workshop on Increasing Organ Donation in the United States: Creating an 'Arc of Change' From Removing Disincentives to Testing Incentives.'' *American Journal of Transplantation* 15: 1173–1179.

[164] Tong A, Chapman JR, Wong G, Craig JC. 2014. ''Perspectives of Transplant Physicians and Surgeons on Reimbursement, Compensation, and Incentives for Living Kidney Donors.'' *American Journal of Kidney Disorders* 64(4):622–632.

[165] Public Law 108–216 (section 377 of the Public Health Service (PHS) Act, 42 U.S.C. 274f).

[166] OPTN & SRTR 2017 Annual Report. Section KI Kidney Transplants. *https://www.srtr.org/reports-tools/srtroptn-annual-data-report/.*

[167] Axelrod DA, Schnitzler MA, Xiao H, *et al.* 2018. ''An Economic Assessment of Contemporary Kidney Transplant Practice.'' *American Journal of Transplantation* 18: 1168–1176.

years for beneficiaries on dialysis. The third scenario—covering the remaining 50 percent of LDKTs– assumes Medicare is not the primary payer when the transplant occurs. In this case, we assumed that Medicare spending is nominal relative to baseline spending and we adjust downward by 33 percent (that is, the beneficiary will take up to 30 months to become a Medicare primary payer enrollee absent the transplant), which projected a savings of approximately $195,000 over 10 years. The projected weighted average program savings for LDKT is $136,000 over 10 years per beneficiary.

Therefore, a 20 percent increase in the rate of LDKT in model markets in a single year, representing about 300 new transplants mainly from relatives of recipients, will produce approximately $41 million in program savings over 10 years (and multiples thereof for each successive year the living donor transplant rate were thusly elevated).

The model also includes an investment in learning and diffusion for improving the utilization of deceased donor kidneys that are currently discarded at a rate of approximately 19 percent nationally.[168] Similar to the previously discussed estimate on the average impact to Medicare spending for LDKT, we estimated an average marginal savings to Medicare for DDKT by adjusting costs reported by Axelrod et al. (2018) for DDKT with high-KDPI to account for effects on Medicare payer status. We include three scenarios based on type of payer.

First, we assumed 50 percent of newly harvested deceased-donor kidneys will be for beneficiaries enrolled in Medicare, regardless of ESRD status. This scenario aligns with the Medicare primary payer estimates from the study, approximately $38,000 higher spending for DDKT with high-KDPI over 10 years relative to maintenance dialysis. Second, we assumed 30 percent of marginal DDKT will be for beneficiaries with Medicare as their primary coverage where the transplant spending was adjusted downward by 33 percent to account for reduced liability for patients returning to non-Medicare status. Third, we assumed 20 percent of DDKT with high-KDPI will involve beneficiaries not yet under Medicare as their primary payer. For this scenario, we adjusted the baseline dialysis spending downward by 33 percent to account for initial non-Medicare status during the waiting period and for the transplant spending we assumed 25 percent of baseline Medicare spending will still be present due to early graft failure before the end of the 10-year window (recognizing the shorter lifespan high-KDPI organs tend to offer recipients).

Combining these assumptions produced an average 10-year savings to Medicare of approximately $32,000 per beneficiary for DDKT with high-KDPI. Overall, we found an increase in marginal kidney utilization such that the national discard rate will drop to 15 percent by the end of the model testing period, representing approximately 2,360 additional transplants and an estimated $76 million in federal savings.

For both living and deceased donor transplants, the illustrated potential effect of the model will reduce long run program spending by $116 million. Costs for this effort include a learning and diffusion investment of $15 million in section 1115A administrative funds over the model testing period and a potential increase in PPA adjustments to clinician and facility payments of approximately $20 million. The projected increase in transplantation is estimated to produce a net savings of $81 million—a net return on investment of approximately 2.3.

(5) Effects of the Revised Transplant Rate

This final rule includes a modified transplant rate that includes two parts, the ''transplant waitlist rate'' and the ''living donor transplant rate.'' The ESRD facility transplant rate is calculated as the sum of the transplant waitlist rate for ESRD facilities, risk adjusted based on age strata, and the living donor transplant rate for ESRD facilities. For purposes of calculating the transplant waitlist rate for ESRD facilities, the sum of the attributed ESRD beneficiary waitlist years is divided by the total attributed ESRD beneficiary dialysis treatment years. For purposes of calculating the living donor transplant rate for ESRD facilities, the living donor transplant years for attributed ESRD beneficiaries is divided by the total attributed ESRD beneficiary dialysis treatment years. The Managing clinician transplant rate is calculated as the sum of the transplant waitlist rate for Managing clinicians, risk adjusted based on age strata, and the living donor transplant rate for Managing clinicians. For purposes of calculating the transplant waitlist rate for Managing clinicians, the sum of the attributed ESRD beneficiary waitlist years is divided by the total attributed ESRD beneficiary dialysis treatment years. For purposes of calculating the living donor transplant rate for Managing clinicians, the living donor transplant years for attributed ESRD beneficiaries is divided by the total attributed ESRD beneficiary dialysis treatment years.

The goal of these revised formulas is to give credit to model participants with beneficiaries who are on the kidney transplant waitlist and who receive a transplant from a living donor transplant. Data from the SRTR show that in 2018, 1.8 percent of all living donor transplant recipients had a preemptive transplant and 62.3 percent had a wait time of less than 1 year.[169] The SRTR data also report that only 39.7 percent of all living donor transplants (including preemptive) had Medicare as the primary payer. We also used the SRTR data to confirm that year 2018, the most recent year with data available, was not an anomaly and we found that years 2016–2018 had similar rates of wait time for living donor transplants. In addition, we calculated total member months from the Medicare data in the IDR and found that in 2018, all living donor transplant member months (regardless of wait time) accounted for only 0.6 percent of total member months among beneficiaries on dialysis.

Because the living donor transplants and pre-emptive living donor transplants (variables ''d'' and ''c'' in the proposed formulas) are limited in frequency among the Medicare primary payer population, their inclusion in the transplant waitlist scores is not estimated to significantly impact overall payments under the model. This is partly due to limited effects expected for the transplant waitlist score at the clinician and facility levels, but also because model payments are more heavily weighted on the home dialysis measure.

(6) Effects on the KDE Benefit and HD Training Add-Ons

The KDE benefit has historically experienced very low uptake, with less than 2 percent of eligible Medicare beneficiaries utilizing this option. A recent report summarized barriers to adequate education on home dialysis.[170] According to this report, kidney disease education may: Not be provided at all, be done only once, not be appropriate for patient's literacy level or not provided in patient's native language, not be done until after patient starts in-

[168] OPTN & SRTR 2017 Annual Report. Section KI Kidney Transplants. *https://www.srtr.org/reports-tools/srtroptn-annual-data-report/.*

[169] SRTR 2018 Annual Report. Section KI Kidney Transplants. *https://srtr.transplant.hrsa.gov/annual_reports/2018/Kidney.aspx#KI_8_char_adult_tx_dem.*

[170] Chan CT, Wallace E, Golper TA, *et al.* 2018. ''Exploring Barriers and Potential Solutions in Home Dialysis: An NKF–KDOQI Conference Outcomes Report.'' *American Journal of Kidney Disease* 73(3): 363–371.

center hemodialysis, and/or not be provided to caregivers.

The ETC Model will incorporate waivers of select KDE benefit requirements that should make these educational sessions on treatment modality options more accessible to beneficiaries targeted by the model and address some of the barriers previously described. We assume the KDE benefit utilization rate to increase from 2.2 in 2021 to 3.2 in 2027. To arrive at this assumption, we began with the current low utilization of the benefit. The utilization rate of the KDE benefit during the first year of the Model was set to 2 percent of beneficiaries eligible to use the KDE benefit, which is consistent with the current rate of utilization of the benefit. We set the utilization growth rate to increase by 0.2 percentage points each year from 2021 to 2027. This results in a projected doubling of the costs attributed to the KDE benefit to approximately $1 million in 2027. Although the ETC Model will allow different types of health care providers to furnish the KDE benefit to beneficiaries, there is no direct evidence that this will cause an increase in the utilization growth rate that differs significantly from the historical rate. Challenges to increasing the utilization rate include: the beneficiary's Managing Clinician may not inform the beneficiary of the option to seek KDE benefit sessions for a variety of reasons (for example—the Managing Clinician is unaware of the KDE benefit, alternative treatment modalities are not feasible for the beneficiary, or the clinician believes that the beneficiary will not be able to make an informed choice about dialysis modality after receiving the KDE benefit); if informed of the KDE benefit option, the beneficiary may prefer to rely on their Managing Clinician's recommendation rather than receive education about their treatment options; and the beneficiary may not want to have an additional one to six sessions with a health care provider for the provision of the KDE benefit, as beneficiaries with late stage CKD and ESRD are medically fragile and already in frequent contact with the health care system.

The impacts of increased utilization of the home dialysis (HD) training add-on payment adjustment under the ESRD PPS are expected to be larger than the KDE benefit costs as these trainings will be required for all incident beneficiaries on home dialysis. Assuming a stable 3 percent growth rate in home dialysis per year, the 7-year total in HD training costs is projected to be $10 million.

3. Effects on Medicare Beneficiaries

a. Radiation Oncology Model

We anticipate that the RO Model will modestly reduce the cost to beneficiaries receiving RT services on average. Under current policy, Medicare FFS beneficiaries are generally required to pay 20 percent of the allowed charge for services furnished by HOPDs and physicians (for example, those services paid for under the OPPS and MPFS, respectively). This policy will remain the same under the RO Model. More specifically, beneficiaries will be responsible for 20 percent of each of the PC and TC episode payments made under the RO Model. Since we are finalizing our proposal to take a percentage ''discount'' off of the total payment to participants for both PC and TC episode payment amounts (this discount representing savings to Medicare), the total allowed charge for services furnished by HOPDs and physicians is expected to decrease. Thus, beneficiary cost-sharing, on average, should be reduced relative to what typically would be paid under traditional Medicare FFS for an episode of care. In addition, the limit on beneficiary cost-sharing in the HOPD setting to the inpatient deductible will continue under the RO Model.

In addition, we note that, because episode payment amounts under the RO Model will include payments for RT services that will be provided over multiple visits, individual beneficiary coinsurance payments will be higher than they would otherwise be for an individual RT service visit. We encourage RO participants to collect coinsurance for services furnished under the RO Model in multiple installments.

We received a few comments regarding the application of coinsurance. Summaries of these comments, our response, and the details on our final policy related to coinsurance are available in section III.C.6.i. of this final rule.

b. ESRD Treatment Choices Model

We anticipate that the ETC Model will have a negligible impact on the cost to beneficiaries receiving dialysis. Under current policy, Medicare FFS beneficiaries are generally responsible for 20 percent of the allowed charge for services furnished by providers and suppliers. This policy will remain the same under the ETC Model. However, we will waive certain requirements of title XVIII of the Act as necessary to test the PPA and HDPA under the Model and to hold beneficiaries harmless from any effect of these payment adjustments on cost sharing. We received a few comments regarding the application of cost sharing under the ETC Model. Summaries of these comments, our response, and the details of our final policy related to cost sharing are available in section IV.C.7.a of this final rule. In addition, the Medicare beneficiary's quality of life has the potential to improve if the beneficiary elects to have home dialysis as opposed to in-center dialysis. Studies have found that home dialysis patients experienced improved quality of life as a result of their ability to continue regular work schedules or life plans; [171] as well as better overall, physical, and psychological health [172] [173] in comparison to other dialysis options.

4. Effects on RO Participants and ETC Participants

RO participants will be given instructions on how to bill for patients, using RO Model-specific HCPCS codes. We expect it will take medical coding staff approximately 0.72 hours [(((~36 pages * 300 words/per page)/250 words per minute)/60 minutes) = 0.72] [174] to read and learn the payment methodology and billing sections of the rule. In addition, we estimate an additional 1 hour to review the relevant MLN Matters publication, 1 hour to read the RO Model billing guide, 1 hour to attend the billing guidance webinar, and 1 hour to review the pricing methodology training materials for a total of 4.72 hours. We estimate the median salary of a Medical Records and Health Information Technician is $19.40 per hour, at 100 percent fringe benefit for a total of $38.80, using the wage information from the BLS.[175] The total

[171] Dąbrowska-Bender M, Dykowska G, Zuk W, et al. 2018. ''The impact on quality of life of dialysis patients with renal insufficiency.'' *Patient Prefer Adherence* 12: 577–583.

[172] Makkar V, Kumar M, Mahajan R, Khaira NS. 2015. ''Comparison of Outcomes and Quality of Life between Hemodialysis and Peritoneal Dialysis Patients in Indian ESRD Population.'' *J Clin Diagn Res.* 9(3): OC28–OC31.

[173] Van Eps CL, Jeffries JK, Johnson DW, et al. 2010. ''Quality of life and alternate nightly nocturnal home hemodialysis.'' *Hemodial Int.*14(1):29–38.

[174] *https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.*

[175] For the RO Model, we use the estimated median hourly wage of $19.40 per hour, plus 100 percent overhead and fringe benefits. Estimating the hourly wage is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate to estimate total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

Continued

cost of learning the billing system for the RO Model thus is $183.14 per participant, or approximately $173,983.00 in total (950 expected participants × $183.14/participant = $173,983 total).

The ETC Model will not alter the way ETC Participants bill Medicare. Therefore, we believe that there will be no additional burden for ETC Participants related to billing practices.

We believe the audit and retention policies of the RO Model and ETC Model are generally consistent with existing policies under Medicare. Additionally, the monitoring requirements for the RO Model and ETC Model are consistent with the monitoring and evaluation requirements already in place under 42 CFR 405.1110(b) for participants in models tested under section 1115A of the Act. Therefore, we believe the audit and retention policies and the monitoring and evaluation requirements do not add additional regulatory burden on participants.

The model evaluation for both the RO Model and the ETC Model will include beneficiaries and providers completing surveys. Burden for these surveys 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 the surveys. A typical survey on average would require 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 believe the burden estimate for quality measure and clinical data element reporting requirements that is provided for Small Businesses in section VII.C.5.a. of this final rule apply to RO participants that are not considered small entities. The burden estimate for collecting and reporting quality measures and clinical data for the RO Model may be equal to or less than that for small businesses, which we estimate to be approximately $1,743.07 per entity per year. We estimate approximately 950 RO participants, then total burden estimate for collecting and reporting quality measures and clinical data was approximately $1,655,916.50.

Additionally, the ETC Model does not require any additional quality measure or clinical data element reporting by ETC Participants. Therefore, we believe that there is no additional burden for ETC Participants related to quality measures or clinical data reporting.

Finally, we believe the burden estimate for reading and interpreting this final rule that is provided for Small Businesses apply to RO participants and ETC Participants that are not considered small entities. The burden estimate for reading and interpreting this final rule may be equal to or less than that for small businesses. We estimate that cost of reading the rule for RO participants would be approximately $1,093.26 per entity with a total cost of approximately $3,170,454.00 (2,900 eligible entities × $1,093.269/participant). In sum, we estimate that reading the RO Model rule, learning the RO billing system, the pricing methodology and submitting quality measures and clinical data to the RO Model will cost approximately $3,019.47 per RO participant ($1,093.26 to read the rule, $183.14 to attend and learn the billing guidance, and $1,743.07 to submit quality measure and CDE information), and collectively cost approximately $2,868,496.50 across the 950 RO participants, and an additional $2,131,350.00 for those providers and suppliers who read the rule, but are not ultimately selected as RO participants, for a total cost $4,999,846.50. Similarly, we base our estimate for the cost of reading the final rule for ETC Participants on the same cost per participant as used for the RO Model, that is, $1,093.26 per entity. We assume that all ESRD facilities and Managing Clinicians will read the rule, even though only a subset of each category will participate in the Model. Therefore, the collective cost will be $6,714,000 (14,380 entities reading the rule (7,097 ESRD facilities plus 7,283 Managing Clinicians) times $466.89).

5. Regulatory Flexibility Act (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. As discussed in sections VII.5.a and VII.5.b. of this final rule, the Secretary has considered small entities and has determined and certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

a. Radiation Oncology Model

This final rule affects: (1) Radiation oncology PGPs that furnish RT services in both freestanding radiation therapy centers and HOPDs; (2) PGPs that furnish RT services only in HOPDs; (3) PGPs that are categorized as freestanding radiation therapy centers; and (4) HOPDs. The majority of HOPDs and other RT providers and RT suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (defined as having minimum revenues of less than $12 million to $41.5 million [176] in any 1 year, depending on the type of provider; the $41.5 million per year threshold is for hospitals, whereas the $12 million per year threshold is for other entities). (*https://www.sba.gov/document/support--table-size-standards*). States and individuals are not included in the definition of small entity.

HHS uses an RFA threshold of at least a 5 percent impact on revenues of small entities to determine whether a final rule is likely to have ''significant'' impacts on small entities.[177] Throughout the rule we describe how the changes to a prospective episode payment may affect PGPs and HOPDs.

In the proposed rule, we provided an analysis for the RO Model's impact on small businesses based on the proposed policies and following analysis (84 FR 34575 through 34577). Our analysis was based on the assumption that the RO Model would include only Medicare FFS beneficiaries receiving RT services by selected PGPs (including freestanding radiation therapy centers) and HOPDs. During 2018, 39 percent of Medicare beneficiaries with both Part A and B coverage on average are estimated to have enrolled in Medicare Advantage plans.[178] PGPs and HOPDs also serve patients with other coverage, for example, through Medicare or commercial insurance. We believed that on average, Medicare FFS payments to PGPs would be reduced by 5.9 percent and Medicare FFS payments to HOPDs would be reduced by 4.2 percent and would not change with an April 1 start date. Given that this Model is limited to only Medicare FFS beneficiaries, not other payers including Medicare Advantage and commercial insurance, which combined we expect to be about 50 to 60 percent of total HOPD and PGP

https://www.bls.gov/ooh/Healthcare/Medical-records-and-health-information-technicians.htm.

[176] Please note these numbers are updated from the proposed rule due to an update on SBA categorizations. The small business revenue numbers were previously $11.5 million and 38.5 million, respectively.

[177] Office of Advocacy, Small Business Administration. (2012). A Guide for Government Agencies, How to Comply with the Regulatory Flexibility Act, Implementing the President's Small Business Agenda and Executive Order 13272, Retrieved from *www.sba.gov/sites/default/files/rfaguide_0512_0.pdf* (accessed March 18, 2019).

[178] This figure comes from the 2018 Medicare Trustees Report, Table IV.V1, p151 from the footnote that has the A and B share.

revenue for RT services, we expected that the anticipated average impact of revenue based solely on Medicare FFS payments to be less than 1 percent. Therefore, we determined that the proposed rule would not have a greater than 5 percent impact on total revenues on a substantial number of small entities (84 FR 34577). We estimated the administrative costs of adjusting to and complying with the quality measure and clinical data element reporting requirements for RO Model for small entities to be approximately $388.00 per entity per year. To estimate the costs per small entity, we assumed that a Medical Records & Health Information Technician with an Hourly salary (from BLS) plus 100 percent fringe benefits would cost $38.80/hour [179] and would report the information on quality measures and clinical data elements. We expected submission of the 4 quality data measures would take approximately 8 hours and would require submission once a year, ($38.80 × 8.0 hours × 1 submission) = $310.40. In the proposed rule, also we estimated that the submission of clinical data elements would take up to an hour, but occur twice a year, that is, ($38.80 × 1-hour × 2 submission) = $77.60 per year (84 FR 34577).

Based on the final design of the RO Model, we believe that on average, Medicare FFS payments to PGPs will be reduced by 6.0 percent and Medicare FFS payments to HOPDs will be reduced by 4.7 percent. We believe that this impact would be less for small providers that provide fewer than 20 episodes in the previous year and choose to opt out of the Model under the low volume opt out policy (see section III.C.3.c. of this final rule) because they would continue to bill FFS for RT services furnished during their opt out year(s). In response to commenter feedback, we are updating our estimate for the administrative costs of adjusting to and complying with the quality measure and clinical data element reporting requirements for RO Model for small entities to be approximately $1,743.06 per entity per year. We assume that our estimate for the submission of quality measures remains an accurate estimate at $310.40 per year. We revisited our clinical data element estimates and now expect the total cost of submission of the clinical data elements would be approximately $1,432.67 per entity ($38.80 × 18.5 hours × 2 submissions) per year. Our estimate was updated based on our review of the potential list of the clinical data elements which may be included across the five cancer types (prostate, breast, lung, bone and brain) finalized in section III.C.8. of this final rule. We note that the final list will be communicated prior to the start of PY1, so our estimate may slightly overstate or understate the final number of CDEs (and thus may slightly understate or overstate the burden) and each RO participant's experience may vary. We still expect the burden costs per small entity associated with measure and data reporting to be small because three of the four measures for the RO Model are already in use in other CMS programs; and compliance with the Treatment Summary Communication (the measure not currently in use) is a best practice that should already be the standard of care across PGPs and HOPDs.

In the proposed rule, we further estimated the administrative cost of reading and interpreting this final rule per small entity at approximately $446.89 (84 FR 34577). We are updating our estimate to approximately $1,093.26 for reading the rule and an additional $183.14 to learn the billing system. We expect that a medical health service manager reading 250 words per minute could review the rule in approximately 11.4 hours [(approximately 569 pages * 300 words/per page)/250 words per minute) [180] 60 minutes)]. We estimated the salary of a medical and health service manager is $95.90 per hour, using the wage information from the BLS including overhead and fringe benefits.[181] Assuming an average reading speed for pages relevant to the RO Model, we estimated that it would take approximately 11.4 hours for the staff to review the RO portion of this final rule. For each provider that reviews the rule, the estimated cost based on the expected time and salary of the person reviewing the rule ($1,093.26 = ($95.90 * 11.4 hrs). RO participants would also review the billing guidance, which we would expect to cost approximately $183.14 as discussed in section VI.C.4. of this final rule.

We solicited public comments on our estimates and analysis of the impact of the final rule on those small entities.

Comment: A commenter expressed concern with the RO Model's payment rates estimates based on their belief that Medicare is a material payer for the majority of providers. The commenter added that Medicare is, or may exceed, 46 percent of their payer mix and that this coupled with episode payment amounts that would reduce payment by up to 50 percent from what participants would have received under FFS, makes furnishing RT services under the Model unsustainable.

Response: We thank this commenter for their feedback. First, as we stated in section III.C.6. of this final rule, we disagree that episode payment amounts would be reduced by 50 percent as compared to non-participants. This might be true for some participants if the case mix and historical experience adjustments were removed from the Model's pricing methodology. We designed the pricing methodology so that episode payment amounts for Professional participants, Dual participants, and Technical participants are largely based on what each participant has been paid historically under FFS and trended forward based on latest payment rates under FFS. In particular, we refer readers to section III.C.6.e.(2). of this final rule for more information regarding the blend used to determine how much participant-specific historical payments and national base rates figure into payment. Second, RT services furnished under the RO Model were assumed to grow with FFS Medicare Part B enrollment as projected in the 2018 Medicare Trustees Report. We assume that participants do not change payer mix as a response to the RO Model. No explicit assumptions were made about the relative amount of RT services paid through private or other forms of insurance.

Comment: A commenter stated that providers and suppliers chosen for the Model will see reductions to their payments under the Hospital Outpatient PPS or PFS, respectively, between 3.9 percent and 4.4 percent (PC) and between 5.7 and 5.1 percent (TC) on average, with participants furnishing RT services in freestanding radiation therapy centers experiencing a higher reduction than those furnishing RT services in the HOPD setting. According to this commenter, the combined effect of the discount factor and efficiency factor, now termed, ''blend,'' will reduce payments by 6.6 percent in the fifth year and the commenter expressed concern that this reduction would not be offset by the APM bonus incentive for technical payments, and even so, this is waived under the Model as proposed.

Response: We appreciate the commenters concerns regarding the combined effect of the discount factor and blend. We believe that the commenters' estimates are consistent with our analysis, though we note, we

[179] *https://www.bls.gov/ooh/Healthcare/Medical-records-and-health-information-technicians.htm.*

[180] *https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.*

[181] For the RO Model, we use an estimated median hourly wage of $47.95 per hour, plus 100 percent overhead and fringe benefits. *https://www.bls.gov/oes/current/oes119111.htm.*

are finalizing policies that reduce the discount factor by 0.25 percent for both the PC and TC, so that the discount rates are 3.75 percent and 4.75 percent for the PC and TC, respectively as we discussed in section III.C.6. We are also finalizing the Model performance period to begin January 1, 2021 in order to give RO participants the necessary time to prepare for implementation.

Comment: A few of commenters stated their belief that the regulatory impact analysis severely underestimates burden on participants. A commenter estimated that the cost of adjusting to the Model could be well over $400,000 in PY1 and $350,000 in each successive PY. Another commenter estimated that 0.3 FTEs per physician would be needed to account for the newly created workflow related to the revenue cycle processes as well as quality metric and data documentation, collection and reporting that will exist alongside the current workflow already established for patients outside of the RO Model.

To better account for cost, a couple of commenters suggested that CMS consider the following: The additional administrative tasks and requirements that the Model imposes, the use of certified EHR technology, the need to prepare multiple billings and participate in a radiation oncology-specific AHRQ patient safety organization, and the need to participate in CMS site visits and medical record audits. A few commenters recommended a review of OCM's cost and utilization reports, which they believe would show that manual data abstraction alone represents 45–90 minutes per patient and requires thousands of dollars in human resources to implement. Another commenter claimed that OCM practices also spend tens of thousands of dollars each year to meet the clinical data element and quality measure reporting requirements under that model, as captured in the OCM cost and resource utilization reports that are submitted to CMS.

Response: We thank these commenters for explaining their concerns. First, we believe the administrative, monitoring, and compliance requirements for the RO Model will not substantially diverge from general monitoring requirements for Medicare Part B providers. RO participants are already subject to site visits and record audits as part of their participation in Medicare, so we do not expect the Model requirements to create additional burden. Second, we disagree that the use of EHR technology should be included in the regulatory impact analysis as part of the cost of the Model. An entity's EHR has many uses within the clinical setting and is not solely used for RO Model measures reporting. The cost of the EHR system should not be reflected in the burden estimates developed specifically for the RO Model. We also note that American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) and Meaningful Use require providers to use EHRs to avoid Medicare payment reductions, which is independent of any proposals in the RO Model. Third, and as we stated in section III.C.7. of this final rule, we believe that we have created a billing process that will be easily implemented within current systems, because it is based on how FFS claims are submitted today and may reduce the amount of time spent billing because coding will be submitted at the beginning and end of the episode. Lastly, we believe that the 45–60 minutes per patient file that one stakeholder estimates is an overestimate of the time it will take to review a chart and submit quality measures for the RO Model, nor do we believe the cost and utilization reports of OCM are comparable to that of the RO Model. The RO Model does not mandate the same OCM reporting requirements. We also believe that we have included measures that are commonly used in the field and reflect common treatment practices. However, as discussed earlier in this section, we are updating our estimates for the burden associated with quality measure and clinical data element submission and our estimates of the cost it would take to read the rule and learn the billing.

We believe that on average the updated policies contained in this final rule will result in reductions of 5.9 percent to underlying fee schedules for RT services over the course of the model test, which is similar to the proposed rule. The final rule payment reduction was estimated by simulating RT episodes using 2018 claims and assuming that the relative value units under the PFS and relative payment weights under the OPPS by providers would remain unchanged in the future. Another key assumption is that the distribution of provider efficiency as defined in (section III.C.1. of this final rule) during 2018 would remain unchanged in future years under the current FFS payment system. Although discounts were reduced by 0.25 percent between the proposed and final rule, this was approximately offset by an additional year of data underlying the distribution of provider efficiency. Moreover, these estimated fee schedule reductions do not include APM bonuses payable to participants. APM bonuses to providers were forecasted to be 0.5 percent of RO episode allowed charges. Please note that for any individual provider a range of potential outcomes may occur due to the RO model and that actual experience may vary.

We expect the anticipated average impact of revenue based solely on Medicare FFS payments to be less than 1 percent. We therefore expect that this final rule would not have a greater than 5 percent impact on total revenues on a substantial number of small entities.

b. ESRD Treatment Choices Model

This final rule includes as ETC Participants Managing Clinicians and ESRD facilities required to participate in the Model pursuant to § 512.325(a). We assume for the purposes of the regulatory impact analysis that the great majority of Managing Clinicians are small entities and that the greater majority of ESRD facilities are not small entities. Throughout the final rule we describe how the adjustments to certain payments for dialysis services and dialysis-related services furnished to ESRD beneficiaries may affect Managing Clinicians and ESRD facilities participating in the ETC Model. The great majority of Managing Clinicians are small entities by meeting the SBA definition of a small business (having minimum revenues of less than $11 million to $38.5 million in any 1 year, varying by type of provider and highest for hospitals) with a minimum threshold for small business size of $38.5 million (*https://www.sba.gov/document/support--table-size-standards http://www.sba.gov/content/small-businesssize-standards*). The great majority of ESRD facilities are not small entities, as they are owned, partially or entirely by entities that do not meet the SBA definition of small entities.

The HDPA in the ETC Model would be a positive adjustment on payments for specified home dialysis and home dialysis-related services. The PPA in the ETC Model, which includes both positive and negative adjustments on payments for dialysis services and dialysis-related services, excludes aggregation groups with fewer than 132 attributed beneficiary-months during the relevant year.

For the remaining small entities that are above the low-volume exclusion threshold and randomly selected for participation, the design of the ETC Model will incorporate a risk adjustment of the transplant waitlist rate and aggregation of the home dialysis rate and transplant waitlist rate to allow for the calculation of home dialysis rates and transplant waitlist rates for both small entities that may be owned in

whole or in part by another company. The transplant waitlist rate is risk adjusted based on age, as described in section IV.C.5.b.(3). of the final rule. The aggregation methodology groups ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area and Managing Clinicians billing under the same TIN within a Selected Geographic Area. This aggregation policy increases the number of beneficiary months, and thus statistical reliability, of the ETC Participant's home dialysis and transplant rate for ESRD facilities that are owned in whole or in part by the same dialysis organization and for Managing Clinicians that share a TIN with other Managing Clinicians.

Taken together, the low volume threshold exclusions, risk adjustments of the transplant rate, and aggregation policies previously described, coupled with the fact that the ETC Model will affect Medicare payment only for select services furnished to Medicare FFS beneficiaries; we have determined that the provisions of this final rule will not have a significant impact on spending for a substantial number of small entities (defined as greater than 5 percent impact). No comments were received regarding the impact of the ETC Model that were not addressed elsewhere.

5. Effects on Small Rural Hospitals

Section 1102(b) of the Act requires CMS to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds.

We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that the RO Model and ETC Model will not have a significant impact on the operations of a substantial number of small rural hospitals.

We received a number of comments regarding the impact of certain RO Model policies on rural hospitals. We direct readers to section III of this final rule and in the policy sections to which they applied where addressed these comments. We also note that in response to stakeholder feedback, we are finalizing a low volume opt out policy, described in section III.C.3.(c). of this final rule.

6. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–04, enacted on March 22, 1995) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that is approximately $168 million. This final rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

7. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications.

This rule would not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a Federalism implication because both the RO Model and ETC Model are Federal payment programs impacting Federal payments only and do not implicate local governments or state law. Therefore, the requirements of Executive Order 13132 are not applicable.

D. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This final rule is not expected to be subject to the requirements of E.O. 13771 because it is estimated to result in no more than *de minimis* costs.

E. Alternatives Considered

Throughout this final rule, we have identified our policies and alternatives that we have considered, and provided information as to the likely effects of these alternatives and the rationale for each of our policies. We solicited comments on our proposals, on the alternatives we have identified, and on other alternatives that we should consider, as well as on the costs, benefits, or other effects of these.

This final rule contains a model specific to radiation oncology. It provides descriptions of the requirements that we will waive, identifies the payment methodology to be tested, and presents rationales for our decisions and, where relevant, alternatives that we considered. We carefully considered the alternatives to this final rule, including whether the RO Model should be implemented by all RT providers and RT suppliers nationwide. We concluded that it would be best to test the model using a subset of all RT providers and RT suppliers in order to compare them to the RT providers and RT suppliers that would not be participating in the RO Model.

This final rule also contains a model specific to ESRD. It provides descriptions of the requirements that we will waive, identifies the performance metrics and payment adjustments to be tested, and presents rationales for our decisions, and where relevant, alternatives that we considered. We carefully considered the alternatives to this final rule, including whether the model should be implemented to include more or fewer ESRD facilities and Managing Clinicians. We concluded that it would be best to test the model with approximately 30 percent of ESRD facilities and Managing Clinicians in the U.S. in order to have an effective comparison group and to provide the best opportunity for an accurate and thorough evaluation of the model's effects.

We solicited comments on our proposals and on any Model alternatives and consequent policies that should be considered. We refer readers to section III.C and IV.C of this final rule for more information on policy-related stakeholder comments, our responses to those comments, and statements of final policy.

F. Accounting Statement and Table

As required by OMB Circular A–4 under Executive Order 12866 (available at *http://www.whitehouse.gov/omb/circulars_a004_a4*) in Tables E3 and E4, we have prepared an accounting statement showing the classification of transfers which represent savings associated with the provisions in this final rule. The accounting statement is based on estimates provided in this regulatory impact analysis.

TABLE 3: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR THE RADIATION ONCOLOGY MODEL

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized ($million/year)	-$40 million	2020	7%	Jan 1, 2021 – December 31, 2025
	-$42 million	2020	3%	Jan 1, 2021 – December 31, 2025
From Whom to Whom	From the federal government to healthcare providers			

TABLE 4: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR END STAGE RENAL DISEASE (ESRD) TREATMENT CHOICES MODEL

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized ($million/year)	-$2 million	2020	7%	Jan 1, 2021 – June 30, 2027
	-$3 million	2020	3%	Jan 1, 2021 – June 30, 2027
From Whom to Whom	From the Federal government to ESRD facilities and Managing Clinicians.			

Note: Negative spending reflects a reduction in Medicare spending.

G. Conclusion

This analysis, together with the remainder of this preamble, provides the Regulatory Impact Analysis of a rule with a significant economic effect. As a result of this final rule, we estimate that the financial impact of the Radiation Oncology Model and ESRD Treatment Choices Model will net a federal savings of $253 million over a 6.5-year performance period (2021 through 2027).

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble and under the authority at 42 U.S.C. 1302, 1315a, and 1395hh, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV by adding part 512 to read as follows:

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

Subpart A—General Provisions Related to Innovation Center Models

Sec.

512.100 Basis and scope.
512.110 Definitions.
512.120 Beneficiary protections.
512.130 Cooperation in model evaluation and monitoring.
512.135 Audits and record retention.
512.140 Rights in data and intellectual property.
512.150 Monitoring and compliance.
512.160 Remedial action.
512.165 Innovation center model termination by CMS.
512.170 Limitations on review.
512.180 Miscellaneous provisions on bankruptcy and other notifications.

Subpart B—Radiation Oncology Model

General

512.200 Basis and scope of subpart.
512.205 Definitions.

RO Model Participation

512.210 RO participants and geographic areas.
512.215 Beneficiary population.
512.217 Identification of individual practitioners.
512.220 RO participant compliance with RO Model requirements.
512.225 Beneficiary notification.

Scope of RO Episodes Being Tested

512.230 Criteria for determining cancer types.
512.235 Included RT services.
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512.245 Included RO episodes.

Pricing Methodology

512.250 Determination of national base rates.
512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts.

Billing and Payment

512.260 Billing.
512.265 Payment.
512.270 Treatment of add-on payments under existing Medicare payment systems.

Data Reporting

512.275 Quality measures, clinical data, and reporting.

Medicare Program Waivers

512.280 RO Model Medicare program waivers.

Reconciliation and Review Process

512.285 Reconciliation process.
512.290 Timely error notice and reconsideration review process.

Subpart C—ESRD Treatment Choices Model

General

512.300 Basis and scope.
512.310 Definitions.

ESRD Treatment Choices Model Scope and Participants

512.320 Duration.
512.325 Participant selection and geographic areas.
512.330 Beneficiary notification.

Home Dialysis Payment Adjustment

512.340 Payments subject to the facility HDPA.
512.345 Payments subject to the clinician HDPA.
512.350 Schedule of home dialysis payment adjustments.

Performance Payment Adjustment

512.355 Schedule of performance assessment and performance payment adjustment.

512.360 Beneficiary population and attribution.
512.365 Performance assessment.
512.370 Benchmarking and scoring.
512.375 Payments subject to adjustment.
512.380 PPA amounts and schedule.
512.385 PPA exclusions.
512.390 Notification and targeted review.

Quality Monitoring

512.395 Quality measures.

Medicare Program Waivers

512.397 ETC Model Medicare program waivers.

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

Subpart A—General Provisions Related to Innovation Center Models

§ 512.100 Basis and scope.

(a) *Basis.* This subpart implements certain general provisions for the Radiation Oncology Model implemented under subpart B (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model implemented under subpart C (ETC Model), collectively referred to in this subpart as Innovation Center models. Except as specifically noted in this part, the regulations do not affect the applicability of other provisions affecting providers and suppliers under Medicare Fee-For-Service (FFS), including provisions regarding payment, coverage, or program integrity.

(b) *Scope.* The regulations in this subpart apply to model participants in the RO Model (except as otherwise noted in § 512.160(b)(6)) and to model participants in the ETC Model. This subpart sets forth the following:

(1) Basis and scope.

(2) Beneficiary protections.

(3) Model participant requirements for participation in model evaluation and monitoring, and record retention.

(4) Rights in data and intellectual property.

(5) Monitoring and compliance.

(6) Remedial action and termination by CMS.

(7) Limitations on review.

(8) Miscellaneous provisions on bankruptcy and notification.

§ 512.110 Definitions.

For purposes of this part, the following terms are defined as follows unless otherwise stated:

Beneficiary means an individual who is enrolled in Medicare FFS.

Change in control means any of the following:

(1) The acquisition by any ''person'' (as this term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the model participant representing more than 50 percent of the model participant's outstanding voting securities or rights to acquire such securities.

(2) The acquisition of the model participant by any individual or entity.

(3) The sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the model participant.

(4) The approval and completion of a plan of liquidation of the model participant, or an agreement for the sale or liquidation of the model participant.

Covered services means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Days means calendar days.

Descriptive model materials and activities means general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, social media, or other materials or activities distributed or conducted by or on behalf of the model participant or its downstream participants when used to educate, notify, or contact beneficiaries regarding the Innovation Center model. The following communications are not descriptive model materials and activities: Communications that do not directly or indirectly reference the Innovation Center model (for example, information about care coordination generally); information on specific medical conditions; referrals for health care items and services; and any other materials that are excepted from the definition of ''marketing'' as that term is defined at 45 CFR 164.501.

Downstream participant means an individual or entity that has entered into a written arrangement with a model participant under which the downstream participant engages in one or more Innovation Center model activities.

Innovation Center model means the RO Model implemented under subpart B or the ETC Model implemented under subpart C.

Innovation Center model activities means any activities impacting the care of model beneficiaries related to the test of the Innovation Center model under the terms of this part.

Medically necessary means reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member.

Model beneficiary means a beneficiary attributed to a model participant or otherwise included in an Innovation Center model under the terms of this part.

Model participant means an individual or entity that is identified as a participant in the Innovation Center model under the terms of this part.

Model-specific payment means a payment made by CMS only to model participants, or a payment adjustment made only to payments made to model participants, under the terms of the Innovation Center model that is not applicable to any other providers or suppliers.

Provider means a ''provider of services'' as defined under section 1861(u) of the Act and codified in the definition of ''provider'' 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.

U.S. Territories means American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands, Palau, Puerto Rico, U.S. Minor Outlying Islands, and the U.S. Virgin Islands.

§ 512.120 Beneficiary protections.

(a) *Beneficiary freedom of choice.* (1) The model participant and its downstream model participants must not restrict beneficiaries' ability to choose to receive care from any provider or supplier.

(2) The model participant and its downstream model participants must not commit any act or omission, nor adopt any policy that inhibits beneficiaries from exercising their freedom to choose to receive care from any provider or supplier or from any health care provider who has opted out of Medicare. The model participant and its downstream model participants may communicate to model beneficiaries the benefits of receiving care with the model participant, if otherwise consistent with the requirements of this part and applicable law.

(b) *Availability of services.* (1) The model participant and its downstream participants must continue to make medically necessary covered services available to beneficiaries to the extent required by applicable law. Model beneficiaries and their assignees retain their rights to appeal claims in accordance with part 405, subpart I of this chapter.

(2) The model participant and its downstream participants must not take any action to select or avoid treating certain Medicare beneficiaries based on their income levels or based on factors that would render the beneficiary an

''at-risk beneficiary'' as defined at § 425.20 of this chapter.

(3) The model participant and its downstream participants must not take any action to selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the model participant's or downstream participant's financial or quality performance, a practice commonly referred to as ''cherry-picking.''

(c) *Descriptive model materials and activities.* (1) The model participant and its downstream participants must not use or distribute descriptive model materials and activities that are materially inaccurate or misleading.

(2) The model participant and its downstream participants must include the following statement on all descriptive model materials and activities: ''The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document.''

(3) The model participant and its downstream participants must retain copies of all written and electronic descriptive model materials and activities and appropriate records for all other descriptive model materials and activities in a manner consistent with § 512.135(c).

(4) CMS reserves the right to review, or have a designee review, descriptive model materials and activities to determine whether or not the content is materially inaccurate or misleading. This review takes place at a time and in a manner specified by CMS once the descriptive model materials and activities are in use by the model participant.

§ 512.130 Cooperation in model evaluation and monitoring.

The model participant and its downstream participants must comply with the requirements of § 403.1110(b) of this chapter and must otherwise cooperate with CMS' model evaluation and monitoring activities as may be necessary to enable CMS to evaluate the Innovation Center model in accordance with section 1115A(b)(4) of the Act and to conduct monitoring activities under § 512.150, including producing such data as may be required by CMS to evaluate or monitor the Innovation Center model, which may include protected health information as defined in 45 CFR 160.103 and other individually-identifiable data.

§ 512.135 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 an Innovation Center model.

(b) *Access to records.* The model participant and its downstream 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 Innovation Center model, including without limitation, documents and other evidence regarding all of the following:

(1) The model participant's and its downstream participants' compliance with the terms of the Innovation Center model, including this subpart.

(2) The accuracy of model-specific payments made under the Innovation Center model.

(3) The model participant's payment of amounts owed to CMS under the Innovation Center model.

(4) Quality measure information and the quality of services performed under the terms of the Innovation Center model, including this subpart.

(5) Utilization of items and services furnished under the Innovation Center model.

(6) The ability of the model participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

(7) Patient safety.

(8) Other program integrity issues.

(c) *Record retention.* (1) The model participant and its downstream participants must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of six years from the last payment determination for the model participant under the Innovation Center model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the model participant at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants, 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.

(2) If CMS notifies the model participant of the special need to retain records in accordance with paragraph (c)(1)(i) of this section or there has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants described in paragraph (c)(1)(ii) of this section, the model participant must notify its downstream participants of this need to retain records for the additional period specified by CMS.

§ 512.140 Rights in data and intellectual property.

(a) CMS may—

(1) Use any data obtained under §§ 512.130, 512.135, and 512.150 to evaluate and monitor the Innovation Center model; and

(2) Disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. Data disseminated may include patient—

(i) De-identified results of patient experience of care and quality of life surveys, and

(ii) De-identified measure results calculated based upon claims, medical records, and other data sources.

(b) Notwithstanding any other provision of this part, for all data that CMS confirms to be proprietary trade secret information and technology of the model participant or its downstream participants, CMS or its designee(s) will not release this data without the express written consent of the model participant or its downstream participant, unless such release is required by law.

(c) If the model participant or its downstream participant wishes to protect any proprietary or confidential information that it submits to CMS or its designee, the model participant or its downstream participant must label or otherwise identify the information as proprietary or confidential. Such assertions are subject to review and confirmation by CMS prior to CMS' acting upon such assertions.

§ 512.150 Monitoring and compliance.

(a) *Compliance with laws.* The model participant and each of its downstream participants must comply with all applicable laws and regulations.

(b) *CMS monitoring and compliance activities.* (1) CMS may conduct monitoring activities to ensure compliance by the model participant

and each of its downstream participants with the terms of the Innovation Center model including this subpart; to understand model participants' use of model-specific payments; and to promote the safety of beneficiaries and the integrity of the Innovation Center model. Such monitoring activities may include, without limitation, all of the following:

(i) Documentation requests sent to the model participant and its downstream participants, including surveys and questionnaires.

(ii) Audits of claims data, quality measures, medical records, and other data from the model participant and its downstream participants.

(iii) Interviews with members of the staff and leadership of the model participant and its downstream participants.

(iv) Interviews with beneficiaries and their caregivers.

(v) Site visits to the model participant and its downstream participants, performed in a manner consistent with paragraph (c) of this section.

(vi) Monitoring quality outcomes and clinical data, if applicable.

(vii) 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 model beneficiaries.

(c) *Site visits.* (1) In a manner consistent with § 512.130, the model participant and its downstream participants must cooperate in periodic site visits performed by CMS or its designees in order to facilitate the evaluation of the Innovation Center model and the monitoring of the model participant's compliance with the terms of the Innovation Center model, including this subpart.

(2) CMS or its designee provides, to the extent practicable, the model participant or downstream participant with no less than 15 days advance notice of any site visit. CMS—

(i) Will attempt, to the extent practicable, to accommodate a request for particular dates in scheduling site visits.

(ii) Will not accept a date request from a model participant or downstream participant that is more than 60 days after the date of the CMS initial site visit notice.

(3) The model participant and its downstream participants must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(4) Additionally, CMS may perform unannounced site visits at the office of the model participant and any of its downstream participants at any time to investigate concerns about the health or safety of beneficiaries or other patients or other program integrity issues.

(5) Nothing in this part shall be construed to limit or otherwise prevent CMS from performing site visits permitted or required by applicable law.

(d) *Reopening of payment determinations.* (1) CMS may reopen a model-specific payment determination on its own motion or at the request of a model participant, within 4 years from the date of the determination, for good cause (as defined at § 405.986 of this chapter).

(2) CMS may reopen a model-specific payment determination at any time if there exists reliable evidence (as defined in § 405.902 of this chapter) that the determination was procured by fraud or similar fault (as defined in § 405.902 of this chapter).

(3) CMS's decision regarding whether to reopen a model-specific payment determination is binding and not subject to appeal.

(e) *OIG authority.* Nothing contained in the terms of the Innovation Center Model or this part limits or restricts the authority of the HHS Office of Inspector General or any other Federal government authority, including its authority to audit, evaluate, investigate, or inspect the model participant or its downstream participants for violations of any Federal statutes, rules, or regulations.

§ 512.160 Remedial action.

(a) *Grounds for remedial action.* CMS may take one or more remedial actions described in paragraph (b) of this section if CMS determines that the model participant or a downstream participant:

(1) Has failed to comply with any of the terms of the Innovation Center Model, including this subpart.

(2) Has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(3) Has taken any action that threatens the health or safety of a beneficiary or other patient.

(4) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Innovation Center model.

(5) Has undergone a change in control that presents a program integrity risk.

(6) Is subject to any sanctions of an accrediting organization or a Federal, State, or local government agency.

(7) Is subject to investigation or action by HHS (including the HHS Office of Inspector General and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or 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.

(8) Has failed to demonstrate improved performance following any remedial action imposed under this section.

(b) *Remedial actions.* If CMS determines that one or more grounds for remedial action described in paragraph (a) of this section has taken place, CMS may take one or more of the following remedial actions:

(1) Notify the model participant and, if appropriate, require the model participant to notify its downstream participants of the violation.

(2) Require the model participant to provide additional information to CMS or its designees.

(3) Subject the model participant to additional monitoring, auditing, or both.

(4) Prohibit the model participant from distributing model-specific payments, as applicable.

(5) Require the model participant to terminate, immediately or by a deadline specified by CMS, its agreement with a downstream participant with respect to the Innovation Center model.

(6) In the ETC Model only, terminate the ETC Participant from the ETC Model.

(7) Require the model participant to submit a corrective action plan in a form and manner and by a deadline specified by CMS.

(8) Discontinue the provision of data sharing and reports to the model participant.

(9) Recoup model-specific payments.

(10) Reduce or eliminate a model-specific payment otherwise owed to the model participant.

(11) Such other action as may be permitted under the terms of this part.

§ 512.165 Innovation center model termination by CMS.

(a) CMS may terminate an Innovation Center model for reasons including, but not limited to, the following:

(1) CMS determines that it no longer has the funds to support the Innovation Center model.

(2) CMS terminates the Innovation Center model in accordance with section 1115A(b)(3)(B) of the Act.

(b) If CMS terminates an Innovation Center model, CMS provides written

notice to the model participant specifying the grounds for model termination and the effective date of such termination.

§ 512.170 Limitations on review.

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for all 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 model participants, to test the Innovation Center models selected, including a decision by CMS to remove a model participant or to require a model participant to remove a downstream participant from the Innovation Center model.

(c) The elements, parameters, scope, and duration of such Innovation Center models for testing or dissemination, including without limitation the following:

(1) The selection of quality performance standards for the Innovation Center model by CMS.

(2) The methodology used by CMS to assess the quality of care furnished by the model participant.

(3) The methodology used by CMS to attribute model beneficiaries to the model participant, if applicable.

(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 Innovation Center model under section 1115A(b)(3)(B) of the Act.

(f) Determinations about expansion of the duration and scope of an Innovation Center model under section 1115A(c) of the Act, including the determination that an Innovation Center model is not expected to meet criteria described in paragraph (a) or (b) of such section.

§ 512.180 Miscellaneous provisions on bankruptcy and other notifications.

(a) *Notice of bankruptcy.* If the model participant has filed a bankruptcy petition, whether voluntary or involuntary, the model participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the model participant under the terms of each model tested under section 1115A of the Act in which the model participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved. The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the model participant is participating or has participated. This list need not identify a model tested under section 1115A of the Act in which the model participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the model participant and CMS have been fully and finally resolved with respect to that model. The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(b) *Notice of legal name change.* A model participant must furnish written notice to CMS at least 30 days after any change in its legal name becomes effective. The notice of legal name change must be in a form and manner specified by CMS and must include a copy of the legal document effecting the name change, which must be authenticated by the appropriate State official.

(c) *Notice of change in control.* (1) A model participant must furnish written notice to CMS in a form and manner specified by CMS at least 90 days before any change in control becomes effective.

(2)(i) If CMS determines, in accordance with § 512.160(a)(5), that a model participant's change in control would present a program integrity risk, CMS may take remedial action against the model participant under § 512.160(b).

(ii) CMS may also require immediate reconciliation and payment of all monies owed to CMS by a model participant that is subject to a change in control.

Subpart B—Radiation Oncology Model

General

§ 512.200 Basis and scope of subpart.

(a) *Basis.* This subpart implements the test of the Radiation Oncology (RO) Model under section 1115A(b) of the Act. Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other regulations affecting providers and suppliers under Medicare FFS, including the applicability of regulations regarding payment, coverage, and program integrity.

(b) *Scope.* This subpart sets forth the following:

(1) RO Model participation.

(2) Episodes being tested under the RO Model.

(3) Methodology for pricing.

(4) Billing and payment under the RO Model.

(5) Data reporting requirements.

(6) Medicare program waivers.

(7) Payment reconciliation and review processes.

(c) RO participants are subject to the general provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

§ 512.205 Definitions.

For purposes of this subpart, the following definitions apply:

Aggregate quality score (AQS) means the numeric score calculated for each RO participant based on its performance on, and reporting of, quality measures and clinical data. The AQS is used to determine an RO participant's quality reconciliation payment amount.

APM means Alternative Payment Model.

ASC means Ambulatory Surgery Center.

Blend means the weight given to an RO participant's historical experience adjustment relative to the geographically-adjusted trended national base rate in the calculation of its participant-specific episode payment amounts.

CAH means Critical Access Hospital.

CEHRT means Certified Electronic Health Record Technology.

Clean period means the 28-day period after an RO episode has ended, during which time an RO participant must bill for medically necessary RT services furnished to the RO beneficiary in accordance with Medicare FFS billing rules.

Core-Based Statistical Area (CBSA) means a statistical geographic area, based on the definition as identified by the Office of Management and Budget, with a population of at least 10,000, which consists of a county or counties anchored by at least one core (urbanized area or urban cluster), plus adjacent counties having a high degree of social and economic integration with the core (as measured through commuting ties with the counties containing the core).

Discount factor means the set percentage by which CMS reduces payment of the professional component and technical component.

(1) The reduction on payment occurs after the trend factor, the geographic

adjustment, and the RO Model-specific adjustments have been applied but before beneficiary cost-sharing and standard CMS adjustments, including sequestration, have been applied.

(2) The discount factor does not vary by cancer type.

(3) The discount factor for the professional component is 3.75 percent; the discount factor for the technical component is 4.75 percent.

Dual participant means an RO participant that furnishes both the professional component and technical component of RT services of an RO episode through a freestanding radiation therapy center, identified by a single TIN.

Duplicate RT service means any included RT service that is furnished to an RO beneficiary by an RT provider or RT supplier that is not excluded from participation in the RO Model at § 512.210(b), and that did not initiate the PC or TC of the RO beneficiary's RO episode. Such services are furnished in addition to the RT services furnished by the RO participant that initiated the PC or TC and continues to furnish care to the RO beneficiary during the RO episode.

Episode means the 90-day period of RT services that begins on the date of service that an RT provider or RT supplier that is not an RO participant furnishes an initial treatment planning service to a beneficiary, provided that an RT provider or RT supplier furnishes a technical component RT service to the beneficiary within 28 days of such initial treatment planning service. Additional criteria for constructing episodes to be included in determining the national base rates are set forth in § 512.250.

EOE stands for ''end of episode'' and means the end of an RO episode.

HCPCS means Healthcare Common Procedure Coding System.

HOPD means hospital outpatient department.

Included cancer types means the cancer types determined by the criteria set forth in § 512.230, which are included in the RO Model test.

Included RT services means the RT services identified at § 512.235, which are included in the RO Model test.

Incomplete episode means an RO episode that is deemed not to have occurred because:

(1) A Technical participant or a Dual participant does not furnish a technical component to an RO beneficiary within 28 days following a Professional participant or the Dual participant furnishing an initial treatment planning service to that RO beneficiary;

(2) An RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer at any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and an EOE modifier; or

(3) An RO beneficiary switches RT provider or RT supplier before all included RT services in the RO episode have been furnished.

Individual practitioner means a Medicare-enrolled physician (identified by an NPI) who furnishes RT services to Medicare FFS beneficiaries, and has reassigned his or her billing rights to the TIN of an RO participant.

Individual practitioner list means a list of individual practitioners who furnish RT services under the TIN of a Dual participant or a Professional participant, which is annually compiled by CMS and which the RO participant must review, revise, and certify in accordance with § 512.217. The individual practitioner list is used for the RO Model as a Participation List as defined in § 414.1305 of this chapter.

Initial reconciliation means the first reconciliation of a PY that occurs as early as August following the applicable PY.

MIPS means Merit based Incentive Payment System.

Model performance period means, January 1, 2021, through December 31, 2025, the last date on which an RO episode may end under the RO Model. No new RO episodes may begin after October 3, 2025, in order for all RO episodes to end by December 31, 2025.

National base rate means the total payment amount for the relevant component of an RO episode, before application of the trend factor, discount factor, adjustments, and applicable withholds, for each of the included cancer types.

NPI means National Provider Identifier.

OPPS means outpatient prospective payment system.

Participant-specific professional episode payment means a payment which is calculated by CMS as set forth in § 512.255 and which is paid by CMS to a Professional participant or Dual participant as set forth in § 512.265, for the provision of the professional component to an RO beneficiary during an RO episode.

Participant-specific technical episode payment means a payment which is calculated by CMS as set forth in § 512.255 and which is paid by CMS to a Technical participant or Dual participant in accordance with § 512.265, for the provision of the technical component to an RO beneficiary during an RO episode.

Performance year (PY) means the 12-month period beginning on January 1 and ending on December 31 of each year during the Model performance period.

PGP means physician group practice.

PPS means prospective payment system.

Professional component (PC) means the included RT services that may only be furnished by a physician.

Professional participant means an RO participant that is a Medicare-enrolled PGP identified by a single TIN that furnishes only the PC of an RO episode.

PSO means patient safety organization.

PY means performance year.

QP means Qualifying APM Participants.

Reconciliation payment means a payment made by CMS to an RO participant, as determined in accordance with § 512.285.

Repayment amount means the amount owed by an RO participant to CMS, as determined in accordance with § 512.285.

Reconciliation report means the annual report issued by CMS to an RO participant for each PY, which specifies the RO participant's reconciliation payment amount or repayment amount.

RO beneficiary means a Medicare beneficiary who meets all of the beneficiary inclusion criteria at § 512.215(a) and whose RO episode meets all the criteria defined at § 512.245.

RO episode means the 90-day period that, as set forth in § 512.245, begins on the date of service that a Professional participant or a Dual participant furnishes an initial treatment planning service to an RO beneficiary in a freestanding radiation therapy center or an HOPD, provided that a Technical participant or the same Dual participant furnishes a technical component RT service to the RO beneficiary within 28 days of such RT treatment planning service.

RO participant means a Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that participates in the RO Model in accordance with § 512.210. An RO participant may be a Dual participant, Professional participant, or Technical participant.

RT provider means a Medicare-enrolled HOPD that furnishes RT services.

RT services are the treatment planning, technical preparation, special services (such as simulation), treatment delivery, and treatment management services associated with cancer

treatment that uses high doses of radiation to kill cancer cells and shrink tumors.

RT supplier means a Medicare-enrolled PGP or freestanding radiation therapy center that furnishes RT services.

SOE stands for ''start of episode'' and means the start of an RO episode.

Stop-loss limit means the set percentage at which loss is limited under the Model used to calculate the stop-loss reconciliation amount.

Stop-loss reconciliation amount means the amount owed to RO participants that have fewer than 60 episodes during 2016–2018 and that were furnishing included RT services on November 30, 2020 in the CBSAs selected for participation for the loss incurred under the Model as described in § 512.285(f).

Technical component (TC) means the included RT services that are not furnished by a physician, including the provision of equipment, supplies, personnel, and administrative costs related to RT services.

Technical participant means an RO participant that is a Medicare-enrolled HOPD or freestanding radiation therapy center, identified by a single CMS Certification Number (CCN) or TIN, which furnishes only the TC of an RO episode.

TIN means Taxpayer Identification Number.

Trend factor means an adjustment applied to the national base rates that updates those rates to reflect current trends in the OPPS and PFS rates for RT services.

True-up reconciliation means the process to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial reconciliation and after a 12-month claims run-out for all RO episodes initiated in the applicable PY.

RO Model Participation

§ 512.210 RO participants and geographic areas.

(a) *RO participants.* Unless otherwise specified in paragraph (b) or (c) of this section, any RO participant that furnishes included RT services in a 5-digit ZIP Code linked to a CBSA selected for participation to an RO beneficiary for an RO episode that begins on or after January 1, 2021, and ends on or before December 31, 2025, must participate in the RO Model.

(b) *Participant exclusions.* A PGP, freestanding radiation therapy center, or HOPD is excluded from participation in the RO Model if it:

(1) Furnishes RT services only in Maryland;

(2) Furnishes RT services only in Vermont;

(3) Furnishes RT services only in U.S. Territories;

(4) Is classified as an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or

(5) Participates in or is identified by CMS as eligible to participate in the Pennsylvania Rural Health Model.

(c) *Low Volume Opt-Out.* A PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model may choose to opt-out of the RO Model for a given PY if it has fewer than 20 episodes of RT services across all CBSAs selected for participation in the most recent year with claims data available prior to the applicable PY. At least 30 days prior to the start of each PY, CMS notifies RO participants eligible for the low volume opt-out for the upcoming PY. The RO participant must attest to its intention of opting out of the RO Model prior to the start of the upcoming PY.

(d) *Selected CBSAs.* CMS randomly selects CBSAs to identify RT providers and RT suppliers to participate in the RO Model through a stratified sample design, allowing for participant and comparison groups to contain approximately 30 percent of all episodes in eligible geographic areas (CBSAs).

§ 512.215 Beneficiary population.

(a) *Beneficiary inclusion criteria.* An individual is an RO beneficiary if:

(1) The individual receives included RT services from an RO participant that billed the SOE modifier for the PC or TC of an RO episode during the Model performance period for an included cancer type; and

(2) At the time that the initial treatment planning service of an RO episode is furnished by an RO participant, the individual:

(i) Is eligible for Medicare Part A and enrolled in Medicare Part B;

(ii) Has traditional FFS Medicare as his or her primary payer (for example, is not enrolled in a PACE plan, Medicare Advantage or another managed care plan, or United Mine Workers insurance); and

(iii) Is not in a Medicare hospice benefit period.

(b) Any individual enrolled in a clinical trial for RT services for which Medicare pays routine costs is an RO beneficiary if the individual satisfies all of the beneficiary inclusion criteria in paragraph (a) of this section.

§ 512.217 Identification of individual practitioners.

(a) *General.* Upon the start of each PY, CMS creates and provides to each Dual participant and Professional participant an individual practitioner list identifying by NPI each individual practitioner associated with the RO participant.

(b) *Review of individual practitioner list.* Within 30 days of receipt of the individual practitioner list, the RO participant must review and certify the individual practitioner list, correct any inaccuracies in accordance with paragraph (d) of this section, and certify the list (as corrected, if applicable) in a form and manner specified by CMS and in accordance with paragraph (c) of this section or correct the individual practitioner list in accordance with paragraph (d) of this section.

(c) *List certification.* (1) Within 30 days of receipt of the individual practitioner list, and at such other times as specified by CMS, an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the individual practitioner list to the best of his or her knowledge, information, and belief.

(2) All Medicare-enrolled individual practitioners that have reassigned their right to receive Medicare payment for provision of RT services to the TIN of the RO participant must be included on the RO participant's individual practitioner list and each individual practitioner must agree to comply with the requirements of the RO Model before the RO participant certifies the individual practitioner list.

(3) If the RO participant does not certify the individual practitioner list:

(i) Eligible clinicians in the RO Model will not be considered participants in a MIPS APM for purposes of MIPS reporting and scoring rules; and

(ii) Eligible clinicians in the RO Model will not have Qualifying APM Participant (''QP'') determinations made based on their participation in the RO Model.

(d) *Changes to the individual practitioner list.* (1) *Additions.*

(i) An RO participant must notify CMS of an addition to its individual practitioner list within 30 days of when an eligible clinician reassigns his or her rights to receive payment from Medicare to the RO participant. The notice must be submitted in the form and manner specified by CMS.

(ii) If the RO participant timely submits notice to CMS, then the addition of an individual practitioner to the RO participant's individual practitioner list is effective on the date

specified in the notice furnished to CMS, but no earlier than 30 days before the date of the notice. If the RO participant fails to submit timely notice to CMS, then the addition of an individual practitioner to the individual practitioner list is effective on the date of the notice.

(2) *Removals.* (i) An RO participant must notify CMS no later than 30 days of when an individual on the RO participant's individual practitioner list ceases to be an individual practitioner. The notice must be submitted in the form and manner specified by CMS.

(ii) The removal of an individual practitioner from the RO participant's individual practitioner list is effective on the date specified in the notice furnished to CMS. If the RO participant fails to submit a timely notice of the removal, then the removal is effective on the date that the individual ceases to be an individual practitioner.

(e) *Update to Medicare enrollment information.* The RO participant must ensure that all changes to enrollment information for an RO participant and its individual practitioners, including changes to reassignment of the right to receive Medicare payment, are reported to CMS consistent with § 424.516 of this chapter.

§ 512.220 RO participant compliance with RO Model requirements.

(a) *RO participant-specific requirements.* (1) RO participants must satisfy the requirements of this section to qualify for the APM Incentive Payment.

(2) Each Professional participant and Dual participant must ensure its individual practitioners:

(i) Starting in PY1, discuss goals of care with each RO beneficiary before initiating treatment and communicate to the RO beneficiary whether the treatment intent is curative or palliative;

(ii) Starting in PY1, adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate in treating RO beneficiaries or, alternatively, document in the medical record the extent of and rationale for any departure from these guidelines;

(iii) Starting in PY1, assess each RO beneficiary's tumor, node, and metastasis cancer stage for the CMS-specified cancer diagnoses;

(iv) Starting in PY1, assess the RO beneficiary's performance status as a quantitative measure determined by the physician;

(v) Starting in PY1, send a treatment summary to each RO beneficiary's referring physician within 3 months of the end of treatment to coordinate care;

(vi) Starting in PY1, discuss with each RO beneficiary prior to treatment delivery his or her inclusion in, and cost-sharing responsibilities under, the RO Model; and

(vii) Starting in PY1, perform and document Peer Review (audit and feedback on treatment plans) before 25 percent of the total prescribed dose has been delivered and within 2 weeks of the start of treatment for:

(A) 50 percent of new patients in PY1,

(B) 55 percent of new patients in PY2,

(C) 60 percent of new patients in PY3,

(D) 65 percent of new patients in PY4,

(E) 70 percent of new patients in PY5.

(3) Starting in PY1, at such times and in the form and manner specified by CMS, each Technical participant and Dual participant must annually attest to whether it actively participates with a AHRQ-listed patient safety organization (PSO). Examples include maintaining a contractual or similar relationship with a PSO for the receipt and review of patient safety work product.

(b) *CEHRT.* (1) Each RO participant must use CEHRT, and ensure that its individual practitioners use CEHRT, in a manner sufficient to meet the applicable requirements of the Advanced APM criteria codified in § 414.1415(a)(1)(i) of this chapter. Before each PY, each RO participant must certify in the form and manner, and by a deadline specified by CMS, that it uses CEHRT throughout such PY in a manner sufficient to meet the requirements set forth in § 414.1415(a)(1)(i) of this chapter.

(2) Within 30 days of the start of PY1, the RO participant must certify its intent to use CEHRT throughout PY1 in a manner sufficient to meet the requirements set forth in § 414.1415(a)(1)(i) of this chapter.

§ 512.225 Beneficiary notification.

(a) *General.* Starting in PY1, each Professional participant and Dual participant must notify each RO beneficiary to whom it furnishes included RT services—

(1) That the RO participant is participating in the RO Model;

(2) That the RO beneficiary has the opportunity to decline claims data sharing for care coordination and quality improvement purposes. If an RO beneficiary declines claims data sharing for care coordination and quality improvement purposes, then the RO participant must inform CMS within 30 days of receiving notification from the RO beneficiary that the beneficiary is declining to have his or her claims data shared in that manner; and,

(3) Of the RO beneficiary's cost-sharing responsibilities.

(b) *Form and manner of notification.* Notification of the information specified in paragraph (a) of this section must be carried out by an RO participant by providing each RO beneficiary with a CMS-developed standardized written notice during the RO beneficiary's initial treatment planning session. The RO participants must furnish the notice to the RO beneficiary in the form and manner specified by CMS.

(c) *Applicability of general Innovation Center provisions.* The beneficiary notifications under this section are not descriptive model materials and activities under § 512.120(c). The requirement described in § 512.120(c)(2) does not apply to the standardized written notice described in paragraph (b) of this section.

Scope of RO Episodes Being Tested

§ 512.230 Criteria for determining cancer types.

(a) *Included cancer types.* CMS includes in the RO Model test cancer types that satisfy all of the following criteria. The cancer type:

(1) Is commonly treated with radiation; and

(2) Has associated current ICD–10 codes that have demonstrated pricing stability.

(b) *Removing cancer types.* CMS removes cancer types in the RO Model if it determines:

(1) RT is no longer appropriate to treat a cancer type per nationally recognized, evidence-based clinical treatment guidelines;

(2) CMS discovers a ≥10 percent error in established national base rates; or

(3) The Secretary determines a cancer type not to be suitable for inclusion in the RO Model.

(c) *ICD–10 codes for included cancer types.* CMS displays on the RO Model website no later than 30 days prior to each PY the ICD–10 diagnosis codes associated with each included cancer type.

§ 512.235 Included RT services.

(a) Only the following RT services furnished using an included modality identified at § 512.240 for an included cancer type are included RT services that are paid for by CMS under § 512.265:

(1) Treatment planning;

(2) Technical preparation and special services;

(3) Treatment delivery; and,

(4) Treatment management.

(b) All other RT services furnished by an RO participant during the Model performance period are subject to Medicare FFS payment rules.

§ 512.240 Included modalities.

The modalities included in the RO Model are 3-dimensional conformal RT (3DCRT), intensity-modulated RT (IMRT), stereotactic radiosurgery (SRS), stereotactic body RT (SBRT), proton beam therapy (PBT), image-guided radiation therapy (IGRT), and brachytherapy.

§ 512.245 Included RO episodes.

(a) *General.* Any RO episode that begins on or after January 1, 2021, and ends on or before December 31, 2025, is included in the Model performance period.

(b) *Death or election of hospice benefit.* An RO episode is included in, and paid for under, the RO Model if the RO beneficiary dies after the TC of an RO episode has been initiated, or if the RO beneficiary elects the Medicare hospice benefit after the initial treatment planning service, provided that the TC is initiated within 28 days following the initial treatment planning service. Each RO participant will receive both installments of the episode payment under such circumstances, regardless of whether the RO beneficiary dies or elects the Medicare hospice benefit before the relevant course of RT treatment has ended.

(c) *Clean periods.* An RO episode must not be initiated for the same RO beneficiary during a clean period.

Pricing Methodology

§ 512.250 Determination of national base rates.

CMS determines a national base rate for the PC and TC for each included cancer type.

(a) National base rates are the historical average cost for an episode of care for each of the included cancer types prior to the Model performance period.

(b) National base rates are determined in the following manner:

(1) CMS excludes claims from RT suppliers and RT providers in Maryland and Vermont and all inpatient and ASC claims from the construction of episodes and;

(2) CMS excludes the following:

(i) episodes with any RT services furnished by a CAH,

(ii) episodes that are not attributed to an RT provider or RT supplier, and

(iii) episodes in which either the PC or TC is attributed to an RT provider or RT supplier with a U.S. Territory service location.

(3) CMS calculates the episode amount CMS paid on average to RT providers and RT suppliers for the PC and TC for each of the included cancer types in the HOPD setting, creating the RO Model's national base rates.

§ 512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts.

(a) Thirty days before the start of each PY, CMS provides each RO participant its case mix and historical experience adjustments for both the PC and TC as calculated in paragraphs (c)(3) and (4) of this section. If an RO participant is not eligible to receive a historical experience adjustment or case mix adjustment as described under paragraph (c)(7) of this section, then CMS provides a zero value for those adjustments.

(b) Any episode used to calculate the participant-specific professional episode payment amounts and the participant-specific technical episode payment amounts for an RO participant is subject to the exclusions described in § 512.250(b)(1) and (2).

(c) CMS calculates the participant-specific professional episode payment amounts and participant-specific technical episode payment amounts for each included cancer type using the following:

(1) *Trend factors.* For every PY, CMS adjusts the national base rates for the PC and TC of each cancer type by calculating a separate trend factor for the PC and TC of each included cancer type.

(2) *Geographic adjustment.* CMS adjusts the trended national base rates prior to applying each RO participant's case mix and historical experience, and prior to applying the discounts and withholds, for local cost and wage indices based on where RT services are furnished, as described by existing geographic adjustment processes in the OPPS and PFS.

(3) *Case mix adjustment.* CMS establishes and applies a case mix adjustment to the national base rate after the trend factor and geographic adjustment have applied. The case mix adjustment reflects episode or RO episode characteristics that may be beyond the control of RO participants such as cancer type, age, sex, presence of a major procedure, death during the episode, and presence of chemotherapy.

(4) *Historical experience adjustment.* CMS establishes and applies a historical experience adjustment to the national base rate after the trend factor, geographic adjustment, and case mix adjustment have been applied. The historical experience adjustments reflect each RO participant's actual historical experience.

(5) *Blend.* CMS blends each RO participant's historical experience adjustment and the geographically-adjusted trended national base rate. The blend for RO participants with a professional historical experience adjustment or technical historical experience adjustment with a value equal to or less than zero is 90/10, meaning the calculation of the participant-specific episode payment amount is weighted according to 90 percent of the RO participant's historical experience adjustment and 10 percent of the geographically-adjusted trended national base for PY1 through PY5. The blend for RO participants with a professional historical experience adjustment or technical historical experience adjustment of more than zero is 90/10 in PY1, 85/15 in PY2, 80/20 in PY3, 75/25 in PY4, and 70/30 in PY5.

(6) *Changes in business structure.* (i) RO participants must notify CMS in writing of a merger, acquisition, or other new clinical or business relationship, at least 90 days before the date of the change as described in § 424.516.

(ii) CMS updates case mix and historical experience adjustments according to the relevant treatment history that applies as a result of a merger, acquisition, or other new clinical or business relationship in the RO participant's case mix and historical experience adjustment calculations from the effective date of the change.

(7) *Adjustments for RO participants with fewer than 60 episodes during 2016–2018.*

(i) RO participants that have fewer than 60 episodes from 2016–2018 do not receive a historical experience adjustment during the Model performance period.

(ii) RO participants that have fewer than 60 episodes from 2016–2018 do not receive a case mix adjustment for PY1.

(iii) RO participants described in § 512.255(b)(7)(ii) that continue to have fewer than 60 episodes in the rolling 3-year period used to determine the case mix adjustment for each PY (2017–2019 for PY2, 2018–2020 for PY3, 2019–2021 for PY4, and 2020–2022 for PY5) and that have never received a case mix adjustment do not receive a case mix adjustment for that PY.

(iv) RO participants that have fewer than 60 episodes from 2016–2018 and were furnishing included RT services in the CBSAs selected for participation on November 30, 2020 are eligible to receive a stop-loss reconciliation amount, if applicable, for the loss incurred under the RO Model as described in § 512.285(f).

(8) *Discount factor.* CMS deducts a percentage discount from each episode payment after applying the trend factor, geographic adjustment, and case mix and historical experience adjustments to the national base rate. The discount factor for the PC is 3.75 percent. The discount factor for TC is 4.75 percent.

(9) *Incorrect payment withhold.* To account for duplicate RT services and incomplete episodes:

(i) CMS withholds from each RO participant 1 percent from each episode payment, after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount to the national base rate.

(ii) CMS determines during the annual reconciliation process set forth at § 512.285 whether an RO participant is eligible to receive a portion or all of the withheld amount or whether any payment is owed to CMS.

(10) *Quality withhold.* In accordance with § 414.1415(b)(1) of this chapter, CMS withholds 2 percent from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate. RO participants may earn back this withhold, in part or in full, based on their AQS.

(11) *Patient experience withhold.* Starting in PY3,

(i) CMS withholds 1 percent from each technical episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate.

(ii) RO participants may earn back their patient-experience withhold, in part or in full, based on their results from the CAHPS® Cancer Care Radiation Therapy survey.

(12) *Coinsurance.* RO participants may collect beneficiary coinsurance payments for services furnished under the RO Model in multiple installments under a payment plan.

(i) The availability of payment plans may not be used as a marketing tool to influence beneficiary choice of health care provider.

(ii) RO participants offering a payment plan may inform the RO beneficiary of the availability of the payment plan prior to or during the initial treatment planning session and as necessary thereafter.

(iii) The beneficiary coinsurance payment equals 20 percent of the episode payment amount to be paid to the RO participant(s) prior to the application of sequestration for the billed RO Model-specific HCPCS code with a SOE modifier and for the billed RO Model-specific HCPCS code with an EOE modifier for the PC and TC, except as provided in paragraph (c)(12)(iv) and(v) of this section.

(iv) In the case of incomplete episodes

(A) The beneficiary coinsurance payment equals 20 percent of the FFS amounts that would have been paid in the absence of the RO Model for the services furnished by the RO participant that initiated the PC and the RO participant that initiated the TC (if applicable), except for a subset of incomplete episodes described in paragraph (c)(12)(iv)(B); or

(B) If an RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and EOE modifier, provided a Technical participant or the same Dual participant that provided the initial treatment planning service furnishes a a technical component RT service to the RO beneficiary within 28 days of such initial treatment planning service, the beneficiary coinsurance payment equals 20 percent of the first installment of the episode payment amount to be paid to the RO participant(s) prior to the application of sequestration for the billed RO Model-specific HCPCS code with an SOE modifier for the PC and TC. If an RO participant bills the RO Model-specific HCPCS code and EOE modifier with a date of service that is prior to the date that the RO beneficiary ceases to have traditional FFS Medicare, then the beneficiary coinsurance payment equals 20 percent of the full episode payment amount for the PC or TC, as applicable.

(v) In the case of duplicate RT services, the beneficiary coinsurance payment equals 20 percent of the episode payment amount to be paid to the RO participant(s) per § 512.255(c)(12)(iii) and 20 percent of the FFS amount to the RT provider and/or RT supplier furnishing one or more duplicate RT services.

(13) *Sequestration.* CMS deducts 2 percent from each episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, discount, withholds, and coinsurance to the national base rate.

Billing and Payment

§ 512.260 Billing.

(a) *Reassignment of billing rights.* Each Professional participant and Dual participant must ensure that its individual practitioners reassign their billing rights to the TIN of the Professional participant or Dual participant.

(b) *Billing under the RO Model.* (1) Professional participants and Dual participants must bill an RO Model-specific HCPCS code and a SOE modifier to indicate that the treatment planning service has been furnished and that an RO episode has been initiated.

(2) Dual participants and Technical participants must bill an RO Model-specific HCPCS code and SOE modifier to indicate that a treatment delivery service was furnished.

(3) RO participants must bill the same RO Model-specific HCPCS code that initiated the RO episode and an EOE modifier to indicate that the RO episode has ended.

(4) RO participants may submit a claim with an EOE modifier only after the RT course of treatment has ended, except that such claim must not be submitted earlier than 28 days after the date of the initial treatment planning service.

(c) *Billing for RT services performed during a clean period.* RO participants must bill for any medically necessary RT services furnished to an RO beneficiary during a clean period in accordance with existing FFS billing processes in the OPPS and PFS.

(d) *Submission of no-pay claims.* RO participants must submit no-pay claims for any medically necessary included RT services furnished to an RO beneficiary during an RO episode pursuant to existing FFS billing processes in the OPPS and PFS.

§ 512.265 Payment.

(a) *Payment for episodes.* CMS pays an RO participant for all included RT services furnished to an RO beneficiary during a completed RO episode as follows:

(1) CMS pays a Professional participant a participant-specific professional episode payment for the professional component furnished to an RO beneficiary during an RO episode.

(2) CMS pays a Technical participant a participant-specific technical episode payment for the technical component furnished to an RO beneficiary during an RO episode.

(3) CMS pays a Dual participant a participant-specific professional episode payment and a participant-specific technical episode payment for the professional component and technical component furnished to an RO beneficiary during an RO episode.

(b) *Payment installments.* CMS makes each of the payments described in paragraph (a) of this section in two equal installments, as follows:

(1) CMS pays one-half of a participant-specific professional episode payment to a Professional participant or Dual participant or one-half of the participant-specific technical episode payment to a Technical participant or Dual participant after the RO participant bills an RO Model-specific HCPCS code with a SOE modifier.

(2) CMS pays the remaining half of a participant-specific professional episode payment to a Professional participant or Dual participant or one-half of the participant-specific technical episode payment to a Technical participant or Dual participant after the RO participant bills an RO Model-specific HCPCS code with an EOE modifier.

(c) *Duplicate RT services.* Duplicate RT services are reimbursed at the FFS amount, whether or not the RT provider or RT supplier that furnished such services is an RO participant.

§ 512.270 Treatment of add-on payments under existing Medicare payment systems.

(a) CMS does not make separate Medicare FFS payments to RO participants for any included RT services that are furnished to an RO beneficiary during an RO episode.

(b) An RO participant may receive Medicare FFS payment for items and services furnished to an RO beneficiary during an RO episode, provided that any such other item or service is not an included RT service.

Data Reporting

§ 512.275 Quality measures, clinical data, and reporting.

(a) *Data privacy compliance.* The RO participant must—

(1) Comply with all applicable laws pertaining to any patient-identifiable data requested from CMS under the terms of the Innovation Center model, including any patient-identifiable derivative data, as well as the terms of any attestation or agreement entered into by the RO participant with CMS as a condition of receiving that data. Such laws may include, without limitation, the privacy and security rules promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as modified, and the Health Information Technology for Economic and Clinical Health Act (HITECH).

(2) Contractually bind all downstream recipients of CMS data to the same terms and conditions to which the RO participant was itself bound in its agreements with CMS as a condition of the downstream recipient's receipt of the data from the RO participant.

(b) *RO participant public release of patient de-identified information.* The RO participant must include the disclaimer codified at § 512.120(c)(2) on the first page of any publicly-released document, the contents of which materially and substantially references or is materially and substantially based upon the RO participant's participation in the RO Model, including but not limited to press releases, journal articles, research articles, descriptive articles, external reports, and statistical/analytical materials.

(c) *Reporting quality measures and clinical data elements.* In addition to reporting described in other provisions in this part, Professional participants and Dual participants must report selected quality measures on all patients and clinical data elements describing cancer stage, disease characteristics, treatment intent, and specific treatment plan information on beneficiaries treated for specified cancer types, in the form, manner, and at a time specified by CMS.

Medicare Program Waivers

§ 512.280 RO Model Medicare program waivers.

(a) *General.* The Secretary may waive certain requirements of title XVIII of the Act as necessary solely for purposes of testing of the RO Model. Such waivers apply only to the participants in the RO Model.

(b) *Hospital Outpatient Quality Reporting (OQR) Program.* CMS waives the application of the Hospital OQR Program 2.0 percentage point reduction under section 1833(t)(17) of the Act for only those Ambulatory Payment Classifications (APCs) that include only RO Model-specific HCPCS codes during the Model performance period.

(c) *Merit-based Incentive Payment System (MIPS).* CMS waives the requirement under section 1848(q)(6)(E) of the Act and § 414.1405(e) of this chapter to apply the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) to the TC of RO Model payments to the extent that the MIPS payment adjustment factors would otherwise apply to the TC of RO Model payments.

(d) *APM Incentive Payment.* CMS waives the requirements of § 414.1450(b) of this chapter such that technical component payment amounts under the RO Model shall not be considered in calculation of the aggregate payment amount for covered professional services as defined in section 1848(k)(3)(A) of the Act for the APM Incentive Payment made under § 414.1450(b)(1) of this chapter.

(e) *PFS Relativity Adjuster.* CMS waives the requirement to apply the PFS Relativity Adjuster to RO Model-specific APCs for RO participants that are non-excepted off-campus provider-based departments (PBDs) identified by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), which amended section 1833(t)(1)(B)(v) and added paragraph (t)(21) to the Social Security Act.

(f) *General payment waivers.* CMS waives the following sections of the Act solely for the purposes of testing the RO Model:

(1) 1833(t)(1)(A).
(2) 1833(t)(16)(D).
(3) 1848(a)(1).
(4) 1833(t)(2)(H).
(5) 1869 claims appeals procedures.

Reconciliation and Review Process

§ 512.285 Reconciliation process.

(a) *General.* CMS conducts an initial reconciliation and a true-up reconciliation for each RO participant for each PY in accordance with this section.

(b) *Annual reconciliation calculations.* (1) To determine the reconciliation payment or the repayment amount based on RO episodes initiated in a PY, CMS performs the following steps:

(i) CMS calculates an RO participant's incorrect episode payment reconciliation amount as described in paragraph (c) of this section.

(ii) CMS calculates the RO participant's quality reconciliation amount as described in paragraph (d) of this section, if applicable.

(iii) CMS calculates the RO participant's patient experience reconciliation amount, as described in paragraph (e) of this section, if applicable.

(iv) CMS calculates the stop-loss reconciliation amount, as described in paragraph (f) of this section, if applicable.

(v) CMS adds, as applicable, the incorrect episode payment reconciliation amount, any quality reconciliation payment amount, any patient experience reconciliation amount, and any stop-loss reconciliation payment amount. The sum of these amounts results in a reconciliation payment or repayment amount.

(2) CMS calculations use claims data available at the time of reconciliation.

(c) *Incorrect episode payment reconciliation amount.* CMS calculates the incorrect episode payment reconciliation amount as follows:

(1) *Total incorrect payment withhold amount.* CMS calculates the total

incorrect payment withhold amount by adding the incorrect payment withhold amount for each episode initiated in the PY.

(2) *Total duplicate RT services amount.* CMS calculates the total duplicate RT services amount by adding all FFS amounts for duplicate RT services furnished during each episode initiated in the PY. The duplicate RT services amount is capped for each episode and will not be more than the participant-specific professional episode payment amount or participant-specific technical episode payment amount received by the RO participant for an RO episode, even if the duplicate RT services amount exceeds the participant-specific professional episode payment amount or the participant-specific technical episode payment amount.

(3) *Total incomplete episode amount.* CMS calculates the total incomplete episode amount for a subset of incomplete episodes.

(i) Incomplete episodes in which an RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer at any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and EOE modifier, provided an RO participant furnishes a technical component RT service to the RO beneficiary within 28 days of such initial treatment planning service, are not included in the incomplete episode amount.

(ii) For all other incomplete episodes initiated in the PY, CMS determines the total incomplete episode amount by calculating the difference between the following amounts:

(A) The sum of all FFS amounts that would have been paid to the RO participant in the absence of the RO Model for any included RT services furnished during such incomplete episodes, as determined by no-pay claims. This sum is what CMS owes the RO participant for such incomplete episodes.

(B) The sum of the participant-specific episode payment amounts paid to the relevant RO participant for such incomplete episodes initiated in the PY.

(4) *Total incorrect episode payment amount.* CMS calculates the total incorrect episode payment amount as follows:

(i) If the sum described in paragraph (c)(3)(ii)(A) of this section is more than the sum described in paragraph (c)(3)(ii)(B) of this section, the difference is subtracted from the total duplicate RT services amount and the resulting amount is the total incorrect episode payment amount.

(ii) If the sum described in paragraph (c)(3)(ii)(A) of this section is less than the sum described in paragraph (c)(3)(ii)(B) of this section, the difference is added to the total duplicate RT services amount and the resulting amount is the total incorrect episode payment amount.

(5) *Incorrect episode payment reconciliation amount.* If the total incorrect episode payment amount represents money owed by the RO participant to CMS, CMS subtracts the total incorrect episode payment amount from the total incorrect payment withhold amount. In the case that the total incorrect episode payment amount represents money owed by CMS to the RO participant, CMS adds the total incorrect episode payment amount to the total incorrect payment withhold amount. The resulting amount is the RO participant's incorrect episode payment reconciliation amount.

(d) *Quality reconciliation payment amount.* For Professional participants and Dual participants, CMS determines the quality reconciliation payment amount for each PY by multiplying the participant's AQS (as a percentage) by the total quality withhold amount for all RO episodes initiated during the PY.

(e) *Patient experience reconciliation amount.* For PY3 and subsequent PYs, CMS determines the patient experience reconciliation amount for RO participants by multiplying the participant's AQS (as a percentage) by the total patient experience withhold amount for all RO episodes initiated during the PY.

(f) *Stop-loss reconciliation amount.* CMS determines the stop-loss reconciliation amount for RO participants that have fewer than 60 episodes during 2016 through 2018 and were furnishing included RT services at November 30, 2020 in the CBSAs selected for participation by—

(1) Using no-pay claims, CMS calculates the total FFS amount by summing the FFS amounts that would have been paid to the RO participant in the absence of the RO Model for all included RT services furnished during the RO episodes initiated in the PY; and

(2) CMS calculates the sum of all participant-specific professional episode payments and participant-specific technical episode payments paid to the RO participant for the RO episodes initiated in the PY.

(3) If the total FFS amount exceeds the sum of the participant-specific episode payment amounts for the PY by more than 20 percent then CMS owes the RO participant the amount that exceeds 20 percent, either increasing the amount of the RO participant's reconciliation payment or reducing the amount of the RO's participant's reconciliation repayment.

(g) *True-up reconciliation.* CMS conducts a true-up reconciliation in the same manner described in paragraph (b) of this section (except that the quality reconciliation payment amount and the patient experience reconciliation amount are not calculated) to determine any additional reconciliation payment or repayment amount that are identified using 12-months of claims run-out.

(h) *Reconciliation report.* CMS issues each RO participant a reconciliation report for each PY. Each reconciliation report contains the following:

(1) The RO participant's reconciliation payment or repayment amount, if any, for the relevant PY.

(2) Any additional reconciliation payment or repayment amount owed for a previous PY as a result of the true-up reconciliation.

(3) The net reconciliation payment or repayment amount owed.

(i) *Payment of amounts owed.* (1) CMS issues a reconciliation payment to the RO participant in the amount specified in the reconciliation report 30 days after the reconciliation report is deemed final.

(2) The RO participant must pay a repayment amount to CMS in the amount specified in the reconciliation report by a deadline specified by CMS. If the RO participant fails to timely pay the full repayment amount, CMS recoups the repayment amount from any payments otherwise owed by CMS to the RO participant, including Medicare payments for items and services unrelated to the RO Model.

(3) No coinsurance is owed by an RO beneficiary with respect to any repayment amount or reconciliation payment.

§ 512.290 Timely error notice and reconsideration review process.

(a) *Timely error notice.* Subject to the limitations on review in § 512.170, an RO participant that identifies and wishes to contest a suspected error in the calculation of its reconciliation payment or repayment amount or AQS must provide written notice of the suspected calculation error to CMS within 45 days of the date of the reconciliation report. Such timely error notice must be in a form and manner specified by CMS. RO participants are not permitted to contest the RO Model pricing methodology or AQS methodology.

(1) Unless a timely error notice is received by CMS within 45 days of the

date of issuance of a reconciliation report, the reconciliation payment or repayment amount determination specified in that reconciliation report is deemed binding and not subject to further review.

(2) If CMS receives a timely error notice, then CMS responds in writing within 30 days either to confirm that there was an error in the calculation or to verify that the calculation is correct. CMS may extend the deadline for its response upon written notice to the RO participant.

(3) Only the RO participant may use the timely error notice process described in this paragraph and the reconsideration review process described in paragraph (b) of this section.

(b) *Reconsideration review.* (1) *Reconsideration request by an RO participant.* (i) If the RO participant is dissatisfied with CMS' response to the timely error notice, then the RO participant may request a reconsideration review as specified in paragraph (b)(2) of this section.

(ii) If CMS does not receive a request for reconsideration from the RO participant within 10 days of the issue date of CMS' response to the RO participant's timely error notice, then CMS' response to the timely error notice is deemed binding and not subject to further review.

(2) *Submission of a reconsideration request.* (i) *Information needed in the reconsideration request.* The reconsideration review request must—

(A) Provide a detailed explanation of the basis for the dispute; and

(B) Include supporting documentation for the RO participant's assertion that CMS or its representatives did not accurately calculate the reconciliation payment or repayment amount or AQS in accordance with the terms of this subpart.

(3) *Form, manner, and deadline for submission of the reconsideration request.* The information specified in paragraph (b)(2)(i) of this section must be submitted—

(i) In a form and manner specified by CMS; and

(ii) Within 10 days of the date of the CMS response described in paragraph (a)(2) of this section.

(4) *Designation of and notification from a CMS-designated reconsideration official.*

(i) *Designation of reconsideration official.* CMS designates a reconsideration official who—

(A) Is authorized to receive such requests; and

(B) Was not involved in the responding to the RO participant's timely error notice.

(ii) *Notification to the RO participant.* The CMS-designated reconsideration official makes reasonable efforts to notify the RO participant and CMS in writing within 15 days of receiving the RO participant's reconsideration review request of the following:

(A) The issue(s) in dispute;

(B) The briefing schedule; and

(C) The review procedures.

(5) *Resolution review.* The CMS reconsideration official makes all reasonable efforts to complete the on-the-record resolution review and issue a written determination no later than 60 days after the submission of the final position paper in accordance with the reconsideration official's briefing schedule.

Subpart C—ESRD Treatment Choices Model

General

§ 512.300 Basis and scope.

(a) *Basis.* This subpart implements the test of the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model under section 1115A(b) of the Act. Except as specifically noted in this subpart, the regulations under this subpart must not be construed to affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, or program integrity.

(b) *Scope.* This subpart sets forth the following:

(1) The duration of the ETC Model.

(2) The method for selecting ETC Participants.

(3) The schedule and methodologies for the Home Dialysis Payment Adjustment and Performance Payment Adjustment.

(4) The methodology for ETC Participant performance assessment for purposes of the Performance Payment Adjustment, including beneficiary attribution, benchmarking and scoring, and calculating the Modality Performance Score.

(5) Monitoring and evaluation, including quality measure reporting.

(6) Medicare payment waivers.

§ 512.310 Definitions.

For purposes of this subpart, the following definitions apply.

Adjusted ESRD PPS per Treatment Base Rate means the per treatment payment amount as defined in § 413.230 of this chapter, including patient-level adjustments and facility-level adjustments, and excluding any applicable training adjustment, add-on payment amount, outlier payment amount, transitional drug add-on payment adjustment (TDAPA) amount, and transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) amount.

Benchmark Year (BY) means the 12-month period that begins 18 months prior to the start of a given measurement year (MY) from which data are used to construct benchmarks against which to score an ETC Participant's achievement and improvement on the home dialysis rate and transplant rate for the purpose of calculating the ETC Participant's MPS.

Clinician Home Dialysis Payment Adjustment (Clinician HDPA) means the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant, for the Managing Clinician's home dialysis claims, as described in §§ 512.345 and 512.350.

Clinician Performance Payment Adjustment (Clinician PPA) means the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant based on the Managing Clinician's MPS, as described in §§ 512.375(b) and 512.380.

Comparison Geographic Area(s) means those HRRs that are not Selected Geographic Areas.

ESRD Beneficiary means a beneficiary who meets either of the following:

(1) Is receiving dialysis or other services for end-stage renal disease, up to and including the month in which the beneficiary receives a kidney transplant up to and including the month in which the beneficiary receives a kidney transplant.

(2) Has already received a kidney transplant and has a non-AKI dialysis or MCP claim—

(i) At least 12 months after the beneficiary's latest transplant date; or

(ii) Less than 12 months after the beneficiary's latest transplant date and has a kidney transplant failure diagnosis code documented on any Medicare claim.

ESRD facility means an ESRD facility as specified in § 413.171 of this chapter.

ETC Participant means an ESRD facility or Managing Clinician that is required to participate in the ETC Model pursuant to § 512.325(a).

Facility Home Dialysis Payment Adjustment (Facility HDPA) means the payment adjustment to the Adjusted ESRD PPS per Treatment Base Rate for an ESRD facility that is an ETC Participant for the ESRD facility's home dialysis claims, as described in §§ 512.340 and 512.350.

Facility Performance Payment Adjustment (Facility PPA) means the payment adjustment to the Adjusted ESRD PPS per treatment base rate for an ESRD facility that is an ETC Participant based on the ESRD facility's MPS, as described in §§ 512.375(a) and 512.380.

Home Dialysis Payment Adjustment (HDPA) means either the Facility HDPA or the Clinician HDPA.

Home dialysis rate means the rate of ESRD Beneficiaries attributed to the ETC Participant who dialyzed at home during the relevant MY, as described in § 512.365(b).

Hospital referral regions (HRRs) means the regional markets for tertiary medical care derived from Medicare claims data as defined by the Dartmouth Atlas Project at *https://www.dartmouthatlas.org/.*

Kidney transplant means a kidney transplant, alone or in conjunction with any other organ.

Living donor transplant (LDT) Beneficiary means an ESRD Beneficiary who received a kidney transplant from a living donor.

Living donor transplant rate means the rate of ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries attributed to the ETC Participant who received a kidney transplant from a living donor during the MY, as described in § 512.365(c)(1)(ii) and § 512.365(c)(2)(ii).

Managing Clinician means a Medicare-enrolled physician or non-physician practitioner, identified by a National Provider Identifier (NPI), who furnishes and bills the MCP for managing one or more adult ESRD Beneficiaries.

Measurement Year (MY) means the 12-month period for which achievement and improvement on the home dialysis rate and transplant rate are assessed for the purpose of calculating the ETC Participant's MPS and corresponding PPA. Each MY included in the ETC Model and its corresponding PPA Period are specified in § 512.355(c).

Modality Performance Score (MPS) means the numeric performance score calculated for each ETC Participant based on the ETC Participant's home dialysis rate and transplant rate, as described in § 512.370(a), which is used to determine the amount of the ETC Participant's PPA, as described in § 512.380.

Monthly capitation payment (MCP) means the monthly capitated payment made for each ESRD Beneficiary to cover all routine professional services related to treatment of the patient's renal condition furnished by the physician or non-physician practitioner as specified in § 414.314 of this chapter.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162.

Performance Payment Adjustment (PPA) means either the Facility PPA or the Clinician PPA.

Performance Payment Adjustment Period (PPA Period) means the six-month period during which a PPA is applied in accordance with § 512.380.

Pre-emptive LDT Beneficiary means a beneficiary who received a kidney transplant from a living donor prior to beginning dialysis.

Selected Geographic Area(s) are those HRRs selected by CMS pursuant to § 512.325(b) for purposes of selecting ESRD facilities and Managing Clinicians required to participate in the ETC Model as ETC Participants.

Subsidiary ESRD facility is an ESRD facility owned in whole or in part by another legal entity.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the Internal Revenue Service in 26 CFR 301.6109–1.

Transplant rate means the sum of the transplant waitlist rate and the living donor transplant rate, as described in § 512.365(c).

Transplant waitlist rate means the rate of ESRD Beneficiaries attributed to the ETC Participant who were on the kidney transplant waitlist during the MY, as described in § 512.365(c)(1)(i)–(ii) and § 512.365(c)(2)(i)–(ii).

ESRD Treatment Choices Model Scope and Participants

§ 512.320 Duration.

CMS will apply the payment adjustments described in this subpart under the ETC Model to claims with claim service dates beginning on or after January 1, 2021, and ending on or before June 30, 2027.

§ 512.325 Participant selection and geographic areas.

(a) *Selected participants.* All Medicare-certified ESRD facilities and Medicare-enrolled Managing Clinicians located in a selected geographic area are required to participate in the ETC Model.

(b) *Selected Geographic Areas.* CMS establishes the Selected Geographic Areas by selecting all HRRs for which at least 20 percent of the component zip codes are located in Maryland, and a random sample of 30 percent of HRRs, stratified by Census-defined regions (Northeast, South, Midwest, and West). CMS excludes all U.S. Territories from the Selected Geographic Areas.

§ 512.330 Beneficiary notification.

(a) *General.* ETC Participants must prominently display informational materials in each of their office or facility locations where beneficiaries receive treatment to notify beneficiaries that the ETC Participant is participating in the ETC Model. CMS provides the ETC Participant with a template for these materials, indicating the required content that the ETC Participant must not change and places where the ETC Participant may insert its own original content. The CMS-provided template for the beneficiary notification will include, without limitation, the following information:

(1) A notification that the ETC Participant is participating in the ETC Model;

(2) Instructions on how to contact the ESRD Network Organizations with any questions or concerns about the ETC Participant's participation in the Model;

(3) An affirmation of the ESRD Beneficiary's protections under Medicare, including the beneficiary's freedom to choose his or her provider or supplier and to select the treatment modality of his or her choice.

(b) *Applicability of general Innovation Center model provisions.* The requirement described in § 512.120(c)(2) shall not apply to the CMS-provided materials described in paragraph (a) of this section. All other ETC Participant communications that are descriptive model materials and activities as defined under § 512.110 must meet the requirements described in § 512.120(c).

Home Dialysis Payment Adjustment

§ 512.340 Payments subject to the Facility HDPA.

CMS adjusts the Adjusted ESRD PPS per Treatment Base Rate by the Facility HDPA on claim lines with Type of Bill 072X, and with condition codes 74 or 76, when the claim is submitted by an ESRD facility that is an ETC Participant with a claim service date during a calendar year subject to adjustment as described in § 512.350 and the beneficiary is at least 18 years old before the first day of the month.

§ 512.345 Payments subject to the Clinician HDPA.

CMS adjusts the amount otherwise paid under Medicare Part B with respect to MCP claims on claim lines with CPT codes 90965 and 90966 by the Clinician HDPA when the claim is submitted by a Managing Clinician who is an ETC Participant with a claim service date during a calendar year subject to

adjustment as described in § 512.350 and the beneficiary is at least 18 years old before the first day of the month.

§ 512.350 Schedule of home dialysis payment adjustments.

CMS adjusts the payments specified in § 512.340 by the Facility HDPA and adjusts the payments specified in § 512.345 by the Clinician HDPA, according to the following schedule:

(a) Calendar year 2021: +3 percent.

(b) Calendar year 2022: +2 percent.

(c) Calendar year 2023: +1 percent.

Performance Payment Adjustment

§ 512.355 Schedule of performance assessment and performance payment adjustment.

(a) *Measurement Years.* CMS assesses ETC Participant performance on the home dialysis rate and the transplant rate during each of the MYs. The first MY begins on January 1, 2021, and the final MY ends on June 30, 2026.

(b) *Performance Payment Adjustment Period.* CMS adjusts payments for ETC Participants by the PPA during each of the PPA Periods, each of which corresponds to a MY. The first PPA Period begins on July 1, 2022, and the final PPA Period ends on June 30, 2027.

(c) *Measurement Years and Performance Payment Adjustment Periods.* MYs and PPA Periods follow the following schedule:

Table 1 to Paragraph (c)--ETC Model Schedule of Measurement Years and PPA Periods

Measurement Year (MY)	Performance Payment Adjustment (PPA) Period
MY 1 – 1/1/2021 through 12/31/2021	PPA Period 1 – 7/1/2022 through 12/31/2022
MY 2 – 7/1/2021 through 6/30/2022	PPA Period 2 – 1/1/2023 through 6/30/2023
MY 3 – 1/1/2022 through 12/31/2022	PPA Period 3 – 7/1/2023 through 12/31/2023
MY 4 – 7/1/2022 through 6/30/2023	PPA Period 4 – 1/1/2024 through 6/30/2024
MY 5 – 1/1/2023 through 12/31/2023	PPA Period 5 – 7/1/2024 through 12/31/2024
MY 6 – 7/1/2023 through 6/30/2024	PPA Period 6 – 1/1/2025 through 6/30/2025
MY 7 – 1/1/2024 through 12/31/2024	PPA Period 7 – 7/1/2025 through 12/31/2025
MY 8 – 7/1/2024 through 6/30/2025	PPA Period 8 – 1/1/2026 through 6/30/2026
MY 9 – 1/1/2025 through 12/31/2025	PPA Period 9 – 7/1/2026 through 12/31/2026
MY 10 – 7/1/2025 through 6/30/2026	PPA Period 10 – 1/1/2027 through 6/30/2027

§ 512.360 Beneficiary population and attribution.

(a) *General.* Except as provided in paragraph (b) of this section, CMS attributes ESRD Beneficiaries to an ETC Participant for each month during a MY based on the ESRD Beneficiary's receipt of services specified in paragraph (c) of this section during that month, for the purpose of assessing the ETC Participant's performance on the home dialysis rate and transplant rate during that MY. Except as provided in paragraph (b) of this section, CMS attributes Pre-emptive LDT Beneficiaries to a Managing Clinician for one or more months during a MY based on the Pre-emptive LDT Beneficiary's receipt of services specified in paragraph (c)(2) of this section during that MY, for the purpose of assessing the Managing Clinician's performance on the living donor transplant rate during that MY. CMS attributes ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries to the ETC Participant for each month during a MY retrospectively after the end of the MY. CMS attributes an ESRD Beneficiary to no more than one ESRD facility and no more than one Managing Clinician for a given month during a given MY. CMS attributes a Pre-emptive LDT Beneficiary to no more than one Managing Clinician for a given MY.

(b) *Exclusions from attribution.* CMS does not attribute an ESRD Beneficiary or Pre-emptive LDT Beneficiary to an ETC Participant for a month if, at any point during the month, the beneficiary—

(1) Is not enrolled in Medicare Part B;

(2) Is enrolled in Medicare Advantage, a cost plan, or other Medicare managed care plan;

(3) Does not reside in the United States;

(4) Is younger than 18 years of age before the first day of the month of the claim service date;

(5) Has elected hospice;

(6) Is receiving dialysis only for any acute kidney injury (AKI);

(7) Has a diagnosis of dementia at any point during the month of the claim service date or the preceding 12 months, as identified using the most recent dementia-related criteria at the time of beneficiary attribution, using the CMS–HCC (Hierarchical Condition Category) Risk Adjustment Model ICD–10–CM Mappings; or

(8) Is residing in or receiving dialysis in a skilled nursing facility (SNF) or nursing facility.

(c) *Attribution services.* (1) *ESRD facility beneficiary attribution.* To be attributed to an ESRD facility that is an ETC Participant for a month, an ESRD Beneficiary must not be excluded based on the criteria specified in paragraph (b) of this section and must have received renal dialysis services during the month from the ESRD facility. CMS does not attribute Pre-emptive LDT Beneficiaries to ESRD facilities.

(i) An ESRD Beneficiary is attributed to the ESRD facility at which the ESRD Beneficiary received the plurality of his or her dialysis treatments in that month, other than renal dialysis services for AKI, as identified by claims with Type of Bill 072X, with claim service dates at the claim header through date during the month.

(ii) If the ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month, CMS attributes the ESRD Beneficiary to the ESRD facility at which the beneficiary received the earliest dialysis treatment that month. If the ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month and the ESRD beneficiary received the earliest dialysis treatment that month from more than one ESRD

facility, CMS attributes the beneficiary to one of the ESRD facilities that furnished the earliest dialysis treatment that month at random.

(2) *Managing Clinician beneficiary attribution.* (i) An ESRD beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to a Managing Clinician who is an ETC Participant for a month if that Managing Clinician submitted an MCP claim for services furnished to the beneficiary, identified with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, with claim service dates at the claim line through date during the month.

(A) If more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary with a claim service date at the claim line during the month, the ESRD Beneficiary is attributed to the Managing Clinician associated with the earliest claim service date at the claim line through date during the month.

(B) If more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary with the same earliest claim service date at the claim line through date for the month, the ESRD Beneficiary is randomly attributed to one of these Managing Clinicians.

(ii) A Pre-emptive LDT Beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to the Managing Clinician with whom the beneficiary has had the most claims between the start of the MY and the month in which the beneficiary received the transplant for all months between the start of the MY and the month of the transplant.

(A) If no Managing Clinician has had the plurality of claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary during the MY, the Pre-emptive LDT Beneficiary is attributed to the Managing Clinician associated with the latest claim service date at the claim line through date during the MY up to and including the month of the transplant.

(B) If no Managing Clinician had the plurality of claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of services for that beneficiary during the MY, and more than one of those Managing Clinicians had the latest claim service date at the claim line through date during the MY up to and including the month of the transplant, the Pre-emptive LDT Beneficiary is randomly attributed to one of these Managing Clinicians.

§ 512.365 Performance assessment.

(a) *General.* For each MY, CMS separately assesses the home dialysis rate and the transplant rate for each ETC Participant based on the population of ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries attributed to the ETC Participant under § 512.360. Information used to calculate the home dialysis rate and the transplant rate includes Medicare claims data, Medicare administrative data, and data from the Scientific Registry of Transplant Recipients.

(b) *Home dialysis rate.* CMS calculates the home dialysis rate for ESRD facilities and Managing Clinicians as follows.

(1) *Home dialysis rate for ESRD facilities.* (i) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is composed of 12 beneficiary months. Months during which attributed ESRD Beneficiaries received maintenance dialysis are identified by claims with Type of Bill 072X.

(ii) The numerator is the total number of home dialysis treatment beneficiary years plus one half the total number of self dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY.

(A) Home dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with Type of Bill 072X and condition codes 74 or 76.

(B) Self dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received self dialysis in center, such that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed ESRD Beneficiary received self dialysis are identified by claims with Type of Bill 072X and condition code 72.

(iii) Information used to calculate the ESRD facility home dialysis rate includes Medicare claims data and Medicare administrative data.

(iv) The ESRD facility home dialysis rate is aggregated, as described in paragraph (e)(1) of this section.

(2) *Home dialysis rate for Managing Clinicians.* (i) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966.

(ii) The numerator is the total number of home dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY plus one half the total number of self dialysis treatment beneficiary years.

(A) Home dialysis treatment beneficiary years included in the numerator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with CPT codes 90965 or 90966.

(B) Self-dialysis treatment beneficiary years included in the numerator are composed of those months during which an attributed ESRD Beneficiary received self dialysis in center, such that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed ESRD Beneficiary received self dialysis are identified by claims with Type of Bill 072X and condition code 72.

(iii) Information used to calculate the Managing Clinician home dialysis rate includes Medicare claims data and Medicare administrative data.

(iv) The Managing Clinician home dialysis rate is aggregated, as described in paragraph (e)(2) of this section.

(c) *Transplant rate.* CMS calculates the transplant rate for ETC Participants as follows.

(1) *Transplant rate for ESRD facilities.* The transplant rate for ESRD facilities is the sum of the transplant waitlist rate for ESRD facilities, as described in paragraph (c)(1)(i) of this section, and the living donor transplant rate for ESRD facilities, as described in paragraph (c)(1)(ii) of this section.

(i) *Transplant waitlist rate for ESRD facilities.* (A) The denominator is the

total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month.

(B) The numerator is the total number of attributed beneficiary years for which attributed ESRD Beneficiaries were on the kidney transplant waitlist. Months during which an attributed ESRD Beneficiary was on the kidney transplant waitlist are identified using data from the SRTR database.

(ii) *Living donor transplant rate for ESRD facilities.* (A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month.

(B) The numerator is the total number of attributed beneficiary years for LDT Beneficiaries during the MY. Beneficiary years for LDT Beneficiaries included in the numerator are composed of those months between the beginning of the MY up to and including the month of the transplant for LDT Beneficiaries attributed to an ESRD facility during the month of the transplant. LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(iii) The ESRD facility transplant waitlist rate is risk adjusted, as described in paragraph (d) of this section. The ESRD facility transplant rate is aggregated, as described in paragraph (e)(1) of this section.

(2) *Transplant rate for Managing Clinicians.* The transplant rate for Managing Clinicians is the sum of the transplant waitlist rate for Managing Clinicians, as described in paragraph (c)(2)(i) of this section, and the living donor transplant rate for Managing Clinicians, as described in paragraph (c)(2)(ii) of this section.

(i) *Transplant waitlist rate for Managing Clinicians.* (A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month.

(B) The numerator is the total number of attributed beneficiary years for which attributed ESRD Beneficiaries were on the kidney transplant waitlist. Months during which an attributed ESRD Beneficiary was on the kidney transplant waitlist are identified using data from the SRTR database.

(ii) *Living donor transplant rate for Managing Clinicians.* (A) The denominator is the sum of the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY and the total Pre-emptive LDT beneficiary years for attributed beneficiaries during the MY.

(*1*) Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month.

(*2*) Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant. Pre-emptive LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(B) The numerator is the sum of the total number of attributed beneficiary years for LDT Beneficiaries during the MY and the total number of attributed beneficiary years for Pre-emptive LDT Beneficiaries during the MY.

(*1*) Beneficiary years for LDT Beneficiaries included in the numerator are composed of those months during which an LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the transplant. LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(*2*) Beneficiary years for Pre-emptive LDT Beneficiaries included in the numerator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the transplant. Pre-emptive LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(iii) The Managing Clinician transplant waitlist rate is risk adjusted, as described in paragraph (d) of this section. The Managing Clinician transplant rate is aggregated, as described in paragraph (e)(2) of this section.

(d) *Risk adjustment.* (1) CMS risk adjusts the transplant waitlist rate based on beneficiary age with separate risk coefficients for the following age categories of beneficiaries, with age computed on the last day of each month of the MY:

(i) 18 to 55.

(ii) 56 to 70.

(iii) 71 to 74.

(2) CMS risk adjusts the transplant waitlist rate to account for the relative percentage of the population of beneficiaries attributed to the ETC Participant in each age category relative to the national age distribution of beneficiaries not excluded from attribution.

(e) *Aggregation.* (1) *Aggregation for ESRD facilities.* An ESRD facility's home dialysis rate and transplant rate are aggregated to the ESRD facility's aggregation group. The aggregation group for a Subsidiary ESRD facility includes all ESRD facilities owned in whole or in part by the same legal entity located in the HRR in which the ESRD facility is located. An ESRD facility that is not a Subsidiary ESRD facility is not included in an aggregation group.

(2) *Aggregation for Managing Clinicians.* A Managing Clinician's home dialysis rate and transplant rate are aggregated to the Managing Clinician's aggregation group. The

aggregation group for a Managing Clinician who is—

(i) In a group practice is the practice group level, as identified by practice TIN; or

(ii) A solo practitioner is the individual clinician level, as identified by NPI.

§ 512.370 Benchmarking and scoring.

(a) *General.* (1) CMS assesses the home dialysis rate and transplant rate for each ETC Participant against the applicable benchmarks to calculate an—

(i) Achievement score, as described in paragraph (b) of this section; and

(ii) Improvement score, as described in paragraph (c) of this section.

(2)(i) CMS calculates the ETC Participant's MPS as the weighted sum of the higher of the achievement score or the improvement score for the ETC Participant's home dialysis rate and transplant rate, as described in paragraph (d) of this section.

(ii) The ETC Participant's MPS determines the ETC Participant's PPA, as described in § 512.380.

(b) *Achievement scoring.* CMS assesses ETC Participant performance at the aggregation group level on the home dialysis rate and transplant rate against benchmarks constructed based on the home dialysis rate and transplant rate among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. CMS uses the following scoring methodology to assess an ETC Participant's achievement score.

(1) *90th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 2 points.

(2) *75th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 1.5 points.

(3) *50th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 1 point.

(4) *30th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 0.5 points.

(5) *<30th Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 0 points.

(c) *Improvement scoring.* CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate against benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year. CMS uses the following scoring methodology to assess an ETC Participant's improvement score.

(1) *Greater than 10 percent improvement relative to the Benchmark Year rate:* 1.5 points.

(2) *Greater than 5 percent improvement relative to the Benchmark Year rate:* 1 point.

(3) *Greater than 0 percent improvement relative to the Benchmark Year rate:* 0.5 points.

(4) *Less than or equal to the Benchmark Year rate:* 0 points.

(d) *Modality Performance Score.* CMS calculates the ETC Participant's MPS as the higher of ETC Participant's achievement score or improvement score for the home dialysis rate, together with the higher of the ETC Participant's achievement score or improvement score for the transplant rate, weighted such that the ETC Participant's score for the home dialysis rate constitutes ⅔ of the MPS and the ETC Participant's score for the transplant rate constitutes ⅓ of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS:

$$\textit{Modality Performance Score} = 2 \times (\textit{Higher of the home dialysis achievement or improvement score}) + (\textit{Higher of the transplant achievement or improvement score})$$

§ 512.375 Payments subject to adjustment.

(a) *Facility PPA.* CMS adjusts the Adjusted ESRD PPS per Treatment Base Rate by the Facility PPA on claim lines with Type of Bill 072X, when the claim is submitted by an ETC Participant that is an ESRD facility and the beneficiary is at least 18 years old before the first day of the month, on claims with claim service dates during the applicable PPA Period as described in § 512.355(c).

(b) *Clinician PPA.* CMS adjusts the amount otherwise paid under Medicare Part B with respect to MCP claims on claim lines with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965 and 90966 by the Clinician PPA when the claim is submitted by an ETC Participant who is a Managing Clinician and the beneficiary is at least 18 years old before the first day of the month, on claims with claim service dates during the applicable PPA Period as described in § 512.355(c).

§ 512.380 PPA Amounts and schedules.

CMS adjusts the payments described in § 512.375 based on the ETC Participant's MPS calculated as described in § 512.370(d) according to the following amounts and schedules in Table 1 and Table 2 to § 512.380.

Table 1 to § 512.380 – Facility PPA Amounts and Schedule

	MPS	Performance Payment Adjustment Period				
		1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Facility Performance Payment Adjustment	≤ 6	+4.0%	+5.0%	+6.0%	+7.0%	+8.0%
	≤ 5	+2.0%	+2.5%	+3.0%	+3.5%	+4.0%
	≤ 3.5	0%	0%	0%	0%	0%
	≤ 2	-2.5%	-3.0%	-3.5%	-4.5%	-5.0%
	≤ .5	-5.0%	-6.0%	-7.0%	-9.0%	-10.0%

Table 2 to § 512.380 – Clinician PPA Amounts and Schedule

	MPS	Performance Payment Adjustment Period				
		1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Clinician Performance Payment Adjustment	≤ 6	+4.0%	+5.0%	+6.0%	+7.0%	+8.0%
	≤ 5	+2.0%	+2.5%	+3.0%	+3.5%	+4.0%
	≤ 3.5	0%	0%	0%	0%	0%
	≤ 2	-2.5%	-3.0%	-3.5%	-4.0%	-4.5%
	≤ .5	-5.0%	-6.0%	-7.0%	-8.0%	-9.0%

§ 512.385 PPA exclusions.

(a) *ESRD facilities.* CMS excludes an aggregation group (as described in § 512.365(e)(1) of Subsidiary ESRD facilities with fewer than 11 attributed ESRD beneficiary years during an MY from the applicability of the Facility PPA for the corresponding PPA Period. CMS excludes ESRD facilities that are not Subsidiary ESRD facilities with fewer than 11 attributed ESRD beneficiary years during an MY from the applicability of the Facility PPA for the corresponding PPA Period.

(b) *Managing Clinicians.* CMS excludes an aggregation group (as described in § 512.365(e)(2)) of Managing Clinicians with fewer than 11 attributed ESRD beneficiary years during an MY from the applicability of the Clinician PPA for the corresponding PPA Period.

§ 512.390 Notification and targeted review.

(a) *Notification.* CMS will notify each ETC Participant, in a form and manner determined by CMS, of the ETC Participant's attributed beneficiaries, MPS, and PPA for a PPA Period no later than one month before the start of the applicable PPA Period.

(b) *Targeted review process.* An ETC Participant may request a targeted review of the calculation of the MPS. Requests for targeted review are limited to the calculation of the MPS, and may not be submitted in regards to: The methodology used to determine the MPS; or the establishment of the home dialysis rate methodology, transplant rate methodology, achievement and improvement benchmarks and benchmarking methodology, or PPA amounts. The process for targeted reviews is as follows:

(1) An ETC Participant has 90 days (or a later date specified by CMS) to submit a request for a targeted review, which begins on the day CMS makes available the MPS.

(2) CMS will respond to each request for targeted review timely submitted and determine whether a targeted review is warranted.

(3) The ETC Participant may include additional information in support of the request for targeted review at the time the request is submitted. If CMS requests additional information from the ETC Participant, it must be provided and received within 30 days of the request. Non-responsiveness to the request for additional information may result in the closure of the targeted review request.

(4) If, upon completion of a targeted review, CMS finds that there was an error in the calculation of the ETC Participant's MPS such that an incorrect PPA has been applied during the PPA period, CMS shall notify the ETC Participant and must resolve any resulting discrepancy in payment that arises from the application of an incorrect PPA in a time and manner determined by CMS.

(5) Decisions based on targeted review are final, and there is no further review or appeal.

Quality Monitoring

§ 512.395 Quality measures.

CMS collects data on these two quality measures for ESRD facilities that are ETC Participants to monitor for changes in quality outcomes. CMS conducts data collection and measure calculation using claims data and other Medicare administrative data, including enrollment data:

(a) Standardized Mortality Ratio (SMR); NQF #0369.

(b) Standardized Hospitalization Ratio (SHR); NQF #1463.

Medicare Program Waivers

§ 512.397 ETC Model Medicare program waivers.

The following provisions are waived solely for purposes of testing the ETC Model.

(a)(1) *Medicare payment waivers.* CMS waives the requirements of sections 1833(a), 1833(b), 1848(a)(1), 1881(b), and 1881(h)(1)(A) of the Act only to the extent necessary to make the payment adjustments under the ETC Model described in this subpart.

(2) *Beneficiary cost sharing.* The payment adjustments under the ETC Model described in this subpart do not affect the beneficiary cost-sharing amounts for Part B services furnished by ETC Participants under the ETC Model.

(b) CMS waives the following requirements of title XVIII of the Act solely for purposes of testing the ETC Model:

(1) CMS waives the requirement under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(a) and (c)(2)(i) of this chapter that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish KDE services to allow KDE services to be provided by clinical staff under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. The KDE benefit must be furnished and billed by a Physician, clinical nurse specialist, licensed social worker, nurse practitioner, physician assistant, registered dietician/nutrition professional, or a clinic/group practice.

(2) CMS waives the requirement that the KDE is covered only for Stage IV chronic kidney disease (CKD) patients under section 1861(ggg)(1)(A) of the Act and § 410.48(b)(1) of this chapter to permit beneficiaries diagnosed with CKD Stage V or within the first 6 months of starting dialysis to receive the KDE benefit.

(3) CMS waives the requirement that the content of the KDE sessions include the management of co-morbidities, including delaying the need for dialysis, under § 410.48(d)(1) of this chapter when such services are furnished to beneficiaries with CKD Stage V or ESRD, unless such content is relevant for the beneficiary.

(4) CMS waives the requirement that an outcomes assessment designed to measure beneficiary knowledge about chronic kidney disease and its treatment be performed by a qualified clinician as part of one of the KDE sessions under § 410.48(d)(5)(iii) of this chapter, provided that such outcomes assessment is performed within 1 month of the final KDE session by qualified staff.

Dated: September 4, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 9, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–20907 Filed 9–21–20; 11:15 am]

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; 12-Month Finding for Purple Lilliput; Threatened Species Status With Section 4(d) Rule for Longsolid and Round Hickorynut and Designation of Critical Habitat; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2020–0010; FF09E21000 FXES11110900000 201]

RIN 1018–BD32

Endangered and Threatened Wildlife and Plants; 12-Month Finding for Purple Lilliput; Threatened Species Status With Section 4(d) Rule for Longsolid and Round Hickorynut and Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; announcement of 12-month findings.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce 12-month findings on a petition to list the purple lilliput (*Toxolasma lividum*), longsolid (*Fusconaia subrotunda*), and round hickorynut (*Obovaria subrotunda*) freshwater mussels as endangered or threatened species and to designate critical habitat under the Endangered Species Act of 1973, as amended (Act). We find that listing the longsolid and round hickorynut is warranted. Accordingly, we propose to list the longsolid and round hickorynut as threatened species with a rule issued under section 4(d) of the Act (''4(d) rule''). If we finalize this rule as proposed, it would add these species to the List of Endangered and Threatened Wildlife and extend the Act's protections to the species. We also propose to designate critical habitat for the longsolid and round hickorynut under the Act. For the longsolid, approximately 1,115 river miles (1,794 kilometers), all of which is occupied by the species, in Pennsylvania, Kentucky, West Virginia, Virginia, Tennessee, and Alabama fall within the boundaries of the proposed critical habitat designation. For the round hickorynut, approximately 921 river miles (1,482 kilometers), all of which is occupied by the species, in Pennsylvania, Ohio, Indiana, Kentucky, West Virginia, Tennessee, Alabama, and Mississippi fall within the boundaries of the proposed critical habitat designation. Finally, we announce the availability of a draft economic analysis of the proposed designation of critical habitat for the longsolid and round hickorynut. After a thorough review of the best available scientific and commercial information, we find that it is not warranted at this time to list the purple lilliput. We ask the public to submit to us at any time new information relevant to the status of purple lilliput or its habitat.

DATES: For the proposed rule to list and designate critical habitat for the longsolid and round hickorynut, we will accept comments received or postmarked on or before December 28, 2020. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by November 13, 2020. *Petition finding for the purple lilliput:* For the purple lilliput, the finding in this document was made on September 29, 2020.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R4–ES–2020–0010, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R4–ES–2020–0010, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: For the critical habitat designation, the coordinates or plot points or both from which the maps are generated are included in the administrative record and are available at *https://www.fws.gov/Asheville/* and at *http://www.regulations.gov* under Docket No. FWS–R4–ES–2020–0010. Any additional tools or supporting information that we may develop for the critical habitat designation will also be available at the Service website set out above, and may also be included in the preamble and/or at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Janet Mizzi, Field Supervisor, U.S. Fish and Wildlife Service, Asheville Ecological Services Field Office, 160 Zillicoa St., Asheville, NC 28801; telephone 828–258–3939. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if we determine that a species is an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within one year. To the maximum extent prudent and determinable, we must designate critical habitat for any species that we determine to be an endangered or threatened species under the Act. Listing a species as an endangered or threatened species and designation of critical habitat can only be completed by issuing a rule.

What this document does. We find that listing the purple lilliput as an endangered or threatened species is not warranted. We propose to list the longsolid and round hickorynut as threatened species with a rule under section 4(d) of the Act, and we propose the designation of critical habitat for these two species.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that threats to the longsolid and round hickorynut include habitat degradation or loss from a variety of sources (*e.g.,* dams and other barriers, resource extraction); degraded water quality from chemical contamination and erosion from development, agriculture, mining, and timber operations; direct mortality from dredging; residual impacts (reduced population size) from historical harvest; and the proliferation of invasive, nonnative species. These threats also contribute to the negative effects associated with the species' small population size.

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary) to designate critical habitat concurrent with listing to the maximum extent prudent and determinable. Section

3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat.

Peer review. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought the expert opinions of 10 appropriate specialists regarding the purple lilliput species status assessment (SSA) report, 11 regarding the longsolid SSA report, and 10 regarding the round hickorynut SSA report. We received responses from three, none, and one specialists, respectively; feedback we received informed our findings and this proposed rule. The purpose of peer review is to ensure that our listing determinations, critical habitat designations, and 4(d) rules are based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise in the biology, habitat, and threats to the species.

Because we will consider all comments and information we receive during the comment period, our final determinations for the longsolid and round hickorynut may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may conclude that either the longsolid or round hickorynut are endangered instead of threatened, or we may conclude that either species does not warrant listing as either an endangered species or a threatened species. Such final decisions would be a logical outgrowth of this proposal, as long as we: (1) Base the decisions on the best scientific and commercial data available after considering all of the relevant factors; (2) do not rely on factors Congress has not intended us to consider; and (3) articulate a rational connection between the facts found and the conclusions made, including why we changed our conclusion.

Acronyms and Abbreviations Used

We use several acronyms and abbreviations throughout the preamble of this finding and proposed rule. To assist the reader, we list them here:

Act = Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*)
AMD = acid mine and saline drainage
BMP = best management practice
CBD = Center for Biological Diversity
DEA = draft economic analysis
IEM = incremental effects memorandum
HUC = hydrologic unit code
LS = longsolid
ppm = parts per million
RFA = Regulatory Flexibility Act
RH = round hickorynut
SSA = species status assessment
TDEC = Tennessee Department of Environment and Conservation
TVA = Tennessee Valley Authority

Information Requested

For the purple lilliput, we ask the public to submit to us at any time new information relevant to the species' status or its habitat.

For the longsolid and round hickorynut, we intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

(1) The species' biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, their habitats, or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to the species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this species, including the locations of any additional populations of this species.

(5) Information on regulations that are necessary and advisable to provide for the conservation of the longsolid and round hickorynut, and that the Service can consider in developing a 4(d) rule for the species. In particular, we seek information concerning the extent to which we should include any of the section 9 prohibitions in the 4(d) rule or whether any other forms of take should be excepted from the prohibitions in the 4(d) rule.

(6) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act, including information to inform the following factors that the regulations identify as reasons why designation of critical habitat may be not prudent:

(a) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(b) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(c) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States; or

(d) No areas meet the definition of critical habitat.

(7) Specific information on:

(a) The amount and distribution of longsolid or round hickorynut habitat;

(b) What areas, that were occupied at the time of listing and that contain the physical or biological features essential to the conservation of the species, should be included in the designation and why;

(c) Special management considerations or protection that may be needed in critical habitat areas we are proposing, including managing for the potential effects of climate change; and

(d) What areas not occupied at the time of listing are essential for the conservation of the species. We particularly seek comments:

(i) Regarding whether occupied areas are inadequate for the conservation of the species; and

(ii) Providing specific information regarding whether or not unoccupied areas would, with reasonable certainty, contribute to the conservation of the species and contain at least one physical or biological feature essential to the conservation of the species.

(8) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(9) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation, and the related benefits of including or excluding specific areas.

(10) Information on the extent to which the description of probable economic impacts in the draft economic analysis is a reasonable estimate of the likely economic impacts (*i.e.,* incremental impacts estimated to be less than $327,000 per year for the next 10 years).

(11) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act.

(12) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES.** We request that you send comments only by the methods described in **ADDRESSES.**

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov.*

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal for the longsolid and round hickorynut, if requested. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT.** We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. For the immediate future, we will provide these public hearings using webinars that will be announced on the Service's website, in addition to the **Federal Register**. The use of these virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

On April 20, 2010, we received a petition from the Center for Biological Diversity (CBD), Alabama Rivers Alliance, Clinch Coalition, Dogwood Alliance, Gulf Restoration Network, Tennessee Forests Council, and West Virginia Highlands Conservancy (referred to below as the CBD petition) to list 404 aquatic, riparian, and wetland species, including the purple lilliput, longsolid, and round hickorynut, as endangered or threatened species under the Act. On September 27, 2011, we published a 90-day finding that the petition contained substantial information indicating listing may be warranted for these three species (76 FR 59836).

On April 17, 2019, CBD filed a complaint challenging the Service's failure to complete 12-month findings for these species within the statutory deadline. The Service and CBD reached a stipulated settlement agreement whereby the Service agreed to deliver 12-month findings for purple lilliput, longsolid, and round hickorynut to the Office of the Federal Register by June 30, 2020. Subsequently, we requested a 30-day extension that was approved by CBD and granted by the Court on May 12, 2020, whereby the Service would deliver 12-month findings to the Office of the Federal Register by July 30, 2020. This document constitutes our 12-month finding on the April 20, 2010, petition to list the purple lilliput, longsolid, and round hickorynut under the Act, and complies with the October 11, 2019, stipulated settlement agreement and May 12, 2020, extension.

Supporting Documents

An SSA team prepared SSA reports for the purple lilliput, longsolid, and round hickorynut. The SSA team was composed of Service biologists, in consultation with other species experts. The SSA reports represent a compilation of the best scientific and commercial data available concerning the status of these species, including the impacts of past, present, and future factors (both negative and beneficial) affecting these species. As discussed above under *Peer review,* we solicited appropriate peer review of all three of the species' SSA reports. In addition, we sent the draft SSA reports for review to Federal partners, State partners, and scientists with expertise in aquatic ecology and freshwater mussel biology, taxonomy, and conservation. Although we notified tribal nations early in the SSA process for these species, we did not receive any information or comments regarding these species on tribal lands in the United States. The round hickorynut SSA report was also shared with the Canadian government and the Walpole Islands First National Indian Reservation in Canada.

I. Finding for Purple Lilliput

Under section 4(b)(3)(B) of the Act, we are required to make a finding whether or not a petitioned action is warranted within 12 months after receiving any petition that we have determined contains substantial scientific or commercial information indicating that the petitioned action may be warranted (''12-month finding''). We must make a finding that the petitioned action is: (1) Not warranted; (2) warranted; or (3) warranted but precluded. ''Warranted but precluded'' means that (a) the petitioned action is warranted, but the immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are endangered or threatened species, and (b) expeditious progress is being made to add qualified species to the Lists of Endangered and Threatened Wildlife and Plants (Lists) and to remove from the Lists species for which the protections of the Act are no longer necessary. Section 4(b)(3)(C) of the Act requires that, when we find that a

petitioned action is warranted but precluded, we treat the petition as though resubmitted on the date of such finding, that is, requiring that a subsequent finding be made within 12 months of that date. We must publish these 12-month findings in the **Federal Register**.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an ''endangered species'' or a ''threatened species.'' The Act defines an endangered species as a species that is ''in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as a species that is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The Act requires that we determine whether any species is an ''endangered species'' or a ''threatened species'' because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Services can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

In conducting our evaluation of the five factors provided in section 4(a)(1) of the Act to determine whether the purple lilliput (*Toxolasma lividum;* Service 2020a, entire) currently meets the definition of ''endangered species'' or ''threatened species,'' we considered and thoroughly evaluated the best scientific and commercial data available regarding the past, present, and future stressors and threats. We reviewed the petition, information available in our files, and other available published and unpublished information. This evaluation may include information from recognized experts; Federal, State, and tribal governments; academic institutions; private entities; and other members of the public. After comprehensive assessment of the best scientific and commercial data available, we determined that the purple lilliput does not meet the definition of an endangered or a threatened species.

The species assessment for the purple lilliput contains more detailed biological information, a thorough analysis of the listing factors, and an explanation of why we determined that this species does not meet the definition of an endangered species or a threatened species. This supporting information can be found on the internet at *http://www.regulations.gov* under docket number FWS–R4–ES–2020–0010. The following is an informational summary for the purple lilliput finding in this document.

Summary of Finding

The purple lilliput is a freshwater mussel that belongs to the order Unionida, also known as the naiads and pearly mussels. Purple lilliput adult mussels are small, with a relatively thick, inflated, oval shell (up to 1.5 inches (in) (38 millimeters (mm)) (Williams et al. 2008, p. 719), and the shell typically darkens with age. The species is currently found in the Great Lakes, Ohio, Cumberland, Tennessee, Arkansas-White-Red, and Lower Mississippi major river basins, within the States of Alabama, Kentucky, Missouri, Arkansas, Ohio, Illinois, Indiana, Michigan, and Tennessee. It is considered extirpated from North Carolina and Georgia, and potentially extirpated from Oklahoma and Virginia. Although it has never been collected within the State of Kansas, it occurs in the Spring River drainage nearby in Missouri, and thus potentially occurs in Kansas, and may eventually be discovered there (Obermeyer et al. 1997, p. 49; Angelo *et al.* 2009, p. 95).

Little information is known specific to purple lilliput; thus, we relied on surrogate life-history information for closely related species when necessary, including for sex-specific information, for information on reproduction, and for determining appropriate temperatures for glochidia metamorphosis. For example, the purple lilliput is a short-lived species, estimated to live 5 to 10

years (possibly up to 15 years), based on the life expectancy of the Savannah lilliput (*Toxolasma pullus*) (9 years; Hanlon and Levine 2004, p. 294), lilliput (*T. parvum*) (at least 5 years; Haag and Rypel 2011, p. 229), and Texas lilliput (*T. texasiense*) (11 years; Haag and Rypel 2011, p. 229).

The purple lilliput can be found in a wide range of habitats and a variety of substrates in rivers and streams at depths less than 3.3 feet (ft) (1 meter (m)) (Gordon and Layzer 1989, p. 34). It may be located in coarse substrates such as cobble and gravel, or fine-particle substrates such as packed sand, silty clay, and mud. It is commonly collected in and near shorelines, in backwaters, and in vegetation and root masses in waters just a few centimeters deep. Purple lilliput also exhibits some ability to inhabit lentic (still water) environments (Roe 2002, p. 5). In unimpounded reaches, the species commonly occurs in a range of slow to swift currents, and from shallow, rocky gravel points, mud, and sandbars in overbank areas and embayments (Parmalee and Bogan 1998, p. 231; Williams et al. 2008, p. 720).

The purple lilliput is a suspension-feeder that filters water and nutrients to eat. Its diet consists of a mixture of algae, bacteria, detritus, and microscopic animals (Gatenby et al. 1996, p. 606; Strayer et al. 2004, p. 430). It has also been surmised that dissolved organic matter may be a significant source of nutrition (Strayer et al. 2004, p. 431). For their first several months, juvenile mussels ingest food through their foot and are thus deposit feeders, although they may also filter interstitial pore water and soft sediments (Yeager et al. 1994, p. 221; Haag 2012, p. 26). Due to the mechanisms by which food and nutrients are taken in, freshwater mussels collect and absorb toxins (Service 2020a, pp. 54–57).

The purple lilliput has a complex life cycle that relies on fish hosts for successful reproduction, similar to other mussels (Service 2020a, pp. 23–25, 29). This complex life history involves an obligate parasitic larval life stage, called glochidia, which are wholly dependent on host fish, including the longear sunfish (*Lepomis megalotis*) and green sunfish (*L. cyanellus*) (Hill 1986, p. 5).

Additional resource needs of the purple lilliput include appropriate water quality and temperatures, and connectivity of aquatic habitat that facilitates dispersal and an abundance of multiple age classes to ensure recruitment.

Status Throughout All of Its Range

We have carefully assessed the best scientific and commercial data available regarding the past, present, and future threats to the purple lilliput, and we evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these stressors. The primary stressors (which are pervasive across the species' range) affecting the purple lilliput's biological status include habitat degradation or loss (*i.e.,* declines in water quality; reduced water levels; riparian and instream fragmentation; and genetic isolation from development, urbanization, contaminants, agricultural activities, impoundments, changing climate conditions, resource extraction, and forest conversion), and impacts associated with invasive and nonnative species.

While threats have acted on the species to reduce available habitat, the purple lilliput persists in 145 of 272 (53 percent) of its historically occupied populations, and its distribution continues to be represented within the six major river basins that it is historically known to occupy. Our projections of purple lilliput viability into the foreseeable future (*i.e.,* approximately 20 to 30 years, which takes into account available climate modeling projections that inform future conditions) suggest that between 10 and 30 populations have a high risk of extirpation, or could become functionally extirpated. However, the purple lilliput is expected to maintain resilient populations (*i.e.,* able to withstand stochastic events arising from random factors) across the six major river basins in which it historically and currently occurs. In other words, we estimate between 116 and 136 populations would continue to be resilient (or between 79 and 93 percent of the currently known populations) into the future. Additionally, we note that the species' host fish has a broad range, and the purple lilliput has the capability to adapt to lentic habitats in certain situations, which is a life-history trait that suggests it may be less susceptible to some potential habitat changes. Thus, after assessing the best available information, we determine that the purple lilliput is not in danger of extinction now or likely to become so in the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. Having determined that the purple lilliput is not in danger of extinction or likely to become so in the foreseeable future throughout all of its range, we now consider whether it may be in danger of extinction or likely to become so in the foreseeable future in a significant portion of its range—that is, whether there is any portion of the species' range for which it is true that both (1) the portion is significant; and, (2) the species is in danger of extinction now or likely to become so in the foreseeable future in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

In undertaking this analysis for the purple lilliput, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered or threatened.

We found two areas (Great Lakes and Cumberland River basins) where there may be a concentration of threats acting on the species such that the species in these portions of the range may be endangered or threatened, but we did not find that these areas constituted significant portions of the species' range. Accordingly, we found that the purple lilliput is not in danger of extinction now and is not likely to become so within the foreseeable future in any significant portion of its range. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that the purple lilliput does not meet the definition of an endangered species or a threatened species in accordance with sections 3(6) and 3(20) of the Act. Therefore, we find that listing the purple lilliput is not warranted at this time. A detailed discussion of the basis for this finding can be found in the purple lilliput species assessment form, and other

supporting documents, such as the accompanying SSA report (Service 2020a, entire) (see *http://www.regulations.gov* under docket number FWS–R4–ES–2020–0010).

II. Proposed Listing Determination for Longsolid and Round Hickorynut

Background

The longsolid (*Fusconaia subrotunda*) is a freshwater river mussel belonging to the Unionidae family, also known as the naiads and pearly mussels. Longsolid adults are light brown in color, darkening with age. The shell is thick and medium-sized (up to 5 inches (in) (125 millimeters (mm)), and typically has a dull sheen (Williams et al. 2008, p. 322). There is variability in the inflation of the shell depending on population and latitudinal location (Ortmann 1920, p. 272; Watters et al. 2009, p. 130).

The longsolid is currently found in the Ohio, Cumberland, and Tennessee River basins, overlapping within the States of Alabama, Kentucky, New York, North Carolina, Ohio, Pennsylvania, Tennessee, Virginia, and West Virginia (Service 2018, Appendix A; Figure 1, below). It is considered extirpated from Georgia, Indiana, and Illinois. Additionally, it is classified as an endangered species by the State of Ohio, and considered to have various levels of concern, imperilment, or vulnerability (see Table 1–1 in the SSA report) by the States of Alabama, Kentucky, North Carolina, Pennsylvania, Tennessee, Virginia, and West Virginia.

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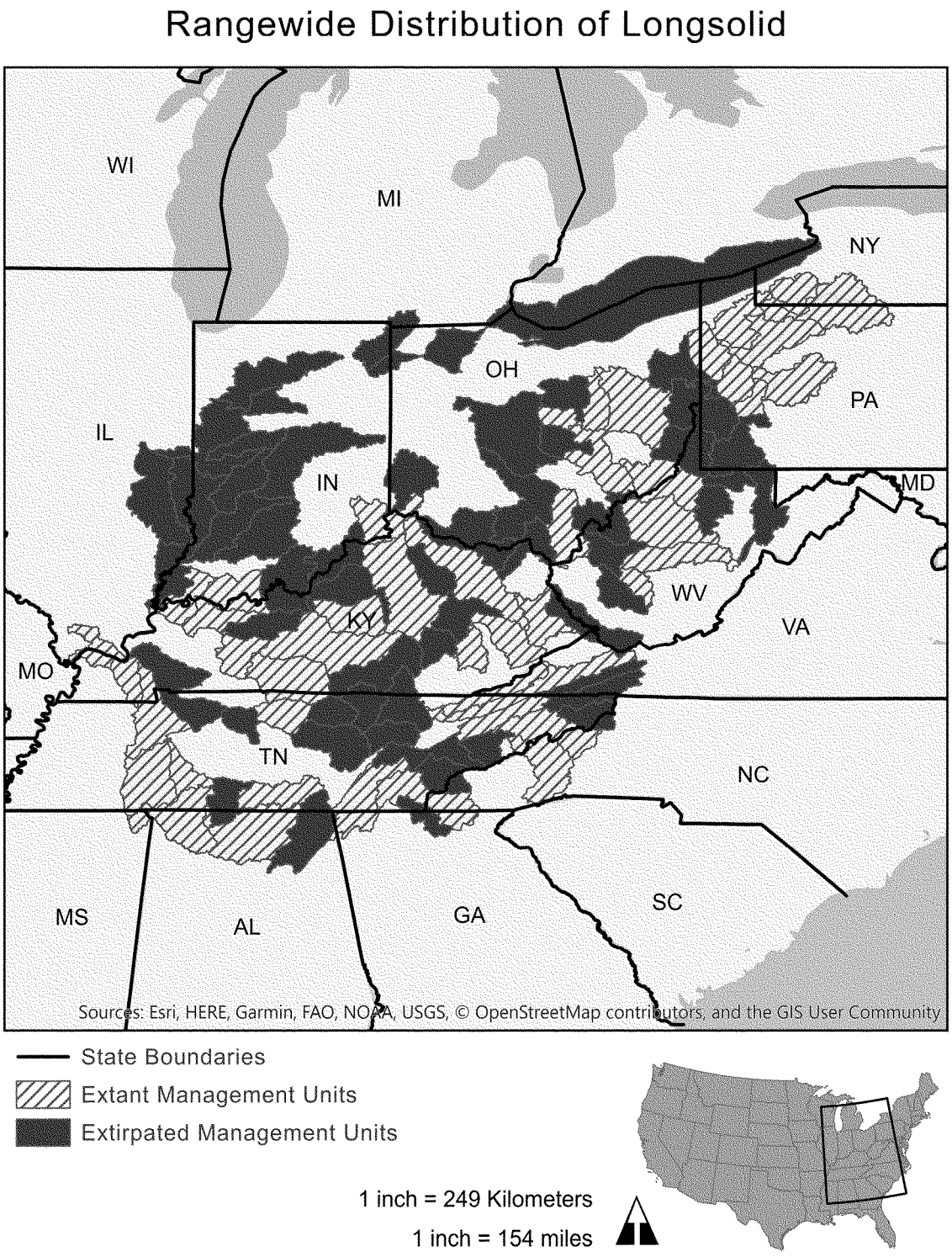

Figure 1. Longsolid range map, distributed across the Ohio, Cumberland, and Tennessee River basins. A total of 60 populations within 45 management units (i.e., 8-digit hydrologic unit code (HUC) watersheds (HUC-8)) are currently considered extant. The species exhibits reduced redundancy and representation compared to historical conditions due to a loss of 102 populations and 60 management units.

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Similar to the longsolid, the round hickorynut also belongs to the Unionidae family of naiads and pearly mussels. Round hickorynut adult mussels are greenish-olive to dark or chestnut brown, sometimes blackish in

older individuals, and may have a yellowish band dorsally (Parmalee and Bogan 1998, p. 168). Inflation of the shell is variable depending on population and latitudinal location (Ortmann 1920, p. 272; Williams et al. 2008, p. 474). The shell is thick, solid, and up to 3 in (75 mm) in length, but usually is less than 2.4 in. (60 mm) (Williams et al. 2008, p. 473; Watters et al. 2009, p. 209). A distinctive characteristic is that the shell is round in shape, nearly circular, and the umbo (the raised portion of the dorsal margin of a shell) is centrally located.

Within the United States, the round hickorynut is currently found in the Great Lakes, Ohio, Cumberland, Tennessee, and Lower Mississippi River basins, overlapping within the States of Alabama, Indiana, Kentucky, Michigan, Mississippi, Ohio, Pennsylvania, Tennessee, and West Virginia (Service 2019, Appendix A; Figure 2, below). It is considered extirpated from Georgia, Illinois, and New York. Additionally, it has State-level conservation status, ranging across various levels of concern, imperilment, or vulnerability (see Table 1–1 in the SSA report), in the States of Alabama, Indiana, Kentucky, Michigan, Pennsylvania, Tennessee, Virginia, and West Virginia. The round hickorynut also occurs within the Canadian Province of Ontario, where it was listed as an endangered species in 2005, due to the loss of and significant declines in populations (Committee on the Status of Species at Risk in Ontario 2013, p. 4); a single remaining population (showing no recruitment (Morris 2018, pers. comm.)) occurs in Lake St. Clair and the East Sydenham River.

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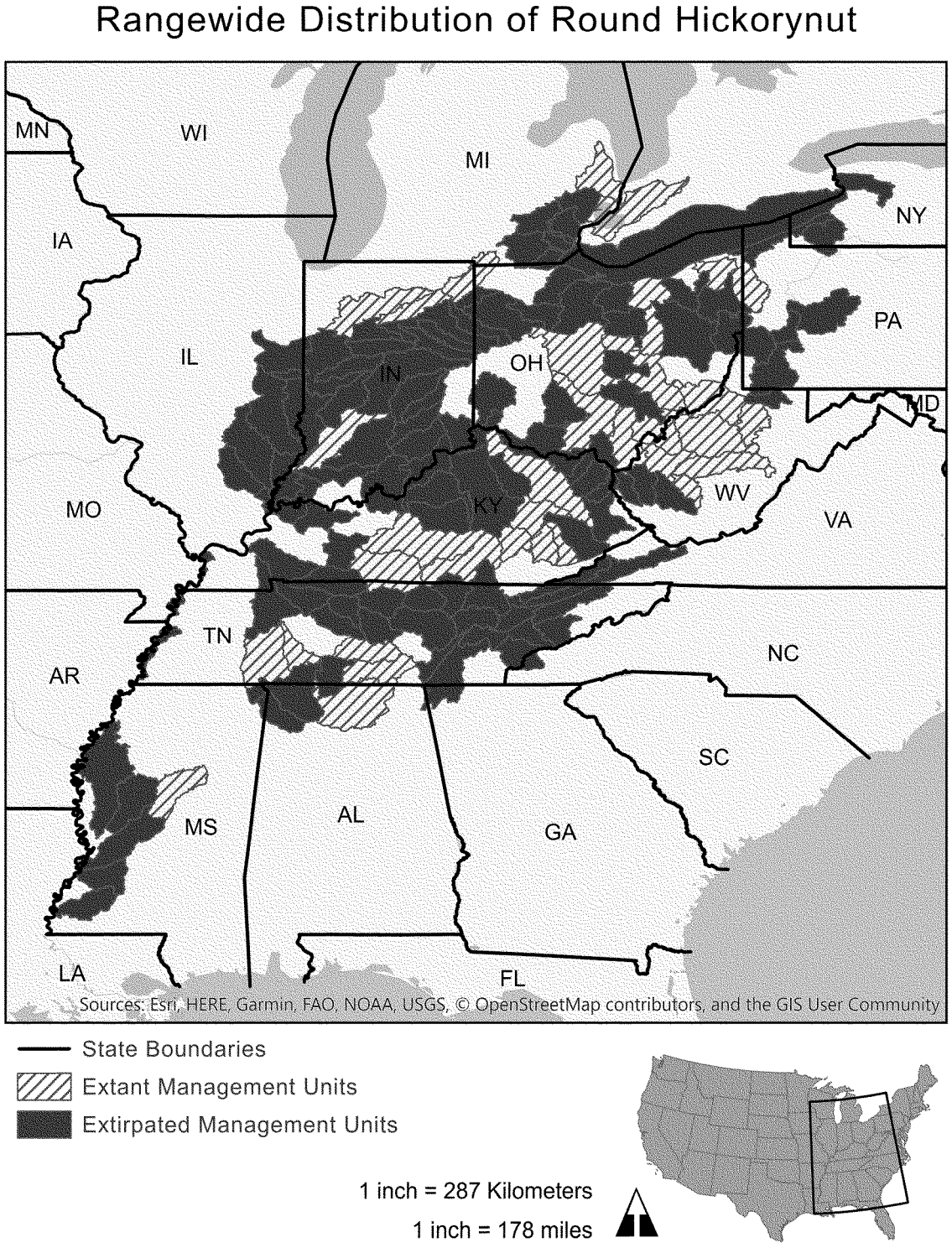

Figure 2. Round hickorynut range map, distributed across the Great Lakes, Ohio, Cumberland, Tennessee, and Lower Mississippi River basins, and the Ontario Province of Canada. A total of 65 populations within 34 management units (HUC-8) are currently considered extant. The species exhibits reduced redundancy and representation compared to historical conditions due to a loss of 232 populations and 104 management units.

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Thorough reviews of the taxonomy, life history, ecology and State listing status of the longsolid and round hickorynut are presented in detail in the SSA reports (Service 2018, pp. 14, 15, 22–30; Service 2019, pp. 14, 15, 22–29).

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an ''endangered species'' or a ''threatened species.'' The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an ''endangered species'' or a ''threatened species'' because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Services can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA reports document the results of our comprehensive biological review of the best scientific and commercial data regarding the status of both species, including an assessment of potential threats to the species. The SSA reports do not represent a decision by the Service on whether either species should be proposed for listing as an endangered or threatened species under the Act. They do, however, provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA reports for the longsolid and round hickorynut; the full SSA reports can be found in docket number FWS–R4–ES–2020–0010 on *http://www.regulations.gov,* and on our internet site *https://www.fws.gov/Asheville/.*

To assess the longsolid's and round hickorynut's viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years), redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the individual species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We use this information to inform our regulatory decision.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the longsolid and round hickorynut, their resources, and the threats that influence both species' current and future condition, in order to

assess each species' overall viability and the risks to that viability.

Species Needs

We assessed the best available information to identify the physical and biological needs to support individual fitness at all life stages for the longsolid and round hickorynut. Full descriptions of all needs are available in chapter 4 of the SSA reports (Service 2018, pp. 25–30; Service 2019, pp. 30–36), which can be found in docket number FWS–R4–ES–2020–0010 on *http://www.regulations.gov,* and on our internet site *https://www.fws.gov/Asheville/.* Based upon the best available scientific and commercial information, and acknowledging existing ecological uncertainties (see section 4.3 in the SSA reports), the resource and demographic needs for both the longsolid and round hickorynut are characterized as:

- Clean, flowing water with appropriate water quality and temperate conditions, such as (but not limited to) dissolved oxygen above 2 to 3 parts per million (ppm), ammonia generally below 0.5 ppm total ammonia-nitrogen, temperatures generally below 86 degrees Fahrenheit (°F) (30 degrees Celsius (°C)), and (ideally) an absence of excessive total suspended solids and other pollutants.
- Natural flow regimes that vary with respect to timing, magnitude, duration, and frequency of river discharge events.
- Predominantly silt-free, stable sand, gravel, and cobble substrates.
- Suspended food and nutrients in the water column including (but not limited to) phytoplankton, zooplankton, protozoans, detritus, and dissolved organic matter.
- Availability of sufficient host fish numbers to provide for glochidia infestation and dispersal. Host fish species for the longsolid include (but may not be limited to): Minnows of the family Cyprinidae and stonerollers (genera *Campostoma* sp.), satinfin shiners (*Cyprinella* sp.), eastern shiners (*Notropis* sp.), and highscale shiners (*Luxilus* sp.), as well as potentially freshwater sculpins of the genus *Cottus.* Host fish species documented for the round hickorynut include the banded sculpin (*Cottus carolinae*), eastern sand darter (*Ammocrypta pellucida*), emerald darter (*Etheostoma baileyi*), greenside darter (*Etheostoma blennioides*), Iowa darter (*Etheostoma exile*), fantail darter (*Etheostoma flabellare*), Cumberland darter (*Etheostoma gore*), spangled darter (*Etheostoma obama*), variegate darter (*Etheostoma variatum*), blackside darter (*Percina maculata*), and frecklebelly darter (*Percina stictogaster*).
- Connectivity among populations. Although the species' capability to disperse is evident through historical occurrence of a wide range of rivers and streams, the fragmentation of populations by small and large impoundments has resulted in isolation and only patches of what once was occupied contiguous river and stream habitat. Genetic exchange occurs between and among mussel beds via sperm drift, host fish movement, and movement of mussels during high flow events. For genetic exchange to occur, connectivity must be maintained. Most freshwater mussels, including the longsolid and round hickorynut, are found in mussel beds that vary in size and are often separated by stream reaches in which mussels are absent or rare (Vaughn 2012, p. 983). The species is often a component of a large healthy mussel assemblage within optimal mussel habitats; therefore, the beds in which they occur are necessary for the species to be resilient over time.

Current Conditions

Current (and future) conditions are described using categories that estimate the overall condition (resiliency) of the longsolid and round hickorynut mussel populations. These categories include:

- High—Resilient populations with evidence of recruitment and multiple age classes represented. They are likely to maintain viability and connectivity among populations, and populations are not linearly distributed (*i.e.,* occur in tributary streams within a management unit). Populations are expected to persist in 20 to 30 years and beyond, and withstand stochastic events. (*Thriving; capable of expanding range.*)
- Medium—Spatially restricted populations with limited levels of recruitment or age class structure. Resiliency is less than under high conditions, but the majority of populations (approximately 75 percent) are expected to persist beyond 20 to 30 years. (*Stable; not necessarily thriving or expanding its range.*)
- Low—Small and highly restricted populations, with no evidence of recent recruitment or age class structure, and limited detectability. These populations have low resiliency, are not likely to withstand stochastic events, and potentially will no longer persist in 20 to 30 years. Populations are linearly distributed within a management unit. (*Surviving and observable, but population likely declining.*)

Given the longsolid's and round hickorynut's ranges include lengthy rivers, such as the Ohio, Allegheny, Cumberland, and Tennessee Rivers, all of which include populations fragmented primarily by dams, we identified separate populations for each hydrologic unit code (HUC) (Seaber et al. 1987, entire; U.S. Geological Survey 2018, entire) at the fourth of 12 levels (*i.e.,* HUC–8 watershed). The HUC–8 watersheds are analogous to medium-sized river basins across the United States. Our analysis describes conditions relevant to longsolid and round hickorynut populations and the overarching HUC–8 watersheds, identified herein as a ''management unit.'' A management unit could harbor one or more populations. See chapter 2 in the SSA reports for further explanation of the analysis methodology (Service 2018, pp. 15–19; Service 2019, pp. 17–22).

Longsolid

The longsolid's current range extends over nine States, including New York, Pennsylvania, West Virginia, Ohio, Kentucky, Virginia, Tennessee, North Carolina, and Alabama; the species is now considered extirpated in Georgia, Illinois, and Indiana. This range encompasses three major river basins (the Ohio, Cumberland, and Tennessee basins); the species now no longer exists in the Great Lakes basin (loss of six historical populations and four management units). In addition, its representation in the Cumberland River basin is currently within a single population and management unit (loss of nine historical populations and eight management units). Overall, the longsolid is presumed extirpated from 63 percent (102 of 162 populations) of its historically occupied populations, including 6 populations (the entirety) in the Great Lakes basin, 65 populations in the Ohio River basin, 9 populations in the Cumberland River basin, and 26 populations in the Tennessee River basin (see Appendix B in the SSA report (Service 2018, pp. 131–154)). Of the current populations, 3 (5 percent) are estimated to be highly resilient, 9 (15 percent) are estimated to be moderately resilient, and 48 (80 percent) are estimated to have low resiliency.

The longsolid was once a common, occasionally abundant component of the mussel assemblage in rivers and streams where it is now extirpated. Examples include the Beaver River, Pennsylvania (Ortmann 1920, p. 276); Ohio River, Pennsylvania (Tolin 1987, p. 11); Mahoning River, Pennsylvania (Ortmann 1920 p. 276); Wabash River, Indiana/Illinois (Cummings et al. 1992, p. 46); Nolin River, Kentucky (Taylor 1983a, p. 111); and the South Fork Holston River, Virginia/Tennessee (Parmalee and Pohemus 2004, p. 234). Significant declines of the longsolid

have been observed and documented in the Ohio and Cumberland Rivers, and in the Muskingum River system, which harbors the last remaining populations (Muskingum, Tuscarawas, and Walhonding) in Ohio (Neel and Allen 1964, p. 434; Watters and Dunn 1993–94, p. 252; Watters et al. 2009, p. 131; Haag and Cicerello 2016, p. 139).

Round Hickorynut

The current range of the round hickorynut extends over nine States, including Alabama, Indiana, Kentucky, Michigan, Mississippi, Ohio, Pennsylvania, Tennessee, and West Virginia; the species is now considered extirpated in Georgia, Illinois, and New York. This range encompasses five major river basins (Great Lakes, Ohio River, Cumberland River, Tennessee River, and Lower Mississippi River). Round hickorynut representation in the Cumberland River basin is restricted to two linear populations within two management units, while it exists in the Lower Mississippi River basin in a single population. Therefore, while the species currently maintains representation from historical conditions, it is at immediate risk of losing 40 percent (2 of 5 basins) of its representation due to these small, isolated populations under a high degree of threats that have resulted from habitat loss and water quality degradation.

Overall, the round hickorynut has lost an approximate 232 of 297 known populations (78 percent), and 104 of 138 management units (75 percent). This includes 25 populations in the Great Lakes basin, 150 populations in the Ohio River basin, 23 populations in the Cumberland River basin, 29 populations in the Tennessee River basin, and 9 populations in the Lower Mississippi River basin (see Appendix B in the SSA report (Service 2019, pp. 191–212)). Of the current populations, 4 (6 percent) are estimated to be highly resilient, 16 (23 percent) are estimated to be moderately resilient, and 45 (69 percent) are estimated to have low resiliency.

The round hickorynut was once a much more common, occasionally abundant, component of the mussel assemblage in rivers and streams across much of the eastern United States. Population extirpations have been extensive and widespread within every major river basin where the round hickorynut is found. Surveys throughout eastern North America have not targeted the round hickorynut specifically, and as a result, there could have been additional population losses or declines that have gone undocumented. Conversely, it is possible that there are populations that have gone undetected. However, the majority of the species' range has been relatively well-surveyed for freshwater mussel communities, and the likelihood is small that there are substantial or stronghold populations that are undetected. Patterns of population extirpation and declines are pronounced particularly in the Ohio River basin, which appears to be the basin most important for redundancy and representation for the species, due to its documented historical distribution and remaining concentration of populations within the basin.

Populations of the round hickorynut have been apparently lost from entire watersheds and management units in which the species once occupied multiple tributaries, such as the Allegheny, Coal, Little Scioto, Miami, and Vermilion River management units in the Ohio River basin. The State of Ohio, for example, has lost 53 populations of round hickorynut, along with 19 management units (Watters et al. 2009, p. 210). The species is also critically imperiled in Canada, and as a result, the future of the species in Canada may be reliant on hatchery-supported activities or augmentation activities coordinated with the United States.

Precipitous declines and extirpations of round hickorynut populations have been documented in the Great Lakes, Ohio, Cumberland, Tennessee, and Lower Mississippi basins. These declines and extirpations are exhibited in museum collections and reported in published literature accounts of the species (see Appendix D in the SSA report (Service 2019, pp. 214–238)). While this documentation could be a result of more intensive survey effort in the core of the species' distribution, regardless, the extirpation of formerly abundant and extensive populations is a cautionary note for current and future condition projections, and has been most pronounced in the Ohio and Cumberland basins.

Examples of rivers where the round hickorynut is extirpated within these basins include: Crooked Creek, Pennsylvania (Ortmann 1913, p. 298); West Branch Mahoning River, Ohio (Swart 1940, p. 42); Coal River, West Virginia (Carnegie Museum and University of Michigan Museum of Zoology records); Olentangy River, Ohio (Stein 1963, p. 109); Alum Creek, Ohio (Ohio State University, Marion records); Blaine Creek, Kentucky (Bay and Winford 1984, p. 19); Embarras River, Illinois (Parmalee 1967, p. 80); Big Vermilion River, Illinois (Parmalee 1967, p. 80); Cumberland River, Kentucky (Neel and Allen 1964, p. 442); Stones River, Tennessee (Ohio State University, Marion records); and Red River, Tennessee/Kentucky (Ohio State University, Marion records).

Threats Analysis

The following discussions include evaluations of three threats and associated sources that are affecting the longsolid and round hickorynut, and their habitats: (1) Habitat degradation or loss, (2) invasive and nonnative species, and (3) negative effects associated with small population size (Service 2018 and 2019, chapter 6). We note that potential impacts associated with overutilization were evaluated, but we found no evidence of current effects on the species' viability (noting historical effects from harvest on the longsolid that no longer occur). In addition, potential impacts from disease, parasites, and predation, as well as potential impacts to host species, were evaluated but were found to have minimal effects on viability of either species based on current knowledge (Service 2018, pp. 70, 73–74; Service 2019, pp. 91–95). Finally, we also considered effects associated with enigmatic population declines, which have been documented in fresh water river mussel populations since the 1960s; despite speculation and repeated aquatic organism surveys and water quality monitoring, the causes of these events are unknown (Haag 2019, p. 43). In some cases, the instream habitat often remains basically intact and continues to support other aquatic organisms such as fish and crayfish. Full descriptions of each of the threats and their sources, including specific examples across the species' range where threats are impacting the species or its habitat, are available in chapter 6 and Appendix A of the SSA reports (Service 2018, pp. 43–76, 134–157; Service 2019, pp. 58–96, 169–187).

Habitat Degradation or Loss

Development/Urbanization

Development and urbanization activities that may contribute to longsolid and round hickorynut habitat degradation and loss, including reduced water quality, occur throughout the species' range. The term ''development'' refers to urbanization of the landscape, including (but not limited to) land conversion for residential, commercial, and industrial uses and the accompanying infrastructure. The effects of urbanization may include alterations to water quality, water quantity, and habitat (both in-stream and streamside) (Ren et al. 2003, p. 649;

Wilson 2015, p. 424). Urban development can lead to increased variability in streamflow, typically increasing the extent and volume of water entering a stream after a storm and decreasing the time it takes for the water to travel over the land before entering the stream (Giddings et al. 2009, p. 1). Deleterious effects on streams (*i.e.,* water collection on impervious surfaces that rapidly flows into storm drains and local streams), including those that may be occupied by the longsolid and round hickorynut include:

(1) Water Quantity: Storm drains deliver large volumes of water to streams much faster than would naturally occur, often resulting in flooding and bank erosion that reshapes the channel and causes substrate instability, resulting in destabilization of bottom sediments. Increased, high-velocity discharges can cause species living in streams (including mussels) to become stressed, displaced, or killed by fast moving water and the debris and sediment carried in it. Displaced individuals may be left stranded out of the water once floodwaters recede.

(2) Water Quality: Pollutants (*e.g.,* gasoline, oil drips, fertilizers) that accumulate on impervious surfaces may be washed directly into streams during storm events. Contaminants contained in point and non-point source discharges degrade water and substrate quality, and can result in reduced survival, growth, and reproduction of mussels.

(3) Water Temperature: During warm weather, rain that falls on impervious surfaces becomes superheated and can stress or kill freshwater species when it enters streams.

Other development-related impacts to the longsolid and round hickorynut, or their habitat, may occur as a result of:

- Water infrastructure. This includes water supply, reclamation, and wastewater treatment, which results in pollution point discharges to streams. Concentrations of contaminants (including nitrogen, phosphorus, chloride, insecticides, polycyclic aromatic hydrocarbons, and personal care products) increase with urban development (Giddings et al. 2009, p. 2; Bringolf et al. 2010, p. 1,311).
- Utility crossings and right-of-way maintenance. Direct impacts from utility crossings include direct exposure or crushing of individuals, sedimentation, and habitat disturbance. The greatest cumulative impact involves cleared rights-of-way that result in direct runoff and increased stream temperature at the crossing location, and potentially promote maintenance utility and all-terrain vehicle access from the rights-of-way (which destroys banks and instream habitat, and thus can lead to increased erosion (see also Service 2017, pp. 48–49)).
- Anthropogenic activities. These types of activities may act to lower water tables, making the longsolid or round hickorynut susceptible to depressed flow levels. Water withdrawals for irrigation, municipal, and industrial water supplies are an increasing concern due to expanding human populations. Water infrastructure development, including water supply, reclamation, and wastewater treatment, results in pollution point discharges to streams. Concentrations of contaminants (including nitrogen, phosphorus, chloride, insecticides, polycyclic aromatic hydrocarbons, and personal care products) increase with urban development (Giddings et al. 2009, p. 2; Bringolf et al. 2010, p. 1,311). It is currently unknown whether anthropogenic effects of development and urbanization are likely to impact the longsolid or round hickorynut at the individual or population level. However, secondary impacts such as the increased likelihood of potential contaminant introduction, stream disturbance caused by impervious surfaces, barrier construction, and forest conversion are likely to act cumulatively on longsolid and round hickorynut populations.

Agricultural activities are pervasive across the range of the longsolid and round hickorynut. Examples include (but are not limited to):

- Longsolid: Agricultural erosion is listed among the factors affecting the Clinch and Powell Rivers (Ahlstedt et al. 2016, p. 8).
- Longsolid: Sedimentation and other non-point source pollution, primarily of agricultural origin, are identified as a primary threat to aquatic fauna of the Nolichucky River (The Tennessee Valley Authority (TVA) 2006, p. 11).
- Longsolid: Agricultural impacts have been noted to take a toll on mussel fauna in the Goose Creek watershed on the South Fork Kentucky River (Evans 2010, p. 15).
- Longsolid and round hickorynut: The Elk River in Tennessee is a watershed with significant agricultural activity (Woodside et al. 2004, p. 10).
- Round hickorynut: Water withdrawals for irrigation for agricultural uses have increased recently in the Tippecanoe River (Fisher 2019, pers. comm.)
- Round hickorynut: Sedimentation and other point and non-point source pollution, primarily of agricultural origin, are identified as a primary threat to aquatic fauna of Big Darby Creek and Killbuck Creek, Ohio (Ohio Department of the Environmental Protection Agency 2004, p. 1; Ohio Department of the Environmental Protection Agency 2011, p. 31).
- Round hickorynut: Approximately 25 percent of the land use area in the West Fork River management unit in West Virginia is in agriculture, and has increased by as much as 9 percent in recent years (U.S. Department of Agriculture 2010, p. 8).
- Round hickorynut: Large-scale mechanized agricultural practices threaten the last remaining population in the Lower Mississippi River basin, in the Big Black River, where the species has already undergone range reduction (Peacock and James 2002, p. 123).
- Round hickorynut: The Duck, Buffalo, and Elk Rivers in Tennessee are watersheds with significant agricultural activity in their headwaters and tributaries, and are a suspected cause for mussel community declines throughout those rivers (Reed 2014, p. 4).

Transportation

Transportation-related impacts include both road development and river navigation. By its nature, road development increases impervious surfaces as well as land clearing and habitat fragmentation. Roads are generally associated with negative effects on the biotic integrity of aquatic ecosystems, including changes in surface water temperatures and patterns of runoff, changes in sedimentation levels, and increased heavy metals (especially lead), salts, organics, and nutrients to stream systems (Trombulak and Frissell 2000, p. 18). The adding of salts through road de-icing results in high salinity runoff, which is toxic to freshwater mussels. In addition, a major impact of road development is improperly constructed culverts at stream crossings, which can act as barriers if flow through the culvert varies significantly from the rest of the stream, or if the culvert ends up becoming perched (*i.e.,* sitting above the downstream streambed), and fishes that serve as mussel hosts cannot pass through them.

With regard to river navigation, dredging and channelization activities (as a means of maintaining waterways) have altered riverine habitats nationwide (Ebert 1993, p. 157). Channelization affects many physical characteristics of streams through accelerated erosion, increased bed load, reduced depth, decreased habitat diversity, geomorphic instability, and riparian canopy loss (Hartfield 1993, p.

139). All of these impacts contribute to loss of habitat for the longsolid and round hickorynut, and alter habitats for host fish. Changes in both the water velocity and deposition of sediments not only alters physical habitat, but the associated increases in turbulence, suspended sediment, and turbidity affect mussel feeding and respiration (Aldridge et al. 1987, p. 25). The scope of channel maintenance activities over extensive areas alters physical habitat and degrades water quality. In addition to dredging and channel maintenance, impacts associated with barge traffic, which includes construction of fleeting areas, mooring cells, docking facilities, and propeller wash, also destroy and disrupt mussel habitat (see Miller et al. (1989, pp. 48–49) as an example for disturbance from barges).

Transportation-related impacts across the range of the longsolid and round hickorynut include (but are not limited to) the following examples:

- Channelization and dredging—Longsolid populations in the Eel, Vermilion, and Embarras Rivers and Killbuck Creek are extirpated. Round hickorynut populations in the Vermilion and Embarras Rivers are extirpated, while populations in the Eel and Killbuck Creek management units are in low condition; these streams have been extensively dredged and channelized (Butler 2007, p. 63; Appendix B). Additionally, dredging is identified by Taylor (1983b, p. 3) as the primary cause for suitable habitat loss in the Kanawha River (below river mile 79) in West Virginia.
- Barge traffic, which includes construction of fleeting areas, mooring cells, docking facilities, and propeller wash, destroys and disrupts mussel habitat, currently affecting at least 15 (25 percent) of the longsolid populations in the Ohio, Cumberland, and Tennessee River basins (Hubbs et al. 2006, p. 169; Hubbs 2012, p. 3; Smith and Meyer 2010, p. 555; Sickel and Burnett 2005, p. 7; Taylor 1983b, p. 5). All six of the Ohio River mainstem longsolid populations that are considered in low condition are affected by channel maintenance and navigation operations; at least five (8 percent) of the round hickorynut populations in the Ohio basin are affected.
- Channel maintenance and navigation are affecting the low condition populations in the lower Allegheny and Tennessee Rivers due to their clustered distribution and proximity to locks and dams. For the longsolid, these include two Allegheny River populations below Redbank, Pennsylvania (Smith and Meyer 2010, p. 556), and three low condition populations in the Tennessee River main stem above Kentucky Dam.
- Although most prevalent on the mainstem Ohio and Tennessee Rivers, commerce and commercial navigation currently affect round hickorynut populations in the Black and Muskingum Rivers.

Contaminants

Contaminants contained in point and non-point discharges can degrade water and substrate quality and adversely impact mussel populations. Although chemical spills and other point sources of contaminants may directly result in mussel mortality, widespread decreases in density and diversity may result in part from the subtle, pervasive effects of chronic, low-level contamination (Naimo 1995, p. 354). The effects of heavy metals, ammonia, and other contaminants on freshwater mussels were reviewed by Mellinger (1972), Fuller (1974), Havlik and Marking (1987), Naimo (1995), Keller and Lydy (1997), and Newton et al. (2003).

The effects of contaminants such as metals, chlorine, and ammonia are profound on juvenile mussels (Augspurger et al. 2003, p. 2,571; Bartsch et al. 2003, p. 2,566). Juvenile mussels may readily ingest contaminants adsorbed to sediment particles while pedal feeding (Newton and Cope 2007, p. 276). These contaminants also affect mussel glochidia, which are sensitive to some toxicants (Goudreau et al. 1993, p. 221; Jacobson et al. 1997, p. 2,386; Valenti et al. 2005, p. 1,243).

Mussels are noticeably intolerant of heavy metals (Havlik and Marking 1987, p. 4). Even at low levels, certain heavy metals may inhibit glochidial attachment to fish hosts. Cadmium appears to be the heavy metal most toxic to mussels (Havlik and Marking 1987, pp. 4–9), although chromium, copper, mercury, and zinc also negatively affect biological processes (Naimo 1995, p. 355; Jacobson et al. 1997, p. 2,389; Valenti et al. 2005, p. 1,243). Chronic mercury contamination from a chemical plant on the North Fork Holston River, Virginia, destroyed a diverse mussel fauna downstream of Saltville, Virginia, and potentially contributed to the extirpation of the longsolid from that river (Brown et al. 2005, p. 1,459). An example of long-term declines and extirpation of mussels attributed to copper and zinc contamination originating from wastewater discharges at electric power plants includes the Clinch River in Virginia (a portion of which the longsolid currently occupies) (Zipper et al. 2014, p. 9). This highlights that, despite localized improvements, these metals can stay bound in sediments, affecting recruitment and densities of the mussel fauna for decades (Price et al. 2014, p. 12; Zipper et al. 2014, p. 9).

Examples of contaminant-related impacts across the range of longsolid and/or round hickorynut include (but are not limited to):

- Contaminants have affected mussel glochidia on the Clinch River, which is a stronghold population for the longsolid (Goudreau et al. 1993, p. 221; Jacobson et al. 1997, p. 2,386; Valenti et al. 2005, p. 1,243); round hickorynut is now considered extirpated in the Tennessee section of the river.
- The toxic effects of high salinity wastewater from oil and natural gas drilling on juvenile and adult freshwater mussels were observed in the Allegheny River, Pennsylvania, and in the Ohio River basin (Patnode et al. 2015, p. 55).
- Numerous streams throughout both species' ranges have experienced mussel and fish kills from toxic chemical spills, such as Fish Creek in Indiana for the round hickorynut (Sparks et al. 1999, p. 12), and the upper Tennessee River system in Virginia for the longsolid (Ahlstedt et al. 2016, p. 8; Neves 1987, p. 9; Jones et al. 2001, p. 20; Schmerfeld 2006, p. 12). Also in the Tennessee River basin, high counts of coliform bacteria originating from wastewater treatment plants have been documented, contributing to degradation of water quality being a primary threat to aquatic fauna (Neves and Angermeier 1990, p. 50).
- Heavy metals and their toxicity to mussels have been documented in the Great Lakes, Clinton, Muskingum, Ohio, Fox, Powell, Clinch, and Tennessee Rivers where one or both of these species occur (Havlik and Marking 1987, pp. 4–9; van Hees et al. 2010, p. 606). Coal plants are also located on the Kanawha, Green, and Cumberland Rivers, and the effects of these facilities on water quality and the freshwater mussel fauna, including the longsolid and round hickorynut, are likely similar.

The degradation of water quality as a result of land-based oil and gas drilling activities is a significant adverse effect on freshwater mussels, and specifically on longsolid in the Ohio River basin and populations in the Allegheny River, as well as the in Kanawha, Little Kanawha, and Elk Rivers.

Agricultural Activities

The advent of intensive row crop agricultural practices has been cited as a potential factor in freshwater mussel decline and species extirpation in the eastern United States (Peacock et al.

2005, p. 550). Nutrient enrichment and water withdrawals, which are threats commonly associated with agricultural activities, are most likely to affect individual longsolid and round hickorynut mussels, although in some instances may be localized and limited in scope. However, chemical control using pesticides, including herbicides, fungicides, insecticides, and their surfactants and adjuvants, are highly toxic to juvenile and adult freshwater mussels (Bringolf et al. 2007, p. 2,092). Waste from confined animal feeding and commercial livestock operations is another potential source of contaminants that comes from agricultural runoff. The concentrations of these contaminants that emanate from fields or pastures may be at levels that can affect an entire population, especially given the highly fragmented distributions of the longsolid and round hickorynut (also see *Contaminants,* above).

Agencies such as the Natural Resources Conservation Service and Soil and Water Conservation Districts provide technical and financial assistance to farmers and private landowners. Additionally, county resource development councils and university agricultural extension services disseminate information on the importance of minimizing land use impacts, specifically agriculture, on aquatic resources. These programs help identify opportunities for conservation through projects such as exclusion fencing and alternate water supply sources, which help decrease nutrient inputs and water withdrawals, and help keep livestock off of stream banks and shorelines, thus reducing erosion. However, the overall effectiveness of these programs over a large scale is unknown given the longsolid's and round hickorynut's wide distribution and varying agricultural intensities.

Given the large extent of private land and agricultural activities within the ranges of the longsolid and round hickorynut, the effects of agricultural activities that degrade water quality and result in habitat deterioration are not frequently detected until after the event(s) occur. In summary, agricultural activities are pervasive across the ranges of the longsolid and round hickorynut. The effects of agricultural activities on the longsolid and round hickorynut are a factor in their historical decline and localized extirpations.

Agricultural activities are pervasive across the range of the longsolid and round hickorynut. Specifically, agricultural impacts have affected and continue to affect high, medium, and low condition longsolid populations within these basins, including:

- Longsolid only: French Creek and Allegheny River (Pennsylvania), Hughes River (West Virginia), Tuscawaras River (Ohio), Rolling Fork River (Kentucky), Little River and Valley River (North Carolina), Nolichucky River (Tennessee), Clinch and Powell Rivers (Tennessee and Virginia), and Estill Fork (Alabama).
- Round hickorynut only: Pine, Belle, and Black Rivers (Michigan).
- Both species: Shenango River (Pennsylvania); Elk, Little Kanawha, and North Fork Hughes Rivers (West Virginia); Licking and Kentucky Rivers (Kentucky); Elk and Buffalo Rivers (Tennessee); and Paint Rock River (Alabama).

Dams and Barriers

The effects of impoundments and barriers on aquatic habitats and freshwater mussels are relatively well-documented (Watters 2000, p. 261). Dams alter and disrupt connectivity, and alter water quality, which affect longsolid and round hickorynut species. Extinction/extirpation of North American freshwater mussels can be traced to impoundment and inundation of riffle habitats in all major river basins of the central and eastern United States (Haag 2009, p. 107). Humans have constructed dams for a variety of reasons: flood prevention, water storage, electricity generation, irrigation, recreation, and navigation (Eissa and Zaki 2011, p. 253). Dams, either natural (by beavers or by aggregations of woody debris) or manmade, have many impacts on stream ecosystems. Reductions in the diversity and abundance of mussels are primarily attributed to habitat shifts caused by impoundments (Neves et al. 1997, p. 63). The survival of mussels and their overall reproductive success are influenced:

- *Upstream of dams,* by the change from flowing to impounded waters, increased depths, increased buildup of sediments, decreased dissolved oxygen, and the drastic alteration in resident fish populations.
- *Downstream of dams,* by fluctuations in flow regimes, minimal releases and scouring flows, seasonal depletion of dissolved oxygen, reduced or increased water temperatures, and changes in fish assemblages.

Additionally, improperly constructed culverts at stream crossings may act as barriers and have some similar negative effects as dams on stream systems. Fluctuating flows through the culvert can vary significantly from the rest of the stream, preventing fish passage and scouring downstream habitats. For example, if a culvert sits above the streambed, aquatic organisms cannot pass through it. These barriers fragment habitats along a stream course and contribute to genetic isolation of the aquatic species inhabiting the streams.

Whether constructed for purposes such as flood control, navigation, hydropower, water supply or multi-purpose uses, the construction and continued operation of dams (per existing licensing schedules) is a pervasive negative influence on the longsolid, round hickorynut, and their habitats throughout their ranges. Although there are recent efforts to remove older, failing dams within the ranges of the longsolid and round hickorynut, such as Lock and Dam 6 on the Green River, and current plans to remove others, such as Six Mile Dam on the Walhonding River, dams and their effects on longsolid and round hickorynut population distributions have had perhaps the greatest documented negative influence on these species (Hardison and Layzer 2001, p. 79; Layzer et al. 1993, p. 68; Parmalee and Polhemus 2004, p. 239; Smith and Meyer 2010, p. 543; Hubbs 2012, p. 8; Watters and Flaute 2010, p. 2).

Over 20 of the rivers and streams currently occupied by the longsolid are directly affected by dams, thus directly influencing the species' distribution rangewide. For the round hickorynut, all occupied rivers and streams are directly or indirectly affected by dams. See section 6.1.5 of the SSA reports for specific areas where dams and other impoundments occur within the range of the species (Service 2018, pp. 59–63; Service 2019, pp. 73–77).

Changing Climate Conditions

Changing climate conditions that can influence freshwater mussels include increasing or decreasing water temperatures and precipitation patterns that result in increased flooding, prolonged droughts, or reduced stream flows, as well as changes in salinity levels (Nobles and Zhang 2011, pp. 147–148). An increase in the number of days with heavy precipitation over the next 25 to 35 years is expected across the longsolid's range (U.S. Global Climate Change Research Program 2017, p. 207). Although changing climate conditions have potentially affected the longsolid to date, the timing, frequency, and extent of these effects is currently unknown. Possible impacts to the species could include alteration of the fundamental ecological processes, such as thermal suitability; changes in seasonal patterns of precipitation and runoff, which could alter the hydrology of streams; and changes in the presence

or combinations of invasive, native or nonnative species.

We examined information on anticipated climate effects to wide-ranging mussels, which included a study that used RCP 2.6 and 8.5 and was conducted on the federally endangered spectaclecase (*Cumberlandia monodonta*). Our analysis of the best available climate change information revealed that within the range of both the longsolid and round hickorynut, shifts in the species-specific physiological thresholds in response to altered precipitation patterns and resulting thermal regimes are possible. Additionally, the expansion of invasive, nonnative species because of climatic changes has the potential for long-term detriments to the mussels and their habitats. Other potential impacts are associated with changes in food web dynamics and the genetic bottleneck that can occur with low effective population sizes (Nobles and Zhang 2011, p. 148). The influences of these changes on the longsolid and round hickorynut are possible in the future (see Scenario 3, *Future Conditions,* below). Multi-scale climate models that can be interpreted at both the rangewide and population levels, and are tailored to benthic invertebrates, which incorporate genetic and life-history information, are needed before the longsolid and round hickorynut declines can be correlated with climate change. At this time, the best available information indicates that climate change is considered a secondary factor influencing the viability of the longsolid and round hickorynut and is not currently thought to be a primary factor in the longsolid's or round hickorynut's occurrence and distribution across their ranges.

Resource Extraction

The most intensive resource extraction activities affecting the longsolid, round hickorynut, and their habitats are coal mining and oil and gas exploration, which are summarized here. Additional less intensive resource extraction activities affecting the species include gravel mining/dredging, which is detailed in the SSA reports (Service 2018, pp. 64–65; Service 2019, pp. 79–83).

Activities associated with coal mining and oil and gas drilling can contribute chemical pollutants to streams. Acid mine and saline drainage (AMD) is created from the oxidation of iron-sulfide minerals such as pyrite, forming sulfuric acid (Sams and Beer 2000, p. 3). This AMD may be associated with high concentrations of aluminum, manganese, zinc, and other constituents (Tennessee Department of Environment and Conservation (TDEC) 2014, p. 72). These metals, and the high acidity typically associated with AMD, can be acutely and chronically toxic to aquatic life (Jones 1964, p. 96).

Natural gas extraction has negatively affected water quality through accidental spills and discharges, as well as increased sedimentation due to increases in impervious surface and tree removal for drill pads and pipelines (Vidic et al. 2013, p. 6). Disposal of insufficiently treated brine wastewater is known to adversely affect freshwater mussels (Patnode et al. 2015, p. 62). Contaminant spills are also a concern.

Sediment appears to be the largest impact to mussel physical habitat in streams as a result of gas extraction activities (Clayton 2018, pers. comm.). Excessive suspended sediments can impair feeding processes, leading to acute short-term or chronic long-term stress. Both excessive sedimentation and excessive suspended sediments can lead to reduced mussel fitness (Ellis 1936, p. 29; Anderson and Kreeger 2010, p. 2). This sediment is generated by construction of the well pads, access roads, and pipelines (for both gas and water).

Examples of the variety of resource extraction activities (coal, oil, gas, and gravel mining) that occur across the range of the longsolid and round hickorynut include (but are not limited to):

- Longsolid: The Cumberland Plateau and Central Appalachian regions of Tennessee and Kentucky (upper Cumberland River system and upper Tennessee River system) continue to experience mining activity that impairs water quality in streams (TDEC 2014, p. 62).
- Longsolid: High levels of copper, manganese, and zinc, metals toxic to freshwater mussels, were found in sediment samples from both the Clinch and Powell Rivers, and mining impacts close to Big Stone Gap, Virginia, have almost eliminated the mussel fauna in the upper Powell River. The longsolid is considered extirpated from the South Fork Powell River and Cane Creek, both tributaries to the upper portion of the Powell River (Ahlstedt and Tuberville 1997, p. 75; Appendix D).
- Round hickorynut: Although populations persist in the Rockcastle River and Buck Creek in the Cumberland basin, coal and gravel mining continues to occur in these watersheds.
- Round hickorynut: The extensive mining of gravel in riparian zones reduces vegetative buffers and causes channel instability, and has been implicated in mussel declines in the Walhonding River, Ohio, which harbors a low condition population (Hoggarth 1995–96, p. 150).
- Both species: Impacts from natural gas pipelines have a high potential to occur in West Virginia and Pennsylvania. Tank trucks hauling such fluids can overturn into mussel streams, which recently occurred in Meathouse Fork of Middle Island Creek (Clayton 2018, pers. comm.).
- Both species: Natural gas extraction in the Marcellus Shale region (the largest natural gas field in the United States that runs through northern Appalachia) has negatively affected water quality through accidental spills and discharges in populations in the Shenango, Elk, Little Kanawha, and Kanawha management units.
- Both species: Coal mining has been implicated in sediment and water chemistry impacts in the Kanawha River in West Virginia, potentially limiting the Elk River populations of both species (Morris and Taylor 1978, p. 153).
- Both species: Resource extraction and AMD have been cited as contributors to the loss of mussel species in the Cumberland basin (Haag and Cicerello 2016, p. 15), including the loss of longsolid from Rockcastle and Caney Fork Rivers, and the loss of round hickorynut in the Caney Fork, Little South Fork, Big South Fork, and Cumberland Rivers (Anderson et al. 1991, p. 6; Layzer and Anderson 1992, p. 97; Warren and Haag 2005, p. 1,383).
- Both species: In the upper Kentucky River watershed, where both species exhibit a lack of recruitment (and also the Red River for round hickorynut), historical un-reclaimed mines and active coal mines are prevalent (Kentucky Department for Environmental Protection 2015, p. 66).

Forest Conversion

Silvicultural activities, when performed according to strict forest practices guidelines or best management practices (BMPs), can retain adequate conditions for aquatic ecosystems; however, when forest practices guidelines or BMPs are not followed, these activities can also cause measurable impacts and contribute to the myriad of stressors facing aquatic systems throughout the eastern United States (Warrington et al. 2017, p. 8). Both small- and large-scale forestry activities have an impact depending on the physical, chemical, and biological characteristics of adjacent streams (Allan and Castillo 2007, p. 107).

Clearing large areas of forested wetlands and riparian systems

eliminates shade once provided by tree canopies, exposing streams to more sunlight and increasing the in-stream water temperature (Wenger 1999, p. 35). The increase in stream temperature and light after deforestation alters macroinvertebrate (and other aquatic species) richness, abundance, and composition in streams to various degrees depending a species' tolerance to temperature change and increased light in the aquatic system (Kishi et al. 2004, p. 283; Couceiro et al. 2007, p. 272; Caldwell et al. 2014, p. 2,196).

Sediment runoff from cleared forested areas is a known stressor to aquatic systems (*e.g.,* Webster et al. 1992, p. 232; Jones III et al. 1999, p. 1,455; Broadmeadow and Nisbet 2004, p. 286; Aust et al. 2011, p. 123). The physical characteristics of stream channels are affected when large quantities of sediment are added or removed (Watters 2000, p. 263). Mussels and fishes are potentially affected by changes in suspended and bed material load, changes in bed sediment composition associated with increased sediment production and runoff, changes in channel formation, stream crossings, and inadequately buffered clear-cut areas, all of which can be sources of sediment entering streams (Taylor et al. 1999, p. 13).

Forest conversion has occurred across the range of the longsolid and round hickorynut. Siltation and erosion from natural forest conversion to monoculture and intensive forestry practices without BMPs is a well-documented stressor to aquatic systems throughout the eastern United States (Warrington et al. 2017, p. 8). Forest conversion has been documented in all basins in which these species occur.

Invasive and Nonnative Species

When a nonnative species is introduced into an ecosystem, it may have many advantages over native species, such as easy adaptation to varying environments and a high tolerance of living conditions that allow it to thrive in its new habitat. There may not be natural predators to keep the nonnative species in check; therefore, it can potentially live longer and reproduce more often, further reducing the biodiversity in the system. The native species may become an easy food source for invasive, nonnative species, or the invasive species may carry diseases that extirpate populations of native species. Invasive, nonnative species are pervasive across the longsolid's and round hickorynut's ranges. Examples of invasive, nonnative species that affect freshwater mussels like the longsolid and round hickorynut are the Asian clam (*Corbicula fluminea*), zebra mussel (*Dreissena polymorpha*), quagga mussel (*Dreissena bugensis*), black carp (*Mylopharyngodon piceus*), didymo (also known as rock snot; *Didymosphenia geminata*), and hydrilla (also known as water-thyme; *Hydrilla verticillata*).

- The Asian clam alters benthic substrates, may filter mussel sperm or glochidia, competes with native species for limited resources, and causes ammonia spikes in surrounding water when they die off en masse (Scheller 1997, p. 2).

- Dreissenid mollusks, such as the zebra mussel and quagga mussel, adversely affect native species through direct colonization, reduction of available habitat, changes in the biotic environment, or a reduction in food sources (MacIsaac 1996, p. 292). Zebra mussels are also known to alter the nutrient cycle in aquatic habitats, affecting other mollusks and fish species (Strayer 1999, p. 22).

- Given their size and diet preferences, black carp have the potential to restructure benthic communities by direct predation and removal of algae-grazing snails. Mussel beds consisting of smaller individuals and juvenile recruits are probably most vulnerable to being consumed by black carp (Nico et al. 2005, p. 192). Furthermore, because black carp attain a large size (well over 3.28-ft (1-m) long), and their life span is reportedly over 15 years, they are expected to persist for many years. Therefore, they have the potential to cause harm to native mollusks by way of predation on multiple age classes (Nico et al. 2005, p. 77).

- The two nonnative plant species that are most problematic for the longsolid and round hickorynut (*i.e.,* impacting the species throughout their ranges) are hydrilla and didymo. Hydrilla is an aquatic plant that alters stream habitat, decreases flows, and contributes to sediment buildup in streams (National Invasive Species Council Management Plan 2018, p. 2). High sedimentation can cause suffocation, reduce stream flow, and make it difficult for mussels' interactions with host fish necessary for development. Didymo can alter the habitat and change the flow dynamics of a site (Jackson et al. 2016, p. 970). Invasive plants grow uncontrolled and can smother habitat, affect flow dynamics, alter water chemistry, and increase water temperatures, especially in drought conditions (Colle et al. 1987, p. 416).

Effects Associated With Small Population Size

Without the level of population connectedness that the species experienced historically (*i.e.,* without barriers such as reservoirs), small isolated populations that may now be comprised predominantly of adult individuals could be slowly dying out. Even given the very improbable absence of other anthropogenic threats, these disjunct populations could be lost simply due to the consequences of below-threshold effective population sizes. Because only 60 primarily disjunct streams among 162 historically occupied areas continue to harbor populations of the longsolid, and 65 primarily disjunct streams of 298 historically occupied areas continue to harbor populations of the round hickorynut, this is likely partial testimony to the principle of effective population size and its role in population loss.

The longsolid and round hickorynut exhibit several traits that influence population viability, including relatively small population size and low fecundity at many locations compared to other mussels (see Appendix A in Service 2018 and 2019). Small population size puts the species at greater risk of extirpation from stochastic events (*e.g.,* drought) or anthropomorphic changes and management activities that affect habitat. In addition, small longsolid or round hickorynut populations may have reduced genetic diversity, be less genetically fit, and be more susceptible to disease during extreme environmental conditions compared to large populations (Frankham 1996, p. 1,505).

Genetic drift occurs in all species, but the lack of drift is more likely to negatively affect populations that have a smaller effective population size (number of breeding individuals) and populations that are geographically spread out and isolated from one another. Relatively low fecundity, commonly observed in species of *Fusconaia,* is another inherent factor that could influence population viability (Geist 2010, p. 91). Survival of juveniles in the wild is already low, and females produce fewer offspring than other mussel species (Haag and Staton 2003, p. 2,125). Factors such as low effective population size, genetic isolation, relatively low levels of fecundity and recruitment, and limited juvenile survival could all affect the ability of these species to maintain current population levels and to rebound if a reduction in population

occurs (*e.g.,* through predation, toxic releases or spills, or poor environmental conditions that inhibit successful reproduction). Additionally, based on our presumption of fish hosts of the longsolid and the known species of fish hosts for the round hickorynut, they are small-bodied fishes that have comparatively limited movement (Vaughn 2012, p. 6); therefore, natural expansion of longsolid and round hickorynut populations is limited.

Dendritic (branched) streams and rivers are highly susceptible to fragmentation and may result in multiple habitat fragments and isolated populations of variable size (Fagan 2002, p. 3,247). In contrast to landscapes where multiple routes of movement among patches are possible, pollution or other habitat degradation at specific points in dendritic landscapes can completely isolate portions of the system (Fagan 2002, p. 3,246).

Cumulative/Synergistic Effects

Populations that have a small effective population size (number of breeding individuals) and that are geographically spread out and isolated from one another are more vulnerable than more robust populations. Factors such as low effective population size, genetic isolation, relatively low levels of fecundity and recruitment, and limited juvenile survival could all affect the ability of these species to maintain current population levels and to rebound if a reduction in population occurs (*e.g.,* through predation, toxic releases or spills, or poor environmental conditions that inhibit successful reproduction). Additionally, fragmentation (*i.e.,* the breaking apart of habitat segments, independent of habitat loss (Fahrig 2003; p. 299)) and isolation contribute to the extinction risk that mussel populations face from stochastic events (see Haag 2012, pp. 336–338). Impoundments result in the genetic isolation of mussel populations as well as fishes that act as hosts (Vaughn 2012, p. 6; Service 2018, pp. 59–60; Service 2019, p. 74). A culvert that is perched (*i.e.,* sitting above the downstream streambed) or improperly maintained at stream crossings can also act as barriers (Service 2018, pp. 50–54, 59–60; Service 2019, pp. 63, 90), and have similar effects as dams on stream systems. Fluctuating flows through a culvert can differ significantly from the rest of the stream, preventing fish passage and scouring downstream habitats.

Future Conditions

In the SSA reports, we forecast the longsolid's and round hickorynut's response to plausible future scenarios of environmental conditions and conservation efforts. The future scenarios project the threats into the future and consider the impacts those threats could have on the viability of the longsolid and round hickorynut. We apply the concepts of resiliency, redundancy, and representation to the future scenarios to describe possible future conditions of the longsolid and round hickorynut. The scenarios described in the SSA reports represent only three possible future conditions for each of the species. Uncertainty is inherent in any risk assessment, so we must consider plausible conditions to make our determinations. When assessing the future, viability is not a specific state, but rather a continuous measure of the likelihood that the species will sustain populations over time.

In the SSA reports, we considered three future scenarios. Scenario 1 assesses the species' response to factors influencing current longsolid and round hickorynut populations and management units, assuming the current level of impacts remain constant into the future. Scenario 2 assesses the species' response when factors that negatively influence most of the extant populations and management units are reduced by additional conservation, beyond the continued implementation of existing regulatory measures or voluntary conservation actions. Scenario 3 assesses the species' response to worsening conditions of the factors that most influence the species due to the implementation of known existing and projected development, resource extraction, hydroelectric projects, etc. An important assumption of the predictive analysis presented herein is that future population resiliency for each species is largely dependent on water quality, water flow, instream habitat conditions, and condition of riparian vegetation (see *Species Needs,* above).

The future conditions timeframe for our analysis is different for each species. A timeframe of 50 to 70 years into the future is evaluated for the longsolid, and 20 to 30 years into the future is evaluated for the round hickorynut. We selected these timeframes based on the availability of trends and threat information, planning documents, and climate modeling that could be reasonably projected into the future, and also the consideration of at least two generations for each species (*i.e.,* 25 to 35 years for the long-lived longsolid, and on average 12–13 years (Shepard 2006, p. 7; Ehlo and Layzer 2014, p. 11) for the round hickorynut).

Longsolid

Our assessment predicts that if conditions remain the same or worsen into the future, all 60 populations would experience negative changes to the species' important habitat requisites (see *Species Needs,* above), including the loss of the single remaining population in the Cumberland River basin, and potentially resulting in no highly resilient populations (Scenario 3). Alternatively, the scenario that suggests additive conservation measures beyond those currently implemented (Scenario 2) could result in the continued persistence of all 60 populations in the future. However, we note that approximately 30 of 60 (50 percent) of these are currently low condition populations, based on either surveys that pre-date 2000 or on the collection of only five or fewer older, non-reproducing individuals. Some of these populations may already be extirpated. The risks facing the longsolid populations varied among scenarios and are summarized below (see Table 8–1 and Table ES–1 in the SSA report).

Under Scenario 1, lowered resiliency, representation, and redundancy are expected. Under this scenario, we predict that 1 population of the current 3 high condition populations would remain in high condition, 8 populations (13 percent) in medium condition, and 33 populations (55 percent) in low condition. Redundancy would be reduced with likely extirpation of 18 out of 60 (30 percent) currently extant populations; only the Ohio River basin (one of the three basins currently occupied by the species) would retain one highly resilient population (*i.e.,* the Green River population in the Upper Green management unit). Representation would be reduced, with two of the three currently occupied river basins continuing to harbor longsolid populations.

Under Scenario 2, we predict higher levels of resiliency in some areas of the longsolid's range than was estimated for Scenario 1; representation and redundancy would remain the same level as current conditions, with the species continuing to occur within all currently occupied management units and States across its range. Nine populations (15 percent) are predicted to be in high condition, compared to the current four populations in high condition. Scenario 2 also predicts 24 populations (40 percent) in medium condition and 27 populations (45 percent) in low condition; no populations would become extirpated. All three currently occupied major river

basins would remain occupied, and the existing levels of redundancy and representation would improve. It is possible that this scenario is the least likely to occur in the future as compared to Scenario 1 or 3 only because it will take many years (potentially beyond the 50- to 70-year timeframe analyzed in the SSA report) for all of the beneficial effects of management actions that are necessary to be implemented and realized on the landscape.

Under Scenario 3, we predict a significant decrease in resiliency, representation, and redundancy across the species' range. Redundancy would be reduced from three major river basins to two basins with no high condition populations remaining, and the likely extirpation of 44 (73 percent) of the currently extant populations. The resiliency of the remaining 16 populations is expected to be reduced to 3 populations (5 percent) in medium condition and 13 (22 percent) in low condition. In addition to the loss of 44 populations, 32 (29 percent) of the management units are predicted to become extirpated. Representation would be reduced to 13 management units, 2 major river basins, and 3 States (as compared to the current 9 States) occupied by the species.

Round Hickorynut

Our assessment predicts that if conditions remain the same (Scenario 1), 40 of 65 populations (62 percent) would experience negative changes to the important habitat requisites, including the potential loss of 23 populations. This includes the predicted extirpation of the two populations in the Cumberland River basin and the population in the Lower Mississippi River basin. Additionally, under Scenario 3, no highly resilient populations are able to persist, and 90 percent of remaining populations are in low condition. Alternatively, the scenario that suggests additive conservation measures beyond those currently implemented (Scenario 2) could result in the continued persistence of all 65 populations in the future. However, approximately 40 of 65 (62 percent) of these populations are currently in low condition. Many of the known populations of the round hickorynut have been collected as 10 or fewer individuals, with limited extent information available, due to the lack of survey effort targeting the species (Service 2019, Appendix A). The risks facing round hickorynut populations varied among scenarios and are summarized below (see also Table 8–1 and Table ES–1 in the SSA report).

Under Scenario 1, lowered resiliency, representation, and redundancy are expected. We predict that only one of the current four high condition populations would remain in high condition. Under this scenario, only the Great Lakes basin (one of the five basins currently occupied by the species) would retain a highly resilient population (*i.e.,* the Grand River). Of the 65 extant populations, 13 (20 percent) would be in medium condition and 28 (43 percent) would be in low condition. We estimate extirpation of 23 out of 65 (35 percent) populations. Redundancy would decline due to these population and management unit losses, resulting in a loss of the species from Pennsylvania and Mississippi. Representation would be reduced through extirpation of populations and management units in the Cumberland and Great Lakes basins, a 40 percent loss of redundancy compared to current conditions. Under this scenario, only three of the five currently occupied river basins (Great Lakes, Ohio, and Tennessee) continue to harbor round hickorynut populations.

Under Scenario 2, we predict higher levels of resiliency in some areas of the round hickorynut's range than is estimated for Scenario 1; representation and redundancy would remain the same level as current conditions with the species continuing to occur within all currently occupied management units and States across the species' 9-State range. Up to 15 populations (23 percent) are predicted to be high condition compared to the current 4 populations in high condition. Scenario 2 also predicts 37 populations (57 percent) in medium condition and 13 populations (20 percent) in low condition. All currently occupied major river basins would remain occupied, and the existing levels of redundancy and representation would improve. There are sufficient population sizes within each basin to facilitate augmentation and restoration efforts, whether it be within-basin translocations or captive propagation techniques. It is possible that this scenario is the least likely to occur in the future as compared to Scenario 1 or 3. This is because it will take many years (potentially beyond the 20- to 30-year time frame analyzed in the SSA report) for all of the beneficial effects of management actions that are necessary to be implemented on the landscape.

Under Scenario 3, we predict a significant decrease in resiliency, representation, and redundancy across the species' range. Redundancy would be reduced from five major river basins to three basins, with extirpations expected to occur in the Cumberland and Lower Mississippi River basins. No high condition populations would remain, and 46 (71 percent) of the 65 extant populations are likely to become extirpated. The resiliency of the remaining 19 populations is expected to be reduced to 2 populations (10 percent) in medium condition and 17 (90 percent) in low condition. In addition to the potential loss of 46 populations, 20 (59 percent) of the extant 34 management units are predicted to no longer harbor the species. Representation could be reduced to 14 management units across 3 major river basins. Extirpations are expected from the States of Pennsylvania, Michigan, and Mississippi, leaving 6 States (as compared to the current 9, and historically 12) occupied by the species.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the species, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. Our assessment of the current and future conditions encompasses and incorporates the threats individually and cumulatively. Our current and future condition assessment is iterative because it accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Determination of Longsolid and Round Hickorynut Status

Introduction

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of ''endangered species'' or ''threatened species.'' The Act defines an ''endangered species'' as a species that is ''in danger of extinction throughout all or a significant portion of its range,'' and a ''threatened species'' as a species that is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The Act requires that we determine whether a species meets the definition of ''endangered species'' or ''threatened

species'' because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence.

In conducting our status assessment of the longsolid and round hickorynut, we evaluated all identified threats under the Act's section 4(a)(1) factors and assessed how the cumulative impact of all threats acts on the viability of the species as a whole. That is, all the anticipated effects from both habitat-based and direct mortality-based threats are examined in total and then evaluated in the context of what those combined negative effects will mean to the future condition of the longsolid and round hickorynut. However, for the vast majority of potential threats, the effect on the longsolid and round hickorynut (*e.g.,* total losses of individual mussels or their habitat) cannot be quantified with available information. Instead, we use the best available information to gauge the magnitude of each individual threat on the longsolid and round hickorynut, and then assess how those effects combined (and as may be ameliorated by any existing regulatory mechanisms or conservation efforts) will impact the longsolid's or round hickorynut's future viability.

Longsolid—Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the section 4(a)(1) factors, we determined that the species' distribution and abundance has been reduced across its range as demonstrated by both the number of occupied management units and the number of populations where it historically occurred. Historically, the species occurred within 162 populations and 105 management units across 12 States; currently, the species occurs in 60 populations and 45 management units across 9 States, which represents a 63 percent reduction of its historically occupied populations (although we note that the remaining populations are well-distributed as opposed to concentrated within its range). The conditions of the remaining 60 extant populations vary between being highly resilient, moderately resilient, or having low resiliency (see *Current Conditions* above, and section 5.2 in the SSA report (Service 2018, pp. 34–37)).

Currently, 3 populations (5 percent) are highly resilient, 9 (15 percent) are moderately resilient, and 48 (80 percent) have low resiliency. Although downward trends are evident compared to historical information, the 12 highly-to moderately-resilient populations continue to persist within three of the four major river basins the species is historically known to occupy. Current and ongoing threats from habitat degradation or loss (Factor A), residual impacts from past harvest and overutilization (Factor B), and invasive, nonnative species (Factor E) contribute to the species' negative effects associated with small population size (Factor E). The persistence of these 12 populations (in addition to some survey information) implies that recent recruitment is occurring in some populations to help maintain a level of resiliency, redundancy, and representation. Thus, after assessing the best available information, we conclude that the longsolid is not currently in danger of extinction throughout all of its range. We, therefore, proceed with determining whether the longsolid is likely to become endangered within the foreseeable future throughout all of its range.

At this point in time, and as noted above, the threats currently acting on the species include habitat degradation or loss from a variety of sources and invasive, nonnative species, all of which contribute to the negative effects associated with the species' small population size. Our analysis revealed that these threats are likely to continue into the foreseeable future, or approximately 30 to 50 years. This timeframe accounts for reasonable predictions of threats continuing into the future based on our examination of empirical data available over the last 30 years (*e.g.,* survey data, how threats are manifesting themselves on the landscape and the species, implementation of management plans and voluntary conservation actions), and also takes into consideration the biology of the species (multiple generations of a long-lived species) and the licensing schedules of dams within the species' range.

The best available information suggests that the threats currently acting upon the longsolid are expected to continue into the foreseeable future, some of which (*e.g.,* water quality and habitat degradation, and invasive, nonnative species) are reasonably expected to worsen over time, including concurrent with increasing human population trends and thus further reducing the species' resiliency, redundancy, and representation across its range. Our analysis reveals the potential for either none or a single population (*i.e.,* the Green River in Kentucky) to persist as highly resilient (*i.e.,* continued reproduction with varied age classes present) in the foreseeable future, assuming threats remain or worsen on the landscape. Additionally, the majority of the remaining populations would exhibit low resiliency, while many (between 30 and 73 percent of the current low condition populations) would potentially become extinct or functionally extinct (*e.g.,* significant habitat degradation, no reproduction due to highly isolated, non-recruiting individuals). Our future analysis also reveals a high risk that the species would become extirpated in one of the four historically occupied river basins (*i.e.,* Cumberland River basin); it has already been lost from the Great Lakes basin. Overall, the current threats acting on the species and its habitat are expected to continue, and there are no indications that these threats would lessen or that declining population trends would be reversed. Thus, after assessing the best available information, we conclude that the longsolid is likely to become in danger of extinction within the foreseeable future throughout all of its range.

Longsolid—Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020) (*Everson*), vacated the aspect of the 2014 Significant Portion of its Range Policy that provided that the Services do not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range. Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and, (2) the species is in danger of extinction in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Everson,* we now consider whether there are any significant portions of the species' range where the species is in danger of extinction now (*i.e.,* endangered). In undertaking this analysis for the longsolid, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered. We examined the following threats: Habitat degradation or loss; invasive, nonnative species; effects associated with small population size; and the potential for cumulative effects. We also considered whether these threats may be exacerbated by small population size (or low condition). Overall, we found that threats are likely acting on individuals or populations, or even basins, similarly across the species' range. These threats are certain to occur, and in those basins with few populations that are predominantly in low condition, these populations are facing the same threats.

One basin—the Cumberland River—has been reduced by 91 percent with one remaining low condition population. Although there are low condition populations in all three basins in which the species occurs, since this basin has seen its populations significantly reduced to a single population currently in low condition, this circumstance—in combination with the other threats acting on the species throughout its range—may indicate there is a concentration of threats in this basin such that the species may be in danger of extinction in this portion of the range.

Small, isolated populations often exhibit reduced levels of genetic variability, which diminishes the species' capacity to adapt and respond to environmental changes, thereby decreasing the probability of long-term persistence. Small populations may experience reduced reproductive vigor, for example, due to inbreeding depression. Isolated individuals may have difficulty reproducing. The problems associated with small population size and vulnerability to random demographic fluctuations or natural catastrophes are further magnified by synergistic interactions with other threats, such as those discussed above. Based on our review of information and the synergistic effects of threats exacerbated by a single low-condition population in the Cumberland River basin, we find that this basin is a portion of the range where the species may be in danger of extinction.

Because we have determined the Cumberland River basin is a portion of the range that may be in danger of extinction, we next evaluate whether this portion may be significant. As an initial note, the Service's most recent definition of ''significant'' within agency policy guidance has been invalidated by court order (see *Desert Survivors* v. *Dep't of the Interior,* No. 16–cv–01165 (N.D. Cal. Aug. 24, 2018)). Therefore, for purposes of this analysis, the Service is evaluating potentially significant portions of the range by applying any reasonable definition of ''significant'' in terms of its biological importance.

We first examined the question of whether this portion could be a significant portion of the longsolid's range by examining its contribution to the resiliency, redundancy, and representation of the species. We determined that this basin contains 1 of 60 populations (1.7 percent) identified in the SSA report. Therefore, this single population does not contribute significantly, either currently or in the foreseeable future, to the species' total resiliency at a biologically meaningful scale compared to other representative areas. The overall representation described herein would likely be the same under two of the three scenarios. We conclude that the Cumberland River basin population does not contribute meaningfully to the species' viability overall. We evaluated the best available information for the Cumberland River basin in this context, assessing its significance in terms of these conservation concepts, and determined that this single population is not biologically significant to the species.

Longsolid populations are widely distributed over nine States and three major river basins, and we considered geographic range as a surrogate for geographic variation and proxy for potential local adaptation and adaptive capacity. A river basin is any area of land where precipitation collects and drains off into a common outlet, such as into a river, bay, or other body of water. The river basin includes all the surface water from precipitation runoff and nearby streams that run downslope towards the shared outlet, as well as the groundwater underneath the earth's surface. River basins connect into other drainage basins at lower elevations in a hierarchical pattern, with smaller sub-drainage basins. There are no data indicating genetic or morphological differentiation between the three major river basins for the species. Further, the longsolid occurs in similar aquatic habitats and does not use unique observable environmental or behavioral characteristics attributable to any of the basins. Therefore, it exhibits similar basin-scale use of habitat.

At a population level, the Cumberland River basin population occurs in stream habitat comprised of similar substrate types to the other basins where the longsolid performs the important life-history functions of breeding, feeding, and sheltering, and occurs in areas with water quality sufficient to sustain these essential life-history traits. The single population in the Cumberland River basin does not act as a refugia for the species or as an important spawning ground. In addition, the water quality is similar throughout the species' range with impaired water quality occurring in all three basins. Since the longsolid occurs in similar aquatic habitats, the Cumberland River basin population exhibits similar habitat use as populations in the remainder of the range. Therefore, there is no unique, observable environmental usage or behavioral characteristics attributable to just the Cumberland River basin population.

Overall, we found no substantial information that would indicate the Cumberland River basin is a portion of the range that may be significant in terms of its overall contribution to the species' resiliency, redundancy, and representation, or that it may be significant in terms of high-quality habitat or habitat that is otherwise important for the species' life history. As a result, we determined there is no portion of the longsolid's range that constitutes a significant portion of the range. Accordingly, we determine that the species is likely to become in danger of extinction within the foreseeable future throughout all of its range. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Longsolid—Determination of Status

Our review of the best available scientific and commercial information indicates that the longsolid meets the definition of a threatened species. Therefore, we propose to list the longsolid as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Round Hickorynut—Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the Act's section 4(a)(1) factors, we determined that the

round hickorynut's abundance has been reduced across its range as demonstrated by both number of occupied management units and the number of populations where the species has historically occurred. Historically, the species occurred within 297 populations and 138 management units across 12 States (plus at least 10 populations and 8 management units within the Canadian Province of Ontario); currently, the species occurs in 65 populations and 34 management units across 9 States, which represents a 78 percent reduction of its historically occupied populations (although we note that the remaining populations are widely distributed as opposed to concentrated within its range). The species also continues to occur in Canada, although it is estimated to have declined by greater than 92 percent, as reported in 2013 (Committee on the Status of Species at Risk in Ontario 2013, p. 4). The condition of the remaining 65 currently extant populations in the United States are categorized as either high, moderate, or low (see the applicable condition description above under *Longsolid—Status Throughout All of Its Range,* and section 5.2 in the round hickorynut's SSA report (Service 2019, pp. 43–47)).

Currently, 4 round hickorynut populations (6 percent) are highly resilient, 16 (25 percent) are moderately resilient, and 45 (69 percent) have low resiliency. Although downward trends are evident compared to historical information, the 20 highly to moderately resilient populations in the United States continue to persist within 4 of the 5 major river basins where the species is historically known to occur. Current and ongoing threats from habitat degradation or loss (Factor A), and invasive, nonnative species (Factor E), contribute to the negative effects associated with the species' small population size (Factor E). The persistence of these 20 populations (in addition to some survey information) implies that recent recruitment is occurring in some populations, and they maintain a level of resiliency, redundancy, and representation. Thus, after assessing the best available information, we conclude that the round hickorynut is not currently in danger of extinction throughout all of its range. We, therefore, proceed with determining whether the round hickorynut is likely to become endangered within the foreseeable future throughout all of its range.

As noted above, the threats acting on the species include habitat degradation or loss from a variety of sources and invasive, nonnative species, both of which contribute to the negative effects associated with the species' small population size. Our analysis revealed that these threats are likely to continue into the foreseeable future, or approximately 20 to 40 years. This timeframe accounts for reasonable predictions of threats continuing into the future based on our examination of empirical data in our files (*e.g.,* survey data, how threats are manifesting themselves on the landscape and the species, implementation of management plans and voluntary conservation actions), and also takes into consideration the biology of the species and the licensing schedules of dams within the species' range.

The best available information suggests that the threats currently acting upon the round hickorynut are expected to continue into the foreseeable future. The effects of water quality and habitat degradation, and invasive, nonnative species are reasonably expected to worsen over time, including concurrent with increasing human population trends and thus further reducing the species' resiliency, redundancy, and representation across its range. Our analysis reveals the potential for either none or a single population (*i.e.,* the Grand River in Ohio) to persist as highly resilient (*i.e.,* continued reproduction with varied age classes present) in the foreseeable future, assuming threats remain or worsen on the landscape. Additionally, the majority of the remaining populations would exhibit low resiliency, while many (between 35 and 62 percent of the current low conditions populations) would potentially become extinct or functionally extinct (*e.g.,* significant habitat degradation, no reproduction due to highly isolated, non-recruiting individuals). Our future analysis also reveals a high risk that the species would become extirpated in two of the five historically occupied river basins (*i.e.,* Cumberland River basin and Lower Mississippi River basin). Overall, the current threats acting on the species and its habitat are expected to continue, and there are no indications that these threats would be lessened or that declining population trends would be reverted. Thus, after assessing the best available information, we conclude that the round hickorynut is likely to become in danger of extinction within the foreseeable future throughout all of its range.

Round Hickorynut—Status Throughout a Significant Portion of Its Range

See above, under *Longsolid—Status Throughout a Significant Portion of Its Range,* for a description of our evaluation methods and our policy application.

In undertaking the analysis for the round hickorynut, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered. We examined the following threats: Habitat degradation or loss; invasive, nonnative species; negative effects associated with small population size; and the potential for cumulative effects. We also considered whether these threats may be exacerbated by small population size (or low condition). Overall, we found that threats are likely acting on individuals or populations, or even basins, similarly across the species' range. These threats are certain to occur, and in those basins with few populations that are predominantly in low condition, these populations are facing the same threats.

Three of five basins where round hickorynut has historically occurred (Great Lakes, Cumberland River, and Lower Mississippi River basins) have been reduced to predominantly low condition populations. Specifically, the Great Lakes basin has been reduced from 25 populations to 5 low condition populations, 1 medium condition population, and 1 high condition population; the Cumberland River basin has been reduced from 23 populations to 2 low condition populations; and the Lower Mississippi River basin has been reduced from 9 populations to a single remaining low condition population. Although there are low condition populations in every basin in which the species occurs, since these three basins have seen their populations significantly reduced and a predominance of the Great Lakes basin populations and the remaining populations for the other two basins are currently in low condition, these circumstances—in combination with the other threats acting on the species throughout its range—may indicate there is a concentration of threats in these areas such that the species may be in danger of extinction in these portions of the range.

As similarly described above for the longsolid, small, isolated populations often exhibit reduced levels of genetic variability, which diminishes the species' capacity to adapt and respond to environmental changes, thereby decreasing the probability of long-term persistence. Small populations may experience reduced reproductive vigor, for example, due to inbreeding depression. Isolated individuals may have difficulty reproducing. The

problems associated with small population size and vulnerability to random demographic fluctuations or natural catastrophes are further magnified by synergistic interactions with other threats, such as those discussed above. Based on our review of information and the synergistic effects of threats exacerbated by a predominance of populations in low condition within the Great Lakes, Cumberland, and Lower Mississippi River basins (where populations have been significantly extirpated), we find that these three basins are portions of the range where the species may be in danger of extinction.

Because we have determined the Great Lakes, Cumberland, and Lower Mississippi River basins are portions of the range where the species may be in danger of extinction, we next evaluate whether those portions may be significant (see additional discussion above for the longsolid). Therefore, for purposes of this analysis, the Service is evaluating potentially significant portions of the range by applying any reasonable definition of ''significant'' in terms of its biological importance.

We first examined the question of whether these portions could be a significant portion of the round hickorynut's range by examining their contribution to the resiliency, redundancy, and representation of the species. Although these basins contain 10 of 65 populations (15 percent) identified in the SSA report, the Great Lakes basin consists of 1 population currently with moderate resiliency and 1 with high resiliency, and the remaining 5 populations demonstrate low resiliency; the remaining 3 populations in the Cumberland River basin and the Lower Mississippi River basin are all low condition populations. These low condition populations do not contribute significantly, either currently or in the foreseeable future, to the species' total resiliency at a biologically meaningful scale compared to other representative areas. Although the low condition populations in these basins are relatively small, the current and future redundancy suggests that threats would be unlikely to extirpate round hickorynut in the Great Lakes basin, but there is potential to lose the remaining three low condition populations under the current level of threats scenario (Scenario 1). Overall representation would be modified through loss of two currently occupied basins. We evaluated the best available information for the Great Lakes, Cumberland River, and Lower Mississippi River basins in this context, assessing its significance in terms of these conservation concepts, and determined that there is not substantial information to indicate that any of these areas may be significant.

Round hickorynut populations are widely distributed over nine States and five major river basins, and we considered geographic range as a surrogate for geographic variation and proxy for potential local adaptation and adaptive capacity. A river basin is any area of land where precipitation collects and drains off into a common outlet, such as into a river, bay, or other body of water. The river basin includes all the surface water from precipitation runoff and nearby streams that run downslope towards the shared outlet, as well as the groundwater underneath the earth's surface. River basins connect into other drainage basins at lower elevations in a hierarchical pattern, with smaller sub-drainage basins. There are no data indicating genetic or morphological differentiation between the five major river basins for the species. Further, the round hickorynut occurs in similar aquatic habitats and does not use unique observable environmental or behavioral characteristics attributable to just the Great Lakes, Cumberland River, or Lower Mississippi River basin populations. Therefore, the species exhibits similar basin-scale use of habitat.

At a population level, the Great Lakes, Cumberland River, and Lower Mississippi River basin populations occur in stream habitat comprised of substrate types similar to the other basins where the round hickorynut performs the important life-history functions of breeding, feeding, and sheltering, and occurs in areas with water quality sufficient to sustain these essential life-history traits. Populations in these three basins do not act as refugia for the species or as an important spawning ground. In addition, the water quality is similar throughout the species' range with impaired water quality occurring in all basins. Since the round hickorynut occurs in similar aquatic habitats, the Great Lakes, Cumberland River, and Lower Mississippi River basin populations exhibit similar habitat use as the remainder of the species' range. Therefore, there is no unique observable environmental usage or behavioral characteristics attributable to just these basins.

Overall, we found no substantial information that would indicate the Great Lakes, Cumberland, or Lower Mississippi River basins constitute portions of the range that may be significant in terms of their contribution to the species' resiliency, redundancy, and representation, or that they may be significant in terms of high-quality habitat or habitat that is otherwise important for the species' life history. As a result, we determined there is no portion of the round hickorynut's range that constitutes a significant portion of the range. Accordingly, we determine that the round hickorynut is likely to become in danger of extinction within the foreseeable future throughout all of its range. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Round Hickorynut—Determination of Status

Our review of the best available scientific and commercial information indicates that the round hickorynut meets the definition of a threatened species. Therefore, we propose to list the round hickorynut as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning consists of preparing draft and final recovery plans, beginning with the development of a recovery outline and making it available to the public within 30 days of a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened (''downlisting'') or removal from protected status (''delisting''), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (*http://www.fws.gov/endangered*).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and tribal lands.

If these species are listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of New York, Pennsylvania, Ohio, Indiana, Michigan, Kentucky, West Virginia, Virginia, North Carolina, Tennessee, Alabama, and Mississippi would be eligible for Federal funds to implement management actions that promote the protection or recovery of the longsolid or round hickorynut or both species. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although the longsolid and round hickorynut are only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for these species. Additionally, we invite you to submit any new information on these species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' range that may require conference or consultation or both as described in the preceding paragraph include actions that fund, authorize, or carry out management and any other landscape-altering activities administered by the following agencies:

(1) U.S. Army Corps of Engineers (channel dredging and maintenance; dam projects including flood control, navigation, hydropower, bridge projects, stream restoration, and Clean Water Act permitting).

(2) U.S. Department of Agriculture, including the Natural Resources Conservation Service and Farm Service Agency (technical and financial assistance for projects) and the Forest Service (aquatic habitat restoration, fire management plans, fire suppression, fuel reduction treatments, forest plans, mining permits).

(3) U.S. Department of Energy (renewable and alternative energy projects).

(4) Federal Energy Regulatory Commission (interstate pipeline construction and maintenance, dam relicensing, and hydrokinetics).

(5) U.S. Department of Transportation (highway and bridge construction and maintenance).

(6) U.S. Fish and Wildlife Service (issuance of section 10 permits for enhancement of survival, habitat conservation plans, and safe harbor agreements; National Wildlife Refuge planning and refuge activities; Partners for Fish and Wildlife program projects benefiting these species or other listed species; Wildlife and Sportfish Restoration program sportfish stocking).

(7) Environmental Protection Agency (water quality criteria, permitting).

(8) Tennessee Valley Authority (flood control, navigation, hydropower, and land management for the Tennessee River system).

(9) Office of Surface Mining Reclamation and Enforcement (land resource management plans, mining permits, oil and natural gas permits, abandoned mine land projects, and renewable energy development).

(10) National Park Service (aquatic habitat restoration, fire management plans, fire suppression, fuel reduction treatments, land management plans, mining permits).

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. The discussion below regarding protective regulations under section 4(d) of the Act complies with our policy.

III. Proposed Rule Issued Under Section 4(d) of the Act for the Longsolid and Round Hickorynut

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the ''Secretary shall issue such regulations as he deems necessary and advisable to provide for the conservation'' of species listed as threatened. The U.S. Supreme Court has noted that statutory language like ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean ''the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act

are no longer necessary.'' Additionally, the second sentence of section 4(d) of the Act states that the Secretary ''may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants.'' Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife, or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to him with regard to the permitted activities for those species. He may, for example, permit taking, but not importation of such species, or he may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising this authority under section 4(d), we have developed a proposed rule that is designed to address the longsolid's and round hickorynut's specific threats and conservation needs. Although the statute does not require us to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the longsolid and round hickorynut. As discussed above under Summary of Biological Status and Threats, we have concluded that the longsolid and round hickorynut are likely to become in danger of extinction within the foreseeable future primarily due to declines in water quality, loss of stream flow, fragmentation, alteration and deterioration of instream habitats, and nonnative species. These threats, which are expected to be exacerbated by continued urbanization and the effects of climate change, were central to our assessment of the future viability of the longsolid and round hickorynut. The provisions of this proposed 4(d) rule would promote conservation of the longsolid and round hickorynut by encouraging management of the landscape in ways that meet the conservation needs of the longsolid and round hickorynut, and are consistent with land management considerations. This proposed 4(d) rule would apply only if and when we make final the listing of the longsolid and round hickorynut as threatened species.

Provisions of the Proposed 4(d) Rule

This proposed 4(d) rule would provide for the conservation of the longsolid and round hickorynut by prohibiting the following activities, except as otherwise authorized or permitted: Importing or exporting; take; possession and other acts with unlawfully taken specimens; delivering, receiving, transporting, or shipping in interstate or foreign commerce in the course of commercial activity; or selling or offering for sale in interstate or foreign commerce.

As discussed above under Summary of Biological Status and Threats, multiple factors are affecting the status of the longsolid and round hickorynut. A range of activities have the potential to affect these species, including declines in water quality, loss of stream flow, riparian and instream fragmentation, alteration and deterioration of instream habitats, and nonnative species. These threats, which are expected to be exacerbated by continued urbanization and the effects of climate change, were central to our assessment of the future viability of the longsolid and round hickorynut. Therefore, we prohibit actions resulting in the incidental take of longsolid and round hickorynut by altering or degrading the habitat. Regulating incidental take resulting from these activities would help preserve the species' remaining populations, slow their rate of decline, and decrease synergistic, negative effects from other stressors.

Under the Act, ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Some of these provisions have been further defined in regulation at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or incidentally. Regulating incidental and/or intentional take would help preserve the species' remaining populations, slow their rate of decline, and decrease synergistic, negative effects from other stressors. Therefore, we propose to prohibit intentional take of the longsolid and round hickorynut. Nothing in this proposed 4(d) rule would change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of the longsolid or round hickorynut. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species' between Federal agencies and the Service, where appropriate. We ask the public, particularly State agencies and other interested stakeholders that may be affected by the proposed 4(d) rule, to provide comments and suggestions regarding additional guidance and methods that the Service could provide or use, respectively, to streamline the implementation of this proposed 4(d) rule (see Information Requested, above).

The proposed 4(d) rule would also provide for the conservation of the species by allowing exceptions to actions and activities that, while they may have some minimal level of disturbance to the longsolid and round hickorynut, are not expected to negatively impact the species' conservation and recovery efforts. The proposed exceptions to these prohibitions include (1) conservation efforts by the Service or State wildlife agencies, (2) channel restoration projects, and (3) bank restoration projects.

The first exception is for conservation and restoration efforts for listed species by the Service or State wildlife agencies, and including, but not limited to, collection of broodstock, tissue collection for genetic analysis, captive propagation, and subsequent stocking into unoccupied areas within the historical range of the species. The Service recognizes our special and unique relationship with our State natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and

landowners, are in a unique position to assist the Services in implementing all aspects of the Act. In this regard, section 6 of the Act provides that the Services shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, would be able to conduct activities designed to conserve the longsolid and round hickorynut that may result in otherwise prohibited take for wildlife without additional authorization.

The second and third exceptions are for channel and bank restoration projects for creation of natural, physically stable, ecologically functioning streams, taking into consideration connectivity with floodplain and groundwater aquifers. These exceptions include a requirement that bank restoration projects require planting appropriate native vegetation, including woody species appropriate for the region and habitat. We also propose language that would require surveys and relocation prior to commencement of restoration actions for longsolid and round hickorynut that would otherwise be negatively affected by the actions.

We reiterate that these actions and activities may have some minimal level of take of the longsolid and round hickorynut, but any such take is expected to be rare and insignificant, and is not expected to negatively impact the species' conservation and recovery efforts. Rather, we expect they would have a net beneficial effect on the species. Across the species' range, instream habitats have been degraded physically by sedimentation and by direct and indirect channel disturbance. The habitat restoration activities in the proposed 4(d) rule are intended to improve habitat conditions for the species in the long term.

Regulations governing permits for threatened wildlife are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: for scientific purposes, to enhance the propagation or survival of the species, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act.

Finally, the proposed 4(d) rule would allow take of the longsolid and round hickorynut without a permit by any employee or agent of the Service or a State conservation agency designated by the agency for such purposes and when acting in the course of their official duties if such action is necessary to aid a sick, injured, or orphaned specimen; to dispose of a dead specimen; or to salvage a dead specimen which may be useful for scientific study. In addition, Federal and State wildlife law enforcement officers, working in coordination with Service field office personnel, may possess, deliver, carry, transport, or ship longsolid and round hickorynut taken in violation of the Act as necessary.

IV. Critical Habitat for the Longsolid and Round Hickorynut

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, habitat restoration, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Designation also does not allow the government or public to access private lands, nor does designation require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult with the Service under section 7(a)(2) of the Act. However, even if the Service were to conclude that the proposed activity would result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives'' to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features that occur in specific occupied areas, we focus on the specific features that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology,

such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. When designating critical habitat, the Secretary will first evaluate areas occupied by the species. The Secretary will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied by the species would be inadequate to ensure the conservation of the species. In addition, for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable certainty both that the area will contribute to the conservation of the species and that the area contains one or more of those physical or biological features essential to the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

As discussed earlier in this document, there is currently no imminent threat of collection or vandalism identified under Factor B for these species, and identification and mapping of critical habitat is not expected to initiate any such threat. In our SSA reports and the proposed listing determination for the longsolid and round hickorynut, we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to the longsolid and round hickorynut, and that those threats in some way can be addressed by section 7(a)(2) consultation measures. The species occur wholly in the jurisdiction of the United States (with the exception of one remnant, small population of round hickorynut in the Ontario Province of Canada, which Canada has listed as an endangered species and designated critical habitat in the East Syndenham River), and we are able to identify areas that meet the definition of critical habitat. Therefore, because none of the circumstances enumerated in our regulations at 50 CFR 424.12(a)(1) have been met and because there are no other circumstances the Secretary has identified for which this designation of critical habitat would be not prudent, we have determined that the designation of critical habitat is prudent for the longsolid and round hickorynut.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the longsolid and round hickorynut is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Data sufficient to perform required analyses are lacking, or

(ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of ''critical habitat.''

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

We reviewed the available information pertaining to the biological needs of the species and habitat characteristics where these species are located. Our review of the best scientific data available led us to conclude that the designation of critical habitat is determinable for the longsolid and round hickorynut.

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat from within the geographical area occupied by the species at the time of listing, we consider the physical or biological features essential to the conservation of the species and that may require special management considerations or protection. The regulations at 50 CFR 424.02 define ''physical or biological features essential to the conservation of the species'' as the features that occur in specific areas that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkali soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic essential to support the life history of the species.

In considering whether features are essential to the conservation of the species, the Service may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance.

As described above under Summary of Biological Status and Threats, longsolid and round hickorynut mussels occur in river or stream reaches. Occasional or regular interaction among individuals in different reaches not interrupted by a barrier likely occurs, but in general, interaction is strongly influenced by habitat fragmentation and distance between occupied river or stream reaches. Once released from their fish host, freshwater mussels are benthic, generally sedentary aquatic organisms and closely associated with appropriate habitat patches within a river or stream.

We derive the specific physical or biological features essential for the longsolid and round hickorynut from studies of these species' (or appropriate surrogate species') habitat, ecology, and life history. The primary habitat elements that influence resiliency of the longsolid and round hickorynut include water quality, water quantity, substrate, habitat connectivity, and the presence of host fish species to ensure recruitment. These features are also described above as resource needs under Summary of Biological Status and Threats, and a full description is available in the SSA reports; the individuals' needs are summarized below in Table 1.

TABLE 1—REQUIREMENTS FOR EACH LIFE STAGE OF THE LONGSOLID AND ROUND HICKORYNUT MUSSELS

Life stage	Resources needed to complete life stage [1]	Source
Fertilized eggs—early spring	• Clear, flowing water • Sexually mature males upstream from sexually mature females. • Appropriate spawning temperatures.	Berg *et al.* 2008, p. 397; Haag 2012, pp. 38–39.
Glochidia—late spring to early summer.	• Clear, flowing water • Enough flow to keep glochidia or conglutinates adrift and to attract drift-feeding host fish. • Presence of host fish for attachment.	Strayer 2008, p. 65; Haag 2012, pp. 41–42.
Juveniles—excystment from host fish to approx. 0.8 in (~20 mm) shell length.	• Clear, flowing water • Host fish dispersal. • Appropriate interstitial chemistry; low salinity, low ammonia, low copper and other contaminants, high dissolved oxygen. • Appropriate substrate (clean gravel/sand/cobble) for settlement.	Dimock and Wright 1993, pp. 188–190; Sparks and Strayer 1998, p. 132; Augspurger *et al.* 2003, p. 2,574; Augspurger *et al.* 2007, p. 2,025; Strayer and Malcom 2012, pp. 1,787–1,788.
Adults—greater than 0.8 in (20 mm) shell length.	• Clear, flowing water • Appropriate substrate (stable gravel and coarse sand free from excessive silt). • Adequate food availability (phytoplankton and detritus). • High dissolved oxygen. • Appropriate water temperature.	Yeager *et al.* 1994, p. 221; Nichols and Garling 2000, p. 881; Chen *et al.* 2001, p. 214; Spooner and Vaughn 2008, p. 308.

[1] These resource needs are common among North American freshwater mussels; however, due to lack of species-specific research, parameters specific to longsolid and round hickorynut are unavailable.

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential to the conservation of the longsolid and round hickorynut from studies of the species' habitat, ecology, and life history as described below. Additional information can be found in chapter 4 of the SSA reports (Service 2018, pp. 27–32; Service 2019, pp. 30–39), both of which are available on *http://www.regulations.gov* under Docket No. FWS–R4–ES–2020–0010. We have determined that the following physical or biological features are essential to the conservation of the longsolid and round hickorynut:

(1) Adequate flows, or a hydrologic flow regime (magnitude, timing, frequency, duration, rate of change, and overall seasonality of discharge over time), necessary to maintain benthic habitats where the species are found and to maintain stream connectivity, specifically providing for the exchange of nutrients and sediment for maintenance of the mussels' and fish host's habitat and food availability, maintenance of spawning habitat for native fishes, and the ability for newly transformed juveniles to settle and become established in their habitats. Adequate flows ensure delivery of oxygen, enable reproduction, deliver food to filter-feeding mussels, and reduce contaminants and fine sediments from interstitial spaces. Stream velocity is not static over time, and variations may be attributed to seasonal changes (with higher flows in winter/spring and lower flows in summer/fall), extreme weather events (*e.g.,* drought or floods), or anthropogenic influence (*e.g.,* flow regulation via impoundments).

(2) Suitable substrates and connected instream habitats, characterized by geomorphically stable stream channels and banks (*i.e.,* channels that maintain lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation) with habitats that support a diversity of freshwater mussel and native fish (such as, stable riffle-run-pool habitats that provide flow refuges consisting of predominantly silt-free, stable sand, gravel, and cobble substrates).

(3) Water and sediment quality necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages, including (but not limited to): dissolved oxygen (generally above 2 to 3 parts per million (ppm)), salinity (generally below 2 to 4 ppm), and temperature (generally below 86 °Fahrenheit (°F) (30 °Celsius (°C)). Additionally, water and sediment should be low in ammonia (generally below 0.5 ppm total ammonia-nitrogen) and heavy metal concentrations, and lack excessive total suspended solids and other pollutants (see *Threats Analysis,* above).

(4) The presence and abundance of fish hosts necessary for recruitment of the longsolid (currently unknown, likely includes minnows of the family Cyprinidae and banded sculpin (*Cottus carolinae*)) and the round hickorynut (*i.e.,* eastern sand darter (*Ammocrypta pellucida*), emerald darter (*Etheostoma baileyi*), greenside darter (*E. blennioides*), Iowa darter (*E. exile*), fantail darter (*E. flabellare*), Cumberland darter (*E. susanae*), spangled darter (*E. obama*), variegate darter (*E. variatum*), blackside darter (*Percina maculata*), frecklebelly darter (*P. stictogaster*), and banded sculpin).

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection.

The features essential to the conservation of the longsolid and round hickorynut may require special management considerations or protections to reduce the following threats: (1) Alteration of the natural flow regime (modifying the natural hydrograph and seasonal flows), including water withdrawals, resulting in flow reduction and available water quantity; (2) urbanization of the landscape, including (but not limited to) land conversion for urban and commercial use, infrastructure (pipelines, roads, bridges, utilities), and urban water uses (resource extraction activities, water supply reservoirs, wastewater treatment, etc.); (3) significant alteration of water quality and nutrient pollution from a variety of activities, such as mining and agricultural activities; (4) impacts from invasive species; (5) land use activities that remove large areas of forested wetlands and riparian systems; (6) culvert and pipe installation that creates barriers to movement for the longsolid and round hickorynut, or their host fishes; (7) changes and shifts in seasonal precipitation patterns as a result of climate change; and (8) other watershed and floodplain disturbances that release sediments, pollutants, or nutrients into the water.

Management activities that could ameliorate these threats include, but are not limited to: Use of best management practices designed to reduce sedimentation, erosion, and bank destruction; protection of riparian corridors and woody vegetation; moderation of surface and ground water withdrawals to maintain natural flow regimes; improved stormwater management; and reduction of other watershed and floodplain disturbances that release sediments, pollutants, or nutrients into the water.

In summary, we find that the occupied areas we are proposing to designate as critical habitat contain the physical or biological features that are essential to the conservation of the species and that may require special management considerations or protection. Special management considerations or protection may be required of the Federal action agency to eliminate, or to reduce to negligible levels, the threats affecting the physical and biological features of each unit.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat. We are not currently proposing to designate any areas outside the geographical area occupied by the longsolid or round hickorynut because we have determined that occupied areas are sufficient to conserve these two species.

Methodology Used for Selection of Proposed Units

First, we included stronghold (high) or medium condition populations (resiliency) remaining from historical conditions. These populations show recruitment or varied age class structure, and could be used for recovery actions to re-establish populations within basins through propagation activities or augment other populations through direct translocations within their basins.

Second, we evaluated spatial representation and redundancy across the species range, to include last remaining consistently observable population(s) in major river basins and

the last remaining population(s) in states if necessary, as states are crucial partners in monitoring and recovery efforts.

Third, we examined the overall contribution of medium condition populations and threats to those populations. Adjacency and connectivity to stronghold and medium populations was considered, and we did not include populations that have potentially low likelihood of recovery due to limited abundances or populations currently under a high level of threats.

Finally, we evaluated overlap of longsolid and round hickorynut occurrences, as well as other listed aquatic species and designated critical habitat, to see if there are ongoing conservation and monitoring efforts that can be capitalized on for efficiency. Rangewide recovery considerations, such as maintaining existing genetic diversity and striving for representation of all major portions of the species' current range, were considered in formulating this proposed critical habitat. For example, in the Cumberland River basin, there is only one remaining population of the longsolid (mainstem Cumberland River) and only two populations remaining of the round hickorynut (Buck Creek and Rockcastle River). In addition, in the Mississippi River basin, only one population of the round hickorynut remains (Big Black River). The distribution of the longsolid and round hickorynut in these basins is substantially reduced when compared to historical data that indicates these species were formerly much more widespread within these drainages. Therefore, these rivers and streams were included to maintain basin representation.

The proposed critical habitat designation does not include all rivers and streams currently occupied by the species, nor all rivers and streams known to have been occupied by the species historically. Instead, it includes only the occupied rivers and streams within the current range that we determined are critical to the conservation of these species. These rivers and streams contain populations large and dense enough and most likely to be self-sustaining over time (despite fluctuations in local conditions), and also have retained the physical or biological features that will allow for the maintenance and expansion of existing populations. These units also represent populations that are stable and distributed over a wide geographic area. We are not proposing to designate any areas outside the geographical area currently occupied by either the longsolid or round hickorynut because we did not find any unoccupied areas that are essential to the conservation of these species, and we determined that occupied areas are sufficient to conserve the two species.

Sources of data for this proposed critical habitat include multiple databases maintained by universities, information from State agencies throughout the species' ranges, and numerous survey reports on streams throughout the species' ranges (see SSA reports (Service 2018, entire; Service 2019, entire)). We have also reviewed available information that pertains to the habitat requirements of these species. Sources of information on habitat requirements include studies conducted at occupied sites and published in peer-reviewed articles, agency reports, and data collected during monitoring efforts (Service 2018, entire; Service 2019, entire).

In summary, for areas within the geographic area occupied by these species at the time of listing, we delineated critical habitat unit boundaries using a precise set of criteria. Specifically, we identified river and stream reaches with observations from 2000 to present, given the variable data associated with timing and frequency of mussel surveys conducted throughout the species' ranges. We determined it is reasonable to find these areas occupied due to the longevity of the longsolid, the potential for incomplete survey detections for the round hickorynut, highly variable recent survey information across both species' ranges, and available State heritage databases and information support for the likelihood of both species' continued presence in these areas within this timeframe. Specific habitat areas were delineated based on Natural Heritage Element Occurrences, and unpublished survey data provided by States, universities, and nongovernmental organizations. These areas provide habitat for longsolid and round hickorynut populations and are large enough to be self-sustaining over time, despite fluctuations in local conditions. The areas within the proposed units represent continuous river and stream reaches of free-flowing habitat patches capable of sustaining host fishes and allowing for seasonal transport of glochidia, which are essential for reproduction and dispersal of longsolid and round hickorynut. We consider portions of the following rivers and streams to be occupied by the species at the time of proposed listing, and appropriate for critical habitat designation:

(1) Longsolid—French Creek, Allegheny River, Shenango River, Middle Island Creek, Little Kanawha River, Elk River, Kanawha River, Licking River, Green River, Cumberland River, Clinch River, and Paint Rock River (see *Unit Descriptions,* below).

(2) Round hickorynut—Shenango River, Grand River, Tippecanoe River, Middle Island Creek, Little Kanawha River, Elk River, Kanawha River, Licking River, Rockcastle River, Buck Creek, Green River, Paint Rock River, Duck River, and Big Black River (see *Unit Descriptions,* below).

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for the longsolid and round hickorynut. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

We propose to designate as critical habitat lands that we have determined are occupied at the time of listing (*i.e.,* currently occupied) and that contain one or more of the physical or biological features that are essential to support life-history processes of the species. Twelve units for the longsolid and 14 units for the round hickorynut are proposed for designation based on the presence of the physical or biological features being present that support the longsolid's or round hickorynut's life-history processes. All of the units for both species contain all of the identified physical or biological features and support multiple life-history processes.

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Proposed Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the

coordinates or plot points or both on which each map is based available to the public on *http://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0010 and on our internet site *https://www.fws.gov/Asheville/*.

Proposed Critical Habitat Designation

We propose designating a total of 1,115 river mi (1,794 km) in 12 units as occupied critical habitat for the longsolid and a total of 921 river mi (1,482 km) in 14 units as occupied critical habitat for the round hickorynut. All or portions of some of these units overlap, and all 26 units are occupied by one or both species. The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for the longsolid and round hickorynut. The 12 areas we propose as critical habitat for the longsolid are: French Creek, Allegheny River, Shenango River, Middle Island Creek, Little Kanawha River, Elk River, Kanawha River, Licking River, Green River, Cumberland River, Clinch River, and Paint Rock River. The 14 areas we propose as critical habitat for the round hickorynut are: Shenango River, Grand River, Tippecanoe River, Middle Island Creek, Little Kanawha River, Elk River, Kanawha River, Licking River, Rockcastle River, Buck Creek, Green River, Paint Rock River, Duck River, and Big Black River. Tables 2 and 3 show the proposed critical habitat units and the approximate river miles of each unit.

TABLE 2—PROPOSED CRITICAL HABITAT UNITS FOR THE LONGSOLID. ALL UNITS ARE OCCUPIED BY THE SPECIES

[Area estimates reflect all land within critical habitat unit boundaries]

Critical habitat unit (state)	Adjacent riparian land ownership by type	Approximate river miles (kilometers)
LS 1. French Creek (Pennsylvania)	Public (Federal, State);	14 (22.1)
	Private	106 (170.6)
		Total = 120 (191.5)
LS 2. Allegheny River (Pennsylvania)	Public (Federal, State);	84 (135.8)
	Private	15 (24.1)
		Total = 99 (159.3)
LS 3. Shenango River (Pennsylvania)	Public (Federal, State);	7 (11.3)
	Private	15 (24.3)
		Total = 22 (35.5)
LS 4. Middle Island Creek (West Virginia)	Public (Local);	0.13 (0.2)
	Private	14 (23.5)
		Total = 14 (23.7)
LS 5. Little Kanawha River (West Virginia)	Public (Federal, State);	0.53 (0.9)
	Private	122 (197.2)
		Total = 123 (198)
LS 6. Elk River (West Virginia)	Public (Federal, State, Local);	7 (12.7)
	Private	93 (150.3)
		Total = 101 (163)
LS 7. Kanawha River (West Virginia)	Public (Federal, State, Local);	2 (4.6)
	Private	18 (29.3)
		Total = 21 (33.9)
LS 8. Licking River (Kentucky)	Public (Federal, State, Local);	19 (31.7)
	Private	161 (259.7)
		Total = 181 (291.5)
LS 9. Green River (Kentucky)	Public (Federal, State, Local);	51 (82.4)
	Private	105 (169.2)
		Total = 156 (251.6)
LS 10. Cumberland River (Tennessee)	Public (Federal)	Total = 48 (77.5)
LS 11. Clinch River (Virginia and Tennessee)	Public (Federal, State);	17 (27.3)
	Private	160 (258.8)
		Total = 177 (286.1)
LS 12. Paint Rock River (Alabama)	Public (Federal, State);	56 (90.4)
	Private	2 (4.1)
		Total = 58 (94.5)
	Public	305 (491)
	Private	810 (1,304)
	Total	1,115 (1,794)

Note: River miles may not sum due to rounding.

TABLE 3—PROPOSED CRITICAL HABITAT UNITS FOR THE ROUND HICKORYNUT. ALL UNITS ARE OCCUPIED BY THE SPECIES

[Area estimates reflect all land within critical habitat unit boundaries]

Critical habitat unit	Adjacent riparian land ownership by type	Approximate river miles (kilometers)
RH 1. Shenango River (Pennsylvania)	Public (Federal, State);	7 (11.1)
	Private	15 (24.3)
		Total = 22 (35.5)

TABLE 3—PROPOSED CRITICAL HABITAT UNITS FOR THE ROUND HICKORYNUT. ALL UNITS ARE OCCUPIED BY THE SPECIES—Continued

[Area estimates reflect all land within critical habitat unit boundaries]

Critical habitat unit	Adjacent riparian land ownership by type	Approximate river miles (kilometers)
RH 2. Grand River (Ohio)	Public (State, Local);	33 (53)
	Private	59 (95.2)
		Total = 92 (148.2)
RH 3. Tippecanoe River (Indiana)	Public (State, Easement);	9 (14.5)
	Private	66 (105.6)
		Total = 75 (120.8)
RH 4. Middle Island Creek (West Virginia)	Public (Federal, State);	0.2 (0.4)
	Private	74.8 (120.4)
		Total = 75 (120.8)
RH 5. Little Kanawha River (West Virginia)	Public (Federal, State, Local);	0.7 (1.2)
	Private	109 (175.4)
		Total = 110 (176.6)
RH 6. Elk River (West Virginia)	Public (Federal, State, Local);	7 (12.7)
	Private	93 (150.3)
		Total = 101 (163)
RH 7. Kanawha River (West Virginia)	Public (Federal, State, Local);	4 (7.2)
	Private	33 (53.2)
		Total = 37.5 (60.4)
RH 8. Licking River (Kentucky)	Public (Federal, State, Local);	18 (30)
	Private	131 (211.8)
		Total = 150 (241.9)
RH 9. Rockcastle River (Kentucky)	Public (Federal);	15 (24.2)
	Private	0.3 (0.4)
		Total = 15.3 (24.6)
RH 10. Buck Creek (Kentucky)	Public (State, Local);	3 (5.5)
	Private	33 (52.6)
		Total = 36 (58.1)
RH 11. Green River (Kentucky)	Public (Federal, State);	37 (59.4)
	Private	61 (98.4)
		Total = 98 (157.7)
RH 12. Paint Rock River (Alabama)	Public (Federal, State);	46 (73.4)
	Private	2 (4.1)
		Total = 48 (77.5)
RH 13. Duck River (Tennessee)	Public (State, Local);	32 (51.1)
	Private	27 (43.7)
		Total = 59 (94.8)
RH 14. Big Black River (Mississippi)	Private	Total = 4 (7)
	Public	212 (341)
	Private	709 (1,141)
	Total	921 (1,482)

Note: River miles may not sum due to rounding.

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for the longsolid and round hickorynut, below. There are a total of 12 units for the longsolid and 14 units for round hickorynut, 8 of which overlap in part or whole for both species, and all of which contain all of the physical and biological features essential to the conservation of both species. Also, the majority of proposed units overlap in part or whole with existing critical habitat designated for other federally endangered species (*i.e.,* diamond darter (*Crystallaria cincotta*), Short's bladderpod (*Physaria globosa*), purple bean (*Villosa perpurpurea*), rough rabbitsfoot (*Quadrula cylindrica strigillata*), Cumberlandian combshell (*Epioblasma brevidens*), oyster mussel (*Epioblasma capsaeformis*), slabside pearlymussel (*Pleuronaia (=Lexingtonia) dolabelloides*), and fluted kidneyshell (*Ptychobranchus subtentus*)) or federally threatened species (*i.e.,* rabbitsfoot (*Quadrula cylindrica cylindrica*), yellowfin madtom (*Noturus flavipinnis*), and slender chub (*Hybopsis cahni,* listed as *Erimystax cahni*)), as specified below.

LS 1: French Creek

Unit LS 1 consists of 120 stream mi (191.5 km) of French Creek in Crawford, Erie, Mercer, and Venango Counties, Pennsylvania, from Union City Dam west of Union City, Erie County, downstream to its confluence with the Allegheny River near the City of Franklin, Venango County. Riparian lands that border the unit include approximately 106 stream mi (170.6 km; 76 percent) in private ownership and 14 stream mi (22.1 km; 24 percent) in public (Federal or State) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes agriculture, several State-managed game lands, the communities of Cambridge Springs and Venango, and the cities of Meadville and Franklin. Union City Dam is operated by the U.S. Army Corps of Engineers. Unit LS 1 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. The entire 120 stream mi (191.5 km) of this unit overlaps with designated critical habitat

for the federally threatened rabbitsfoot mussel (80 FR 24692; April 30, 2015).

Threats identified within this unit include the degradation of habitat and water quality from impoundments, siltation and pollution due to resource extraction, agriculture, timbering practices, and human development; flow reduction and water quality degradation due to water withdrawals and wastewater treatment plants; and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include monitoring water quality degradation within the species' range resulting from row crop agriculture and oil and gas development, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

LS 2: Allegheny River

Unit LS 2 consists of 99 river mi (159.3 km) of the Allegheny River in Warren, Crawford, Forest, Venango, and Clarion Counties, Pennsylvania, from Kinzua Dam east of Warren, Warren County, downstream to the Pennsylvania Route 58 crossing at Foxburg, Clarion County, Pennsylvania. Riparian lands that border the unit include approximately 15 river mi (24.1 km; 14 percent) in private ownership and 84 river mi (135.8 km; 86 percent) in public (Federal or State government) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, and State-managed game lands. The public land ownership for this unit is a combination of Allegheny National Forest lands and State lands, and the Kinzua Dam is operated by the U.S. Army Corps of Engineers. Unit LS 2 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. There is overlap of approximately 35 river mi (57 km) of this unit with designated critical habitat for the federally threatened rabbitsfoot mussel (80 FR 24692; April 30, 2015).

Threats identified within Unit LS 2 include the degradation of habitat and water quality from impoundments, channelization, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying dam releases from Kinzua Dam to mimic the natural hydrograph, improvements to water quality to reverse degradation resulting from row crop agriculture and oil and gas development, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

LS 3: Shenango River

Unit LS 3 is the same as Unit RH 1, described below for the round hickorynut. Unit LS 3 consists of 22 river mi (35.5 km) of the Shenango River in Crawford County, Pennsylvania, from Pymatuning Dam downstream to the point of inundation by Shenango River Lake near Big Bend, Mercer County, Pennsylvania. Riparian lands that border the unit include approximately 15 river mi (24.3 km; 32 percent) in private ownership and 7 river mi (11.3 km; 68 percent) in public (Federal or State) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes the City of Greenville and its associated industry, and the unincorporated communities of Jamestown and New Harrisburg. Pymatuning Dam is owned by the State of Pennsylvania. Unit LS 3 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. There is overlap of approximately 14.5 river mi (23.4 km) of this unit with designated critical habitat for the federally threatened rabbitsfoot mussel (80 FR 24692; April 30, 2015).

Threats identified within Unit LS 3 include the degradation of habitat and water quality from impoundments, domestic and industrial pollution due to human development, resource extraction, water withdrawals, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying dam releases from Pytmatuning Dam to mimic the natural hydrograph, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

LS 4: Middle Island Creek

Unit LS 4 partially overlaps with Unit RH 4 for the round hickorynut, described below. Unit LS 4 consists of 14 stream mi (23.7 km) of Middle Island Creek in Doddridge and Tyler Counties, West Virginia, from the mouth of Meathouse Fork south of Smithburg, Doddridge County, downstream to its confluence with Arnold Creek at the Tyler/Doddridge County line. Riparian lands that border the unit include approximately 14 stream mi (23.5 km; 99 percent) in private ownership and 0.13 river mi (0.2 km; less than 1 percent) in public (local government) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry and the communities of Smithburg, Avondale, and West Union. Unit LS 4 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species.

Threats identified within Unit LS 4 include degradation of habitat and water quality from impoundments, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include actions to alleviate the threats of water quality and habitat degradation from hydrofracking wastewater discharges and impoundments downstream on the Ohio River, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

LS 5: Little Kanawha River

Unit LS 5 partially overlaps with Unit RH 5 for the round hickorynut, described below. Unit LS 5 consists of 123 river mi (198 km) of the Little Kanawha River in Calhoun, Gilmer, Ritchie, and Wood Counties, West Virginia, from Burnsville Dam in Braxton County downstream to its confluence with the Ohio River in Parkersburg, Wood County, West Virginia. Riparian lands that border the unit include approximately 122 river mi (197.2 km; 99 percent) in private ownership and 0.53 river mi (0.9 km; less than 1 percent) in public (Federal or State government) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, industry, and numerous cities and municipalities. Burnsville Dam is operated by the U.S. Army Corps of Engineers. Unit LS 5 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species.

Threats identified within Unit LS 5 include the degradation of habitat and water quality from impoundments, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatments plants, and the presence of invasive, nonnative species. Special management considerations or

protection measures to reduce or alleviate the threats may include modifying dam releases from Burnsville Dam to mimic the natural hydrograph, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

LS 6: Elk River

Unit LS 6 is the same as Unit RH 6, described below for the round hickorynut. Unit LS 6 consists of 101 river mi (163 km) of the Elk River in Braxton, Clay, and Kanawha Counties, West Virginia, from Sutton Dam in Braxton County downstream to its confluence with the Kanawha River at Charleston, Kanawha County, West Virginia. Riparian lands that border the unit include approximately 93 river mi (150.3 km; 92 percent) in private ownership and 7 river mi (12.7 km; 8 percent) in public (Federal, State, and local government) ownership. General land use on adjacent riparian lands and the surrounding HUC–8 level management unit includes forestry, agriculture, industry, and numerous cities and municipalities. Sutton Dam is operated by the U.S. Army Corps of Engineers. Unit LS 6 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. There is overlap of approximately 28 river mi (44.6 km) of this unit with designated critical habitat for the federally endangered diamond darter (78 FR 52364; August 22, 2013).

Threats identified within Unit LS 6 include the degradation of habitat and water quality from impoundments, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying dam releases from Sutton Dam to mimic the natural hydrograph and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

LS 7: Kanawha River

Unit LS 7 partially overlaps with Unit RH 7 for the round hickorynut, described below. Unit LS 7 consists of 21 river mi (33.9 km) of the Kanawha River in Fayette and Kanawha Counties, West Virginia, from Kanawha Falls in Fayette County downstream to its confluence with Cabin Creek at Chelyan, Kanawha County, West Virginia. Riparian lands that border the unit include approximately 18 river mi (29.3 km; 90 percent) in private ownership and 2 river mi (4.6 km; 10 percent) in public (Federal, State, and local government) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, industry, and numerous cities and municipalities. London and Marmet locks and dams within this unit are operated by the U.S. Army Corps of Engineers. Unit LS 7 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species.

Threats identified within Unit LS 7 include the degradation of habitat and water quality from impoundments, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying dam releases from London and Marmet locks and dams to mimic the natural hydrograph, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

LS 8: Licking River

Unit LS 8 partially overlaps with Unit RH 8 for the round hickorynut, described below. Unit LS 8 consists of 181 river mi (291.5 km) of the Licking River in Bath, Campbell, Fleming, Harrison, Kenton, Morgan, Nicholas, Pendleton, Robertson, and Rowan Counties, Kentucky, from Cave Run Dam in Bath/Rowan Counties downstream to its confluence with the Ohio River at Newport, Campbell/Kenton County, Kentucky. Riparian lands that border the unit include approximately 161 river mi (259.7 km; 90 percent) in private ownership and 19 river mi (31.7 km; 10 percent) in public (Federal, State, and local government) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture industry, and numerous cities and municipalities. The Cave Run Dam is operated by the U.S. Army Corps of Engineers. Unit LS 8 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species.

Threats identified within Unit LS 8 include the degradation of habitat and water quality from impoundments and associated cold water discharges, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying dam releases from Cave Run Dam to mimic the natural hydrograph and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

LS 9: Green River

Unit LS 9 partially overlaps with Unit RH 11 for the round hickorynut, described below. Unit LS 9 consists of 156 river mi (251.6 km) of the Green River in Butler/Warren, Edmonson, Green, Hart, and Taylor Counties, Kentucky, from Green River Lake Dam south of Campbellsville in Taylor County downstream to its confluence with the Barren River at Woodbury, Warren/Butler County, Kentucky. Riparian lands that border the unit include approximately 105 river mi (169.2 km; 67 percent) in private ownership and 51 river mi (82.4 km; 33 percent) in public (Federal, State, and local government) ownership; Federal lands include a portion of Mammoth Cave National Park. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, industry, and numerous cities and municipalities, and Cave Run Dam is operated by the U.S. Army Corps of Engineers. Unit LS 9 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. The entire approximately 156-river-mi (252-km) unit overlaps with designated critical habitat for the federally endangered diamond darter (78 FR 52364; August 22, 2013) and the federally threatened rabbitsfoot mussel (80 FR 24692; April 30, 2015).

Threats identified within Unit LS 9 include the degradation of habitat and water quality from impoundments and associated cold water discharges, siltation and pollution due to improper timbering and agricultural practices, resource extraction, water withdrawals, and development, all of which affect channel stability; wastewater treatment plants; and the presence of invasive, nonnative species. Special management considerations or protection measures may be needed to reduce or alleviate habitat degradation such as channelization and channel instability. Additional special management considerations or protection measures may be needed to address thermal and

flow regimes associated with tail water releases from the Green River Lake Dam, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

LS 10: Cumberland River

Unit LS 10 consists of 48 river mi (77.5 km) of the Cumberland River in Smith, Trousdale, and Wilson Counties, Tennessee, from Cordell Hull Dam north of Carthage in Smith County downstream to reservoir influence of Old Hickory Reservoir at U.S. Route 231 north of Lebanon, Wilson County, Tennessee. Riparian lands that border the unit are all public (Federal) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, and the municipalities of Carthage and Rome, Tennessee; both Cordell Hull and Old Hickory Dams upstream and downstream of this unit are operated by the U.S. Army Corps of Engineers. Unit LS 10 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. There is overlap of approximately 1 river mi (1.7 km) of this unit with designated critical habitat for the federally endangered Short's bladderpod (79 FR 50990; August 26, 2014).

Threats identified within Unit LS 10 include the degradation of habitat and water quality from upstream and downstream impoundments and associated cold water discharges, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include channel stability, thermal regimes, altered flow regimes associated with tail water releases from Cordell Hull Reservoir, actions to address channelization, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

LS 11: Clinch River

Unit LS 11 consists of 177 river mi (286.1 km) of the Clinch River in Russell, Scott, Tazewell, and Wise Counties in Virginia, and Claiborne, Hancock, and Hawkins Counties in Tennessee. This unit extends from Secondary Highway 637 west of Pounding Mill in Tazewell County, Virginia, downstream to County Highway 25, Claiborne County, Tennessee, northwest of Thorn Hill. The Tennessee portion of this unit is also encompassed by the Tennessee Wildlife Resources Agency's Clinch River Sanctuary. Riparian lands that border the unit include approximately 160 river mi (258.8 km; 90 percent) in private ownership and 17 river mi (27.3 km; 10 percent) in public (Federal and State) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, industry, and numerous cities and municipalities. Unit LS 11 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. There is overlap of approximately 171 river mi (274.4 km) of this unit with designated critical habitat for the federally endangered purple bean, oyster mussel, rough rabbitsfoot, and Cumberlandian combshell (69 FR 53136; August 31, 2004); the federally endangered slabside pearlymussel and fluted kidneyshell (78 FR 59556; September 26, 2013); and with the federally threatened yellowfin madtom and slender chub (42 FR 45526; September 9, 1977).

Threats identified within Unit LS 11 include the degradation of habitat and water quality from downstream impoundment, mining discharges, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include management of the Norris Reservoir downstream to provide additional riverine habitat, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

LS 12: Paint Rock River

Unit LS 12 partially overlaps with Unit RH 12 for the round hickorynut, described below. Unit LS 12 consists of 58 river mi (94.5 km) of the Paint Rock River in Jackson and Madison/Marshall Counties, Alabama, from the confluence of Hurricane Creek and Estill Fork in Jackson County, Alabama, downstream to its confluence with the Tennessee River west of Hebron, Madison/Marshall County, Alabama. Riparian lands that border the unit include approximately 2 river mi (4.1 km; 3 percent) in private ownership and 56 river mi (90.4 km; 97 percent) in public (Federal and State) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, and several small municipalities (Princeton, Hollytree, Trenton, and Paint Rock). Unit LS 12 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. There is overlap of approximately 53 river mi (85 km) of this unit with designated critical habitat for the federally endangered slabside pearlymussel (78 FR 59556; September 26, 2013) and the federally threatened rabbitsfoot mussel (80 FR 24692; April 30, 2015).

Threats identified within Unit LS 12 include the degradation of habitat and water quality from downstream impoundment, siltation and pollution due to improper agricultural and timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include management of Wheeler Reservoir downstream to provide additional riverine habitat, working with landowners to implement best management practices to reduce erosion and sedimentation associated with agricultural lands, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 1: Shenango River

Unit RH 1 is the same as Unit LS 3 for the longsolid, described above. It consists of 22 river mi (35.5 km) of the Shenango River in Crawford County, Pennsylvania, from Pymatuning Dam downstream to the point of inundation by Shenango River Lake near Big Bend, Mercer County, Pennsylvania. Riparian lands that border the unit include approximately 15 river mi (24.3 km; 32 percent) in private ownership and 7 river mi (11.1 km; 68 percent) in public (Federal or State) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes the City of Greenville and its associated industry, and the unincorporated communities of Jamestown and New Harrisburg. Pymatuning Dam is owned by the State of Pennsylvania. Unit RH 1 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. There is overlap of approximately 14.5 river mi (23.4 km) of this unit with designated critical habitat for the federally threatened rabbitsfoot mussel (80 FR 24692; April 30, 2015).

Threats identified within Unit RH 1 include the degradation of habitat and water quality from impoundments,

domestic and industrial pollution due to human development, resource extraction, water withdrawals, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying dam releases from Pytmatuning Dam to mimic the natural hydrograph, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 2: Grand River

Unit RH 2 consists of 92 river mi (148.2 km) of the Grand River in Ashtabula, Lake, and Trumbull Counties, Ohio, from the Trumbull/Geauga County line south of Lake County, Ohio State Route 88, downstream to the mouth of the Grand River at its confluence with Lake Erie. Riparian lands that border the unit include approximately 59 river mi (95.2 km; 64 percent) in private ownership and 33 river mi (53 km; 36 percent) in public (State and local government) ownership. The Grand River is a State Wild and Scenic River, with a ''Wild River'' designation for approximately 23 river mi (37 km) from the Harpersfield Covered Bridge downstream to the Norfolk and Western Railroad Trestle in Lake County, and ''Scenic River'' designation for approximately 33 river mi (53 km) from the U.S. 322 Bridge in Ashtabula County downstream to the Harpersfield Covered Bridge. General lands use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, and several municipalities (West Farmington, Windsor, Rock Creek, and Perry). Harpersfield Dam is operated by the U.S. Army Corps of Engineers. Unit RH 2 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species.

Threats identified within Unit RH 2 include degradation of habitat and water quality from impoundments, domestic and industrial pollution due to human development, resource extraction, water withdrawals, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying dam releases from the Harpersfield Dam to mimic the natural hydrograph, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 3: Tippecanoe River

Unit RH 3 consists of 75 river mi (120.8 km) of the Tippecanoe River in Fulton, Marshall, Pulaski, and Starke Counties, Indiana, from the railroad crossing west of the communities of Tippecanoe, Marshall County, downstream to the Pulaski/White County line, southwest of the community of Star City, Indiana. Riparian lands that border the unit include approximately 66 river mi (105.6 km; 89 percent) in private ownership and 9 river mi (14.5 km; 11 percent) in public ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes agriculture and the communities of Tippecanoe, Pershing, and Ora. Unit RH 3 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. There is overlap of approximately 19 river mi (29.9 km) of this unit with designated critical habitat for the federally threatened rabbitsfoot mussel (80 FR 24692; April 30, 2015).

Threats identified within Unit RH 3 include the degradation of habitat and water quality from impoundments, domestic and industrial pollution due to human development, resource extraction, water withdrawals, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying operations of downstream impoundments to provide additional riverine habitats, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 4: Middle Island Creek

Unit RH 4 partially overlaps with Unit LS 4 for the longsolid, described above. Unit RH 4 consists of 75 stream mi (120.8 km) of the Middle Island Creek in Doddridge, Pleasants, and Tyler Counties, West Virginia, from the Tyler/Doddridge County line northeast of Deep Valley downstream to the confluence with the Ohio River, at St. Mary's, Pleasants County, West Virginia. Riparian lands that border the unit include approximately 74.8 stream mi (120.4 km; 99 percent) in private ownership and 0.2 stream mi (0.4 km; less than 1 percent) in public (Federal and State) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes the communities of Smithburg, Avondale, West Union, Alma, and Centerville. Unit RH 4 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species.

Threats identified within Unit RH 4 include the degradation of habitat and water quality from siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include monitoring hydrofracking wastewater discharges and impoundments downstream on the Ohio River, and implementing efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 5: Little Kanawha River

Unit RH 5 partially overlaps with Unit LS 5 for the longsolid, also described above. Unit RH 5 consists of 110 river mi (176.6 km) of the Little Kanawha River in Calhoun, Gilmer, Ritchie, and Wood Counties, West Virginia, from Burnsville Dam in Braxton County downstream to West Virginia Route 47 at Parkersburg, Wood County, West Virginia. Riparian lands that border the unit include approximately 109 river mi (175.4 km; 99 percent) in private ownership and 0.7 river mi (1.2 km; 1 percent) in public (Federal, State, and local government) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, industry, and numerous cities and municipalities. Burnsville Dam is operated by the U.S. Army Corps of Engineers. Unit RH 5 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species.

Threats identified within Unit RH 5 include the degradation of habitat from impoundments, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying dam releases from Burnsville Dam to mimics the natural hydrograph, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 6: Elk River

Unit RH 6 is the same as Unit LS 6 for the longsolid, described above. Unit

RH 6 consists of 101 river mi (163 km) of the Elk River in Braxton, Clay, and Kanawha Counties, West Virginia, from the Sutton Dam in Braxton County downstream to its confluence with the Kanawha River at Charleston, Kanawha County, West Virginia. Riparian lands that border the unit include approximately 93 river mi (150.3 km; 92 percent) in private ownership and 7 river mi (12.7 km; 8 percent) in public (Federal, State, and local government) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, industry, and numerous cities and municipalities. Sutton Dam is operated by the U.S. Army Corps of Engineers. Unit RH 6 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. There is overlap of approximately 28 river mi (44.6 km) of this unit with the designated critical habitat for the federally endangered diamond darter (78 FR 52364; August 22, 2013).

Threats identified within Unit RH 6 include the degradation of habitat and water quality from impoundments, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying dam releases from Sutton Dam to mimic the natural hydrograph, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 7: Kanawha River

Unit RH 7 partially overlaps with Unit LS 7 for the longsolid, described above. Unit RH 7 consists of 37.5 river mi (60.4 km) of the Kanawha River in Fayette and Kanawha Counties, West Virginia, from Kanawha Falls in Fayette County downstream to its confluence with the Elk River at Charleston, Kanawha County, West Virginia. Riparian lands that border the unit include approximately 33 river mi (53.2 km; 90 percent) in private ownership and 4 river mi (7.2 km; 10 percent) in public (Federal, State, and local government) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, industry, and numerous cities and municipalities. London and Marmet locks and dams within this unit are operated by the U.S. Army Corps of Engineers. Unit RH 7 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species.

Threats identified within Unit RH 7 include the degradation of habitat and water quality from impoundments, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying dam releases from London and Marmet locks and dams to mimic the natural hydrograph, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 8: Licking River

Unit RH 8 partially overlaps with Unit LS 8 for the longsolid, described above. Unit RH 8 consists of 150 mi (241.9 km) of the Licking River in Bath, Campbell, Fleming, Harrison, Kenton, Morgan, Nicholas, Pendleton, Robertson, and Rowan Counties, Kentucky, from Cave Run Dam in Bath/Rowan Counties downstream to the Railroad crossing at the Campbell/Kenton/Pendleton County line at De Mossville, northwest of Butler, Pendleton County, Kentucky. Riparian lands that border the unit include approximately 131 river mi (211.8 km; 87 percent) in private ownership and 18 river mi (30 km; 13 percent) in public (Federal, State, and local government) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture industry, and numerous cities and municipalities. Cave Run Dam is operated by the U.S. Army Corps of Engineers. Unit RH 8 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species.

Threats identified within Unit RH 8 include the degradation of habitat and water quality from impoundments and associated cold water discharges, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include modifying dam releases from Cave Run Dam to mimic the natural hydrograph, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 9: Rockcastle River

Unit RH 9 consists of 15.3 river mi (24.6 km) of the Rockcastle River in Laurel, Pulaski, and Rockcastle Counties, Kentucky, from Kentucky Route 1956 at Billows downstream to Kentucky Route 192, near its confluence with Cane Creek along the Laurel/Pulaski County line, northwest of Baldrock, Laurel County, Kentucky. Riparian lands that border the unit include approximately 0.3 river mi (0.4 km; less than 1 percent) in private ownership and 15 river mi (24.2 km; 99 percent) in public (Federal) ownership. Federal ownership is the Daniel Boone National Forest. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit is predominantly forestry. Unit RH 9 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. There is overlap of approximately 15 river mi (23.7 km) of this unit with designated critical habitat for the federally endangered fluted kidneyshell (78 FR 59556; September 26, 2013).

Threats identified within Unit RH 9 include the degradation of habitat and water quality from siltation and pollution due to improper timbering practices and resource extraction, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include management of Lake Cumberland, located downstream, to provide more riverine habitat upstream, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 10: Buck Creek

Unit RH 10 consists of 36 stream mi (58.1 km) of Buck Creek in Pulaski County, Kentucky, from its confluence with Glade Fork Creek northeast of Goochtown, downstream to its confluence with Whetstone Creek, northeast of Dykes, Pulaski County, Kentucky. Riparian lands that border the unit include approximately 33 stream mi (52.6 km; 92 percent) in private ownership and 3 stream mi (5.5 km; 8 percent) in public (State and local government) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, and several small communities. Unit RH 10 is occupied by the species and contains all of the physical or biological features

essential to the conservation of the species. There is overlap of approximately 35 stream mi (56.7 km) with designated critical habitat for the federally endangered Cumberlandian combshell and oyster mussel (69 FR 53136; August 31, 2004), and the federally endangered fluted kidneyshell (78 FR 59556; September 26, 2013).

Threats identified within Unit RH 10 include the degradation of habitat and water quality from instream gravel mining, silviculture-related activities, illegal off-road vehicle use, nonpoint source pollution from agriculture, and development activities, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include management of Lake Cumberland, located downstream, to provide more riverine habitat upstream, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 11: Green River

Unit RH 11 partially overlaps with Unit LS 9 for the longsolid, described above. Unit RH 11 consists of 98 river mi (157.7 km) of the Green River in Butler/Warren, Edmonson, Green, and Hart Counties, Kentucky, from the mouth of Lynn Camp Creek east of Linwood in Hart County downstream to its confluence with the Barren River at Woodbury, Warrant/Butler Counties, Kentucky. Riparian lands that border the unit include approximately 61 river mi (98.4 km; 62 percent) in private ownership and 37 river mi (59.4 km; 38 percent) in public (Federal and State) ownership; Federal lands include a portion of Mammoth Cave National Park. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, industry, and numerous cities and municipalities, and Green River Lake Dam (located upstream of this unit) is operated by the U.S. Army Corps of Engineers. Unit RH 11 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. The entire 98-river-mi (157.7-km) unit overlaps with designated critical habitat for the federally endangered diamond darter (78 FR 52364; August 22, 2013) and the federally threatened rabbitsfoot mussel (80 FR 24692; April 30, 2015).

Threats identified within Unit RH 11 include the degradation of habitat and water quality from Green River Lake Dam and associated cold water discharges, siltation and pollution due to improper timbering and agricultural practices, resource extraction, water withdrawals, and development, all of which affect channel stability; wastewater treatment plants; and the presence of invasive, nonnative species. Special management considerations or protection measures may be needed to reduce or alleviate habitat degradation such as channelization and channel instability. Additional special management considerations or protection measures may be needed to address thermal and flow regimes associated with tail water releases from the Green River Lake Dam, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 12: Paint Rock River

Unit RH 12 partially overlaps with Unit LS 12 for the longsolid, described above. Unit RH 12 consists of 48 river mi (77.5 km) of the Paint Rock River in Jackson and Madison/Marshall Counties, Alabama, from the confluence of Hurricane Creek and Estill Fork in Jackson County, Alabama, downstream to U.S. Route 431, south of New Hope, Madison/Marshall Counties, Alabama. Riparian lands that border the unit include approximately 2 river mi (4.1 km; 2 percent) in private ownership and 46 river mi (73.4 km; 98 percent) in public (Federal and State) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, and several small municipalities (Princeton, Hollytree, Trenton, and Paint Rock). Unit RH 12 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. The entire approximately 48-river-mi (77.5-km) unit overlaps with designated critical habitat for the federally endangered slabside pearlymussel (78 FR 59556; September 26, 2013), and the federally threatened rabbitsfoot mussel (80 FR 24692; April 30, 2015).

Threats identified within Unit RH 12 include the degradation of habitat and water quality from impoundments, siltation and pollution due to improper timbering practices, resource extraction, water withdrawals, development, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include management of Wheeler Reservoir downstream to provide additional riverine habitat, working with landowners to implement best management practices to reduce erosion and sedimentation associated with agricultural lands, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 13: Duck River

Unit RH 13 consists of 59 river mi (94.8 km) of the Duck River in Bedford, Marshall, and Maury Counties, Tennessee, from its confluence with Sinking Creek in Bedford County, downstream to the mouth of Goose Creek, east of Columbia, Maury County, Tennessee. Riparian lands that border the unit include approximately 27 river mi (43.7 km; 47 percent) in private ownership and 32 river mi (51.1 km; 53 percent) in public (State and local government) ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit includes forestry, agriculture, and several municipalities (Milltown, Leftwich, and Philadelphia). Normandy Dam is operated by the Tennessee Valley Authority. Unit RH 13 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species. There is overlap of approximately 55 river mi (88.9 km) of this unit with designated critical habitat for the federally endangered slabside pearlymussel and fluted kidneyshell (78 FR 59556; September 26, 2013), and the federally endangered Cumberlandian combshell and oyster mussel (69 FR 53136; August 31, 2004).

Threats identified within Unit RH 13 include the degradation of habitat and water quality from impoundments, siltation and pollution due to improper timbering practices, agricultural activities (livestock), row crop agriculture and channelization, resource extraction, water withdrawals, and wastewater treatment plants, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include seasonally adjusted flow regimes associated with tail water releases from Normandy Dam, working with landowners to implement best management practices to reduce erosion and sedimentation associated with agricultural lands, planting adequate riparian buffers to minimize agriculture impacts, and implementing efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

RH 14: Big Black River

Unit RH 14 consists of 4 river mi (7 km) of the Big Black River in Montgomery County, Mississippi, from its confluence with Poplar Creek in Bedford County, downstream to its confluence with Lewis Creek, Mississippi. Riparian lands that border the unit are all (100 percent) in private ownership. General land use on adjacent riparian lands and the surrounding HUC 8-level management unit is predominantly agricultural activities. Unit RH 14 is occupied by the species and contains all of the physical or biological features essential to the conservation of the species.

Threats identified within Unit RH 14 include degradation of habitat and water quality from impoundments, siltation and pollution due to improper agricultural activities, row crop agriculture and channelization, and water withdrawals, and the presence of invasive, nonnative species. Special management considerations or protection measures to reduce or alleviate the threats may include working with landowners to implement best management practices to reduce erosion and sedimentation associated with agricultural lands and water quality degradation, and efforts to prevent the spread of invasive, nonnative species (see Special Management Considerations or Protection, above).

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

We published a final rule revising the definition of destruction or adverse modification on August 27, 2019 (84 FR 44976). Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation.

Compliance with the requirements of section 7(a)(2) is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinitiate formal consultation on previously reviewed actions. These requirements apply when the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law) and, subsequent to the previous consultation, we have listed a new species or designated critical habitat that may be affected by the Federal action, the amount or extent of taking specified in the incidental take statement is exceeded, new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered, or the action has been modified in a manner that affects the species or critical habitat in a way not considered in the previous consultation. In such situations, Federal agencies sometimes may need to request reinitiation of consultation with us, but the regulations also specify some exceptions to the requirement to reinitiate consultation on specific land management plans after subsequently listing a new species or designating new critical habitat. See the regulations for a description of those exceptions.

Application of the ''Destruction or Adverse Modification'' Standard

The key factor related to the destruction or adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat as a whole for the conservation of the listed species. As discussed above, the role of critical habitat is to support physical or biological features essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may violate section 7(a)(2) of the Act by destroying or adversely modifying such habitat, or that may be affected by such designation.

Activities that the Services may, during a consultation under section 7(a)(2) of the Act, find are likely to destroy or adversely modify critical habitat include, but are not limited to, actions that would: (1) Alter the geomorphology of their stream and river habitats (*e.g.,* instream excavation or dredging, impoundment,

channelization, sand and gravel mining, clearing riparian vegetation, and discharge of fill materials); (2) significantly alter the existing flow regime where these species occur (*e.g.,* impoundment, urban development, water diversion, water withdrawal, water draw-down, and hydropower generation); (3) significantly alter water chemistry or water quality (*e.g.,* hydropower discharges, or the release of chemicals, biological pollutants, or heated effluents into surface water or connected groundwater at a point source or by dispersed release (nonpoint source)); and (4) significantly alter stream bed material composition and quality by increasing sediment deposition or filamentous algal growth (*e.g.,* construction projects, gravel and sand mining, oil and gas development, coal mining, livestock grazing, timber harvest, and other watershed and floodplain disturbances that release sediments or nutrients into the water). Consulting agencies and such activities could include, but are not limited to:

(1) U.S. Army Corps of Engineers (channel dredging and maintenance; dam projects including flood control, navigation, hydropower, and water supply; and Clean Water Act permitting including bridge projects and stream restoration activities).

(2) U.S. Department of Agriculture, including the Natural Resources Conservation Service and Farm Service Agency (technical and financial assistance for projects) and the Forest Service (aquatic habitat restoration, fire management plans, fire suppression, fuel reduction treatments, forest plans, and mining permits).

(3) U.S. Department of Energy (renewable and alternative energy projects).

(4) Federal Energy Regulatory Commission (interstate pipeline construction and maintenance, dam relicensing, and hydrokinetics).

(5) U.S. Department of Transportation (highway and bridge construction and maintenance).

(6) U.S. Fish and Wildlife Service (issuance of section 10 permits for enhancement of survival, habitat conservation plans, and safe harbor agreements; Partners for Fish and Wildlife program projects benefiting these species or other listed species; and Wildlife and Sportfish Restoration program sportfish stocking).

(7) Environmental Protection Agency (water quality criteria and permitting).

(8) Tennessee Valley Authority (flood control, navigation, hydropower, and land management for the Tennessee River system).

(9) Office of Surface Mining (land resource management plans, mining permits, oil and natural gas permits, abandoned mine land projects, and renewable energy development).

(10) National Park Service (land management plans and permitting).

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that: ''The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan [INRMP] prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.'' There are no Department of Defense (DoD) lands within the proposed critical habitat designation.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making the determination to exclude a particular area, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

The first sentence in section 4(b)(2) of the Act requires that we take into consideration the economic, national security, or other relevant impacts of designating any particular area as critical habitat. We describe below the process that we undertook for taking into consideration each category of impacts and our analyses of the relevant impacts.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. To assess the probable economic impacts of a designation, we must first evaluate specific land uses or activities and projects that may occur in the area of the critical habitat. We then must evaluate the impacts that a specific critical habitat designation may have on restricting or modifying specific land uses or activities for the benefit of the species and their habitat within the areas proposed. We then identify which conservation efforts may be the result of the species being listed under the Act versus those attributed solely to the designation of critical habitat for these particular species. The probable economic impact of a proposed critical habitat designation is analyzed by comparing scenarios both ''with critical habitat'' and ''without critical habitat.''

The ''without critical habitat'' scenario represents the baseline for the analysis, which includes the existing regulatory and socio-economic burden imposed on landowners, managers, or other resource users potentially affected by the designation of critical habitat (*e.g.,* under the Federal listing as well as other Federal, State, and local regulations). The baseline, therefore, represents the costs of all efforts attributable to the listing of the species under the Act (*i.e.,* conservation of the species and its habitat incurred regardless of whether critical habitat is designated). The ''with critical habitat'' scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts would not be expected without the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat, above and beyond the baseline costs. These are the costs we use when evaluating the benefits of inclusion and exclusion of particular areas from the final designation of critical habitat should we choose to conduct a discretionary 4(b)(2) exclusion analysis.

For these particular designations, we developed an incremental effects memorandum (IEM; Service 2020b, entire) considering the probable incremental economic impacts that may result from this proposed designation of critical habitat. The information contained in our IEM was then used to develop a screening analysis of the probable effects of the designation of critical habitat for the longsolid and round hickorynut (Industrial Economics, Inc. 2020, entire). We began by conducting a screening analysis of

the proposed critical habitat designation in order to filter out particular geographic areas of critical habitat that are already subject to such protections and are, therefore, unlikely to incur incremental economic impacts. In particular, the screening analysis considers baseline costs (*i.e.,* absent critical habitat designation) and includes probable economic impacts where land and water use may be subject to conservation plans, land management plans, best management practices, or regulations that protect the habitat area as a result of the Federal listing status of the species. Ultimately, the screening analysis allows us to focus our analysis on evaluating the specific areas or sectors that may incur probable incremental economic impacts as a result of the designation. The screening analysis also assesses whether units are unoccupied by the species and thus may require additional management or conservation efforts as a result of the critical habitat designation for the species; these additional efforts may incur incremental economic impacts. This screening analysis combined with the information contained in our IEM are what we consider our draft economic analysis (DEA) of the proposed critical habitat designation for the longsolid and round hickorynut; our DEA is summarized in the narrative below.

Executive Orders (E.O.s) 12866 and 13563 direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consistent with the E.O. regulatory analysis requirements, our effects analysis under the Act may take into consideration impacts to both directly and indirectly affected entities, where practicable and reasonable. If sufficient data are available, we assess, to the extent practicable, the probable impacts to both directly and indirectly affected entities. As part of our screening analysis, we considered the types of economic activities that are likely to occur within the areas likely affected by the critical habitat designation. In our evaluation of the probable incremental economic impacts that may result from the proposed designation of critical habitat for the longsolid and round hickorynut, first we identified, in the IEM dated February 13, 2020 (Service 2020b, entire), probable incremental economic impacts associated with the following categories of activities: Instream excavation or dredging; impoundments; channelization; sand and gravel mining; clearing riparian vegetation; discharge of fill materials; urban development; water diversion; water withdrawal; water draw-down; hydropower generation and discharges; release of chemicals, biological pollutants, or heated effluents into surface water or connected ground water at a point source or by dispersed release (nonpoint); construction projects; oil and gas development; coal mining; livestock grazing; timber harvest; and other watershed or floodplain activities that release sediments or nutrients into the water. We considered each industry or category individually. Additionally, we considered whether their activities have any Federal involvement. Critical habitat designation generally will not affect activities that do not have any Federal involvement; under the Act, designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. If we list these species, in areas where the longsolid or round hickorynut are present, Federal agencies would be required to consult with the Service under section 7 of the Act on activities they authorize, fund, or carry out that may affect the species. If, when we list these species, we also finalize this proposed critical habitat designation, consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into the existing consultation process.

In our IEM, we attempted to clarify the distinction between the effects that would result from the species being listed and those attributable to the critical habitat designation (*i.e.,* difference between the jeopardy and adverse modification standards) for the longsolid's and round hickorynut's critical habitat. Because the designation of critical habitat for the longsolid and round hickorynut is proposed concurrently with the listings, it has been our experience that it is more difficult to discern which conservation efforts are attributable to the species' being listed and those which would result solely from the designation of critical habitat; this is particularly difficult where there is no unoccupied critical habitat and, thus, there would already be consultations for all areas. However, the following specific circumstances in this case help to inform our evaluation: (1) The essential physical or biological features identified for critical habitat are the same features essential for the life requisites of the species, and (2) any actions that would result in sufficient harm or harassment to constitute jeopardy to the longsolid or round hickorynut would also likely adversely affect the essential physical or biological features of critical habitat. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this proposed designation of critical habitat.

The proposed critical habitat designation for the longsolid includes 12 units, all of which are occupied by the species. Ownership of riparian lands adjacent to the proposed units includes 810 river mi (1,304 km; 74 percent) in private ownership and 305 river mi (491 km; 26 percent) in public (Federal, State, or local government) ownership. The proposed critical habitat designation for the round hickorynut includes 14 units, all of which are occupied by the species. Ownership of riparian lands adjacent to the proposed units includes 709 river mi (1,141 km; 77 percent) in private ownership and 212 river mi (341 km; 23 percent) in public (Federal, State, or local government) ownership.

Total incremental costs of critical habitat designation for the longsolid and round hickorynut are anticipated to be approximately $327,000 (2020 dollars) per year for the next 10 years. The costs are reflective of the proposed critical habitat area (*i.e.,* 1,115 river mi (1,794 km) for the longsolid and 921 river mi (1,482 km) for the round hickorynut (some of which overlap each other)), the presence of the species (*i.e.,* already occupied) in these areas, and the presence of other federally listed species and designated critical habitats. Since consultation is already required in these areas as a result of the presence of other listed species and critical habitats and would be required as a result of the listing of the longsolid and round hickorynut, the economic costs of the critical habitat designation would likely be primarily limited to additional administrative efforts to consider adverse modification for these two species in section 7 consultations. In total, 159 section 7 consultation actions (approximately 3 formal consultations, 114 informal consultations, and 38 technical assistance efforts) are anticipated to occur annually in proposed critical habitat areas. Critical habitat may also trigger additional regulatory changes. For example, the designation may cause other Federal, State, or local permitting or regulatory agencies to expand or change standards or requirements. Regulatory uncertainty generated by critical habitat may also have impacts. For example, landowners

or buyers may perceive that the rule would restrict land or water use activities in some way and therefore value the use of the land less than they would have absent critical habitat. This is a perception, or stigma, effect of critical habitat on markets.

We are soliciting data and comments from the public on the DEA discussed above, as well as all aspects of this proposed rule and our required determinations. During the development of a final designation, we will consider the information presented in the DEA and any additional information on economic impacts we receive during the public comment period to determine whether any specific areas should be excluded from the final critical habitat designations under authority of section 4(b)(2) and our implementing regulations at 50 CFR 424.19. In particular, we may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of either species.

Exclusions

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security discussed above. We consider a number of factors including whether there are permitted conservation plans covering the species in the area, such as habitat conservation plans, safe harbor agreements, or candidate conservation agreements with assurances, or whether there are non-permitted conservation agreements and partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at the existence of tribal conservation plans and partnerships and consider the government-to-government relationship of the United States with tribal entities. We also consider any social impacts that might occur because of the designation.

In preparing this proposal, we have determined that there are currently no habitat conservation plans or other management plans for the longsolid or round hickorynut, and the proposed designations do not include any tribal lands or trust resources. Thus, we anticipate no impact on tribal lands, partnerships, or habitat conservation plans from these proposed critical habitat designations. During the development of a final designation, we will consider any additional information we receive during the public comment period regarding other relevant impacts to determine whether any specific areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 424.19.

Consideration of National Security Impacts

In preparing this proposal, we have determined that the lands within the proposed designation of critical habitat for longsolid or round hickorynut are not owned, managed, or used by the DoD or DHS, and, therefore, we anticipate no impact on national security or homeland security. However, during the development of a final designation we will consider any additional information received through the public comment period on the impacts of the proposed designation on national security or homeland security to determine whether any specific areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 424.19.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

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

(3) Use clear language rather than jargon;

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

(5) Use lists and tables wherever possible.

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

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has waived their review regarding their significance determination of this proposed rule.

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

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these

small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

Under the RFA, as amended, and as understood in the light of recent court decisions, Federal agencies are required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require agencies to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies would be directly regulated if we adopt the proposed critical habitat designations. There is no requirement under the RFA to evaluate the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities would be directly regulated by this rulemaking, the Service certifies that, if made final as proposed, the proposed critical habitat designations will not have a significant economic impact on a substantial number of small entities.

In summary, we have considered whether the proposed designations would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if made final, the proposed critical habitat designations will not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Executive Order 13771

We do not believe this proposed rule is an E.O. 13771 (''Reducing Regulation and Controlling Regulatory Costs'') (82 FR 9339, February 3, 2017) regulatory action because we believe this rule is not significant under E.O. 12866; however, the Office of Information and Regulatory Affairs has waived their review regarding their E.O. 12866 significance determination of this proposed rule.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Facilities that provide energy supply, distribution, or use occur within some units of the proposed critical habitat designations (*e.g.,* dams, pipelines) and may potentially be affected. We determined that consultations, technical assistance, and requests for species lists may be necessary in some instances. However, in our economic analysis, we did not find that these proposed critical habitat designations would significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following finding:

(1) This proposed rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule would significantly or uniquely affect small governments because it will not produce a Federal mandate of $100 million or greater in any year, that is, it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State or local governments and, as such, a Small Government Agency Plan is not required. Therefore, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the longsolid and round hickorynut in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not

affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed for the proposed designations of critical habitat for the longsolid and round hickorynut, and it concludes that, if adopted, these designations of critical habitat do not pose significant takings implications for lands within or affected by the designations.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of these proposed critical habitat designations with, appropriate State resource agencies. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the proposed rule does not have substantial direct effects either on the States, or on the relationship between the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The proposed designations may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary for the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist State and local governments in long-range planning because they no longer have to wait for case-by-case section 7 consultations to occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) of the Act would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule would not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, this proposed rule identifies the elements of physical or biological features essential to the conservation of the species. The proposed areas of designated critical habitat are presented on maps, and the proposed rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes. We have determined that no tribal lands fall within the boundaries of the proposed critical habitat designations for the longsolid and round hickorynut, so no tribal lands would be affected by the proposed designations.

References Cited

A complete list of references cited in the petition finding for the purple lilliput and this rulemaking for the longsolid and round hickorynut is available on the internet at *http://www.regulations.gov* and upon request from the Asheville Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this document are the staff members of the Fish and Wildlife Service's Species Assessment Team, Ecological Services Program, and the Service's Asheville Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by adding entries for ''Hickorynut, round'' and ''Longsolid'' to the List of Endangered and Threatened Wildlife in alphabetical order under CLAMS to read as set forth below:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
	* * * * * * *			
CLAMS				
	* * * * * * *			
Hickorynut, round	*Obovaria subrotunda*	Wherever found	T	[**Federal Register** citation when published as a final rule]; 50 CFR 17.45(d);[4d] 50 CFR 17.95(f).[CH]
	* * * * * * *			
Longsolid	*Fusconaia subrotunda*	Wherever found	T	[**Federal Register** citation when published as a final rule]; 50 CFR 17.45(d);[4d] 50 CFR 17.95(f).[CH]
	* * * * * * *			

■ 3. Revise § 17.45 to read as follows:

§ 17.45 Special rules—snails and clams.

(a)–(c) [Reserved]

(d) Longsolid (*Fusconaia subrotunda*) and round hickorynut (*Obovaria subrotunda*).

(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the longsolid and round hickorynut. Except as provided under paragraph (d)(2) of this section and §§ 17.4 and 17.5, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to these species:

(i) Import or export, as set forth at § 17.21(b) for endangered wildlife.

(ii) Take, as set forth at § 17.21(c)(1) for endangered wildlife.

(iii) Possession and other acts with unlawfully taken specimens, as set forth at § 17.21(d)(1) for endangered wildlife.

(iv) Interstate or foreign commerce in the course of a commercial activity, as set forth at § 17.21(e) for endangered wildlife.

(v) Sale or offer for sale, as set forth at § 17.21(f) for endangered wildlife.

(2) *Exceptions from prohibitions.* In regard to these species, you may:

(i) Conduct activities as authorized by a permit under § 17.32.

(ii) Take, as set forth at § 17.21(c)(2) through (c)(4) for endangered wildlife.

(iii) Take as set forth at § 17.31(b).

(iv) Take incidental to an otherwise lawful activity caused by:

(A) Conservation and restoration efforts for listed species by the Service or State wildlife agencies, including, but not limited to, collection of broodstock, tissue collection for genetic analysis, captive propagation, and subsequent stocking into unoccupied areas within the historical range of the species.

(B) Channel restoration projects that create natural, physically stable, ecologically functioning streams (or stream and wetland systems). These projects can be accomplished using a variety of methods, but the desired outcome is a natural channel with low shear stress (force of water moving against the channel); bank heights that enable reconnection to the floodplain; connection of surface and groundwater systems, resulting in perennial flows in the channel; riffles and pools comprised of existing soil, rock, and wood instead of large imported materials; low compaction of soils within adjacent riparian areas; and inclusion of riparian wetlands. Streams reconstructed in this way would offer suitable habitats for the longsolid and round hickorynut and contain stable channel features, such as pools, glides, runs, and riffles, which could be used by the species and its host fish for spawning, rearing, growth, feeding, migration, and other normal behaviors. Prior to commencement of restoration actions, surveys to determine presence of the longsolid and round hickorynut must be performed, and if located, in coordination with the local Service field office, mussels must be relocated prior to project implementation, and monitored post-implementation. To qualify under this exemption, a channel restoration project must satisfy all Federal, State, and local permitting requirements.

(C) Bank restoration projects that use bioengineering methods to replace pre-existing, bare, eroding stream banks with vegetated, stable stream banks, thereby reducing bank erosion and instream sedimentation and improving habitat conditions for the species. Following these bioengineering methods, stream banks may be stabilized using native species live stakes (live, vegetative cuttings inserted or tamped into the ground in a manner that allows the stake to take root and grow), native species live fascines (live branch cuttings, usually willows, bound together into long, cigar-shaped bundles), or native species brush layering (cuttings or branches of easily rooted tree species layered between successive lifts of soil fill). Bank restoration projects would require planting appropriate native vegetation, including woody species appropriate for the region and habitat. These methods will not include the sole use of quarried rock (rip-rap) or the use of rock baskets or gabion structures. Prior to commencement of bank stabilization actions, surveys to determine presence of longsolid and round hickorynut must be performed, and if located, in coordination with the local Service field office, mussels must be relocated prior to project implementation, and monitored post-implementation. To

qualify under this exemption, a bank restoration project must satisfy all Federal, State, and local permitting requirements.

(v) Possess and engage in other acts with unlawfully taken wildlife, as set forth at § 17.21(d)(2) for endangered wildlife.

■ 4. Amend § 17.95(f) by:

■ a. Adding, immediately following the entry for ''Carolina Heelsplitter (*Lasmigona decorata*),'' an entry for ''Round Hickorynut (*Obovaria subrotunda*)''; and

■ b. Adding, immediately following the new entry for ''Round Hickorynut (*Obovaria subrotunda*),'' an entry for ''Longsolid (*Fusconaia subrotunda*)''.

The additions read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(f) *Clams and Snails.*

* * * * *

Round Hickorynut (*Obovaria subrotunda*)

(1) Critical habitat units for the round hickorynut are depicted on the maps in this entry for Jackson, Madison, and Marshall Counties, Alabama; Fulton, Marshall, Pulaski, and Starke Counties, Indiana; Bath, Butler, Campbell, Edmonson, Fleming, Green, Harrison, Hart, Kenton, Laurel, Morgan, Nicholas, Pendleton, Pulaski, Rockcastle, Robertson, Rowan, and Warren Counties, Kentucky; Montgomery County, Mississippi; Bedford, Marshall, and Maury Counties, Tennessee; Ashtabula, Lake, and Trumbull Counties, Ohio; Crawford and Mercer Counties, Pennsylvania; and Braxton, Calhoun, Clay, Doddridge, Fayette, Gilmer, Kanawha, Pleasants, Ritchie, Tyler, and Wood Counties, West Virginia.

(2) Within these areas, the physical or biological features essential to the conservation of the round hickorynut consist of the following components:

(i) Adequate flows, or a hydrologic flow regime (magnitude, timing, frequency, duration, rate of change, and overall seasonality of discharge over time), necessary to maintain benthic habitats where the species are found and to maintain stream connectivity, specifically providing for the exchange of nutrients and sediment for maintenance of the mussel's and fish host's habitat and food availability, maintenance of spawning habitat for native fishes, and the ability for newly transformed juveniles to settle and become established in their habitats. Adequate flows ensure delivery of oxygen, enable reproduction, deliver food to filter-feeding mussels, and reduce contaminants and fine sediments from interstitial spaces. Stream velocity is not static over time, and variations may be attributed to seasonal changes (with higher flows in winter/spring and lower flows in summer/fall), extreme weather events (*e.g.,* drought or floods), or anthropogenic influence (*e.g.,* flow regulation via impoundments).

(ii) Suitable substrates and connected instream habitats, characterized by geomorphically stable stream channels and banks (*i.e.,* channels that maintain lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation) with habitats that support a diversity of freshwater mussel and native fish (such as, stable riffle-run-pool habitats that provide flow refuges consisting of predominantly silt-free, stable sand, gravel, and cobble substrates).

(iii) Water and sediment quality necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages, including (but not limited to): Dissolved oxygen (generally above 2 to 3 parts per million (ppm)), salinity (generally below 2 to 4 ppm), and temperature (generally below 86 °Fahrenheit (°F) (30 °Celsius (°C)). Additionally, water and sediment should be low in ammonia (generally below 0.5 ppm total ammonia-nitrogen) and heavy metal concentrations, and lack excessive total suspended solids and other pollutants.

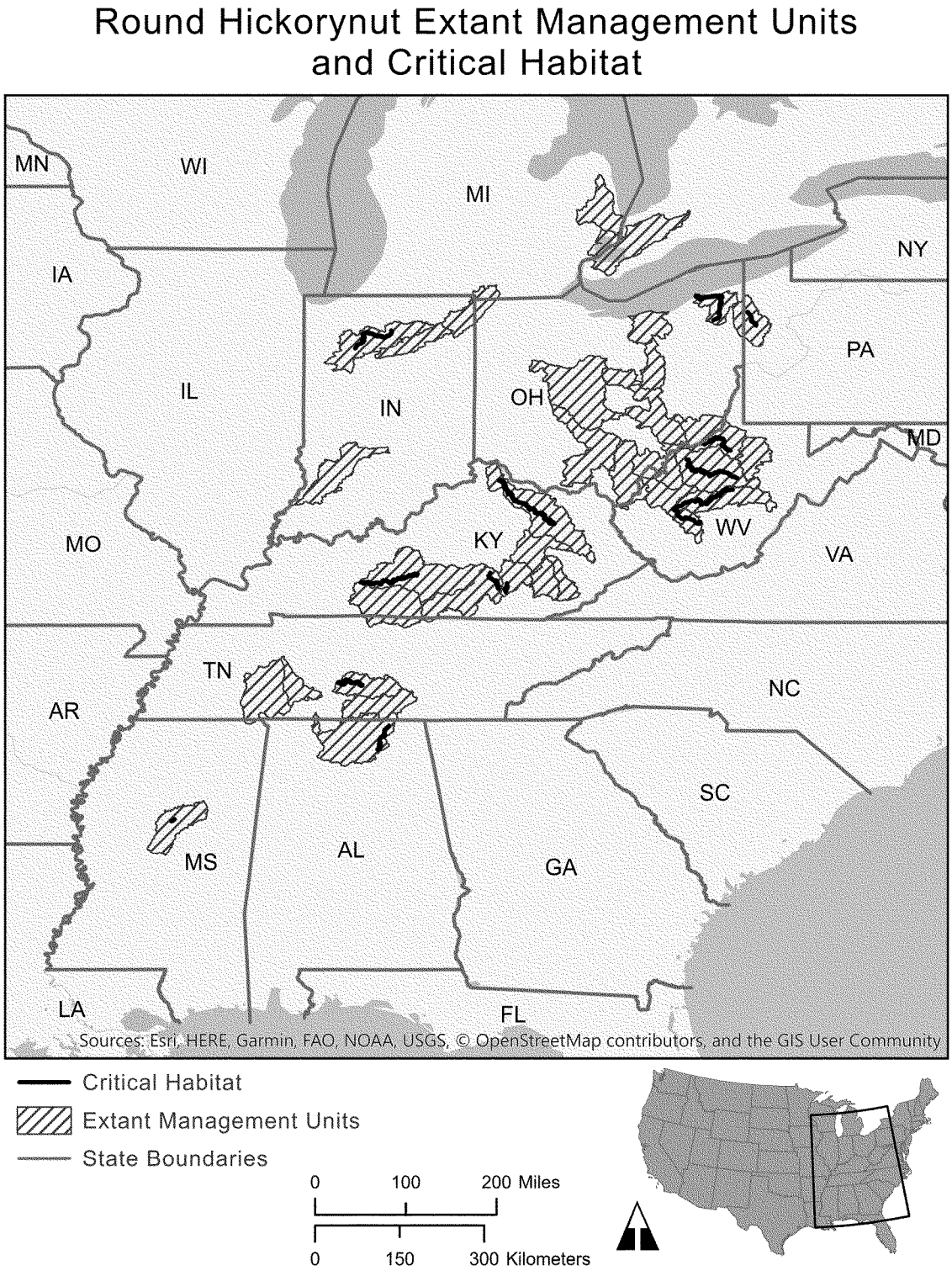
(iv) The presence and abundance of fish hosts necessary for recruitment of the round hickorynut (*i.e.,* eastern sand darter (*Ammocrypta pellucida*), emerald darter (*Etheostoma baileyi*), greenside darter (*E. blennioides*), Iowa darter (*E. exile*), fantail darter (*E. flabellare*), Cumberland darter (*E. susanae*), spangled darter (*E. obama*), variegate darter (*E. variatum*), blackside darter (*Percina maculata*), frecklebelly darter (*P. stictogaster*), and banded sculpin (*Cottus carolinae*)).

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of this rule.

(4) *Critical habitat map units.* Data layers defining map units were created by overlaying Natural Heritage Element Occurrence data and U.S. Geological Survey hydrologic data for stream reaches. The hydrologic data used in the critical habitat maps were extracted from the U.S. Geological Survey 1:1M scale nationwide hydrologic layer (*https://www.usgs.gov/core-science-systems/ngp/national-hydrography*) with a projection of EPSG:4269—NAD83 Geographic. Natural Heritage program and State mussel database species presence data from Pennsylvania, Ohio, Indiana, West Virginia, Kentucky, Tennessee, Alabama, and Mississippi were used to select specific river and stream segments for inclusion in the critical habitat layer. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's internet site at *https://www.fws.gov/Asheville/,* at *http://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0010, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) *Note:* Index map for the round hickorynut follows:

BILLING CODE 4333–15–P

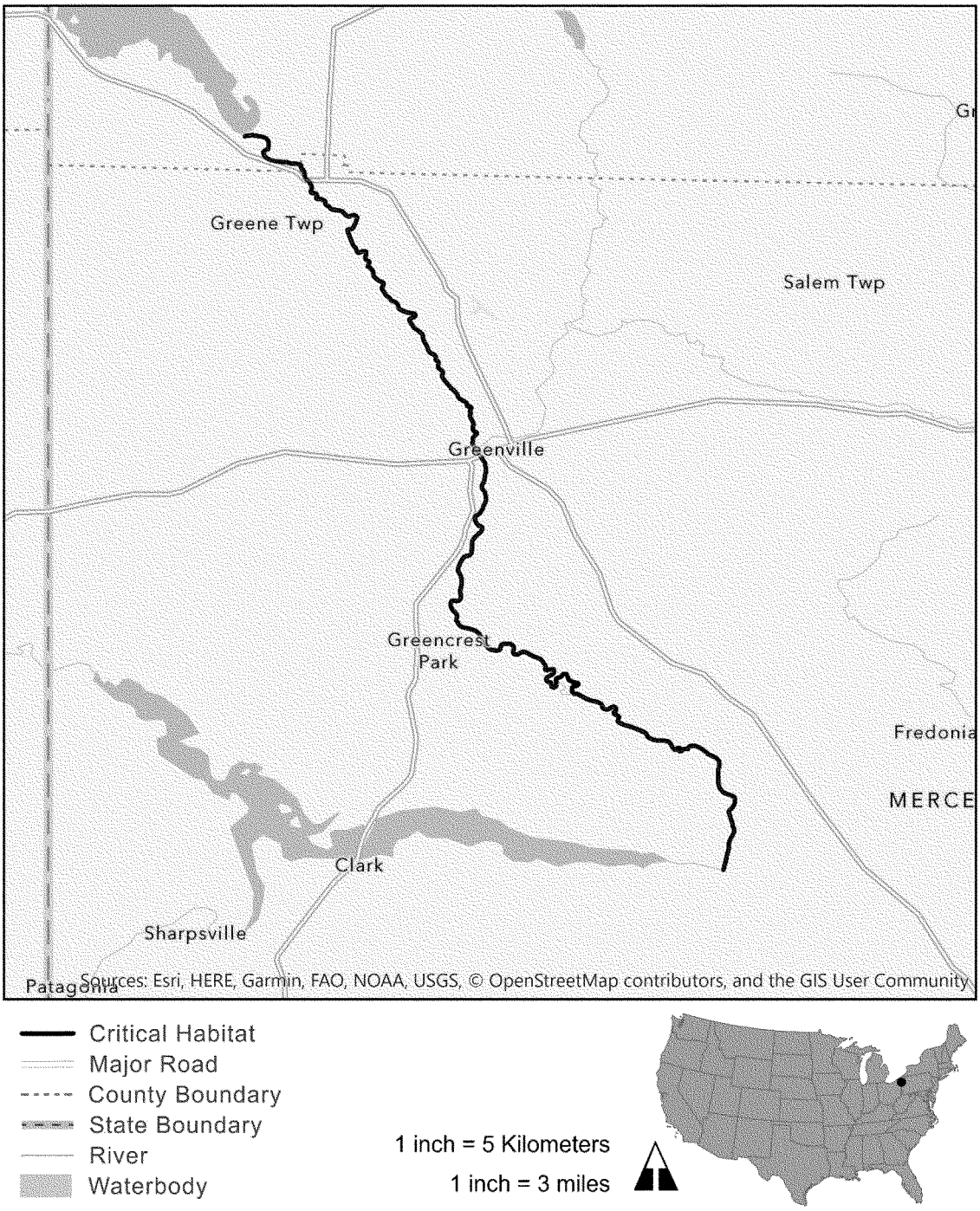


(6) Unit RH 1: Shenango River; Crawford and Mercer Counties, Pennsylvania.

(i) *General description:* Unit RH 1 consists of 22 river miles (mi) (35.5 kilometers (km)) of the Shenango River in Crawford County, Pennsylvania, from Pymatuning Dam downstream to the point of inundation by Shenango River Lake near Big Bend, Mercer County, Pennsylvania. Approximately 15 river mi (24.3 km; 68 percent) of riparian lands that border the unit are private ownership, and 7 river mi (11.1 km; 32 percent) are public (Federal or State) ownership. This unit is immediately downstream from Pymatuning Dam, which is owned by the State of Pennsylvania.

(ii) Map of Unit RH 1 follows:

Critical Habitat for Round Hickorynut
RH1 Shenango River; Crawford and Mercer Counties, Pennsylvania

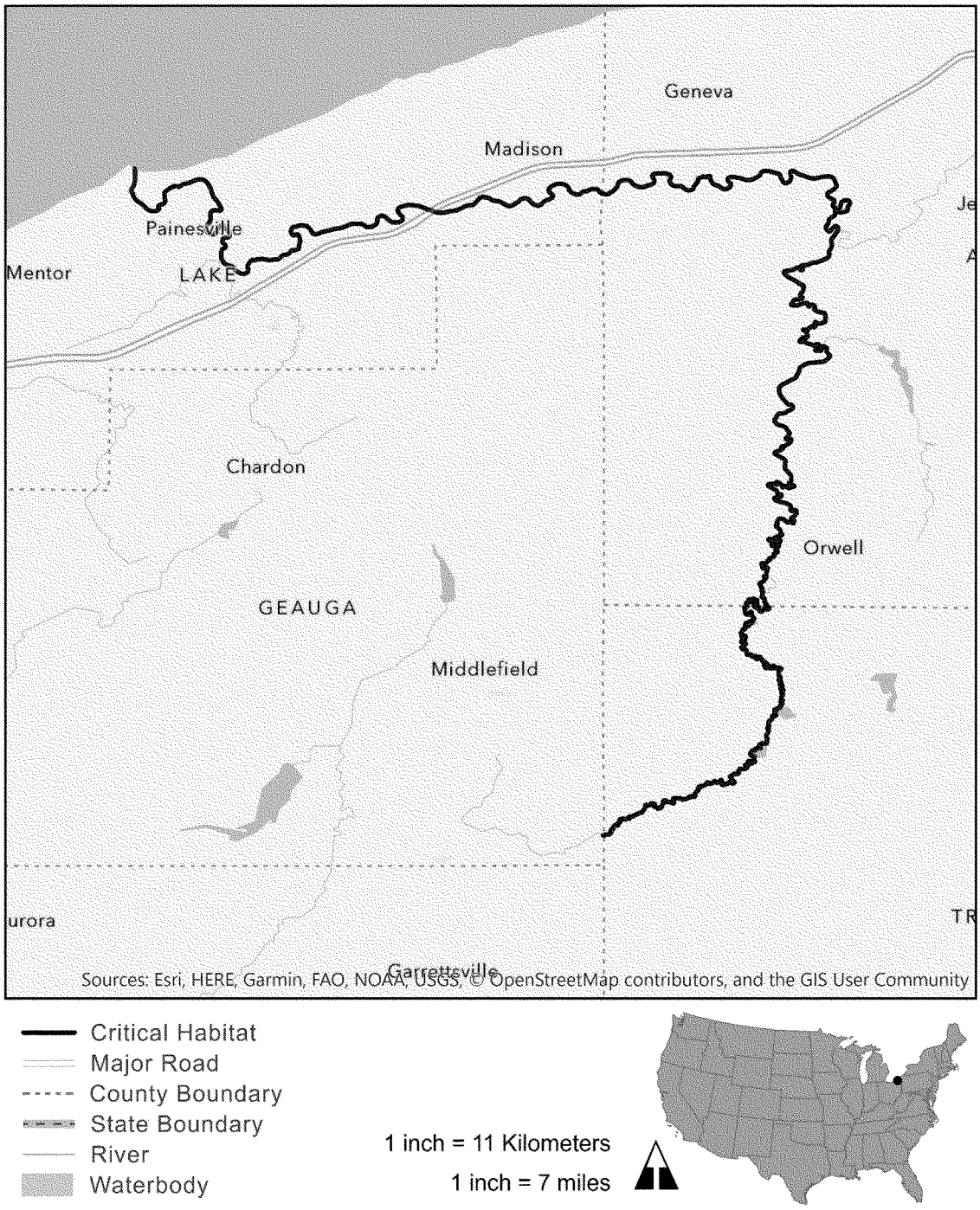


(7) Unit RH 2: Grand River; Ashtabula, Lake, and Trumbull Counties, Ohio.

(i) *General description:* Unit RH 2 consists of 92 river mi (148.2 km) of the Grand River in Ashtabula, Lake, and Trumbull Counties, Ohio. Approximately 59 river mi (95.2 km; 64 percent) of riparian lands that border the unit are private ownership, and 33 river mi (53 km; 36 percent) are public (State or local) ownership. The Grand River is a State Wild and Scenic River. The Wild River designation includes approximately 23 river mi (37 km) from the Harpersfield Covered Bridge downstream to the Norfolk and Western Railroad Trestle in Lake County, and approximately 33 mi (53 km) from the U.S. Route 322 Bridge in Ashtabula County downstream to the Harpersfield Covered Bridge. Harpersfield Dam within this unit is operated by the U.S. Army Corps of Engineers.

(ii) Map of Unit RH 2 follows:

Critical Habitat for Round Hickorynut
RH2 Grand River; Ashtabula, Lake, and Trumbull Counties, Ohio

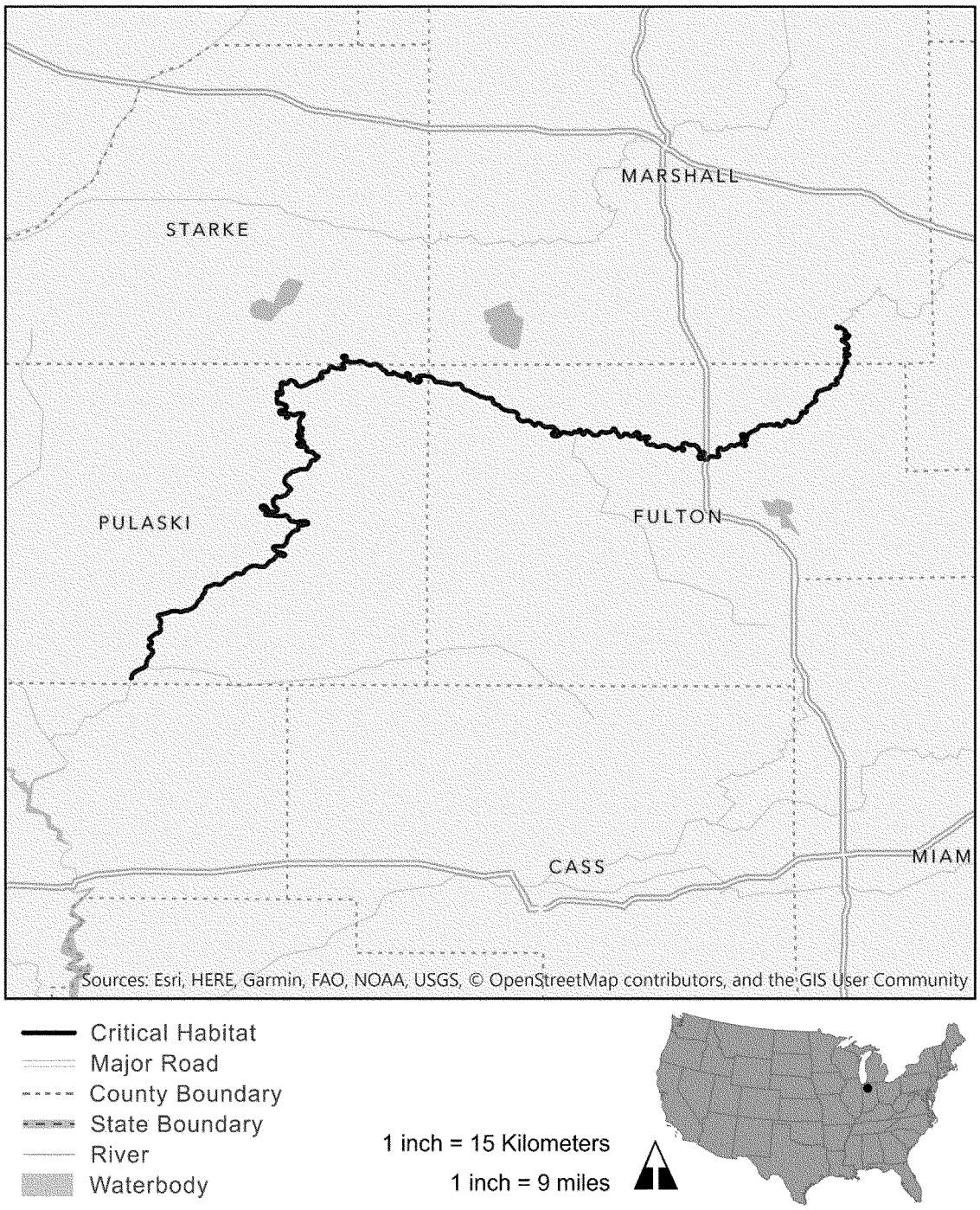


(8) Unit RH 3: Tippecanoe River; Fulton, Marshall, Pulaski, and Starke Counties, Indiana.

(i) *General description:* Unit RH 3 consists of 75 river mi (120.8 km) of the Tippecanoe River in Fulton, Marshall, Pulaski, and Starke Counties, Indiana. Approximately 66 river mi (105.6 km; 89 percent) of riparian lands that border the unit are private ownership, and 9 river mi (14.5 km; 11 percent) are public (State or easement) ownership.

(ii) Map of Unit RH 3 follows:

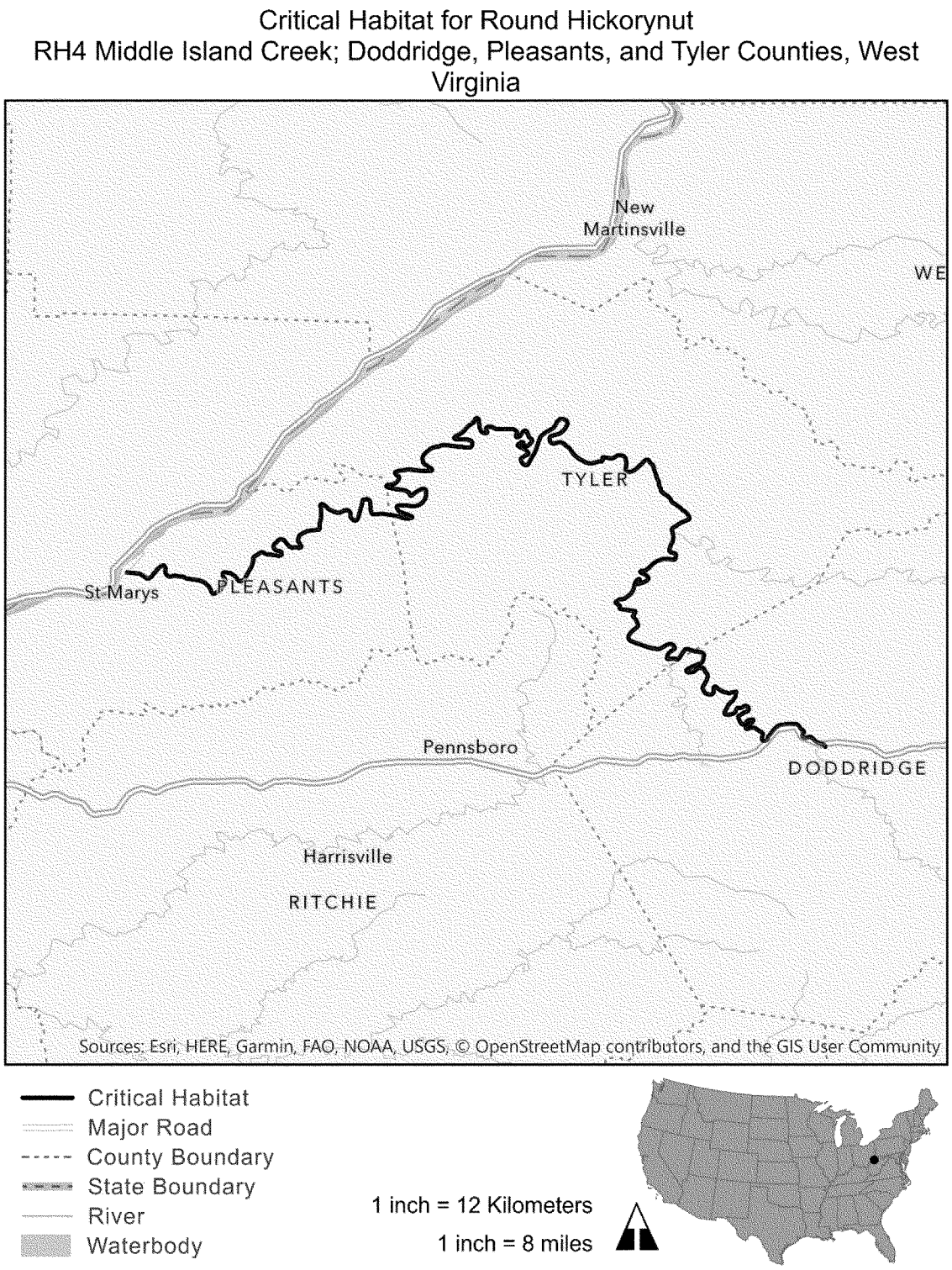
Critical Habitat for Round Hickorynut
RH3 Tippecanoe River; Fulton, Marshall, Pulaski, and Starke Counties, Indiana



(9) Unit RH 4: Middle Island Creek; Doddridge, Pleasants, and Tyler Counties, West Virginia.

(i) *General description:* Unit RH 4 consists of 75 stream mi (120.8 km) of Middle Island Creek in Doddridge, Pleasants, and Tyler Counties, West Virginia. Approximately 74.8 stream mi (120.4 km; 99 percent) of riparian lands that border the unit are private ownership, and 0.2 stream mi (0.4 km; less than 1 percent) is public ownership.

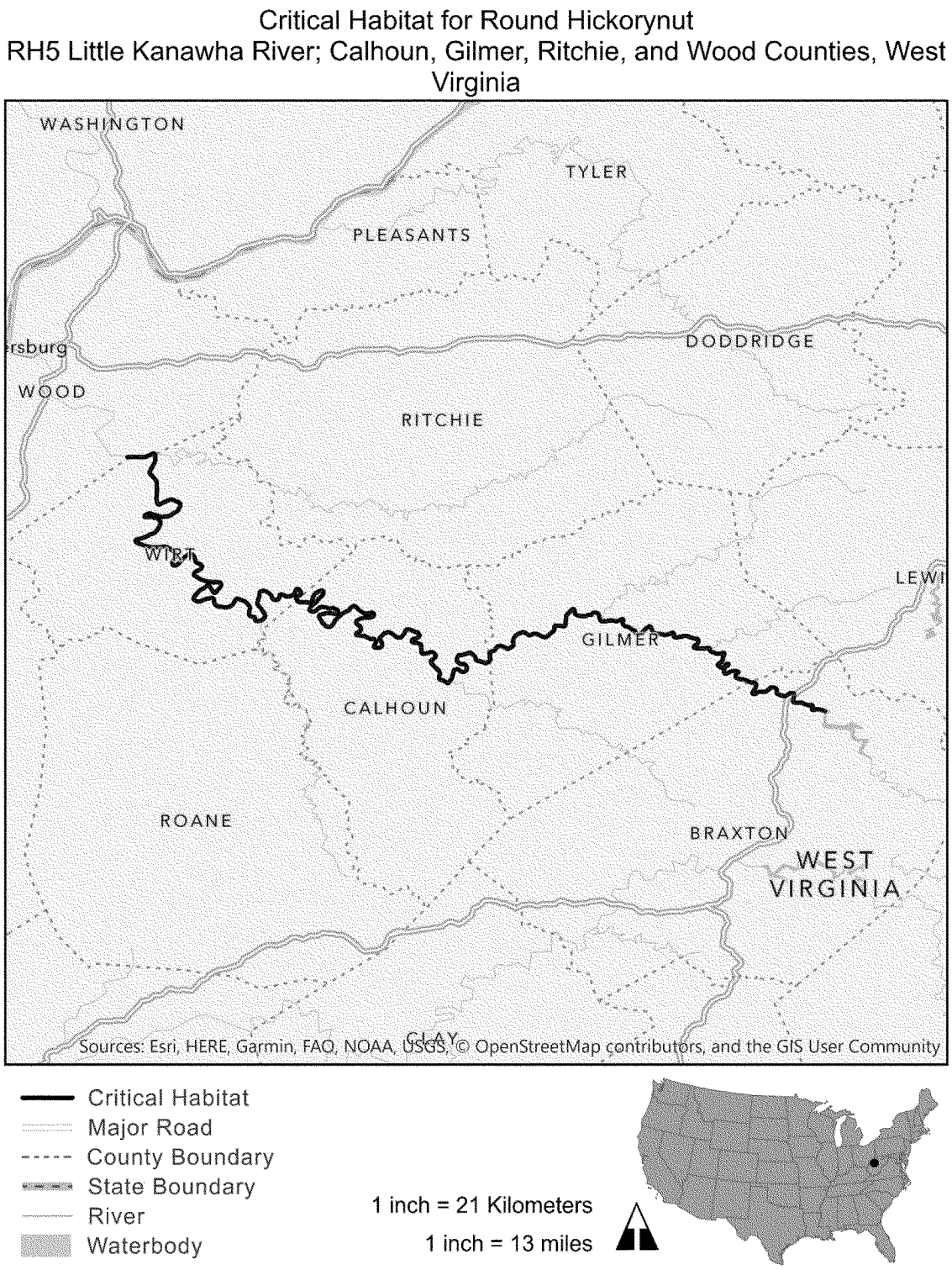
(ii) Map of Unit RH 4 follows:



(10) Unit RH 5: Little Kanawha River; Calhoun, Gilmer, Ritchie, and Wood Counties, West Virginia.

(i) *General description:* Unit RH 5 consists of 110 stream mi (176.6 km) of the Little Kanawha River in Calhoun, Gilmer, Ritchie, and Wood Counties, West Virginia. Approximately 109 river mi (175.4 km; 99 percent) of riparian lands that border the unit are private ownership, and 0.7 river mi (1.2 km; 1 percent) are public (Federal, State, or local) ownership. This unit is directly below Burnsville Dam, which is operated by the U.S. Army Corps of Engineers.

(ii) Map of Unit RH 5 follows:

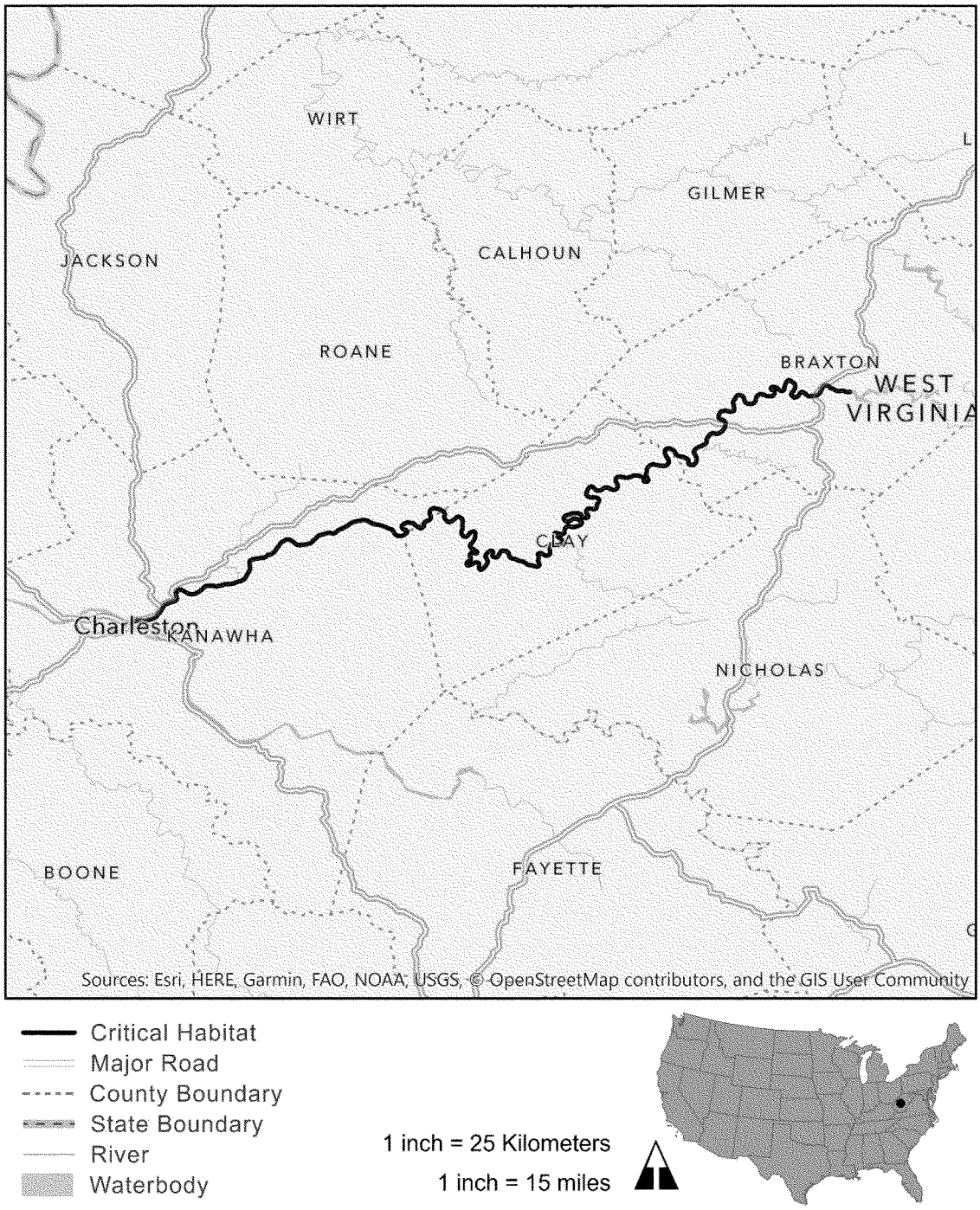


(11) Unit RH 6: Elk River; Braxton, Clay, and Kanawha Counties, West Virginia.

(i) *General description:* Unit RH 6 consists of 101 river mi (163 km) of the Elk River in Braxton, Clay, and Kanawha Counties, West Virginia. Approximately 93 river mi (150.3 km; 92 percent) of riparian lands that border the unit are private ownership, and 7 river mi (12.7 km; 8 percent) are public (Federal, State, or local) ownership. This unit is immediately below Sutton Dam, which is operated by the U.S. Army Corps of Engineers.

(ii) Map of Unit RH 6 follows:

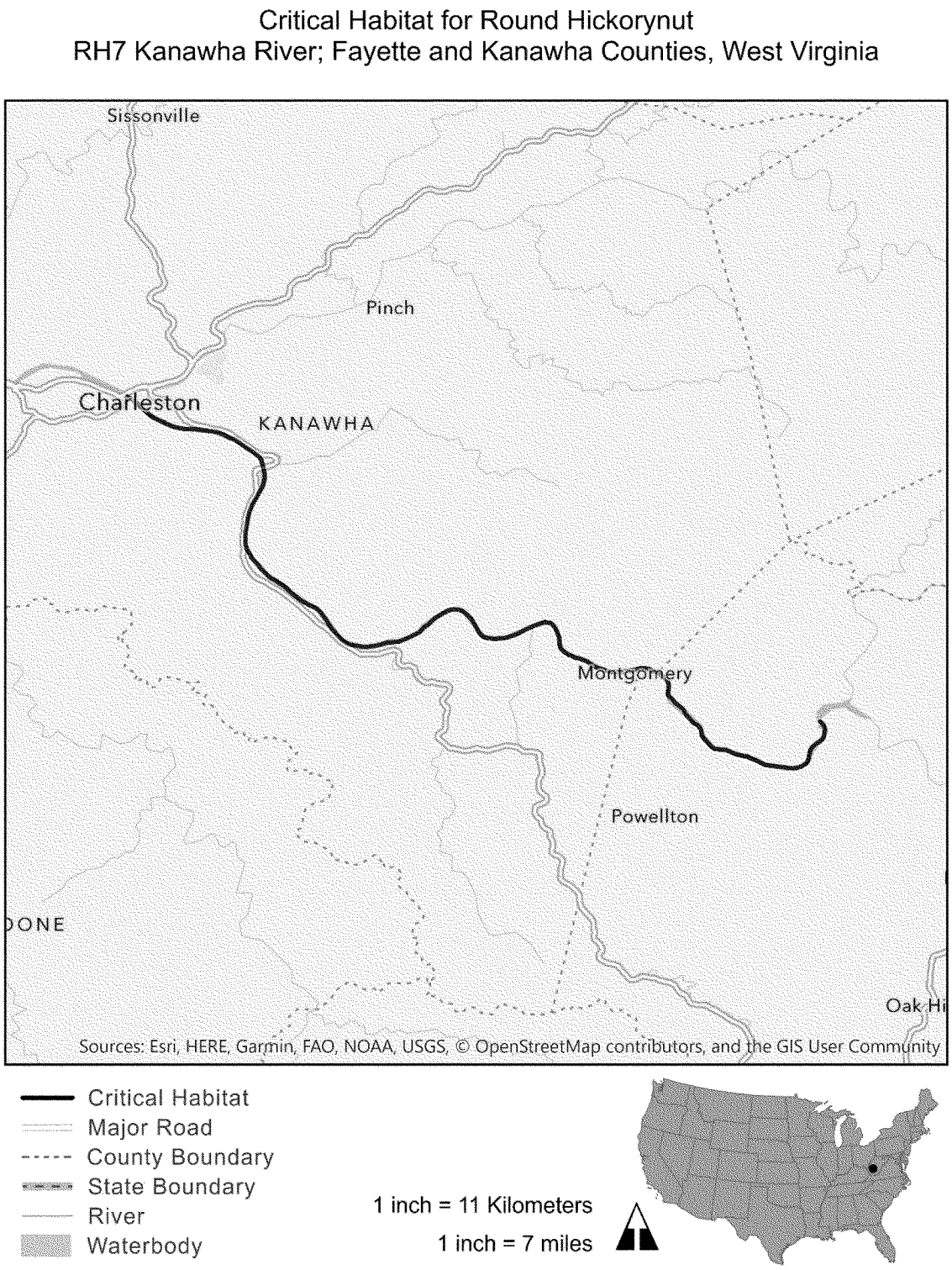
Critical Habitat for Round Hickorynut
RH6 Elk River; Braxton, Clay, and Kanawha Counties, West Virginia



(12) Unit RH 7: Kanawha River; Fayette and Kanawha Counties, West Virginia.

(i) *General description:* Unit RH 7 consists of 37.5 river mi (60.4 km) of the Kanawha River in Fayette and Kanawha Counties, West Virginia. Approximately 33 river mi (53.2 km; 90 percent) of riparian lands that border the unit are private ownership, and 4 river mi (7.2 km; 10 percent) are public (Federal, State, or local) ownership. London and Marmet locks and dams within this unit are operated by the U.S. Army Corps of Engineers.

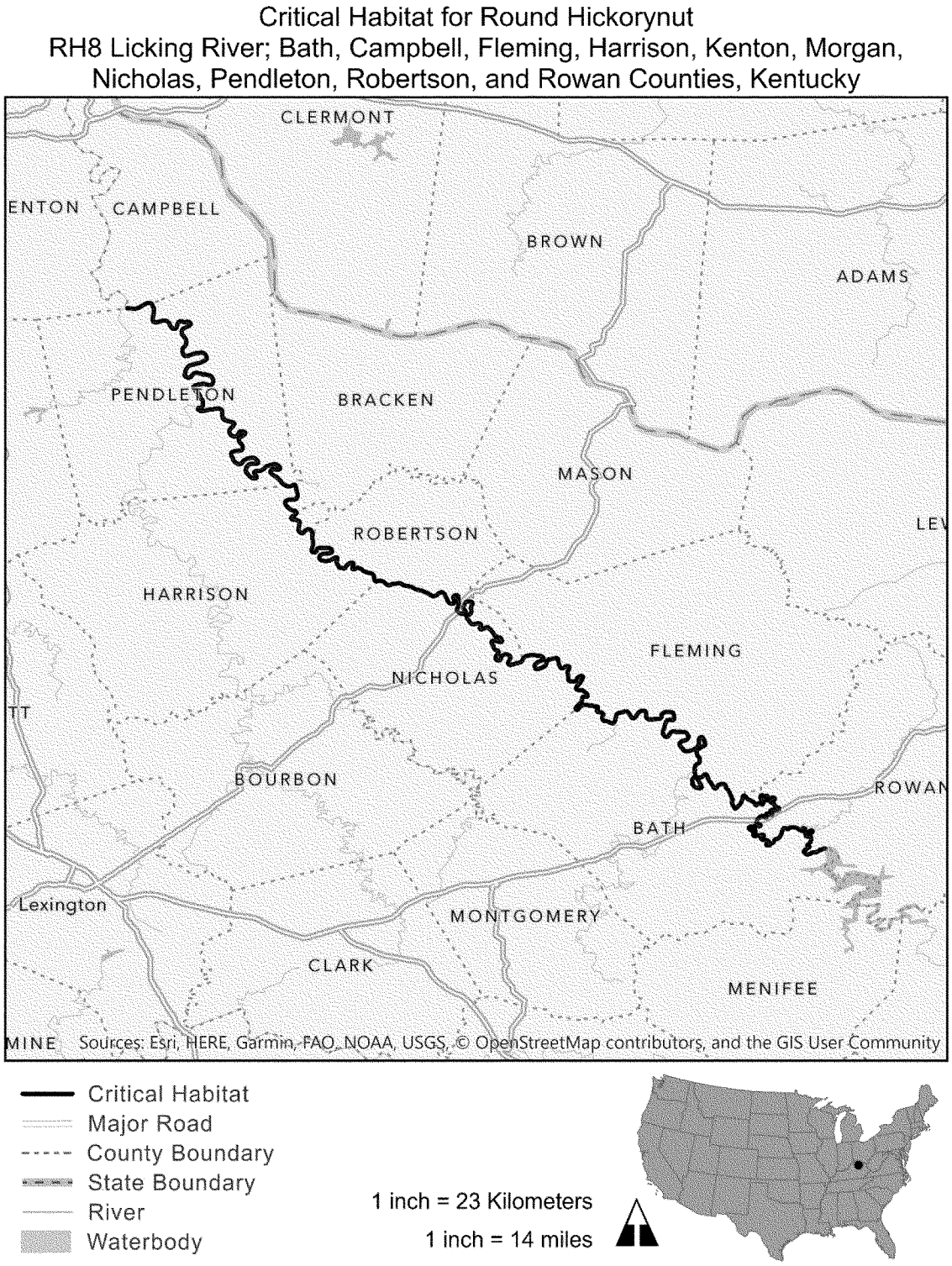
(ii) Map of Unit RH 7 follows:



(13) Unit RH 8: Licking River; Bath, Campbell, Fleming, Harrison, Kenton, Morgan, Nicholas, Pendleton, Robertson, and Rowan Counties, Kentucky.

(i) *General description:* Unit RH 8 consists of 150 river mi (241.9 km) of the Licking River in Bath, Campbell, Fleming, Harrison, Kenton, Morgan, Nicholas, Pendleton, Robertson, and Rowan Counties, Kentucky. Approximately 131 river mi (211.8 km; 87 percent) of riparian lands that border the unit are private ownership, and 18 river mi (30 km; 13 percent) are public (Federal, State, or local) ownership. This unit is directly below Cave Run Dam, which is operated by the U.S. Army Corps of Engineers.

(ii) Map of Unit RH 8 follows:

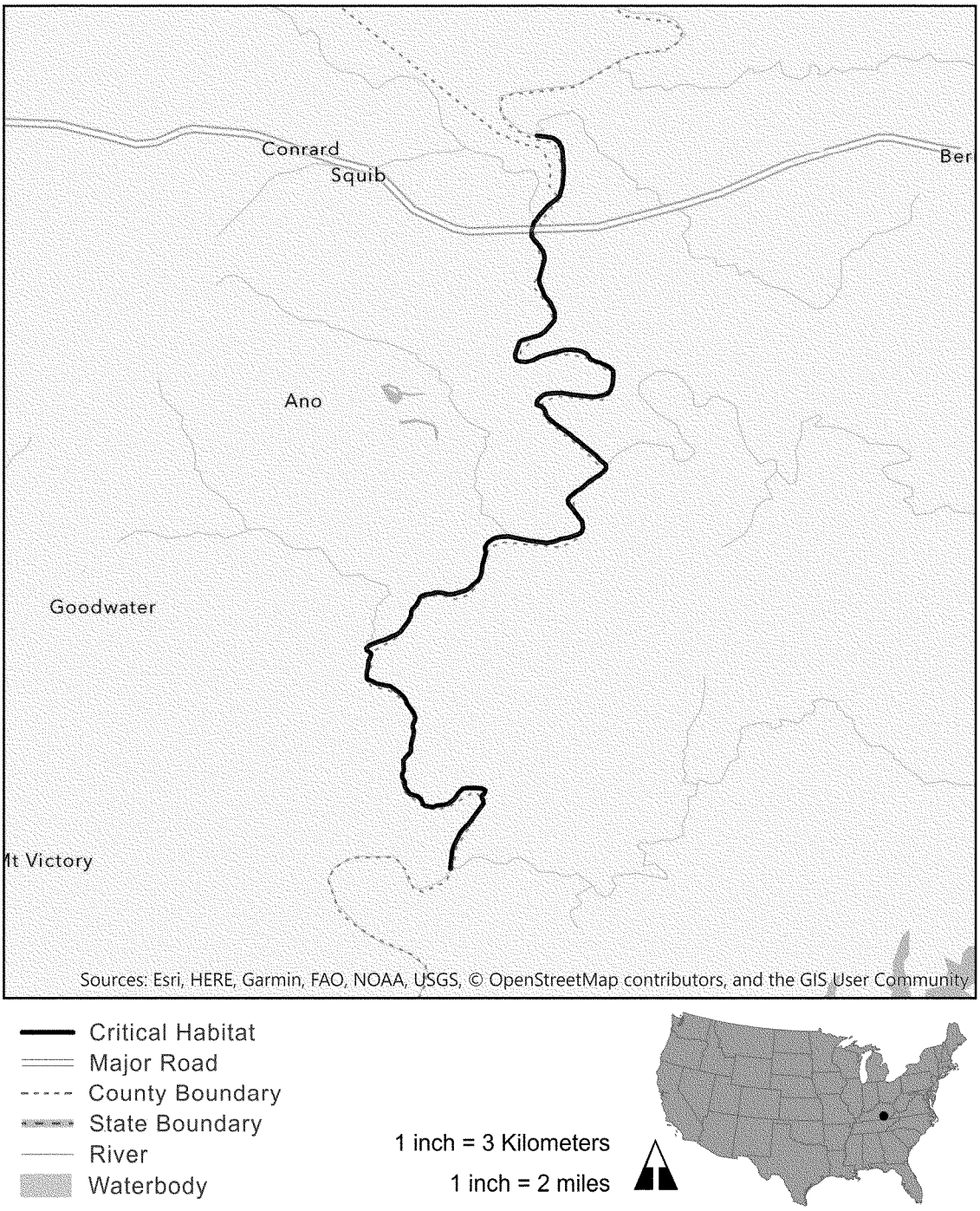


(14) Unit RH 9: Rockcastle River; Laurel, Pulaski, and Rockcastle Counties, Kentucky.

(i) *General description:* Unit RH 9 consists of 15.3 river mi (24.6 km) of the Rockcastle River in Laurel, Pulaski, and Rockcastle Counties, Kentucky. Approximately 0.3 river mi (0.4 km; 1 percent) of riparian lands that border the unit is private ownership, and 15 river mi (24.2 km; 99 percent) are public (Federal; Daniel Boone National Forest) ownership.

(ii) Map of Unit RH 9 follows:

Critical Habitat for Round Hickorynut
RH9 Rockcastle River; Laurel, Pulaski, and Rockcastle Counties, Kentucky

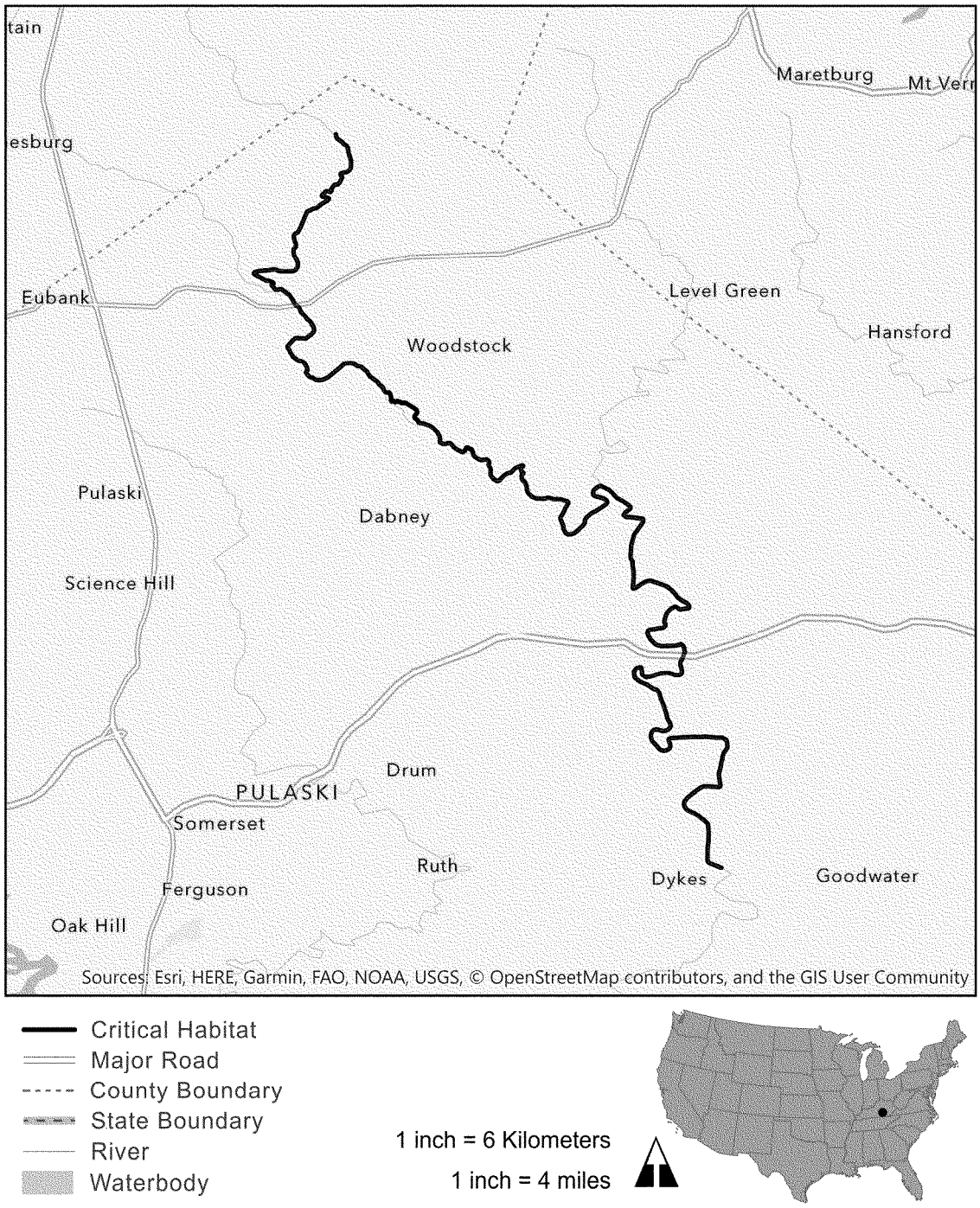


(15) Unit RH 10: Buck Creek, Pulaski County, Kentucky.

(i) *General description:* Unit RH 10 consists of 36 stream mi (58.1 km) of Buck Creek in Pulaski County, Kentucky. Approximately 33 stream mi (52.6 km; 92 percent) of riparian lands that border the unit are private ownership, and 3 stream mi (5.5 km; 8 percent) are public (State or local) ownership.

(ii) Map of Unit RH 10 follows:

Critical Habitat for Round Hickorynut
RH10 Buck Creek; Pulaski County, Kentucky

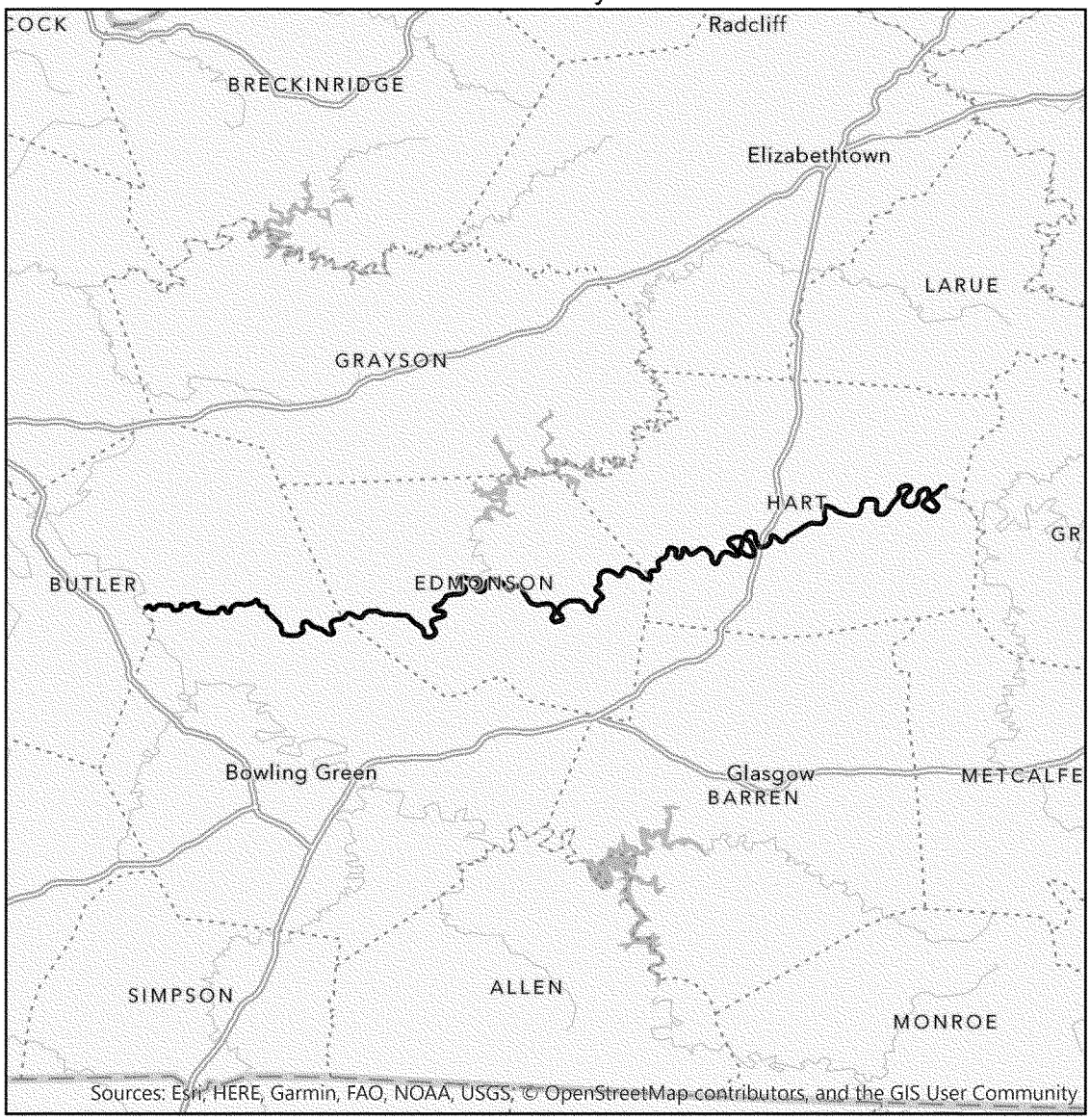


(16) Unit RH 11: Green River; Hart, Edmonson, Green, Butler, and Warren Counties, Kentucky.

(i) *General description:* Unit RH 11 consists of 98 river mi (157.7 km) of the Green River in Butler, Edmonson, Green, Hart, and Warren Counties, Kentucky. Approximately 61 river mi (98.4 km; 62 percent) of riparian lands that border the unit are private ownership, and 37 river mi (59.4 km; 38 percent) are public (Federal or State) ownership, including portions of Mammoth Cave National Park. This unit is located directly below Green River Lake Dam, which is operated by the U.S. Army Corps of Engineers.

(ii) Map of Unit RH 11 follows:

Critical Habitat for Round Hickorynut
RH11 Green River; Butler, Edmonson, Green, Hart, and Warren Counties, Kentucky

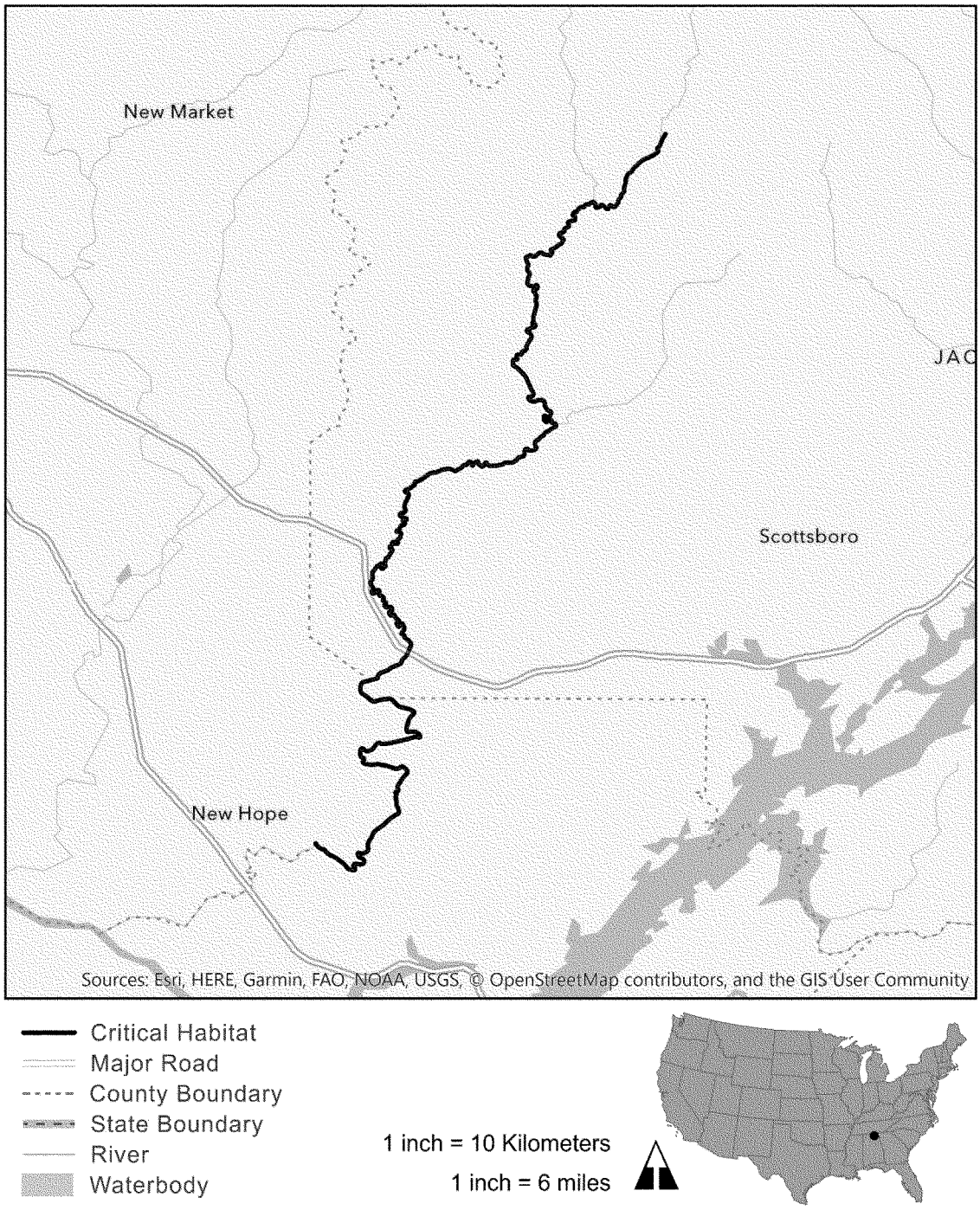


(17) Unit RH 12: Paint Rock River; Jackson, Madison, and Marshall Counties, Alabama.

(i) *General description:* Unit RH 12 consists of 48 river mi (77.5 km) of the Paint Rock River in Jackson, Madison, and Marshall Counties, Alabama. Approximately 2 river mi (4.1 km; 2 percent) of riparian lands that border the unit are private ownership, and 46 river mi (73.4 km; 98 percent) are public (Federal or State) ownership.

(ii) Map of Unit RH 12 follows:

Critical Habitat for Round Hickorynut
RH12 Paint Rock River; Jackson, Madison, and Marshall Counties, Alabama

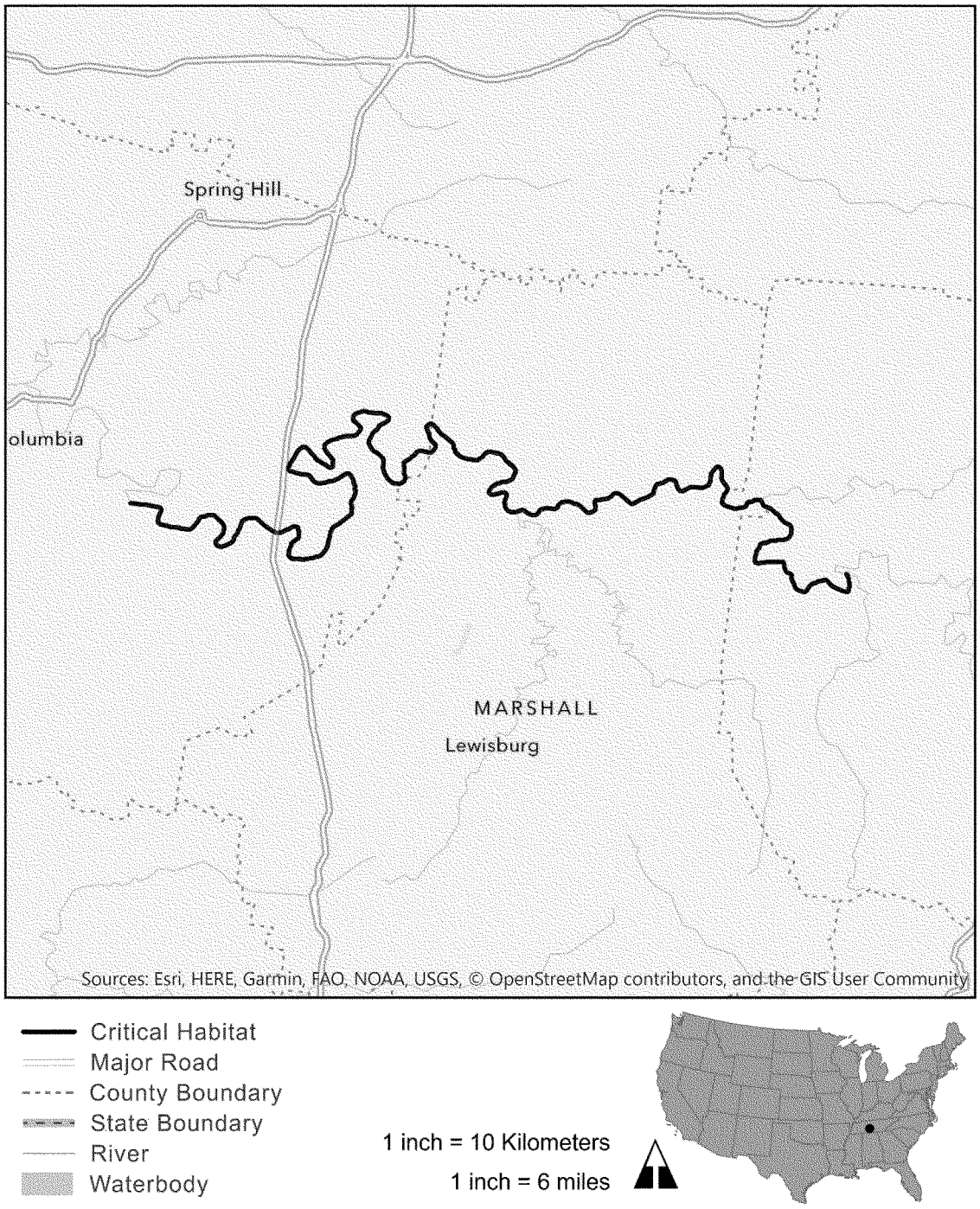


(18) Unit RH 13: Duck River; Bedford, Marshall, and Maury Counties, Tennessee.

(i) *General description:* Unit RH 13 consists of 59 river mi (94.8 km) of the Duck River in Bedford, Marshall, and Maury Counties, Tennessee. Approximately 27 river mi (43.7 km; 47 percent) of riparian lands that border the unit are private ownership, and 32 river mi (51.1 km; 53 percent) are public (State or local) ownership.

(ii) Map of Unit RH 13 follows:

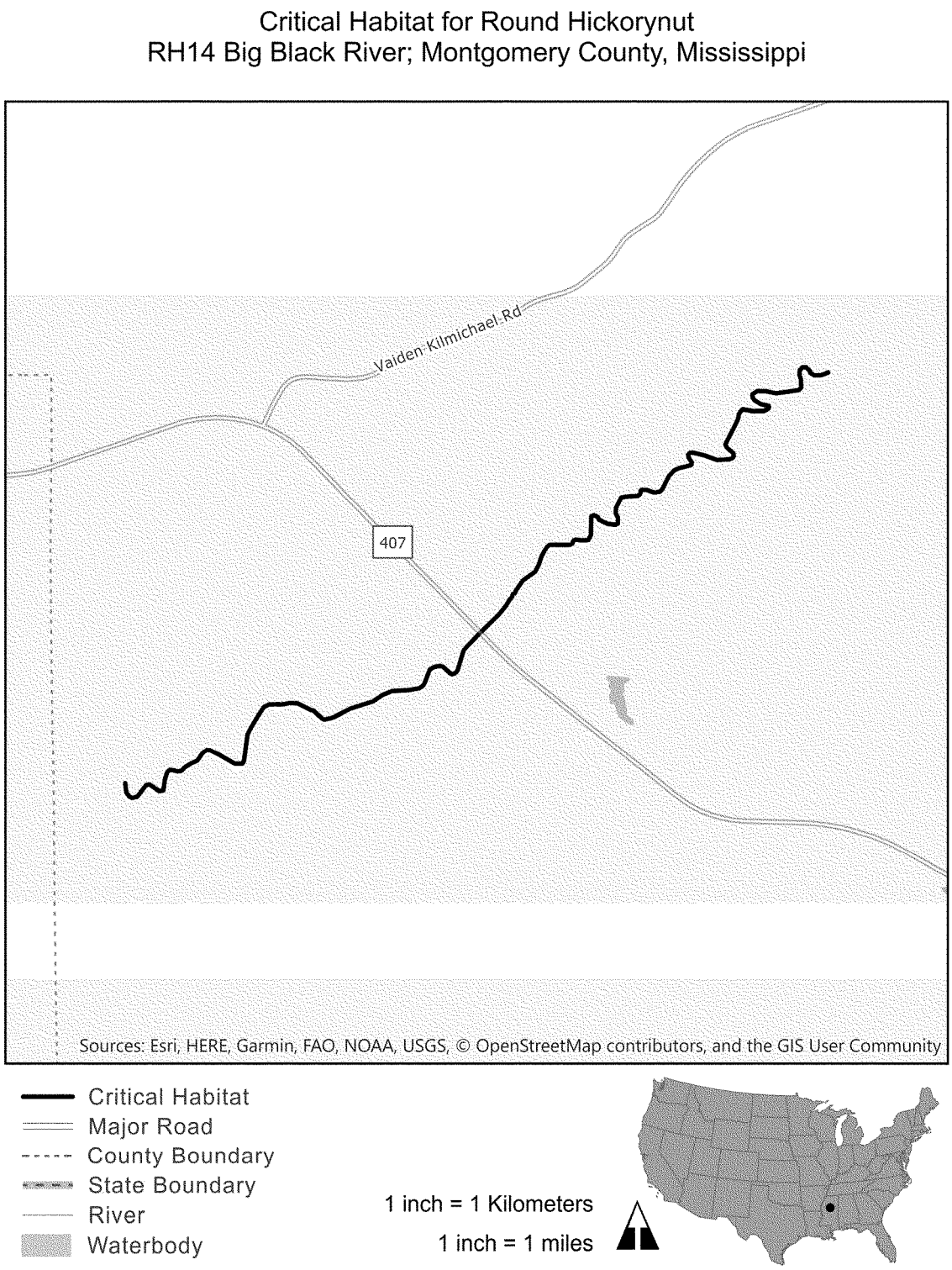
Critical Habitat for Round Hickorynut
RH13 Duck River; Bedford, Marshall, and Maury Counties, Tennessee



(19) Unit RH 14: Big Black River, Montgomery County, Mississippi.

(i) *General description:* Unit RH 14 consists of 4 river mi (7 km) of the Big Black River in Montgomery County, Mississippi. All of riparian lands that border the unit are private ownership.

(ii) Map of Unit RH 14 follows:



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* * * * *

Longsolid (*Fusconaia subrotunda*)

(1) Critical habitat units for the longsolid are depicted on the maps in this entry for Jackson, Madison, and Marshall Counties, Alabama; Bath, Butler, Campbell, Edmonson, Fleming, Green, Harrison, Hart, Kenton, Morgan, Nicholas, Pendleton, Robertson, Rowan, Taylor, and Warren Counties, Kentucky; Clarion, Crawford, Erie, Forest, Mercer, Venango, and Warren Counties, Pennsylvania; Claiborne, Hancock, Hawkins, Smith, Trousdale, and Wilson Counties, Tennessee; Russell, Scott, Tazewell, and Wise Counties, Virginia; and Braxton, Calhoun, Clay, Doddridge, Fayette, Gilmer, Kanawha, Ritchie, Tyler, and Wood Counties, West Virginia.

(2) Within these areas, the physical or biological features essential to the conservation of the longsolid consist of the following components:

(i) Adequate flows, or a hydrologic flow regime (magnitude, timing, frequency, duration, rate of change, and overall seasonality of discharge over

time), necessary to maintain benthic habitats where the species are found and to maintain stream connectivity, specifically providing for the exchange of nutrients and sediment for maintenance of the mussel's and fish host's habitat and food availability, maintenance of spawning habitat for native fishes, and the ability for newly transformed juveniles to settle and become established in their habitats. Adequate flows ensure delivery of oxygen, enable reproduction, deliver food to filter-feeding mussels, and reduce contaminants and fine sediments from interstitial spaces. Stream velocity is not static over time, and variations may be attributed to seasonal changes (with higher flows in winter/spring and lower flows in summer/fall), extreme weather events (*e.g.,* drought or floods), or anthropogenic influence (*e.g.,* flow regulation via impoundments).

(ii) Suitable substrates and connected instream habitats, characterized by geomorphically stable stream channels and banks (*i.e.,* channels that maintain lateral dimensions, longitudinal profiles, and sinuosity patterns over time without an aggrading or degrading bed elevation) with habitats that support a diversity of freshwater mussel and native fish (such as, stable riffle-run-pool habitats that provide flow refuges consisting of predominantly silt-free, stable sand, gravel, and cobble substrates).

(iii) Water and sediment quality necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages, including (but not limited to): Dissolved oxygen (generally above 2 to 3 parts per million (ppm)), salinity (generally below 2 to 4 ppm), and temperature (generally below 86 °Fahrenheit (°F) (30 °Celsius (°C)). Additionally, water and sediment should be low in ammonia (generally below 0.5 ppm total ammonia-nitrogen) and heavy metal concentrations, and lack excessive total suspended solids and other pollutants.

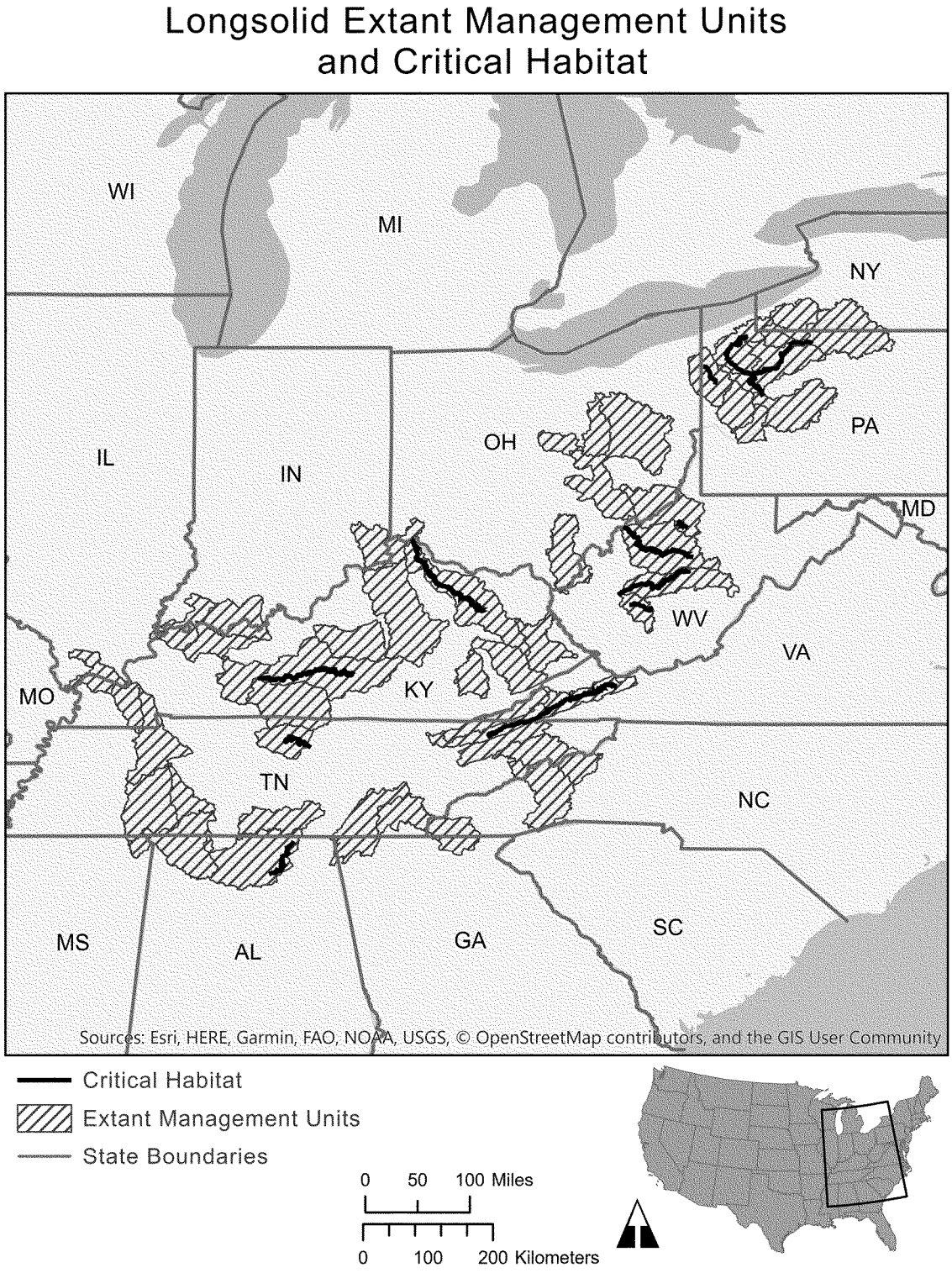
(iv) The presence and abundance of fish hosts necessary for recruitment of the longsolid (currently unknown, likely includes the minnows of the family Cyprinidae, and banded sculpin (*Cottus carolinae*)).

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of the rule.

(4) *Critical habitat map units.* Data layers defining map units were created by overlaying Natural Heritage Element Occurrence data and U.S. Geological Survey hydrologic data for stream reaches. The hydrologic data used in the critical habitat maps were extracted from the U.S. Geological Survey 1:1M scale nationwide hydrologic layer (*https://www.usgs.gov/core-science-systems/ngp/national-hydrography*) with a projection of EPSG:4269—NAD83 Geographic. Natural Heritage program and State mussel database species presence data from Pennsylvania, West Virginia, Virginia, Kentucky, Tennessee, and Alabama were used to select specific river and stream segments for inclusion in the critical habitat layer. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's internet site at *https://www.fws.gov/Asheville/,* at *http://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0010, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) *Note:* Index map for the longsolid follows:

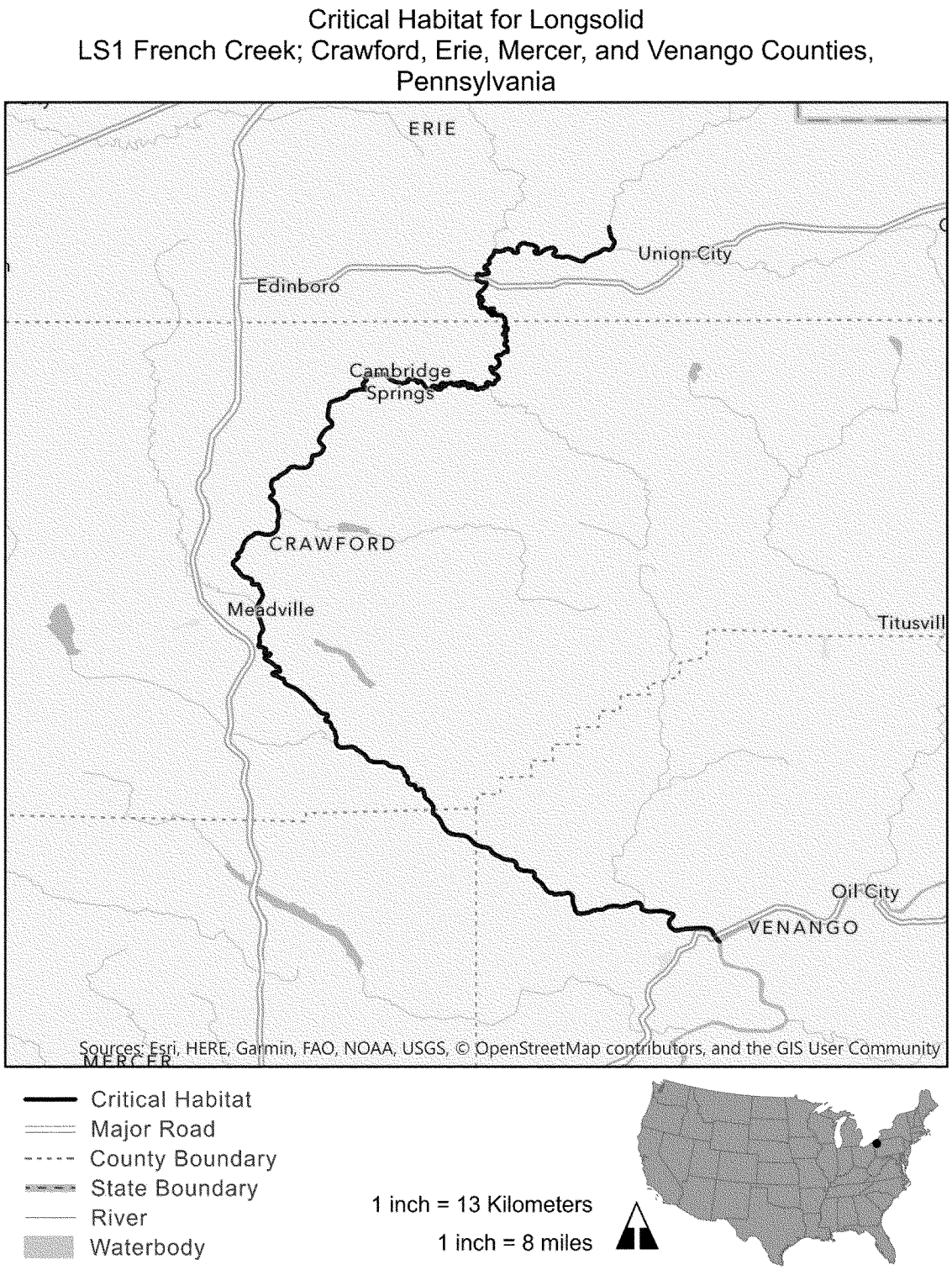
BILLING CODE 4333–15–P



(6) Unit LS 1: French Creek; Crawford, Erie, Mercer, and Venango Counties, Pennsylvania.

(i) *General description:* Unit LS 1 consists of 120 stream mi (191.5 km) of French Creek in Crawford, Erie, Mercer, and Venango Counties, Pennsylvania. Approximately 106 stream mi (170.6 km; 76 percent) of riparian lands that border the unit are private ownership, and 14 stream mi (22.1 km; 24 percent) are public (Federal or State) ownership. This unit begins immediately downstream of the Union City Dam, which is operated by the U.S. Army Corps of Engineers.

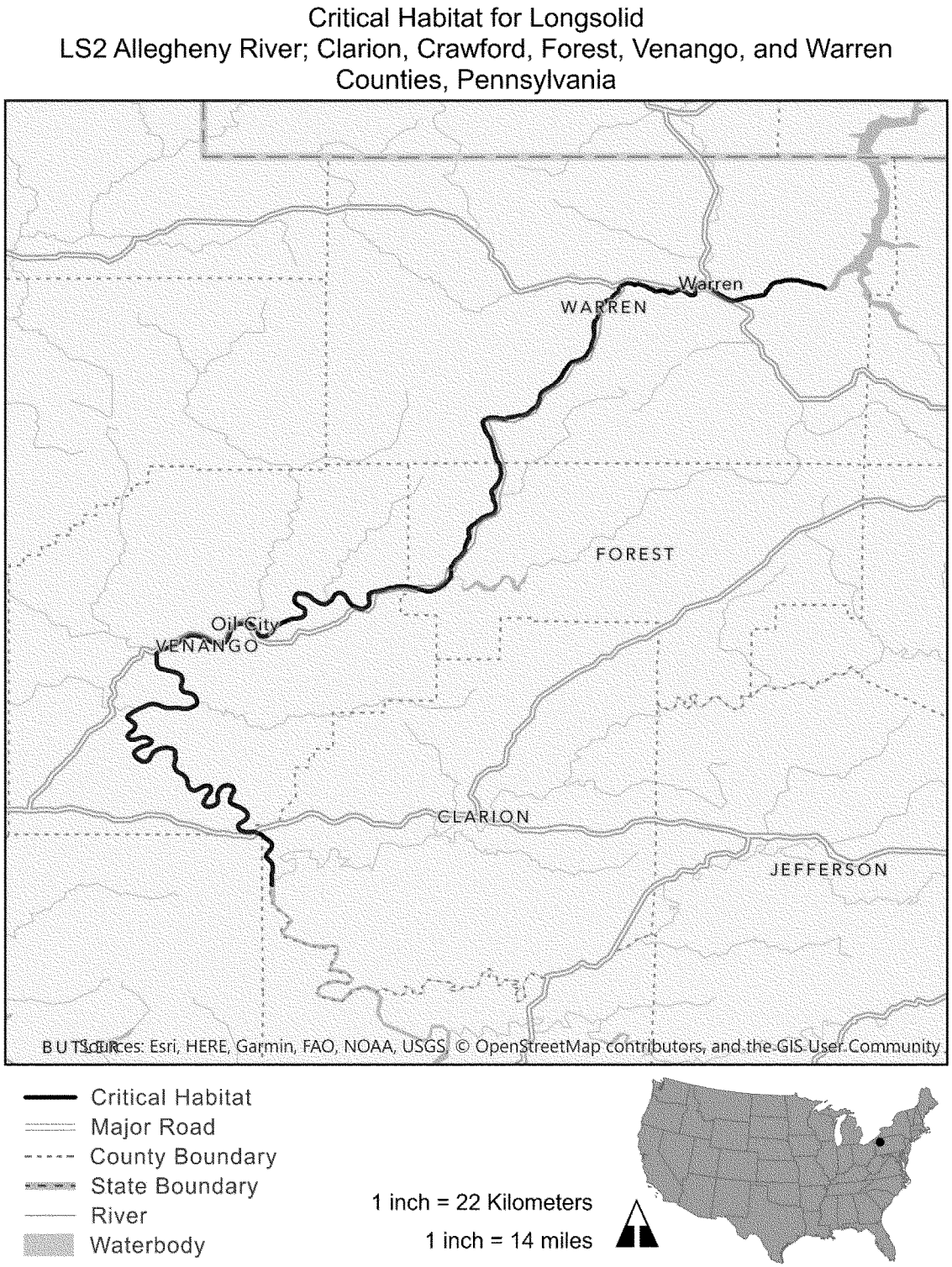
(ii) Map of Unit LS 1 follows:



(7) Unit LS 2: Allegheny River; Clarion, Crawford, Forest, Venango, and Warren Counties, Pennsylvania.

(i) *General description:* Unit LS 2 consists of 99 river mi (159.3 km) of the Allegheny River in Clarion, Crawford, Forest, Venango, and Warren Counties, Pennsylvania. Approximately 15 river mi (24.1 km; 14 percent) of riparian lands that border the unit are private ownership, and 84 river mi (135.8 km; 86 percent) are public (Federal or State; primarily Allegheny National Forest) ownership. This unit is immediately downstream of Kinzua Dam, which is operated by the U.S. Army Corps of Engineers.

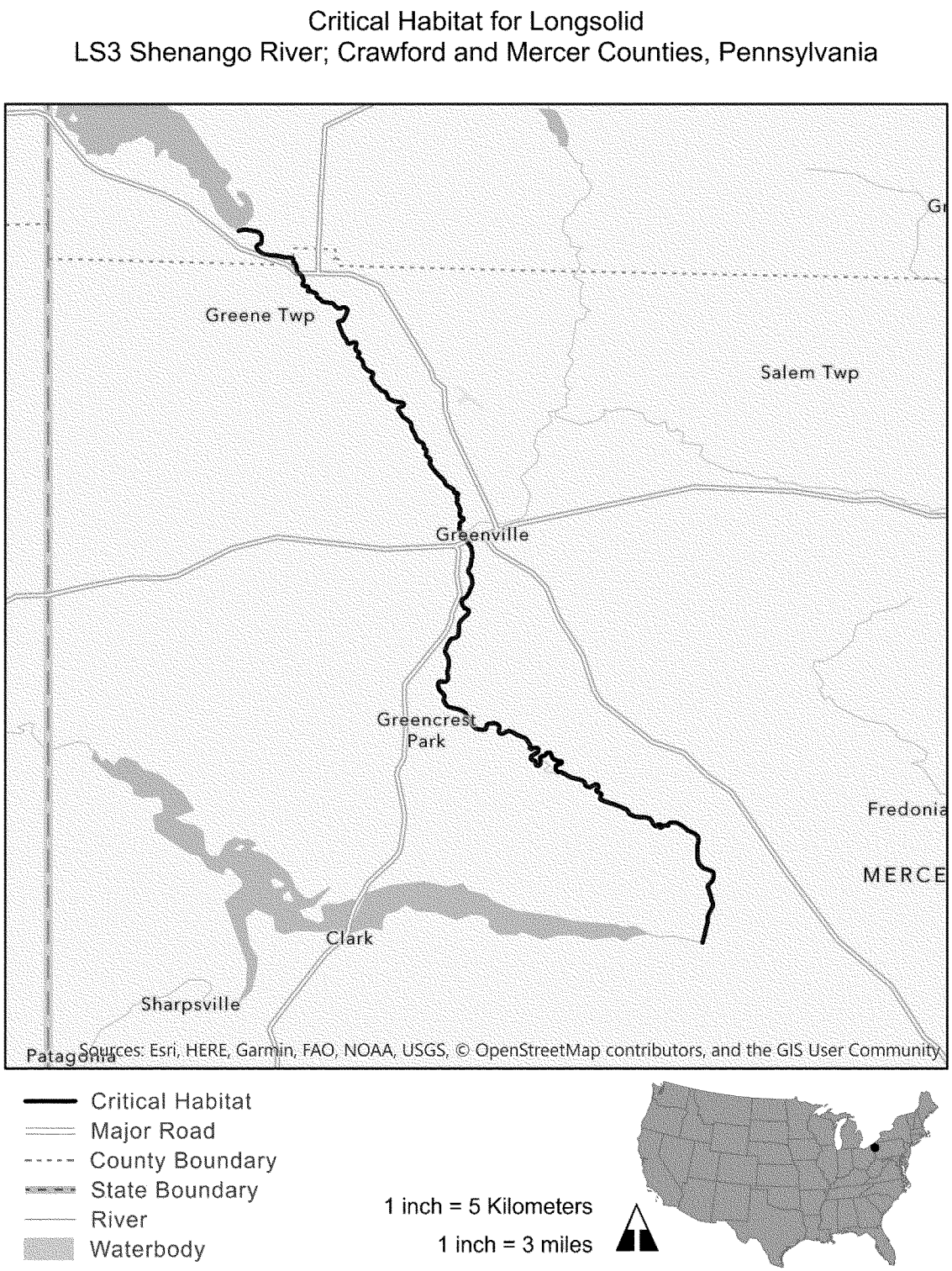
(ii) Map of Unit LS 2 follows:



(8) Unit LS 3: Shenango River, Crawford and Mercer Counties, Pennsylvania.

(i) *General description:* Unit LS 3 consists of 22 river miles (mi) (35.5 kilometers (km)) of the Shenango River in Crawford County, Pennsylvania, from Pymatuning Dam downstream to the point of inundation by Shenango River Lake near Big Bend, Mercer County, Pennsylvania. Approximately 15 river mi (24.3 km; 68 percent) of riparian lands that border the unit are private ownership, and 7 river mi (11.3 km; 32 percent) are public (Federal or State) ownership. This unit is immediately downstream from the Pymatuning Dam, which is owned by the State of Pennsylvania.

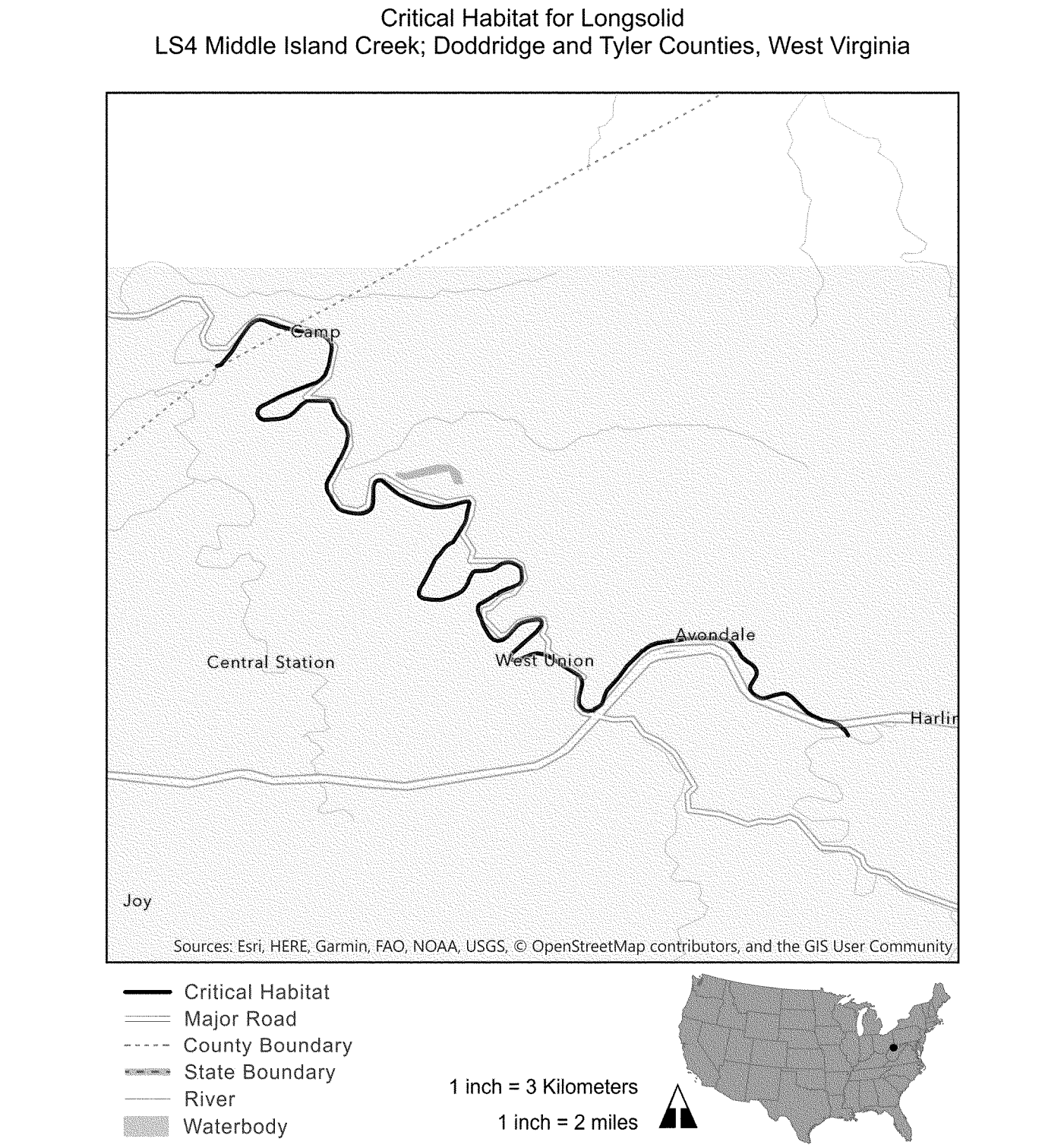
(ii) Map of Unit LS 3 follows:



(9) Unit LS 4: Middle Island Creek; Doddridge and Tyler Counties, West Virginia.

(i) *General description:* Unit LS 4 consists of 14 stream mi (23.7 km) of Middle Island Creek in Doddridge and Tyler Counties, West Virginia. Approximately 14 stream mi (23.5 km; 99 percent) of riparian lands that border the unit are private ownership, and 0.1 stream mi (0.2 km; less than 1 percent) are public (local) ownership.

(ii) Map of Unit LS 4 follows:

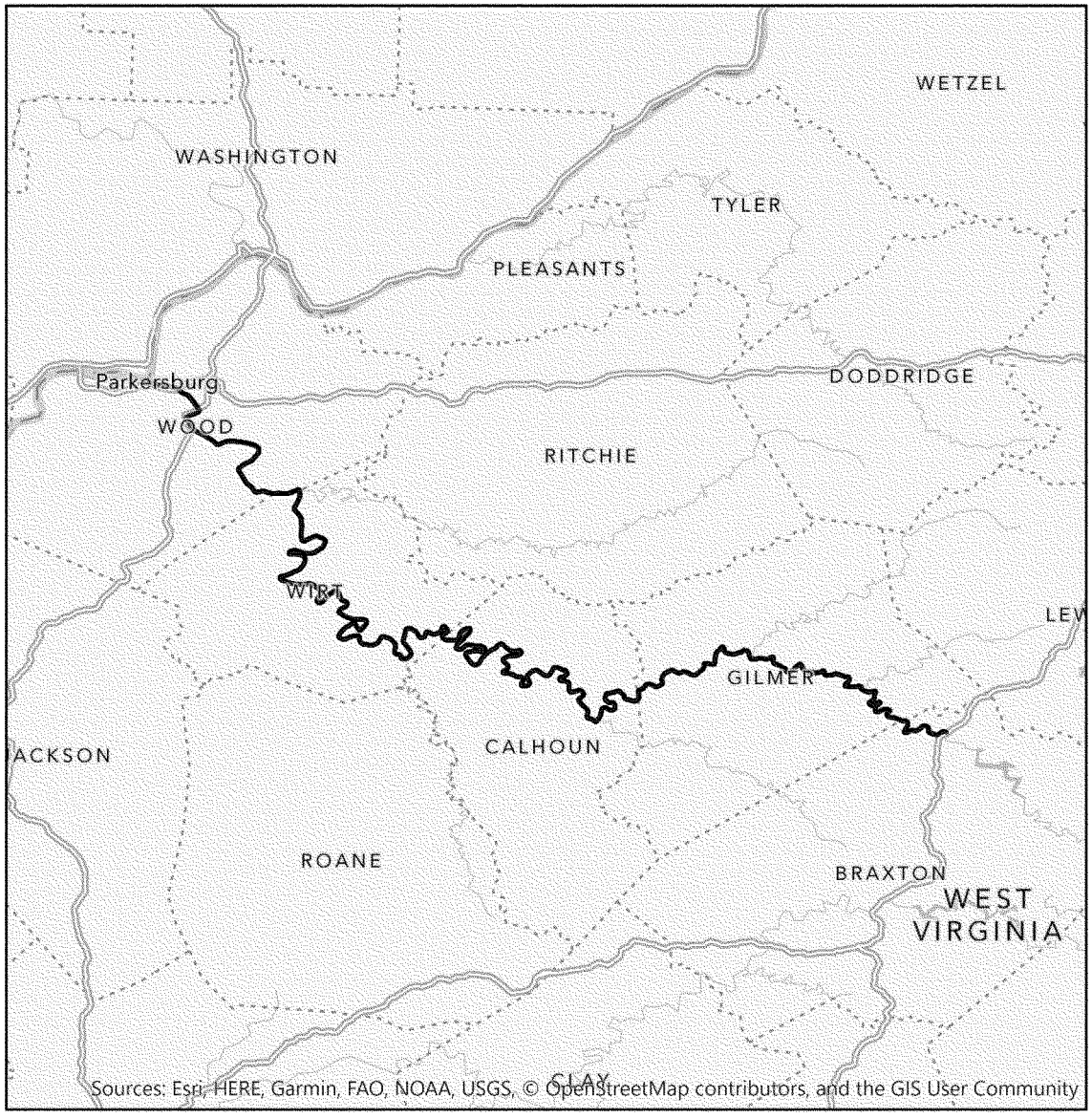


(10) Unit LS 5: Little Kanawha River; Calhoun, Gilmer, Ritchie, and Wood Counties, West Virginia.

(i) *General description:* Unit LS 5 consists of 123 river mi (198 km) of the Little Kanawha River in Calhoun, Gilmer, Ritchie, and Wood Counties, West Virginia. Approximately 122 river mi (197.2 km; 99 percent) are private ownership, and 0.5 river mi (0.9 km; 1 percent) are public (Federal or State) ownership. This unit is directly below the Burnsville Dam, which is operated by the U.S. Army Corps of Engineers.

(ii) Map of Unit LS 5 follows:

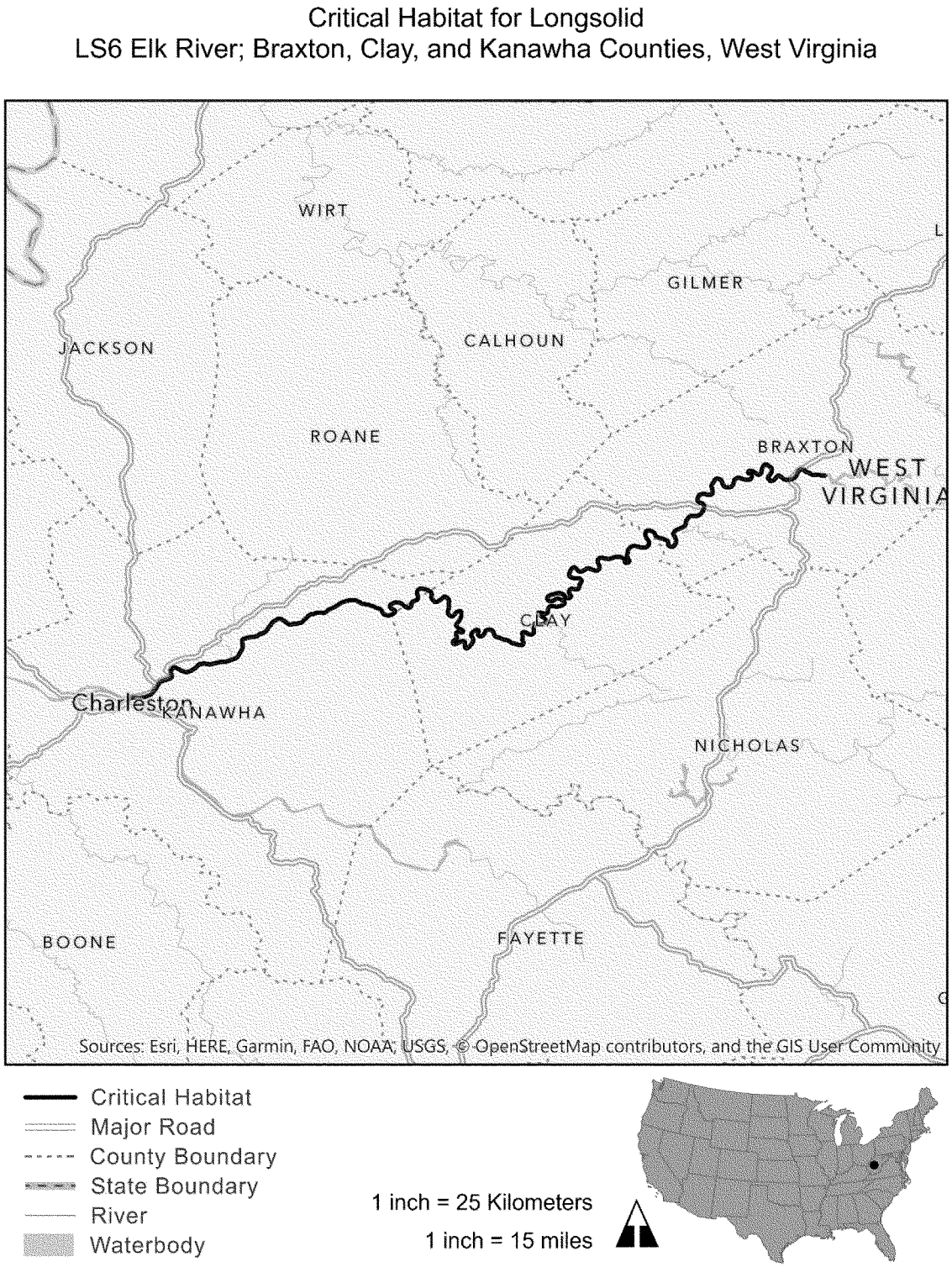
Critical Habitat for Longsolid
LS5 Little Kanawha River; Calhoun, Gilmer, Ritchie, and Wood Counties, West Virginia



(11) Unit LS 6: Elk River; Braxton, Clay, and Kanawha Counties, West Virginia.

(i) *General description:* Unit LS 6 consists of 101 river mi (163 km) of the Elk River in Braxton, Clay, and Kanawha Counties, West Virginia. Approximately 93 river mi (150.3 km; 92 percent) of riparian lands that border the unit are private ownership, and 7 river mi (12.7 km; 8 percent) are public (Federal, State, or local) ownership. This unit is directly below Sutton Dam, which is operated by the U.S. Army Corps of Engineers.

(ii) Map of Unit LS 6 follows:

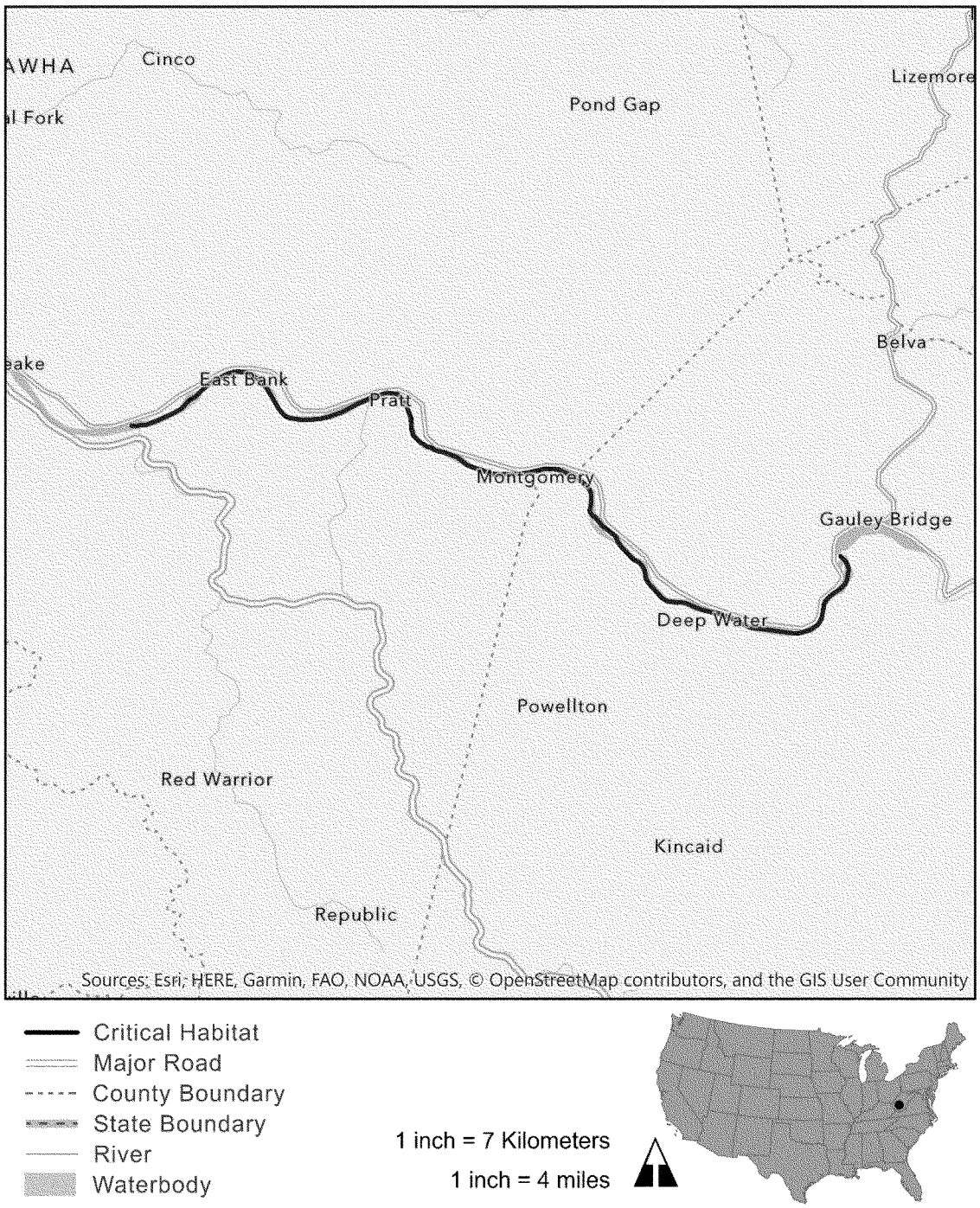


(12) Unit LS 7: Kanawha River; Fayette and Kanawha Counties, West Virginia.

(i) *General description:* Unit LS 7 consists of 21 river mi (33.9 km) of the Kanawha River in Fayette and Kanawha Counties, West Virginia. Approximately 18 river mi (29.3 km; 90 percent) of riparian lands that border the unit are private ownership, and 2 river mi (4.6 km; 10 percent) are public (Federal, State, or local) ownership. London and Marmet locks and dams within this unit are operated by the U.S. Army Corps of Engineers.

(ii) Map of Unit LS 7 follows:

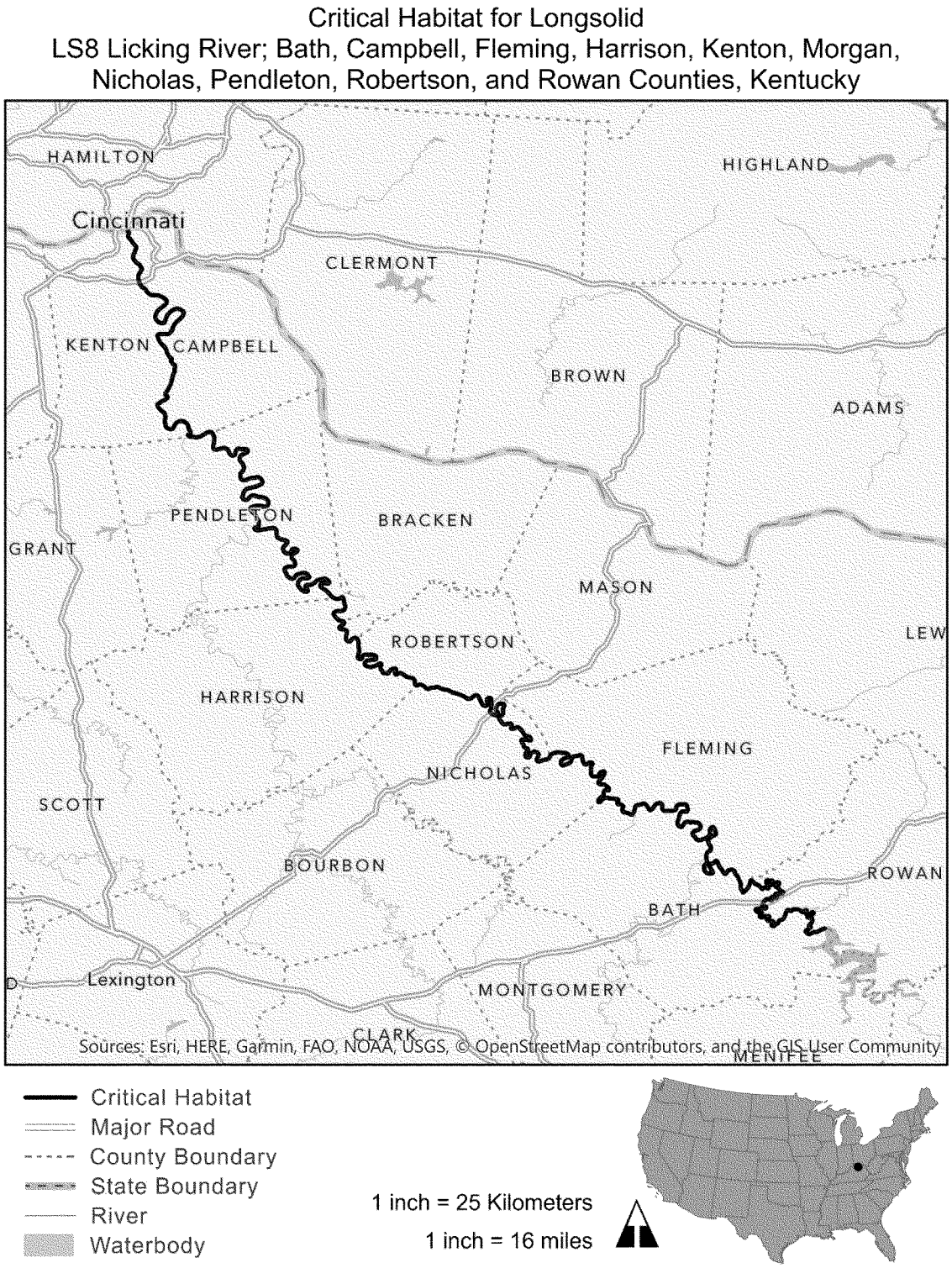
Critical Habitat for Longsolid
LS7 Kanawha River; Fayette and Kanawha Counties, West Virginia



(13) Unit LS 8: Licking River; Bath, Campbell, Fleming, Harrison, Kenton, Morgan, Nicholas, Pendleton, Robertson, and Rowan Counties, Kentucky.

(i) *General description:* Unit LS 8 consists of 181 river mi (291.5 km) of the Licking River in Bath, Campbell, Fleming, Harrison, Kenton, Morgan, Nicholas, Pendleton, Robertson, and Rowan Counties, Kentucky. Approximately 161 river mi (259.7 km; 90 percent) of riparian lands that border the unit are private ownership, and 19 river mi (31.7 km; 10 percent) are public (Federal, State, or local) ownership. This unit is directly below Cave Run Dam, which is operated by the U.S. Army Corps of Engineers.

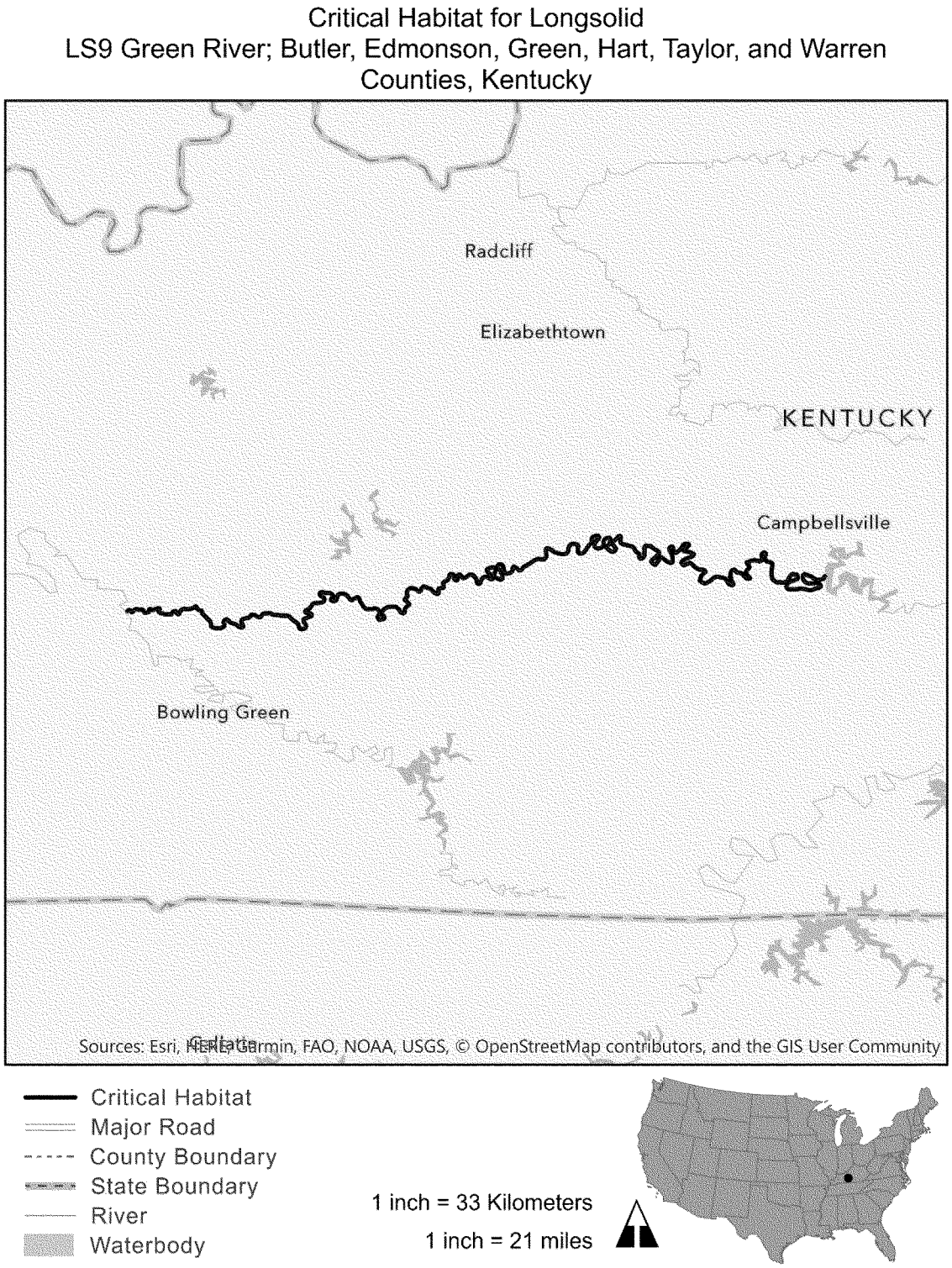
(ii) Map of Unit LS 8 follows:



(14) Unit LS 9: Green River; Butler, Edmonson, Green, Hart, Taylor, and Warren Counties, Kentucky.

(i) *General description:* Unit LS 9 consists of 156 river mi (251.6 km) of the Green River in Butler, Edmonson, Green, Hart, Taylor, and Warren Counties, Kentucky. Approximately 105 river mi (169.2 km; 67 percent) of riparian lands that border the unit are private ownership, and 51 river mi (82.4 km; 33 percent) are public (Federal, State, or local) ownership, including Mammoth Cave National Park. This unit is directly below Green River Dam, which is operated by the U.S. Army Corps of Engineers.

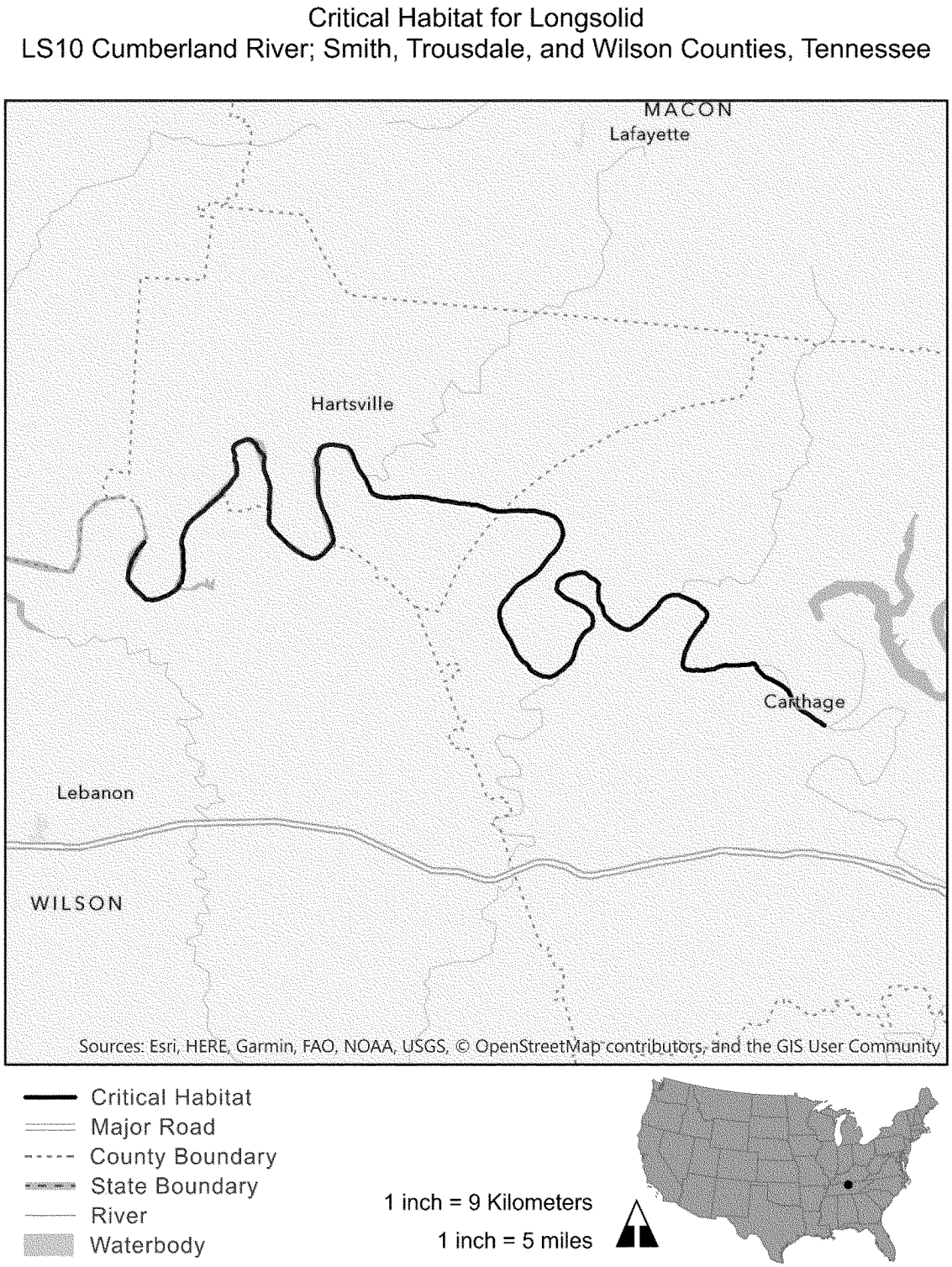
(ii) Map of Unit LS 9 follows:



(15) Unit LS 10: Cumberland River; Smith, Trousdale, and Wilson Counties, Tennessee.

(i) *General description:* Unit LS 10 consists of 48 river mi (77.5 km) of the Cumberland River in Smith, Trousdale, and Wilson Counties, Tennessee. All riparian lands that border the river are owned by the U.S. Army Corps of Engineers (Federal; 48 river mi (77.5 km)). This unit also falls within the Tennessee Wildlife Resources Agency Rome Landing Sanctuary. Cordell Hull and Old Hickory Dams, upstream and downstream of this unit, respectively, are operated by the U.S. Army Corps of Engineers.

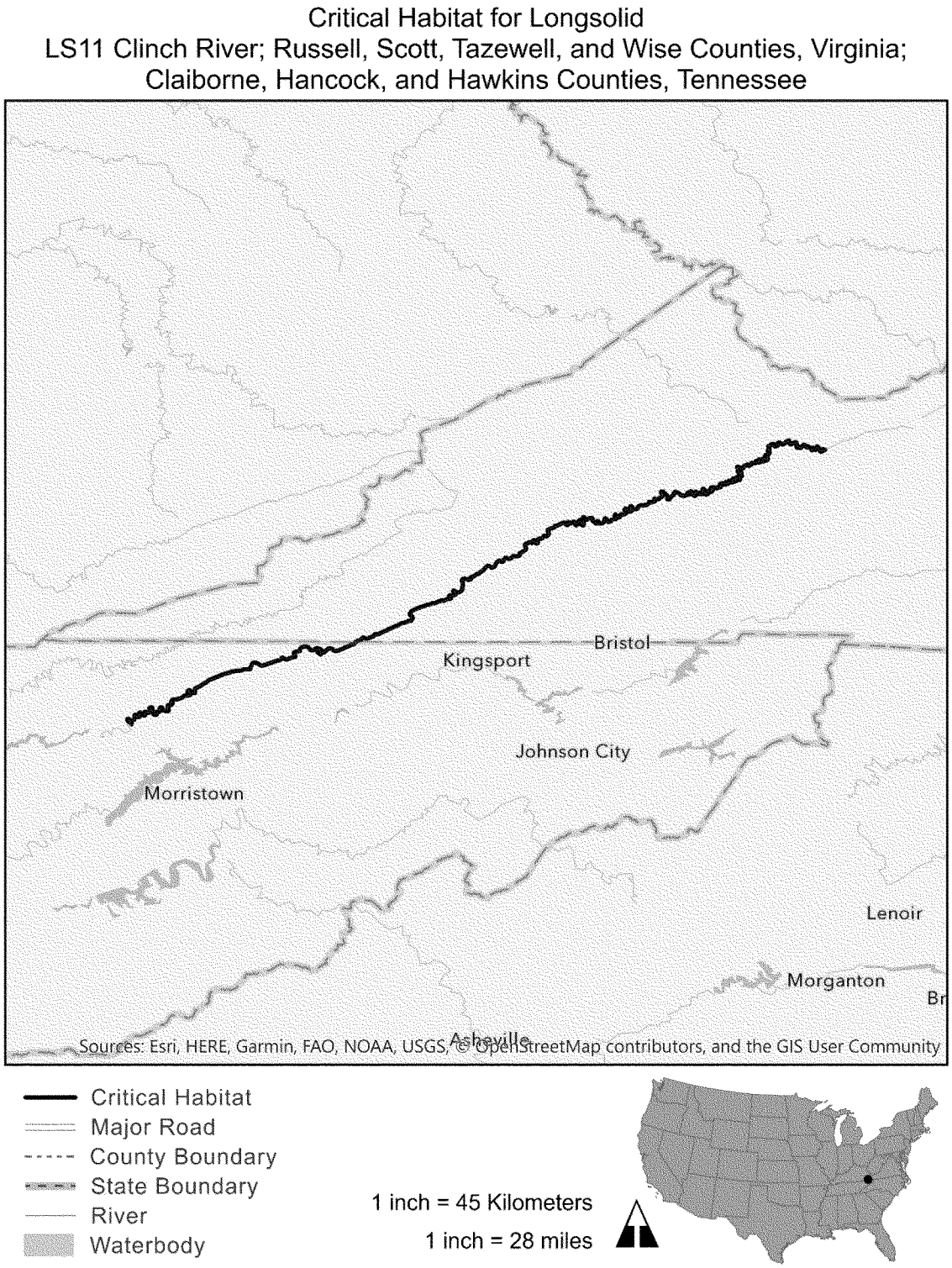
(ii) Map of Unit LS 10 follows:



(16) Unit LS 11: Clinch River; Russell, Scott, Tazewell, and Wise Counties, Virginia; Claiborne, Hancock, and Hawkins Counties, Tennessee.

(i) *General description:* Unit LS 11 consists of 177 river mi (286.1 km) of the Clinch River in Russell, Scott, Tazewell, and Wise Counties, Virginia, and Claiborne, Hancock, and Hawkins Counties, Tennessee. Approximately 160 river mi (258.8 km; 90 percent) of riparian lands that border the unit are private ownership, and 17 river mi (27.3 km; 10 percent) are public (Federal or State) ownership. The Tennessee portion of this unit is encompassed by the Tennessee Wildlife Resources Agency Clinch River Sanctuary.

(ii) Map of Unit LS 11 follows:

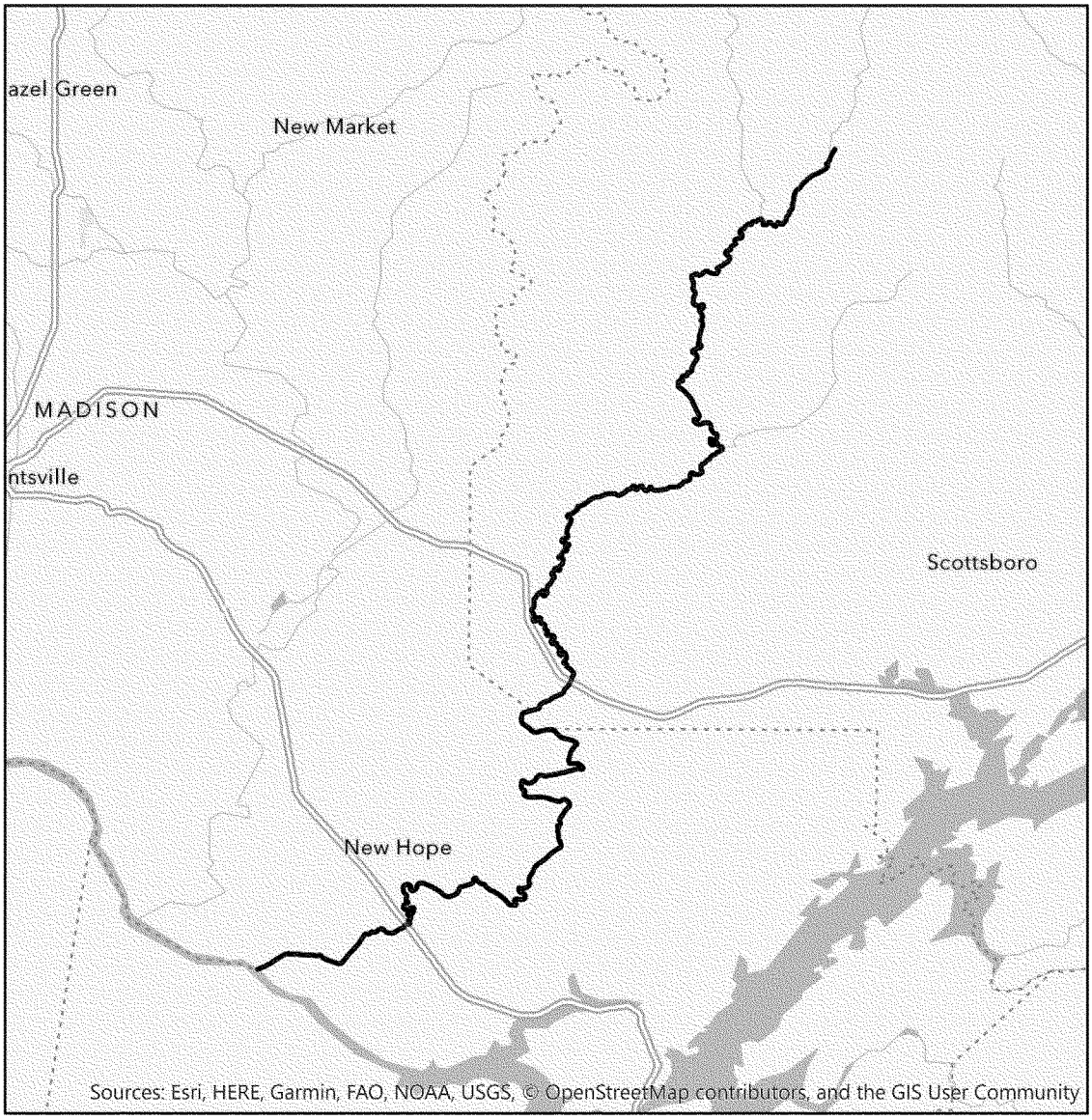


(17) Unit LS 12: Paint Rock River; Jackson, Madison, and Marshall Counties, Alabama.

(i) *General description:* Unit LS 12 consists of 58 river mi (94.5 km) of the Paint Rock River in Jackson, Madison, and Marshall Counties, Alabama. Approximately 2 river mi (4.1 km; 3 percent) of riparian lands that border the unit are private ownership, and 56 river mi (90.4 km; 97 percent) are public (Federal or State) ownership.

(ii) Map of Unit LS 12 follows:

Critical Habitat for Longsolid
LS12 Paint Rock River; Jackson, Madison, and Marshall Counties, Alabama



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Aurelia Skipwith,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2020–17015 Filed 9–28–20; 8:45 am]

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Part IV

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Threatened Species Status for the Wright's Marsh Thistle (*Cirsium wrightii*) With a 4(d) Rule and Designation of Critical Habitat; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2018–0071; FF09E21000 FXES11110900000 201]

RIN 1018–BC34

Endangered and Threatened Wildlife and Plants; Threatened Species Status for the Wright's Marsh Thistle (Cirsium wrightii) With a 4(d) Rule and Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the Wright's marsh thistle (*Cirsium wrightii*), a plant species from New Mexico, as a threatened species and designate critical habitat under the Endangered Species Act of 1973, as amended (Act). After a review of the best available scientific and commercial information, we find that listing the species is warranted. Accordingly, we propose to list the Wright's marsh thistle as a threatened species with a rule issued under section 4(d) of the Act (''4(d) rule''). If we finalize this rule as proposed, it would add this species to the List of Endangered and Threatened Plants and extend the Act's protections to the species. We also propose to designate critical habitat for Wright's marsh thistle under the Act. The proposed critical habitat totals approximately 64.3 hectares (ha) (159 acres (ac)) in Chaves, Eddy, Guadalupe, Otero, and Socorro Counties, New Mexico. We also announce the availability of a draft economic analysis of the proposed designation of critical habitat for Wright's marsh thistle.

DATES: We will accept comments received or postmarked on or before November 30, 2020. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by November 13, 2020.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R2–ES–2018–0071, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R2–ES–2018–0071; U.S. Fish and Wildlife Service, MS: JAO/1N, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: For the critical habitat designation, the coordinates or plot points or both from which the maps are generated are included in the administrative record and are available at the New Mexico Ecological Services website *https://www.fws.gov/southwest/es/NewMexico/index.cfm and* at *http://www.regulations.gov* under Docket No. FWS–R2–ES–2018–0071. Any additional tools or supporting information that we may develop for the critical habitat designation will also be available at the Service website set out above, and may also be included in the preamble and/or at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Shawn Sartorius, Field Supervisor, New Mexico Ecological Services Field Office, 2105 Osuna Rd. NE, Albuquerque, NM 87113; telephone 505–346–2525; facsimile 505–346–2542. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if a species is determined to be an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within 1 year. Critical habitat shall be designated, to the maximum extent prudent and determinable, for any species determined to be an endangered or threatened species under the Act. Listing a species as an endangered or threatened species and designations and revisions of critical habitat can only be completed by issuing a rule.

What this document does.

- Proposes to list Wright's marsh thistle as a threatened species. Wright's marsh thistle is a candidate species for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing rule has been precluded by other higher priority listing activities. This proposed rule reassesses all available information regarding the status of and threats to this species.
- Proposes a rule issued under section 4(d) of the Act (''4(d) rule'') that would make it unlawful to remove and reduce to possession the species from areas under Federal jurisdiction; maliciously damage or destroy the species on areas under Federal jurisdiction; or remove, cut, dig up, or damage or destroy the species on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law. Nothing in the proposed 4(d) rule affects in any way other provisions of the Act, such as the designation of critical habitat under section 4, the recovery planning provisions of section 4(f), and the consultation requirements under section 7.
- Proposes to designate critical habitat for the species on approximately 64.3 ha (159 ac) in Chaves, Eddy, Guadalupe, Otero, and Socorro Counties, New Mexico.

The basis for our action. Under the Act, we can determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that stressors related to Factors A and E are causing Wright's marsh thistle to be threatened.

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary) to designate critical habitat concurrent with listing to the maximum extent prudent and determinable. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas

within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species.

Peer review. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought the expert opinions of three appropriate and independent specialists during the analysis of the status of the species and the creation of the SSA report (USFWS 2017). The purpose of peer review was to ensure that our listing determination and critical habitat designation are based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise in Wright's marsh thistle's biology, life history, habitat, and range, and in the physical or biological features of its habitat. One of three peer reviewers provided comments on the species status assessment, which were integrated into the SSA report; these comments will be available along with other public comments in the docket for this proposed rule (see *http://www.regulations.gov,* Docket No. FWS–R2–ES–2018–0071).

Because we will consider all comments and information we receive during the comment period on this proposed rule, our final determinations may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may conclude that the species is endangered instead of threatened, or we may conclude that the species does not warrant listing as either an endangered species or a threatened species. Such final decisions would be a logical outgrowth of this proposal, as long as we: (1) Base the decisions on the best scientific and commercial data available after considering all of the relevant factors; (2) do not rely on factors Congress has not intended us to consider; and (3) articulate a rational connection between the facts found and the conclusions made, including why we changed our conclusion.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) Wright's marsh thistle's biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for all life cycle stages, seed production and dispersal, and seed germination and growth;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this species, including the locations of any additional populations of this species.

(5) Information on regulations that are necessary and advisable to provide for the conservation of the Wright's marsh thistle and that the Service can consider in developing a 4(d) rule for the species. In particular, information concerning the extent to which we should include any of the section 9 prohibitions in the 4(d) rule or whether any other forms of take should be excepted from the prohibitions in the 4(d) rule.

(6) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including information to inform the following factors such that a designation of critical habitat may be determined to be not prudent:

(a) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(b) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(c) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(d) No areas meet the definition of critical habitat.

(7) Specific information on:

(a) The amount and distribution of Wright's marsh thistle habitat;

(b) What areas, that were occupied at the time of listing and that contain the physical or biological features essential to the conservation of the species, should be included in the critical habitat designation and why;

(c) Special management considerations or protections that may be needed in the critical habitat areas we are proposing, including managing for the potential effects of climate change; and

(d) What areas not occupied at the time of listing that are essential for the conservation of the species. We particularly seek comments:

(i) Regarding whether occupied areas are inadequate for the conservation of the species; and,

(ii) Providing specific information that supports the determination that unoccupied areas will, with reasonable certainty, contribute to the conservation of the species and, contain at least one physical or biological feature essential to the conservation of the species.

(8) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(9) Any probable economic, national security, or other relevant impacts of designating any area as critical habitat that may be included in the final designation, and the related benefits of including or excluding areas.

(10) Information on the extent to which the description of probable economic impacts in the draft economic analysis is a reasonable estimate of the likely economic impacts.

(11) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act.

(12) Whether we could improve or modify our approach to designating critical habitat in any way to provide for

greater public participation and understanding, or to better accommodate public concerns and comments.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES.** We request that you send comments only by the methods described in **ADDRESSES.**

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov.*

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT.** We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. For the immediate future, we will provide these public hearings using webinars that will be announced on the Service's website, in addition to the **Federal Register**. The use of these virtual public hearings is consistent with our regulation at 50 CFR 424.16(c)(3).

Previous Federal Actions

On October 15, 2008, we received a petition from WildEarth Guardians requesting that we list Wright's marsh thistle as an endangered or threatened species under the Act. Additionally, the petitioner requested that critical habitat be designated concurrent with the listing of Wright's marsh thistle (thistle). On September 10, 2009, we published a 90-day finding in the **Federal Register** (74 FR 46542) that the petition presented substantial information that listing Wright's marsh thistle may be warranted. The 90-day finding stated that the petition provided substantial information indicating that listing Wright's marsh thistle may be warranted. At that time, we initiated a status review of the species.

On February 11, 2010, WildEarth Guardians filed suit against the Service for failure to issue a 12-month finding on the petition (*WildEarth Guardians* v. *Salazar,* No. 10–cv–00122 BRB–DJS (D.N.M.)). Under a stipulated settlement agreement, the 12-month finding was due to the **Federal Register** by October 31, 2010. On November 4, 2010, after review of all available scientific and commercial information, we published a 12-month petition finding (75 FR 67925), in which we found that listing Wright's marsh thistle as endangered or threatened throughout its range is warranted, but that listing of the thistle was precluded by higher priority actions to amend the Lists of Endangered and Threatened Wildlife and Plants. As a result of the 12-month finding, we added Wright's marsh thistle to our candidate species list, with a listing priority number of 8, indicating that the thistle faced imminent threats that were of moderate magnitude. Thereafter, we reassessed the status of the species annually and determined that listing the thistle remained warranted but was precluded by higher priority activities under the Act (see 77 FR 69994, November 21, 2012; 78 FR 70104, November 22, 2013; 79 FR 72450, December 5, 2014; 80 FR 80584, December 24, 2015; 81 FR 87246, December 2, 2016).

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the Wright's marsh thistle. The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species. The Service sent the SSA report to 3 independent peer reviewers and received 1 response.

I. Proposed Listing Determination

Background

Species Description

Wright's marsh thistle (Gray 1853, p. 101), a member of the Asteraceae (sunflower) family, produces a 0.9- to 2.4-meter (m) (3- to 8-foot (ft)) single stalk covered with succulent leaves. There are two regional varieties of this species. The more eastern populations in the Pecos River valley of New Mexico have pink flowers and dark green foliage with higher plant height, while the more western and southern populations in New Mexico (and the previous populations in Arizona and Mexico) have white or pale pink flowers and pale green foliage (Sivinski 2011, pp. 27–28). The differences serve as evidence of ecological adaptability within the species, and we believe these differences represent genetic diversity between the eastern and western populations.

Life History

Depending on local environmental conditions, Wright's marsh thistle can display life-history traits of a biennial (a plant completing development in 2 years, flowering in its second year) or a weak monocarpic perennial (a plant that flowers, sets seed, and then dies). Cross pollination is achieved by insect pollinators, primarily bees. Like other species in the genus *Cirsium,* Wright's marsh thistle produces numerous seeds per flowering plant. After germination, seedlings develop into an intermediate rosette form for most of a year or longer before bolting (producing a stem) and growing into the mature, flowering plant. It does not reproduce vegetatively (asexually from parent plant). In order to progress through its life cycle, the thistle requires adequate soil alkalinity, water availability for permanent root saturation, and access to full sunlight. Specifically, seeds require water-saturated soils and access to fairly direct sunlight for germination. Rosettes also require water-saturated soils and access to fairly direct sunlight in order to grow into a mature plant. Mature plants must also maintain permanent root saturation via water-saturated soils and tend to thrive better in full sunlight. For more details of the biology and life history of Wright's marsh thistle, please refer to chapter 2 of the SSA report (USFWS 2017).

Habitat and Distribution

Wright's marsh thistle is a rare wetland species that grows in marshy habitats with year-round, water-saturated soils, at elevations between 1,150 and 2,390 m (3,450 and 7,850 ft) in elevation (Sivinski 1996, p. 1; 2005, pp. 3–4). Wright's marsh thistle is an obligate of seeps, springs, and wetlands that have saturated soils with surface or subsurface water flow (Sivinski 1996, p. 1; USFWS 1998, p. 2; Worthington 2002, p. 2; NMRPTC 2009, p. 1). Within those spring and seep areas, it is usually associated with alkaline soils (Sivinski 2005, p. 3).

Historical Range

Wright's marsh thistle was historically known to occur in Arizona and New Mexico in the United States, and Chihuahua and Sonora in Mexico (Sivinski 2012, p. 2). The single location in Arizona was a historical 1851 collection from San Bernardino Cienega, which straddles the international border with Mexico, and no longer has suitable wetland habitat on the Arizona side of the border (Baker 2011, p. 7). There were 10 historical occurrences in New Mexico; however, in a recent search effort at one of the sites (Lake County), the thistle was not found (Sivinski 2011, p. 40), and another of the 10 records (Rattlesnake Springs, Eddy County) is now thought to be a hybrid between Wright's marsh thistle and the Texas thistle (*C. texanum*) (NMRPTC 2009, p. 2). Reports of Wright's marsh thistle from Texas were common (Keil 2006, p. 131; Sivinski 1996, pp. 2–4), but in subsequent examinations of Texas specimens purporting to be Wright's marsh thistle, the specimens were found to be Texas thistle or other *Cirsium* species (75 FR 67928; November 4, 2010).

The status of the Wright's marsh thistle in Mexico is presumed extirpated. There have been few verified historical collections, and the most recent site visit to Fronteras, Mexico, and Cerro Angostura, Mexico, indicated that the habitat had been mostly dried out and is no longer suitable (Sivinski 2017, entire).

Therefore, Wright's marsh thistle has been extirpated from all previously known locations in Arizona, two historical locations in New Mexico, and all known locations in Mexico, and it was misidentified and likely not ever present in Texas.

Current Range

In New Mexico, eight general confirmed locations of Wright's marsh thistle cover an area of approximately 43 ha (106 ac): Santa Rosa, in Guadalupe County; Bitter Lake National Wildlife Refuge (NWR), in Chaves County; Blue Spring, in Eddy County; La Luz Canyon, Karr/Haynes Canyon, Silver Springs, and Tularosa Creek, in Otero County; and Alamosa Creek, in Socorro County (Bridge 2001, p. 1; Sivinski and Bleakly 2004, p. 2; NMRPTC 2009, p. 1; Sivinski 1994, p. 1; Sivinski 1996, p. 2; Sivinski 2005, p. 1, 3–5; Sivinski 2009; USFWS 1998, p. 1; Worthington 2002, p. 1–3). In Otero County, the Sacramento Mountains have four unique populations of the species clustered within about 16 kilometers (km) (10 miles (mi)) of each other on the west slope of the mountains. The remaining four localities are widely disjunct, separated from the Sacramento localities by about 120 to 225 km (75 to 140 mi) and from each other by about 120 to 345 km (75 to 215 mi). In the Sacramento Mountains, two of these four localities occur on the Lincoln National Forest, one locality is on private land, and the remaining locality is on the Mescalero Apache Reservation. In the Pecos River Valley, one locality is on public lands on Bitter Lake NWR; one is on private land near Blue Springs and the Black River; and one is in the vicinity of Santa Rosa on private, municipal, and State lands. The remaining locality is on private land on Alamosa Creek, Socorro County. Localities vary in relative population size from fewer than 20 individuals covering only about 0.02 ha (0.03 ac) at the Silver Springs locality (Sivinski 2012, p. 21), to several thousand individuals on Bitter Lake NWR, covering almost 9.3 ha (23 ac).

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an ''endangered species'' or a ''threatened species.'' The Act defines an endangered species as a species that is ''in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as a species that is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The Act requires that we determine whether any species is an ''endangered species'' or a ''threatened species'' because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable

future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Services can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA report for Wright's marsh thistle (USFWS 2017) documents the results of our comprehensive biological status review for the species, including an assessment of the potential threats to the species. The SSA report does not represent a decision by the Service on whether the species should be proposed for listing as an endangered or threatened species under the Act. It does, however, provide the scientific basis that informs our regulatory decisions, which involves the further application of standards within the Act and its implementing regulations and policies.

To assess Wright's marsh thistle viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years), redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the individual species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic influences. This process used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We use this information to inform our regulatory decision.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability.

To determine the species' current condition, we ranked each population based on six factors relating to population and habitat variables including habitat quantity, number of patches, abundance, reproduction, permanent root saturation, and full sun. For each of these six factors, we defined criteria for low, moderate, and high conditions, which are outlined in table 3.3 in chapter 3 of the SSA report. These criteria were used to determine an overall condition for each of the eight extant populations (USFWS 2017). The overall condition of a population refers to the likelihood of persistence over time. We expect a population in high overall condition to have a greater than 90 percent likelihood of persistence over the foreseeable future (in other words a 10 percent or less likelihood of extirpation). For a population in moderate condition, we estimate that the likelihood of persistence over the foreseeable future would be approximately 66 to 90 percent (10 to 33 percent likelihood of extirpation). For a population in low condition, we estimated a likelihood of persistence of approximately 25 to 66 percent over the foreseeable future (33 to 75 percent likelihood of extirpation) and a population in very low condition to have a likelihood of persistence of approximately 0 to 25 percent over the foreseeable future (75 to 100 percent likelihood of extirpation).

For Wright's marsh thistle to maintain viability, its populations or some portion thereof must be able to withstand stochastic disturbance. Resource needs that influence the resiliency of populations include constant soil saturation, alkaline soils, abundance of insect pollinators, and availability of direct sunlight. Additionally, secondary resource needs include agents of seed dispersal (wind, water, mammals, and birds), and water availability for seed germination. For more details on these resource needs and their impact on species viability, refer to chapter 2 of the SSA report (USFWS 2017). Factors that influence those resource needs will determine whether Wright's marsh thistle populations are able to sustain adequate numbers within habitat patches of adequate area and quality to maintain survival and reproduction in spite of disturbance, thereby increasing the resiliency of populations.

Maintaining representation in the form of genetic or environmental diversity is important to maintain Wright's marsh thistle's capacity to adapt to future environmental changes. A healthy community of insect pollinators, particularly bees and butterflies, leads to genetic diversity by the process of cross pollination between patches within a population. The differences in flower color (and perhaps differences in mature plant maximum growth height) represent differences in ecological adaptability between the eastern and western populations of the thistle, which may also represent a form of genetic diversity. There is a need to maintain the genetic and environmental diversity between the eastern and western groups, as their potential genetic and life-history attributes may buffer the thistle's response to environmental changes over time. Wright's marsh thistle has likely lost genetic and environmental diversity as populations have been reduced or extirpated. As such, maintaining the remaining representation in the form of genetic and environmental diversity may be important to the capacity of Wright's marsh thistle to adapt to future environmental change.

Wright's marsh thistle needs to have multiple resilient populations distributed throughout its range to provide for redundancy. The more populations, and the wider the distribution of those populations, the more redundancy the species will exhibit. In addition, populations of the

species can exhibit internal redundancy through the presence of multiple patches within the population. For example, the eastern populations of Wright's marsh thistle have multiple patches of occupied habitat within each population location, while the western populations typically have only one patch. The presence of multiple patches contributes to the ability of the population to maintain resiliency when faced with various risk factors. Redundancy reduces the risk that a large portion of the species' range will be negatively affected by a catastrophic natural or anthropogenic event at a given point in time. Species that are well-distributed across their historical range are considered less susceptible to extinction and have higher viability than species confined to a small portion of their range (Carroll *et al.* 2010, entire; Redford *et al.* 2011, entire).

Current Condition of Wright's Marsh Thistle

As stated above, the best available information indicates that Wright's marsh thistle is currently only found in eight localities in New Mexico. We believe the plant has been extirpated in Arizona, Mexico, and two locations in New Mexico, and never occurred in Texas. According to our current condition rankings outlined in chapter 3 of the SSA report, of the eight extant populations in New Mexico, three have been determined to have moderate resiliency, two have low resiliency, and three have very low resiliency and are at risk of extirpation. We consider the thistle to have representation in the form of genetic and environmental diversity resulting in two distinct phenotypes in the eastern and western populations, as described above. Within the two representation areas (east and west), three populations are extant in the east, and five populations are extant in the west. While there is greater redundancy in terms of number of populations in the western phenotype, the five extant populations in the western representation are much smaller in both the area occupied and population size. Therefore, the western populations are less resilient. This circumstance impacts the overall viability of the species by reducing the overall resiliency of the thistle to stochastic events.

Influence Factors for Wright's Marsh Thistle

The largest threats to the future viability of Wright's marsh thistle relate to habitat degradation from various stressors influencing the availability of the thistle's resource needs (*e.g.,* water availability). A brief summary of these primary stressors is presented below, followed by a table identifying the particular stressors, and the magnitude of those stressors, affecting each of the eight populations (Table 1). We also include a discussion of current conservation measures for the thistle and any existing regulatory mechanisms that may ameliorate or reduce the impact of the stressors. For a full description of these stressors, refer to chapter 4 of the SSA report (USFWS 2017).

Decreased Water Availability

The drying of Wright's marsh thistle habitat over approximately the last 25 years has led to shrinking population boundaries, a reduction in the numbers of plants, and, in some cases, a loss of all individuals at several localities (Sivinski 1996; Sivinski 2005, pp. 3–4; Sivinski 2012). Because the thistle occurs only in areas that are water-saturated, populations have a high potential for extirpation when the habitat dries up. Loss of water from Wright's marsh thistle habitat occurs through changing precipitation patterns or drought, or as a result of human impacts from groundwater pumping (withdrawal) or diversion of surface water, which can lead to the degradation and extirpation of the species' habitat (Sivinski 1996, p. 5; Sivinski 2005, p. 1; USFS 2008, p. 19). In addition to experiencing periods of drought, much of the habitat of Wright's marsh thistle has been and continues to be severely altered and degraded because of past and present land and water management practices that have led to ground and surface water depletion. For specific examples for each population, please refer to chapter 4, section 1 of the SSA report (USFWS 2017). All of the extant localities may be affected by long-term drought, whereas four of the largest localities at Blue Spring, Bitter Lake NWR, Santa Rosa, and Alamosa Creek have the potential to be further modified by ongoing and future water management practices. Drought, along with ground and surface water depletion, serve to decrease the amount of water available in Wright's marsh thistle habitat, which impacts the species' need for permanent root saturation. Reductions in precipitation and temperature are predicted, which suggests that these impacts will increase in the future, leading to further impacts to the thistle (NOAA 2017).

Decreased Water Availability: Drought

According to the United States Drought Monitor (2017), large portions (over 30 percent) of New Mexico, including Wright's marsh thistle habitat, experienced drought from approximately April 2011 until mid-2014. Within New Mexico, monsoonal summer precipitation can be very patchy, with some areas receiving considerably less rainfall than others. Newton *et al.* (2012) provides information on drought conditions in the range of the species, specifically in the Pecos River valley and Sacramento Mountains. The three eastern populations of Wright's marsh thistle in the Pecos River valley have not been affected by drought to the same extent as the western populations, because the Pecos River valley's marshy habitats are maintained by large regional aquifers. The western populations often rely on wet periods during summer months to recharge the ground water. In the Sacramento Mountains, because these wet periods are extremely rare events (Newton *et al.* 2012, p. 66), drought has notably impacted the area's groundwater tables (USFS 2008, p. 22). For this reason, the seasonal distribution of yearly precipitation can result in temporary drought conditions and reduced water availability for some Wright's marsh thistle localities within this mountain range.

Wright's marsh thistle is vulnerable to reduced water availability because the species occupies relatively small areas of spring or seep habitat in an arid region that is plagued by drought and ongoing aquifer withdrawals (*e.g.,* in the Roswell Basin). If future episodes of drought increase in frequency, duration, or intensity, additional dewatering and decrease of the thistle's habitat are likely to occur. Projected increases in temperature and increased variability in precipitation in locations where Wright's marsh thistle is currently located demonstrate the vulnerability of the habitat to reductions in water availability. The vulnerability of the habitat to increased drought depends, in large part, on the sources of their water supply. Habitats that are sustained mainly by precipitation in the Sacramento Mountains (five populations) are the most likely to be affected by increased drought, making drought a significant stressor to these populations. Alternatively, localities that are supplied primarily by groundwater in the Pecos River Basin (three populations) will likely have the greatest resistance to increased drought due to water stored in aquifers, making drought a slightly less significant stressor to the populations (*e.g.,* see Poff *et al.* 2002, pp. 18–19).

Decreased Water Availability: Ground and Surface Water Depletion

Wright's marsh thistle is a wetland plant that can be extirpated when its habitat dries out. The effects of ongoing and past maintenance and operation of existing water diversions can also limit the size of thistle populations (USACE 2007, p. 29). Sivinski (1994, pp. 1–2; 1996, p. 4; 2005, p. 1; 2006, p. 4) reported loss and degradation of habitat from water diversion or draining of wetlands that historically supported Wright's marsh thistle in Chaves, Otero, and Sierra Counties, New Mexico. The extent of ongoing and future water diversions is related to the extent of urban and agricultural development within a given area. Thus, the significance of the impacts of this stressor to each population can be correlated to the number of water diversions within the area for both urban and agricultural purposes. Specific details on impacts to each population can be found in chapter 4 of the SSA report (USFWS 2017). The alteration and loss of habitat that currently supports Wright's marsh thistle, due to groundwater and surface water depletion, will continue and likely increase in the foreseeable future. This projection is based on current and future development plans in areas surrounding each population; specific details are located in chapter 4 of the SSA report (USFWS 2017).

Decreased Water Availability: Effects of Climate Change

Because Wright's marsh thistle occupies relatively small areas of spring or seep habitat in an arid region plagued by drought and ongoing aquifer withdrawals (*e.g.,* in the Roswell Basin), it is expected to be vulnerable to changes in climate that decrease the availability of water to suitable habitat. Springs and wet valleys have been affected by drought in at least three canyons of the Sacramento Mountains, New Mexico, resulting in reduced population sizes. Similar water loss may occur within other Wright's marsh thistle localities (USFWS 2017). If changes in climate lead to future drought, additional dewatering and reduction of habitat for the thistle may occur.

Downscaled projections as of 2018 were available for our analysis of Wright's marsh thistle from the Climate Explorer program in the U.S. Climate Resilience Toolkit (NOAA 2017). The Climate Explorer is based on 32 models and produces a mean which can be used to predict changes in air temperature and precipitation for counties, cities or specific zip codes in the contiguous United States and portions of Canada and Mexico. Scenario RCP 4.5 is a moderate emissions scenario for atmospheric concentrations of greenhouse gases. Based on climate change projections for emissions at RCP 4.5, all locations where Wright's marsh thistle is currently located show increases in mean daily maximum temperature over the next 50 years by approximately 1.7 degrees Celsius (°C) (3 degrees Fahrenheit (°F)). For example, in Chaves County, New Mexico, mean daily maximum temperature is expected to rise from approximately 24.7 °C (76.5 °F) in 2010, to approximately 26.9 °C (80.5 °F) in 2060. Climate change scenario RCP 8.5 projects climate conditions based on higher CO_2 emissions. This scenario results in a projected change of approximately 3 °C (5.5 °F) over the next 50 years in Chaves County, New Mexico leading to a mean daily maximum of 28.2 °C (82.7 °F).

While mean daily precipitation is not expected to vary drastically over the next 50 years, the variability in precipitation throughout the year will increase. For example, in Otero County, mean daily average precipitation is projected to decrease during certain times of the year and increase during other times of the year relative to current conditions. In addition, the timing of maximum precipitation events may occur during different months than experienced in the past. This variability in precipitation will contribute to more periods of extreme drought and severe flooding events, which may impact the availability of water during times critical to life-history traits of Wright's marsh thistle (NOAA 2017).

Specific details on the effects of climate change are located in chapter 4 of the SSA report (USFWS 2017). Projected increases in temperature and increased variability in precipitation in locations where Wright's marsh thistle is currently located demonstrate the vulnerability of the species' habitat to changes in climate that will exacerbate the impact of existing stressors relating to availability of water and the extent of current and ongoing water withdrawals.

Decreased Water Availability: Summary

In summary, ground and surface water withdrawal and potential future increases in the frequency, duration, or intensity of drought, individually and in combination, pose a threat to Wright's marsh thistle and its habitat in the future. In addition, as Wright's marsh thistle has small, isolated populations, we expect the stressor of decreased water availability to further impact the species' overall viability. Thus, we expect that this threat will likely remain a significant stressor to the thistle and will likely intensify in the foreseeable future.

Livestock Grazing

In the semi-arid southwestern United States, wet marshes and other habitat of Wright's marsh thistle attract ungulates (*e.g.,* livestock, elk, and deer) because of the availability of water and high-quality forage (Hendrickson and Minckley 1984, p. 134). Livestock grazing is present at localities in the Sacramento Mountains, Santa Rosa, Blue Springs, and Alamosa Springs. At the Santa Rosa locality, photographs indicate that the growth of Wright's marsh thistle and the integrity of its habitat have been negatively affected by livestock herbivory and trampling (Sivinski 2012 pp. 33–53). Dry periods likely increase the effects of livestock trampling and herbivory on Wright's marsh thistle when other water and forage plants are not available (75 FR 67925). Grazing may be more concentrated within habitats similar to those occupied by Wright's marsh thistle during drought years, when livestock are prone to congregate in wetland habitats or where forage production is greater than in adjacent dry uplands (USFS 2003, entire). Livestock may trample individual plants and eat the thistle when other green forage is scarce, and when the seedlings or rosettes are developing and abundant. Further, livestock may eat mature plant inflorescences (the complete flower head), which could reduce seed production. For example, the threatened Sacramento Mountains thistle (*C. vinaceum*) (52 FR 22933), which is also found in New Mexico and associated with habitats similar to those occupied by Wright's marsh thistle, is eaten by livestock and appears to be the preferred forage at some times of the year. It may provide some of the only green forage during droughts (NMRPTC 2009, p. 2). Also, it is possible that livestock grazing within and adjacent to spring ecosystems could alter or remove habitat or limit the distribution of the thistle (USFWS 2017).

Effects of grazing on Wright's marsh thistle depend on timing; winter grazing (after seed dispersal and before seedling growth in spring) probably has a low effect on survival and reproduction, although there could be some trampling of rosettes. On the other hand, spring and early summer grazing probably reduces growth, survival, and reproduction. Late summer and early fall grazing is most severe, as flowering plants typically set seed at this time;

therefore, grazing during this period would inhibit reproduction. Finally, if a patch of Wright's marsh thistle was heavily grazed during the time of bolting or flowering over 2 or more consecutive years, the seed bank and long-term population trend in the affected patch could be negatively impacted. For example, observations of the impacts of grazing at some of the Wright's marsh thistle localities show that fewer thistles mature into flowering adults when the population experiences grazing pressure (Sivinski 2012 pp. 33–53). Livestock activities are considered a widespread stressor at the current time; localized impacts have been observed and there is a high potential for effects to populations. Increased use of wet springs and marshes by livestock during drought conditions constitutes a significant stressor in the future.

In summary, we find that livestock grazing poses a current and future threat to Wright's marsh thistle and its habitat through direct mortality and habitat degradation, and we expect that this threat will likely intensify at some localities (Sacramento Mountains, Santa Rosa, Blue Spring, Alamosa Springs) due to projected increases in drought periods that cause livestock to concentrate around Wright's marsh thistle localities. Because the thistle only occurs in small, isolated populations, the impacts of grazing could be a significant stressor to the species.

Native and Nonnative Plants

Some native and nonnative plants pose a threat to Wright's marsh thistle and its habitat through habitat encroachment and competition for resources at most localities. The native plants include cattails (*Typha* spp.); nonnative species include the common reed (*Phragmites australis*), purple loosestrife (*Lythrum salicaria*), Russian olive (*Elaeagnus angustifolia*), saltcedar (*Tamarix* spp.), and Russian thistle (*Salsola* spp.) (Sivinski 1996, p. 6). These particular native and nonnative species all have the same effect on Wright's marsh thistle by functioning as invasive species with respect to the thistle's habitat. Though cattails and Wright's marsh thistle may have evolved in the same area, decreased water availability has altered habitat conditions such that cattails have a competitive advantage in Wright's marsh thistle habitat. These plants present unique challenges and potential threats to the habitat, including shade effects on Wright's marsh thistle seedlings and rosettes.

For example, the common reed, a nonnative invasive plant introduced from Europe and Asia, increases the potential for wildfire and is increasing in density at some locations in New Mexico. The dense plant growth blocks sunlight to other plants growing in the immediate area and occupies all available habitat (PCA 2005, p. 1). The increase of the common reed in Wright's marsh thistle habitat is a current threat to the species through increased wildfire risk, competition, and changes in hydrology (impacts on degree of soil saturation), especially when habitat is disturbed through burning or drying. The impacts vary based on location, with the greatest impacts occurring at Santa Rosa, Bitter Lake NWR, Blue Spring, and Tularosa Creek.

We expect that the threats caused by native and nonnative plant competition and habitat loss will likely continue and possibly intensify, due to lack of vegetation management practices at several locations (Santa Rosa, Blue Spring, Tularosa Creek) and the pervasiveness of native and nonnative plants despite ongoing efforts for habitat restoration at other locations (Bitter Lake NWR). As this species is comprised of small, isolated populations, the impacts of native and nonnative plants could pose a significant stressor to the thistle. Attempts to manage native and nonnative plants through herbicide use and mowing may also exacerbate effects to Wright's marsh thistle as these techniques are difficult to preferentially apply to only the native and nonnative plant species when habitat is shared. In addition, we expect increases in drought periods to exacerbate the effects of this stressor.

Oil and Gas Development and Mining

Oil and gas development occurs within and adjacent (*i.e.,* within 10 miles) of some areas occupied by Wright's marsh thistle including Santa Rosa, Bitter Lake NWR, and Blue Spring (New Mexico State Lands Office, 2017; NMDGF 2007, pp. 18–19; NMDGF 2005, p. 35). There are also mining activities adjacent (*i.e.,* within 5 miles) to other areas such as a potential beryllium mine at Alamosa Springs, and subsurface drilling and exploration of the mineral bertrandite on Sullivan Ranch near Alamosa Springs (New Mexico Mining and Minerals Division 2010; New Mexico State Lands Office, 2017; Sivinski 2012, p. 9). As of February 2020, the Service has no information on any new actions towards developing the potential beryllium mine at Alamosa Springs. The main impacts from oil and gas development and mining include the potential for contamination. Contamination from oil and gas development has been observed within close proximity (*i.e.,* within 16 km (10 mi) of some Wright's marsh thistle localities (New Mexico State Lands Office, 2017). While laws and regulations related to water quality have reduced the risk of contamination in and near occupied locations from oil and gas production, the likelihood that a spill could impact these habitats is still present based on the high volume of oil and gas leases near these areas.

Potential contamination from both oil and gas development and mining could have several impacts on plants (such as Wright's marsh thistle), including the following: increased available nutrients, which may favor competitive or nonnative plant growth; altered soil pH (either higher or lower), which can kill plants; absorption of chemicals, which can poison plants or cause poor growth or dead spots on leaves; and plant mortality. In addition, oil and other contaminants from development and drilling activities throughout these areas could enter the aquifer supplying the springs and seeps inhabited by Wright's marsh thistle when the limestone layers are pierced by drilling activities. An accidental oil spill or groundwater contamination has the potential to pollute water sources that support Wright's marsh thistle, and mining activities could alter or destroy habitat.

The largest occupied habitat area is less than 16 ha (40 ac), and more than half the known populations are less than 2 ha (5 ac) in size. Even a small, localized spill has the potential to contaminate and destroy a population. The loss of even one of the eight populations would result in loss of representation and redundancy to the species as a whole. Because this species is comprised of small, isolated populations, these stressors could potentially negatively affect the thistle, but it is unclear whether these impacts would be localized or widespread stressors as the interaction between contaminant spills and groundwater and surface water hydrology is poorly understood. Therefore, we have determined that oil and gas development and mining functions as a stressor to the future viability of the species via impacts to water sources that provide habitat for Wright's marsh thistle.

TABLE 1—STRESSORS IMPACTING EACH OF THE EIGHT POPULATIONS OF WRIGHT'S MARSH THISTLE

[USFWS 2017, chapter 4]

Population	Stressors to population					
	Decreased water availability			Livestock grazing	Native and nonnative plants	Oil and gas development
	Drought	Groundwater and surface water depletion	Effects of climate change			
Eastern Populations						
Santa Rosa Basin	XX	XX	XX	XXX	XX	X
Bitter Lake NWR	XX	XX	XX	.....	XX	XX
Blue Spring	XX	XXX	XX	XX	X	XX
Western Populations						
Alamosa Springs	XXX	XX	XX	X	.....	X
Tularosa Creek	XXX	XX	XX	.....	X	.....
Silver Springs	XXX	XXX	XX	X	.....	.....
La Luz Canyon	XXX	XXX	XX	X	.....	.....
Karr/Haynes Canyon	XXX	XXX	XX	X	X	.....

Note: XXX indicates a significant stressor to the population, XX indicates a moderate stressor to the population, and X indicates a mild stressor to the population.

Conservation Measures and Regulatory Mechanisms

Minimal conservation of Wright's marsh thistle is occurring on the Federal level. The Bitter Lake NWR manages invasive reeds in their moist soil/wetland units where the species is located. This management helps increase sunlight availability and decrease competition with nonnative species. The NWR also recently received a grant to complete seed collection efforts for Wright's marsh thistle. The Lincoln National Forest does not have active conservation for the thistle, but implements a 61-m (200-ft) buffer around occupied sites when projects occur within or near occupied areas.

At the State level, Wright's marsh thistle is listed as endangered, under the authority of the New Mexico Statutes Annotated 1978, at title 19 of the New Mexico Administrative Code at chapter 21, part 2, section 9 (19 NMAC 21.2.9). The provisions in New Mexico state law prohibit the taking of endangered plants on all lands of New Mexico (except tribal lands), except under valid permit issued by the State, and encourage conservation by State government agencies. In this instance, ''taking'' means the removal, with the intent to possess, transport, export, sell, or offer for sale. Further, if Wright's marsh thistle is listed under the Act, the State may enter into agreements with Federal agencies to administer and manage any area required for the conservation, management, enhancement, or protection of listed species. Funds for these activities could be made available under section 6 of the Act (Cooperation with the States). Thus, the Federal protection afforded to this plant by listing it as an endangered or threatened species would be reinforced and supplemented by protection under State law. In addition to the state endangered listing for Wright's marsh thistle, some protection is offered to the species through Title 19 of the New Mexico Administrative Code at chapter 15, part 2 (19 NMAC 15.2) which outlines general environmental provisions for water and wildlife relating to oil and gas operations including information on methods to reduce risk of contamination to the surrounding habitat. While this reduces the risks associated with oil and gas production to nearby occupied locations of the thistle, the high volume of oil and gas leases near these sites means the risk of impacts from a spill still persist.

Future Scenarios Considered

As there are a range of possibilities regarding the intensity of stressors (*i.e.,* decreased water availability to habitat, ungulate grazing, native and nonnative plants, oil and gas development, and mining) acting on the populations, we forecast Wright's marsh thistle's resiliency, representation, and redundancy under four plausible scenarios in the SSA report. For these scenarios, we considered four different trajectories for all threats acting on the species (*i.e.,* all threats increasing at two different rates, decreasing, or remaining at the current level). We did not look at interactions between threats (*i.e.,* one threat increasing with another threat decreasing), as data were not sufficient for this type of analysis. These four scenarios incorporate the best available information on projection of threat data up to 50 years in the future. Sources of data include, but are not limited to, development (urban, agricultural, oil and gas and mining) plans for various areas and climate change models. For example, we referenced the City of Alamogordo's 50-year development plan for projections of future water withdrawals. In regards to climate change models, we used a moderate emissions climate change scenario of RCP 4.5 from the 2017 U.S. Climate Resilience Toolkit, which provides a range of projections for temperature and precipitation through 2100 (NOAA 2017). We also used the U.S. Geological Survey's Monthly Water Balance Model Futures Portal that provides projections out to the year 2095 for changes in evapotranspiration (USGS 2017, entire). Some, but not all, of the threats could be projected beyond 50 years into the future. Therefore, to develop our future scenarios, we only used projection information up to 50-years into the future, the timeframe that includes projections for all future threats and for which we could predict the expected future resiliency and overall condition for each population based on our knowledge of the species' expected response to identified threats.

First, the ''Continuing Current Conditions'' scenario projects the condition of Wright's marsh thistle populations if the current risks to population viability continue with the same trajectory as experienced currently. Decreased water availability

continues to impact the populations via continuing levels of drought, along with ground and surface water depletion. Grazing continues where it has been occurring, and the impacts will accumulate. Competition from native and nonnative plants continues, along with any current impacts from oil and gas development. For this scenario, we used the mean level of projected values in temperature (an increase in mean daily maximum temperature of approximately 0.83 °C (1.5 °F) over 50 years).

Second, the ''Optimistic'' scenario projects the condition of Wright's marsh thistle populations if conservation measures are put in place to limit the impacts of current risks to population viability, including conservation efforts to address decreased water availability, livestock grazing, and competition with native and nonnative plants. For this scenario, we used the low level of projected values in temperature (an increase in mean daily maximum temperature of approximately 0.56 °C (1.0 °F) over 50 years and increases in mean monthly potential evapotranspiration of 0 to 10 millimeters (mm) (0 to 0.4 inches (in)) over 50 years), leading to less severe effects of drought on the riparian ecosystems of which Wright's marsh thistle is a part.

Third, the ''Major Effects'' scenario projects the condition of Wright's marsh thistle if stressors on the populations are increased. We expect a decrease in water availability, along with increased negative impacts from grazing, native and nonnative plants, oil and gas development, and mining. For this scenario, we used the moderate level of projected values in temperature (an increase in mean daily maximum temperature of approximately 1.7 °C (3.0 °F) over 50 years, and increases in mean monthly potential evapotranspiration of 10 to 30 mm (0.4 to 1.2 in) over 50 years), with increased impacts of drought.

Finally, the ''Severe Effects'' scenario projects the condition of Wright's marsh thistle populations under the assumption that stressors on the populations are highly increased. Compared to the ''Major Effects'' scenario, we expect a further decrease in water availability, along with further increased negative impacts from ungulate grazing, native and nonnative plants, oil and gas development, and mining. For this scenario, we used the high level of projected values in temperature (an increase in mean daily maximum temperature of approximately 2.8 °C (5.0 °F) over 50 years and increases in mean monthly potential evapotranspiration of 30 to 80 mm (1.2 to 3.1 in) over 50 years) with increased impacts of drought.

Thus, we considered the range of potential likely scenarios that represent different possibilities for how the stressors outlined above may influence the future condition of the species. The results of this analysis for each scenario are presented below in Table 2. For specific details on how each scenario impacted the six factors (habitat quantity, number of patches, abundance, reproduction, permanent root saturation, and full sun) contributing to overall condition of each population, refer to chapter 5 of the SSA report (USFWS 2017).

TABLE 2—CONDITION RATINGS FOR EACH OF THE EIGHT POPULATIONS OF WRIGHT'S MARSH THISTLE UNDER FOUR POSSIBLE FUTURE SCENARIOS

[USFWS 2017, Chapter 5]

Population	Current condition	Scenario 1: Continuing current conditions	Scenario 2: Optimistic	Scenario 3: Major effects	Scenario 4: Severe effects
Eastern Populations					
Santa Rosa Basin	Moderate	Moderate	High	Moderate	Low.
Bitter Lake NWR	Moderate	Moderate	High	Moderate	Low.
Blue Spring	Moderate	Low	Moderate	Low	Low.
Western Populations					
Alamosa Springs	Low	Low	Low	Very Low	Extirpated.
Tularosa Creek	Very Low	Extirpated	Very Low	Extirpated	Extirpated.
Silver Springs	Very Low	Very Low	Very Low	Extirpated	Extirpated.
La Luz Canyon	Very Low	Very Low	Very Low	Extirpated	Extirpated.
Karr/Haynes Canyon	Low	Low	Low	Low	Extirpated.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the species, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. Our assessment of the current and future conditions encompasses and incorporates the threats individually and cumulatively. Our current and future condition assessment is iterative because it accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Determination of the Status of Wright's Marsh Thistle

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines ''endangered species'' as a species ''in danger of extinction throughout all or a significant portion of its range,'' and ''threatened species'' as a species ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The Act requires that we determine whether a species meets the definition of ''endangered species'' or ''threatened species'' because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational

purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Status Throughout All of Its Range

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats and the cumulative effect of the threats under the section 4(a)(1) factors to Wright's marsh thistle.

Wright's marsh thistle is a narrow endemic (restricted to a small range) with a historical, documented decline. The historical range of the species included 10 locations in New Mexico, 2 locations in Arizona, and 2 locations in Mexico. Wright's marsh thistle has been extirpated from all previously known locations in Arizona and Mexico, as well as two locations in New Mexico. In addition, the currently extant populations have declined in population numbers over time based on comparisons between 1995 and 2012 surveys (Sivinski 1996 entire, 2012 entire). As a result, the remaining extant area of the eight populations has contracted in recent years, and is currently approximately only 43 ha (106 ac). Of the remaining eight extant populations, three have moderate resiliency, two have low resiliency, and three have very low resiliency and are likely at risk of extirpation (USFWS 2017). The species historically had representation in the form of two morphologically distinct and geographically separate forms; the species continues to maintain representation currently in these forms, although population sizes have decreased.

Wright's marsh thistle faces threats from habitat degradation due to decreased water availability, livestock grazing, native and nonnative plants, and oil and gas development and mining (Factor A). These threats, which are expected to be exacerbated by continued drought and the effects of climate change (Factor E), were important factors in our assessment of the future viability of Wright's marsh thistle. In addition, small, isolated populations and lack of connectivity contribute to the thistle's low resiliency to stochastic events (Factor E). We expect a further decrease in water availability, along with increased negative impacts from grazing, native and nonnative plants, oil and gas development, and mining. Given current and anticipated future decreases in resiliency, populations would become more vulnerable to extirpation from stochastic events, in turn, resulting in concurrent losses in representation and redundancy. The range of plausible future scenarios of the species' habitat conditions and population factors suggest possible extirpation in as many as five of eight currently extant populations. The most optimistic model predicted that while no populations were likely to become extirpated, three of the eight populations were expected to have very low resiliency.

As assessed in the SSA report and displayed above in Table 2, the current condition rankings for the eight extant populations show that three populations are in moderate condition, two population are in low condition, and three populations are in very low condition. Wright's marsh thistle also exhibits representation across two morphologically distinct and geographically separate forms. While threats are currently acting on the thistle throughout its range, the three eastern populations (Santa Rosa, Bitter Lake, and Blue Springs) were found to have high or moderate resiliency for their current condition. Therefore, we did not find that the thistle is currently in danger of extinction throughout all of its range, based on the current condition of the species; thus, an endangered status is not appropriate.

Wright's marsh thistle meets the definition of a threatened species because it is facing threats across its range that have led to reduced resiliency, redundancy, and representation. According to our assessment of plausible future scenarios, the species is likely to become an endangered species within the foreseeable future throughout all of its range. For the purposes of this determination, the foreseeable future is considered approximately 25 years into the future. This timeframe was arrived at by looking at the various future projections associated with data from the Intergovernmental Panel on Climate Change (IPCC), U.S. Climate Resilience Toolkit, future development plans from the City of Alamogordo and Santa Rosa, and grazing management information from the U.S. Forest Service. These data sources covered a variety of time frames, but all covered a span of at least 50 years. We therefore looked at the projections from these sources in each of our future scenarios out to three time steps: 10 years, 25 years, and 50 years. We found that as the projections for the various stressors went past 25 years in the scenarios, the uncertainties associated with some of those projections, particularly water use and depletion, increased. Thus, for the purposes of this determination, we were most confident in setting the foreseeable future at 25 years.

Our analysis of the species' current and future conditions show that the population and habitat factors used to determine the resiliency, representation, and redundancy for Wright's marsh thistle are likely to continue to decline to the degree that the thistle is likely to become in danger of extinction within the foreseeable future throughout all or a significant portion of its range. While the ''Optimistic'' scenario resulted in two of the populations with moderate current condition improving to high condition due to increased conservation measures, the other three scenarios all resulted in decreased resiliency for some if not most populations. The ''Continuing Condition'' scenario resulted in one of the current eight extant populations becoming extirpated, the ''Major Effects'' scenario resulted in three of the current eight extant populations becoming extirpated, and the ''Severe Effects'' scenario resulted in five of the current eight extant populations becoming extirpated. Based on our understanding of the increasing trends in threats as analyzed into the foreseeable future (*i.e.,* 25 years), the likelihood of occurrence of the ''Major Effects'' and ''Severe Effects'' scenarios increases as time progresses. The decreased resiliency of populations projected in three of the four scenarios would lead to subsequent losses in redundancy and representation, and an overall decline in species viability in the foreseeable future. Further details on the likelihood of scenarios can be found in chapter 5 of the SSA report (USFWS 2017).

Due to the continuation of threats at increasing levels, we anticipate a severe reduction in the thistle's future overall range and the extirpation of several populations. Furthermore, we anticipate that the variety of factors acting in combination on the remaining habitat and populations are likely to reduce the overall viability of the species to a dangerously low level. In addition, the conservation measures currently in place are not adequate to overcome the negative impacts from increasing threats, and future conservation measures are not considered highly plausible. The risk of extinction will be high because the remaining populations are small, are isolated, and have limited or no potential for recolonization after local population extirpations. Thus, after assessing the best available information, we determine that Wright's marsh thistle is not currently in danger of extinction, but is likely to become in danger of extinction within the

foreseeable future, throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020) (*Center for Biological Diversity*), vacated the aspect of the 2014 Significant Portion of its Range Policy that provided that the Services do not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range. Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and, (2) the species is in danger of extinction in that portion. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Center for Biological Diversity,* we now consider whether there are any significant portions of the species' range where the species is in danger of extinction now (*i.e.,* endangered). In undertaking this analysis for Wright's marsh thistle, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered.

For Wright's marsh thistle, we considered whether the threats are geographically concentrated in any portion of the species' range at a biologically meaningful scale. In light of the species' needs (*i.e.,* permanent root saturation; alkaline soils; full, direct, or nearly full sunlight; and abundant pollinators), we examined the following threats (including cumulative threats): Habitat degradation due to decreased water availability, livestock grazing, native and non-native plants, and oil and gas development and mining; continued drought and the effects of climate change; and small, isolated populations. Each population of Wright's marsh thistle was determined to have some level of impact from each threat listed above, with variations in source and intensity. For example, habitat degradation due to decreased water availability at the Santa Rosa population location is influenced by agricultural use, while the La Luz Canyon population location is influenced primarily by municipal use. In another example, livestock grazing tends to be present with greater intensity near the Santa Rosa population location than near the La Luz Canyon population location. While there may be some variation in the source and intensity of each individual threat at each population location, we found no concentration of threats in any portion of Wright's marsh thistle's range at a biologically meaningful scale. Thus, there are no portions of the species' range where the species has a different status from its rangewide status.

Therefore, no portion of the species' range provides a basis for determining that the species is in danger of extinction in a significant portion of its range, and we determine that the species is likely to become in danger of extinction within the foreseeable future throughout all of its range. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that Wright's marsh thistle meets the definition of a threatened species. Therefore, we propose to list Wright's marsh thistle as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness and conservation by Federal, State, Tribal, and local agencies; private organizations; and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and subsequent preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened (''downlisting'') or for removal from protected status (''delisting''), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (*http://www.fws.gov/endangered*).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To

achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State of New Mexico would be eligible for Federal funds to implement management actions that promote the protection or recovery of Wright's marsh thistle. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although Wright's marsh thistle is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the U.S. Fish and Wildlife Service and U.S. Forest Service; issuance of section 404 Clean Water Act (33 U.S.C. 1251 *et seq.*) permits by the U.S. Army Corps of Engineers; and construction and maintenance of roads or highways by the Federal Highway Administration.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. The discussion below regarding protective regulations under section 4(d) of the Act complies with our policy.

II. Proposed Rule Issued Under Section 4(d) of the Act

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the ''Secretary shall issue such regulations as he deems necessary and advisable to provide for the conservation'' of species listed as threatened. The U.S. Supreme Court has noted that statutory language like ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean ''the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to [the Act] are no longer necessary.'' Additionally, the second sentence of section 4(d) of the Act states that the Secretary ''may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants.'' Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife, or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to him with regard to the permitted activities for those species. He may, for example, permit taking, but not importation of such species, or he may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising its authority under section 4(d), the Service has developed a proposed rule that is designed to address Wright's marsh thistle's specific threats and conservation needs. Although the statute does not require the Service to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the Wright's marsh thistle. As discussed above under Summary of Biological Status and Threats, the Service has concluded that Wright's marsh thistle is likely to become in danger of extinction within the foreseeable future primarily due to habitat loss and modification. The provisions of this proposed 4(d) rule would promote conservation of the species by encouraging management of the landscape in ways that meet landowner's management priorities while providing for the conservation needs of Wright's marsh thistle. The provisions of this proposed rule are one of many tools that the Service would use to promote the conservation of the Wright's marsh thistle. This proposed 4(d) rule would apply only if and when the Service makes final the listing of Wright's marsh thistle as a threatened species.

Provisions of the Proposed 4(d) Rule

This proposed 4(d) rule would provide for the conservation of Wright's marsh thistle by prohibiting, except as otherwise authorized or permitted, any person subject to the jurisdiction of the United States from the following: Removing and reducing to possession the species from areas under Federal jurisdiction; maliciously damaging or destroying the species on any area under Federal jurisdiction; or removing, cutting, digging up, or damaging or

destroying the species on any area under Federal jurisdiction in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law. Almost 30 percent of occupied Wright's marsh thistle habitat is on Federal land.

As discussed in the Summary of Biological Status and Threats (above), habitat loss and modification are affecting the viability of Wright's marsh thistle. A range of activities that occur on Federal land have the potential to impact the thistle, including changes in water availability, ungulate grazing, and oil and gas development. The regulation of these activities through this 4(d) rule would help enhance the conservation of Wright's marsh thistle by preserving the species' remaining populations on Federal lands and decrease synergistic, negative effects from other stressors. As a whole, the proposed 4(d) rule would help in the efforts to recover the species.

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened plants under certain circumstances. Regulations governing permits for threatened plants are codified at 50 CFR 17.72, which states that ''the Director may issue a permit authorizing any activity otherwise prohibited with regard to threatened species.'' That regulation also states, ''The permit shall be governed by the provisions of this section unless a special rule applicable to the plan is provided in sections 17.73 to 17.78.'' We interpret that second sentence to mean that permits for threatened species are governed by the provisions of section 17.72 unless a special rule provides otherwise. We recently promulgated revisions to section 17.71 providing that section 17.71 will no longer apply to plants listed as threatened in the future. We did not intend for those revisions to limit or alter the applicability of the permitting provisions in section 17.72, or to require that every special rule spell out any permitting provisions that apply to that species and special rule. To the contrary, we anticipate that permitting provisions would generally be similar or identical for most species, so applying the provisions of section 17.72 unless a special rule provides otherwise would likely avoid substantial duplication. Moreover, this interpretation brings section 17.72 in line with the comparable provision for wildlife at 50 CFR 17.32, in which the second sentence states, ''Such permit shall be governed by the provisions of this section unless a special rule applicable to the wildlife, appearing in sections 17.40 to 17.48, of this part provides otherwise.'' Under 50 CFR 17.12, with regard to threatened plants, a permit may be issued for the following purposes: Scientific purposes, to enhance propagation or survival, for economic hardship, for botanical or horticultural exhibition, for educational purposes, or other purposes consistent with the purposes of the Act. Additional statutory exemptions from the prohibitions are found in sections 9 and 10 of the Act.

The Service recognizes the special and unique relationship with our state natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist the Services in implementing all aspects of the Act. In this regard, section 6 of the Act provides that the Services shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency which is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, would be able to conduct activities designed to conserve Wright's marsh thistle that may result in otherwise prohibited activities without additional authorization.

Nothing in this proposed 4(d) rule would change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of Wright's marsh thistle. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service, where appropriate. We ask the public, particularly State agencies and other interested stakeholders that may be affected by the proposed 4(d) rule, to provide comments and suggestions regarding additional guidance and methods that the Service could provide or use, respectively, to streamline the implementation of this proposed 4(d) rule (see Information Requested, above).

III. Proposed Designation of Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features.

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require

implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult with the Service under section 7(a)(2) of the Act. However, even if the Service were to conclude that the proposed activity would result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives'' to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features that occur in specific areas, we focus on the specific features that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic, or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. When designating critical habitat, the Secretary will first evaluate areas occupied by the species. The Secretary will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied by the species would be inadequate to ensure the conservation of the species. In addition, for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable certainty both that the area will contribute to the conservation of the species and that the area contains one or more of those physical or biological features essential to the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and, (3) the Act's prohibitions on certain actions that may affect the species or its habitat. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

As discussed earlier in this document, there is currently no imminent threat of

collection or vandalism identified under Factor B for this species, and identification and mapping of critical habitat is not expected to initiate any such threat. In our SSA and proposed listing determination for Wright's marsh thistle, we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to Wright's marsh thistle and that those threats in some way can be addressed by section 7(a)(2) consultation measures. The species occurs wholly in the jurisdiction of the United States, and we are able to identify areas that meet the definition of critical habitat. Therefore, because none of the circumstances enumerated in our regulations at 50 CFR 424.12(a)(1) has been met and because there are no other circumstances the Secretary has identified for which this designation of critical habitat would be not prudent, we have determined that the designation of critical habitat is prudent for Wright's marsh thistle.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for Wright's marsh thistle is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Data sufficient to perform required analyses are lacking, or

(ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of ''critical habitat.''

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

We reviewed the available information pertaining to the biological needs of the species and habitat characteristics where this species is located. This and other information represent the best scientific data available and led us to conclude that the designation of critical habitat is determinable for Wright's marsh thistle.

Physical or Biological Features

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas within the geographical area occupied by the species at the time of listing to designate as critical habitat, we consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. The regulations at 50 CFR 424.02 define ''physical or biological features essential to the conservation of the species'' as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkali soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic needed to support the life history of the species.

In considering whether features are essential to the conservation of the species, the Service may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, or rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance.

Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements

Water availability is a requirement for three of the four life stages of Wright's marsh thistle's life cycle: Seedlings, rosettes, and mature plants. Optimal habitat should include seeps, springs, cienegas, and streams spreading water normally both above and below ground, with surface or subsurface water flow. The water present in this habitat should be sufficient to allow for permanent root saturation of Wright's marsh thistle in order to provide conditions needed for successful reproduction and survival.

Alkaline soils are required by all four life stages of Wright's marsh thistle's life cycle: Seeds, seedlings, rosettes, and mature plants. These soils are typically found associated with alkaline springs and seeps ranging from low desert up to ponderosa pine forest. Often, water may be available on the landscape in a variety of riparian areas; however, without the presence of alkaline soils in conjunction with water availability, Wright's marsh thistle is unlikely to maintain viability.

Full sunlight is necessary for development of rosettes into mature plants, as well as the survival of mature plants. Optimal habitat includes areas which provide access to sufficient sunlight exposure with no obstructions of sunlight during most life stages of Wright's marsh thistle. These areas should not have dense vegetative cover, which creates competition for sunlight and can negatively impact maturation and flowering of the thistle.

Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring

Diverse native floral communities are necessary to attract pollinators in order to complete cross pollination of Wright's marsh thistle plants. These communities vary depending on location but may include bulrush (*Scirpus* spp.), beaked spikerush (*Eleocharis rostellata*), Pecos sunflower (*Helianthus paradoxus*), rush (*Juncus* spp.), cattail (*Typha* spp.), and other native flowering plants (Sivinski 1996, pp. 2–4). Many generalist pollinators may visit Wright's marsh thistle (Sivinski 2017, entire). The most common pollinators of the thistle are bees, especially bumble bees (*Bombus* spp.) (Sivinski 2017, entire). A diverse native floral community ensures sufficient pollinators to promote cross pollination within and among patches of Wright's marsh thistle.

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential to the conservation of Wright's marsh thistle from studies of the species' habitat, ecology, and life history as described below. Additional information can be found in the SSA report (USFWS 2017,

p. 39) available on *http://www.regulations.gov* under Docket No. FWS–R2–ES–2018–0071). We have determined that the following physical or biological features are essential to the conservation of Wright's marsh thistle:

- Water-saturated soils with surface or subsurface water flow that allows permanent root saturation and seed germination;
- Alkaline soils;
- Full sunlight; and
- Diverse floral communities to attract pollinators.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. As mentioned above, in the case of Wright's marsh thistle, these features include water-saturated soils with surface or subsurface water flow that allows permanent root saturation and seed germination, alkaline soils, full sunlight, and diverse floral communities to attract pollinators. The features may require special management considerations or protection to reduce the following threats: Ground and surface water depletion, increasing drought and changes in climate change, livestock grazing, oil and gas development and mining, and native and nonnative plants. Localized stressors may also include herbicide use and mowing. The species occupies small areas of seeps, springs, and wetland habitat in an arid region that is experiencing drought as well as ongoing and future water withdrawals. The species' highly specific requirements of saturated soils with surface or subsurface water flow make it particularly vulnerable to desiccation and loss of suitable habitat. Furthermore, the thistle's need for full sunlight makes it particularly vulnerable to native and nonnative grass planting and habitat encroachment.

Special management considerations or protections are required within critical habitat areas to address these threats. Management activities that could ameliorate these threats include, but are not limited to: (1) Conservation efforts to ensure sufficient water availability; (2) managing livestock grazing via the use of exclosures; (3) control of native and nonnative plants via controlled burning or mechanical treatments; (4) spill prevention and groundwater protection during oil and gas development and mining; (5) watershed/wetland restoration efforts; and (6) efforts to restore a diverse floral community sufficient to attract pollinators.

These management activities would protect the physical or biological features for Wright's marsh thistle by providing for surface or subsurface water flow for permanent root saturation, soil alkalinity necessary for all life stages, the availability of direct sunlight for plant development, and habitat for pollinators to complete cross pollination of the thistle. Additionally, management of critical habitat lands would help limit the impacts of current risks to population viability.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific and commercial data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat. We are not currently proposing to designate any areas outside the geographical area occupied by the species because we did not find any areas that were essential for the conservation of the species.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge. In this case, we used existing occurrence data for Wright's marsh thistle and information on the habitat and ecosystems upon which the species depends. These sources of information included, but were not limited to:

(1) Data used to prepare the species status assessment and this proposed rule to list the species;

(2) Information from biological surveys;

(3) Various agency reports and databases;

(4) Information from the U.S. Forest Service and other cooperators;

(5) Information from species experts;

(6) Data and information presented in academic research theses; and

(7) Regional Geographic Information System (GIS) data (such as species occurrence data, land use, topography, aerial imagery, soil data, wetland data, and land ownership maps) for area calculations and mapping.

Areas Occupied at the Time of Listing

The proposed critical habitat designation includes currently occupied sites within the species' historical range that have retained the necessary physical and biological features that will allow for the maintenance and expansion of existing populations. Wright's marsh thistle was historically known to occur in an additional site in Arizona (Sivinski 2012, p. 2). The single location in Arizona was collected in 1851 from San Bernardino Cienega, which straddles the international border with Mexico; the location no longer has suitable wetland habitat on the Arizona side of the line (Baker 2011, p. 7), and we do not consider the site essential for the conservation of the thistle because of the lack of suitable habitat and very low restoration potential. Ten historical occurrences occurred in New Mexico, but in a recent search effort at one of the sites (Lake County), the thistle was not found (Sivinski 2011, p. 40) and the habitat was found to be converted to an impervious surface. Another of the 10 records (Rattlesnake Springs, Eddy County) is now thought to be a hybrid between Wright's marsh thistle and Texas thistle (*C. texanum*) (NMRPTC 2009, p. 2), and the site where it was recorded is now a golf course. We do not consider either of these two sites in New Mexico to be essential for the conservation of the thistle, because the species is no longer present, the habitat is no longer available, or the species was misidentified. However, the remaining eight locations in New Mexico meet the definition of areas occupied by the thistle at the time of listing; they are: Santa Rosa, Guadalupe County; Bitter Lake NWR, Chaves County; Blue Spring, Eddy County; La Luz Canyon, Karr/Haynes Canyon, Silver Springs, and Tularosa Creek, Otero County; and Alamosa Creek, Socorro County.

In summary, for areas within the geographic area occupied by the species at the time of listing, we delineated critical habitat unit boundaries using the following process:

(1) We obtained point observations of all currently occupied areas;

(2) We drew minimum convex polygons around the point observations; and

(3) We expanded the polygons to include all adjacent areas containing the essential physical and biological features (specifically the wetted area/moist soil outside of highly vegetated locations) to support life-history processes essential to the conservation of the species.

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for Wright's marsh thistle. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

We propose for designation as critical habitat lands that we have determined are occupied at the time of listing and contain one or more of the physical or biological features that are essential to support life-history processes of the species. We are not proposing to designate any areas that are not currently occupied by the species.

Eight units and 13 subunits are proposed for designation based on one or more of the physical or biological features being present to support Wright's marsh thistle's life-history processes. All eight units contain all of the identified physical or biological features and support multiple life-history processes. Some subunits contain only some of the physical or biological features necessary to support Wright's marsh thistle's particular use of that habitat.

The proposed critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Proposed Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *http://www.regulations.gov* at Docket No. FWS–R2–ES–2018–0071 and on the New Mexico Ecological Services' website at *https://www.fws.gov/southwest/es/NewMexico/index.cfm.*

Proposed Critical Habitat Designation

We propose to designate 64.3 ha (159 ac) in 8 units and 13 subunits as critical habitat for Wright's marsh thistle. The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for the species. Table 3 provides the approximate area of each proposed critical habitat unit. Table 4 breaks down the approximate percentage and size of the total critical habitat designation by ownership type. Table 5 provides currently listed species with occupied habitat on, and designated critical habitat that overlaps with, proposed critical habitat for Wright's marsh thistle. Species with existing critical habitat that overlaps with proposed critical habitat for Wright's marsh thistle include the Koster's springsnail (*Juturnia kosteri*), Noel's amphipod (*Gammarus desperatus*), Roswell springsnail (*Pyrgulopsis roswellensis*), Pecos sunflower (*Helianthus paradoxus*), and the New Mexico meadow jumping mouse (*Zapus hudsonius luteus*). Other listed species in the boundaries of proposed critical habitat include the Alamosa springsnail (*Tryonia alamosae*), Chiricahua leopard frog (*Lithobates chiricahuensis*), least tern (*Sterna antillarum*), and Pecos gambusia (*Gambusia nobilis*). Three other listed species (or their critical habitat) that are found in close proximity (<1609 m (1 mi)) to proposed critical habitat for Wright's marsh thistle include the pecos pupfish (*Cyprinodon pecosensis*), the Sacramento prickly poppy (*Argemone pinnatisecta*), and the Sacramento Mountains thistle.

TABLE 3—PROPOSED CRITICAL HABITAT UNITS FOR WRIGHT'S MARSH THISTLE

Unit No. and name	Subunit No. and name	Ownership	Area
1—Santa Rosa	1a—Blue Hole Hatchery	City of Santa Rosa	0.93 ha (2.3 ac).
	1b—Blue Hole Road South	State	0.45 ha (1.1 ac).
	1c—State Highway 91 North	State	12.2 ha (30.1 ac).
	1d—Santa Rosa Ballpark South	City of Santa Rosa	0.97 ha (2.4 ac).
	1e—State Highway 91 South	City of Santa Rosa	5.9 ha (14.6 ac).
		Private	0.78 ha (1.92 ac).
	1f—Perch Lake	City of Santa Rosa	1.9 ha (4.6 ac).
	1g—Sheehan Trust	Private	2.4 ha (6.0 ac).
	1h—Freeman Property	City of Santa Rosa	0.18 ha (0.44 ac).
		Private	0.91 ha (2.24 ac).
2—Alamosa Springs		Private	1.58 ha (3.9 ac).
3—Bitter Lake	3a—NWR Unit 5	U.S. Fish and Wildlife Service	3.16 ha (7.8 ac).
	3b—NWR Unit 6	U.S. Fish and Wildlife Service	15.9 ha (39.2 ac).
4—Tularosa Creek		Tribal	0.65 ha (1.6 ac).
5—La Luz Canyon		U.S. Forest Service	0.01 ha (0.03 ac).
6—Silver Springs		U.S. Forest Service	0.38 ha (0.95 ac).
		Tribal	0.23 ha (0.58 ac).
7—Karr/Haynes Canyon	7a—Haynes Canyon Road	Private	0.008 ha (0.02 ac).
	7b—Karr Canyon Road	Private	0.73 ha (1.8 ac).
	7c—Raven Road	Private	1.05 ha (2.6 ac).
8—Blue Springs		Private	14.04 ha (34.7 ac).

Note: Area estimates reflect all land within critical habitat unit boundaries, and estimates may not sum due to rounding.

TABLE 4—APPROXIMATE PERCENTAGE AND SIZE OF TOTAL PROPOSED CRITICAL HABITAT DESIGNATION FOR WRIGHT'S MARSH THISTLE PER OWNERSHIP TYPE

Ownership type	Percent of total designation	Size of designation
Private	33.5	21.5 ha (53.13 ac).
Federal	30	19.45 ha (48 ac).
State	19.7	12.65 ha (31.26 ac).
City	15.4	9.88 ha (24.4 ac).
Tribal	0.004	0.65 ha (1.6 ac).

TABLE 5—WRIGHT'S MARSH THISTLE PROPOSED CRITICAL HABITAT UNITS AND CO-OCCURRING LISTED SPECIES OR EXISTING CRITICAL HABITAT

Unit No. and name	Subunit No. and name	Co-occurring listed species (ha (ac) of overlapping occupied habitat)	Existing designated critical habitat for other listed species (ha (ac) of overlapping critical habitat)
1—Santa Rosa	1a—Blue Hole Hatchery	Pecos sunflower (0.42 ha (1.0 ac))	Pecos sunflower (0.93 ha (2.3 ac)).
	1b—Blue Hole Road South.	n/a	Pecos sunflower (0.45 ha (1.0 ac)).
	1c—State Highway 91 North.	Pecos sunflower (0.15 ha (0.4 ac))	Pecos sunflower (12.2 ha (30.0 ac)).
	1d—Santa Rosa Ballpark South.	n/a	n/a.
	1e—State Highway 91 South.	Pecos sunflower (0.15 ha (.04 ac))	n/a.
	1f—Perch Lake	Pecos sunflower (0.03 ha (.07 ac))	n/a.
	1g—Sheehan Trust	n/a	n/a.
	1h—Freeman Property	n/a	n/a.
2—Alamosa Springs		Alamosa springsnail (1.58 ha (3.9 ac)); Chiricahua leopard frog (1.58 ha (3.9 ac)).	n/a.
3—Bitter Lake	3a—NWR Unit 5	Least tern (0.98 ha (2.4 ac)); (Koster's springsnail,* Noel's amphipod,* Pecos gambusia,* Pecos pupfish,* Roswell springsnail*).	Pecos sunflower (3.16 ha (7.8 ac)).
	3b—NWR Unit 6	Koster's springsnail (2.4 ha (5.9 ac)); Least tern (2.8 ha (6.9 ac)); Roswell springsnail (2.4 ha 5.9 ac)); Noel's amphipod (2.4 ha (5.9 ac)); (Pecos gambusia,* Pecos pupfish*).	Koster's springsnail (2.4 ha (5.9 ac)); Pecos sunflower (15.9 ha (39.3 ac)); Roswell springsnail (2.4 ha (5.9 ac)); Noel's amphipod (2.4 ha (5.9 ac)).
4—Tularosa Creek		n/a	na.
5—La Luz Canyon		(Sacramento prickly poppy*)	n/a.
6—Silver Springs		New Mexico meadow jumping mouse (0.38 ha (0.9 ac)); (Sacramento Mountains thistle*).	New Mexico meadow jumping mouse (0.38 ha (0.9 ac)).
7—Karr/Haynes Canyon	7a—Haynes Canyon Road	n/a	n/a.
	7b—Karr Canyon Road	n/a	n/a.
	7c—Raven Road	n/a	n/a.
8—Blue Springs		Pecos gambusia (11.7 ha (28.9 ac))	n/a.

*Species and/or critical habitat found in close proximity (<1,609 m (1 mi)) critical habitat unit, but not overlapping exactly.

We present brief descriptions of all units below and reasons why they meet the definition of critical habitat for Wright's marsh thistle, below.

Unit 1: Santa Rosa

Unit 1 consists of eight subunits comprising 26.6 ha (65.7 ac) in Guadalupe County, New Mexico. This unit consists of land owned by the City of Santa Rosa, the State of New Mexico, and private landowners. This unit partially overlaps with occupied habitat and designated critical habitat for the federally threatened Pecos sunflower.

Subunit 1a: Blue Hole Hatchery

Subunit 1a consists of 11 small land parcels comprising 0.93 ha (2.3 ac) in Guadalupe County, New Mexico. This subunit lies north of Blue Hole Road on City of Santa Rosa property at the abandoned Blue Hole Hatchery. Special management considerations or protection may be required in Subunit 1a to address ground and surface water depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts.

Subunit 1b: Blue Hole Road South

Subunit 1b consists of a small, 0.45-ha (1.1-ac) land parcel in Guadalupe County, New Mexico. This subunit lies south of Blue Hole Road and east of El Rito Creek on State of New Mexico land, which is an undeveloped portion of a wetland preserve. Special management considerations or protection may be required in Subunit 1b to address ground and surface water depletion, as well as native and nonnative invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts.

Subunit 1c: State Highway 91 North

Subunit 1c consists of 12.2 ha (30.1 ac) in Guadalupe County, New Mexico. This subunit lies north of State Highway 91, near Subunit 1b on State of New Mexico land, which is an undeveloped portion of a wetland preserve. Special management considerations or protection may be required in Subunit 1c to address ground and surface water

depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts.

Subunit 1d: Santa Rosa Ballpark South

Subunit 1d consists of two small land parcels comprising 0.97 ha (2.4 ac) in Guadalupe County, New Mexico. This subunit lies south of the City of Santa Rosa ballpark, on an undeveloped portion of City of Santa Rosa land. Special management considerations or protection may be required in Subunit 1d to address ground and surface water depletion, as well as native and nonnative invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts. Other special management considerations or protection may be required to address localized stressors from herbicide use and mowing in recreational areas.

Subunit 1e: State Highway 91 South

Subunit 1e consists of 6.7 ha (16.5 ac) in Guadalupe County, New Mexico. This subunit lies south of State Highway 91 on City of Santa Rosa and private lands. Special management considerations or protection may be required in Subunit 1e to address ground and surface water depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts.

Subunit 1f: Perch Lake

Subunit 1f consists of 1.9 ha (4.6 ac) in Guadalupe County, New Mexico. This subunit includes most of the shores of Perch Lake on City of Santa Rosa property, extending south into an undeveloped area. Special management considerations or protection may be required in Subunit 1f to address ground and surface water depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts. Other special management considerations or protection may be required to address localized stressors from herbicide use and mowing in areas around Perch Lake, which is located inside the subunit.

Subunit 1g: Sheehan Trust

Subunit 1g consists of 2.4 ha (6.0 ac) in Guadalupe County, New Mexico. This subunit lies east of River Road and the Pecos River on privately owned lands, which are currently held in a land trust. Special management considerations or protection may be required in Subunit 1g to address ground and surface water depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts. As this property was formerly grazed and may be grazed again in the future, special management or protection may be required to address impacts of livestock grazing as appropriate.

Subunit 1h: Freeman Property

Subunit 1h consists of five small parcels of land comprising 1.09 ha (2.68 ac) in Guadalupe County, New Mexico. This subunit lies west of Subunit 1g on City of Santa Rosa property and privately owned lands. Special management considerations or protection may be required in Subunit 1h to address ground and surface water depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts.

Unit 2: Alamosa Springs

Unit 2 consists of 1.58 ha (3.9 ac) in Socorro County, New Mexico. This unit lies mostly north of Forest Road 140 along Alamosa Creek, on privately owned land. This unit entirely overlaps with occupied habitat for the federally endangered Alamosa springsnail and federally threatened Chiricahua leopard frog. Special management considerations or protection may be required in this unit to address ground and surface water depletion, water quality, soil alkalinity, and native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, to protect ground water and soil from contaminants during mining activities, and to decrease competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts.

Unit 3: Bitter Lake

Unit 3 consists of two subunits comprising 19.0 ha (47 ac) in Chaves County, New Mexico, on Bitter Lake National Wildlife Refuge (NWR). Unit 3 is entirely managed by the U.S. Fish and Wildlife Service. This unit overlaps with occupied habitat for the federally endangered Koster's springsnail, Noel's amphipod, Roswell springsnail, and least tern. The unit also overlaps with designated critical habitat for the Koster's springsnail, Noel's amphipod, Roswell springsnail, and Pecos sunflower.

Subunit 3a: NWR Unit 5

Subunit 3a consists of 3.16 ha (7.8 ac) in Chaves County, New Mexico, within Wetland Management Unit 5 on Bitter Lake NWR. Special management considerations or protection may be required in Subunit 3a to address ground and surface water depletion, water quality, soil alkalinity, and native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, spill prevention and groundwater protection during oil and gas development, and decreasing competition with native and nonnative plants via prescribed burning and mechanical and herbicide treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts.

Subunit 3b: NWR Unit 6

Subunit 3b consists of 15.9 ha (39.2 ac) in Chaves County, New Mexico, within Wetland Management Unit 6 on Bitter Lake NWR. Special management considerations or protection may be required in Subunit 3b to address

ground and surface water depletion, water quality, soil alkalinity, and native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, spill prevention and groundwater protection during oil and gas development, and decreasing competition with native and nonnative plants via prescribed burning and mechanical and herbicide treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts.

Unit 4: Tularosa Creek

Unit 4 consists of 0.65 ha (1.6 ac) in Otero County, New Mexico. This unit lies along Indian Service Route 10, north of Tularosa Creek, on land owned by the Mescalero Apache Tribe. Special management considerations or protection may be required in this unit to address ground and surface water depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts.

Unit 5: La Luz Canyon

Unit 5 consists of 0.01 ha (0.03 ac) in Otero County, New Mexico, on the Lincoln National Forest. This unit lies north of La Luz Canyon Road, along La Luz Creek, on lands managed by the U.S. Forest Service. Special management considerations or protection may be required in this unit to address ground and surface water depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts. As this property has the potential to be grazed, special management or protection may be required to address impacts of livestock grazing as appropriate.

Unit 6: Silver Springs

Unit 6 consists of 0.62 ha (1.53 ac) in Otero County, New Mexico. This unit lies east of State Highway 224, along Silver Springs Creek. This unit contains land on the Lincoln National Forest, which is managed by the U.S. Forest Service, and land owned by the Mescalero Apache Tribe. This unit overlaps with occupied habitat and critical habitat for the federally endangered New Mexico meadow jumping mouse. Special management considerations or protection may be required in this unit to address ground and surface water depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts. As this property has the potential to be grazed, special management or protection may be required to address impacts of livestock grazing as appropriate.

Unit 7: Karr/Haynes Canyon

Unit 7 consists of three subunits that comprise 1.79 ha (4.42 ac) in Otero County, New Mexico. This unit consists of privately owned lands.

Subunit 7a: Haynes Canyon Road

Subunit 7a consists of 0.008 ha (0.02 ac) in Otero County, New Mexico. This subunit lies south of Haynes Canyon Road on privately owned lands. Special management considerations or protection may be required in Subunit 7a to address ground and surface water depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts. As this property has the potential to be grazed, special management or protection may be required to address impacts of livestock grazing as appropriate.

Subunit 7b: Karr Canyon Road

Subunit 7b consists of two small parcels comprising 0.73 ha (1.8 ac) in Otero County, New Mexico. This subunit lies along either side of Karr Canyon Road on privately owned lands. Special management considerations or protection may be required in Subunit 7b to address ground and surface water depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts. As this property has the potential to be grazed, special management or protection may be required to address impacts of livestock grazing as appropriate.

Subunit 7c: Raven Road

Subunit 7c consists of two small parcels comprising 1.05 ha (2.6 ac) in Otero County, New Mexico. This subunit lies along either side of Raven Road on privately owned lands. Special management considerations or protection may be required in Subunit 7c to address ground and surface water depletion, as well as native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, along with decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts. As this property has the potential to be grazed, special management or protection may be required to address impacts of livestock grazing as appropriate.

Unit 8: Blue Springs

Unit 8 consists of 14.04 ha (34.7 ac) in Eddy County, New Mexico. This unit lies along a small tributary north of the Black River on privately owned land. This unit overlaps with occupied habitat for the federally endangered Pecos gambusia. Special management considerations or protection may be required in this unit to address ground and surface water depletion, water quality, soil alkalinity, and native and nonnative plant invasion. Such special management or protection may include conservation efforts to ensure water availability, spill prevention and groundwater protection during oil and gas development, and decreasing competition with native and nonnative plants via prescribed burning and mechanical treatments, if necessary. Special management or protection may also include watershed/wetland restoration efforts.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened

species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

We published a final regulation with a revised definition of destruction or adverse modification on August 27, 2019 (84 FR 44976). Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation.

Compliance with the requirements of section 7(a)(2) is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate formal consultation on previously reviewed actions. These requirements apply when the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law) and, subsequent to the previous consultation, we have listed a new species or designated critical habitat that may be affected by the Federal action, or the action has been modified in a manner that affects the species or critical habitat in a way not considered in the previous consultation. In such situations, Federal agencies sometimes may need to request reinitiation of consultation with us, but the regulations also specify some exceptions to the requirement to reinitiate consultation on specific land management plans after subsequently listing a new species or designating new critical habitat. See the regulations for a description of those exceptions.

Application of the ''Adverse Modification'' Standard

The key factor related to the destruction or adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat as a whole for the conservation of the listed species. As discussed above, the role of critical habitat is to support physical or biological features essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may violate 7(a)(2) of the Act by destroying or adversely modifying such designation.

Activities that the Services may, during a consultation under section 7(a)(2) of the Act, find are likely to destroy or adversely modify critical habitat include, but are not limited to:

(1) Actions that would diminish permanent root saturation. Such activities could include, but are not limited to, water diversions and water withdrawals for agricultural, mineral mining, or urban purposes. These activities could reduce Wright's marsh thistle's water availability, and increase its competition for water resources, thereby depleting a resource necessary for the plant's normal growth and survival.

(2) Actions that would alter the alkalinity of the soil. Such activities could include, but are not limited to, oil and gas development and mining. These activities could result in significant ground disturbance that could alter the chemical and physical properties of the soil.

(3) Actions that would diminish the availability of full sunlight. Such activities could include, but are not limited to, vegetation management that encourages growth of competing native and nonnative species. These activities could lead to habitat encroachment resulting in a decreased availability of sunlight.

(4) Actions that would decrease the diversity and abundance of floral resources and pollinators. Such activities could include, but are not limited to, the use of pesticides and herbicides, livestock grazing, and oil and gas development and mining. These activities could lead to direct mortality of pollinators and diminish the floral resources available to pollinators.

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that: ''The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (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.'' There are no DoD lands with a

completed INRMP within the proposed critical habitat designation.

Exclusions

Application of Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

The first sentence in section 4(b)(2) of the Act requires that we take into consideration the economic, national security, or other relevant impacts of designating any particular area as critical habitat. We describe below the process that we undertook for taking into consideration each category of impacts and our analyses of the relevant impacts.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. To assess the probable economic impacts of a designation, we must first evaluate specific land uses or activities and projects that may occur in the area of the critical habitat. We then must evaluate the impacts that a specific critical habitat designation may have on restricting or modifying specific land uses or activities for the benefit of the species and its habitat within the areas proposed. We then identify which conservation efforts may be the result of the species being listed under the Act versus those attributed solely to the designation of critical habitat for this particular species. The probable economic impact of a proposed critical habitat designation is analyzed by comparing scenarios both ''with critical habitat'' and ''without critical habitat.''

The ''without critical habitat'' scenario represents the baseline for the analysis, which includes the existing regulatory and socio-economic burden imposed on landowners, managers, or other resource users potentially affected by the designation of critical habitat (*e.g.,* under the Federal listing as well as other Federal, State, and local regulations). The baseline, therefore, represents the costs of all efforts attributable to the listing of the species under the Act (*i.e.,* conservation of the species and its habitat incurred regardless of whether critical habitat is designated). The ''with critical habitat'' scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts would not be expected without the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat, above and beyond the baseline costs. These are the costs we use when evaluating the benefits of inclusion and exclusion of particular areas from the final designation of critical habitat should we choose to conduct a discretionary 4(b)(2) exclusion analysis.

For this particular designation, we developed an incremental effects memorandum (IEM) considering the probable incremental economic impacts that may result from this proposed designation of critical habitat. The information contained in our IEM, along with the SSA, was then used to develop a screening analysis of the probable effects of the designation of critical habitat for Wright's marsh thistle (Industrial Economics, Inc. 2018). We began by conducting a screening analysis of the proposed designation of critical habitat in order to focus our analysis on the key factors that are likely to result in incremental economic impacts. The purpose of the screening analysis is to filter out the geographic areas in which the critical habitat designation is unlikely to result in probable incremental economic impacts. In particular, the screening analysis considers baseline costs (*i.e.,* absent critical habitat designation) and includes probable economic impacts where land and water use may be subject to conservation plans, land management plans, best management practices, or regulations that would protect the habitat area as a result of the Federal listing status of the species. The screening analysis filters out particular areas of critical habitat that are already subject to such protections and are, therefore, unlikely to incur incremental economic impacts. Ultimately, the screening analysis allows us to focus our analysis on evaluating the specific areas or sectors that may incur probable incremental economic impacts as a result of the designation. The screening analysis also assesses whether units are unoccupied by the species and may require additional management or conservation efforts as a result of the critical habitat designation for the species, which may incur incremental economic impacts. This screening analysis, combined with the information contained in our IEM, is what we consider our draft economic analysis of the proposed critical habitat designation for Wright's marsh thistle and is summarized in the narrative below.

Executive Orders (E.O.s) 12866 and 13563 direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consistent with the E.O. regulatory analysis requirements, our effects analysis under the Act may take into consideration impacts to both directly and indirectly affected entities, where practicable and reasonable. If sufficient data are available, we assess to the extent practicable the probable impacts to both directly and indirectly affected entities. As part of our screening analysis, we considered the types of economic activities that are likely to occur within the areas likely affected by the critical habitat designation.

In our evaluation of the probable incremental economic impacts that may result from the proposed designation of critical habitat for Wright's marsh thistle, first we identified, in the IEM dated March 2, 2018, probable incremental economic impacts associated with the following categories of activities: (1) Water quantity/supply, (2) oil and gas development and mining, and (3) livestock grazing. We considered each industry or category individually. Additionally, we considered whether their activities have any Federal involvement. Critical habitat designation generally will not affect activities that do not have any Federal involvement; under the Act, designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. If we finalize the listing of Wright's marsh thistle, in areas where the species is present, Federal agencies would already be required to consult with the Service under section 7 of the Act on activities they fund, permit, or implement that may affect the thistle. If we finalize this proposed critical habitat designation, consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into the existing consultation process.

In our IEM, we attempted to clarify the distinction between the effects that will result from the species being listed and those attributable to the critical habitat designation (*i.e.,* difference between the jeopardy and adverse modification standards) for Wright's marsh thistle's critical habitat. Because the designation of critical habitat for Wright's marsh thistle is being proposed concurrently with the listing, it has been our experience that it is more difficult to discern which conservation efforts are attributable to the species being listed and those which will result solely from the designation of critical habitat. However, the following specific circumstances in this case help to inform our evaluation: (1) The essential physical or biological features identified for critical habitat are the same features essential for the life requisites of the species and (2) any actions that would result in sufficient harm or harassment to constitute jeopardy to Wright's marsh thistle would also likely adversely affect the essential physical or biological features of critical habitat. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this proposed designation of critical habitat.

The Service is proposing to designate 64.3 ha (159 ac) across five New Mexico counties as critical habitat for Wright's marsh thistle. The Service has divided the proposed critical habitat into eight units, with some further divided into subunits. All eight units are considered occupied because they contain reproducing populations of the thistle. We are not proposing to designate any units of unoccupied habitat. Approximately 29 percent of the proposed designation is located on Federal lands, 20 percent is on State-owned lands, and 1 percent on land owned by the Mescalero Tribe. Fifteen percent of proposed lands are owned by the City of Santa Rosa, and 35 percent are privately owned. In these areas, any actions that may affect the species or its habitat would also affect designated critical habitat, and it is unlikely that any additional conservation efforts would be recommended to address the adverse modification standard over and above those recommended as necessary to avoid jeopardizing the continued existence of Wright's marsh thistle. Therefore, the potential incremental economic effects of the critical habitat designation are expected to be limited to administrative costs.

The entities most likely to incur incremental costs are parties to section 7 consultations, including Federal action agencies and, in some cases, third parties, most frequently State agencies or municipalities. Our analysis of economic impacts makes the following assumptions about consultation activity over the next 10 years, most of which are more likely to overstate than understate potential impacts due to the history of biological assessments and implementation of project conservation measures by the action agencies. The analysis assumes that approximately five section 7 consultations will occur annually in the designated critical habitat, across all eight units, based on the previous consultation history in the area. Most of these are anticipated to occur in areas with Federal lands, including units 3, 5, and 6, as well as the large unit 1.

This may overstate the number of consultations that will occur given available information on forecast activity. As stated above, we anticipate that conservation efforts needed to avoid adverse modification are likely to be the same as those needed to avoid impacts to the species itself. As such, costs of critical habitat designation for Wright's marsh thistle are anticipated to be limited to administrative costs. We anticipate that the incremental administrative costs of addressing adverse modification of critical habitat for the species in a section 7 consultation will be minor.

The incremental administrative burden resulting from the designation of critical habitat for Wright's marsh thistle, based on the anticipated annual number of consultations and associated consultation costs, is not expected to exceed $25,000 in most years. The designation is unlikely to trigger additional requirements under State or local regulations. Furthermore, the designation is quite small, limited to 64.3 ha (159 ac) in total, with the local government, municipal, and private lands limited to 31.33 ha (77.4 ac); therefore, the designation is not expected to have significant perceptional effects. Because the designation is not expected to result in incremental conservation efforts for the species, the designation is also unlikely to measurably increase the probability that the species will be conserved, and benefits are also unlikely to exceed $25,000 in a given year. In our DEA, we did not identify any ongoing or future actions that would warrant additional recommendations or project modifications to avoid adversely modifying critical habitat above those we would recommend for avoiding jeopardy to the species, and we anticipate minimal change in management at Bitter Lake NWR and Lincoln National Forest due to the designation of critical habitat for Wright's marsh thistle.

We are soliciting data and comments from the public on the DEA, as well as all aspects of the proposed rule and our required determinations. During the development of a final designation, we will consider any additional economic impact information we receive during the public comment period to determine whether any specific areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 424.19. In particular, we may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of this species.

Consideration of National Security Impacts

In preparing this proposal, we have determined that the lands within the proposed designation of critical habitat for Wright's marsh thistle are not owned, managed, or used by the DoD or Department of Homeland Security, and, therefore, we anticipate no impact on national security or homeland security. However, during the development of a final designation we will consider any additional information received through the public comment period on the impacts of the proposed designation on national security or homeland security to determine whether any specific areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 424.19.

Consideration of Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security. We consider a number of factors including whether there are permitted conservation plans covering the species in the area such as Habitat Conservation Plans, safe harbor agreements, or candidate conservation agreements with assurances, or whether there are non-permitted conservation agreements and partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at the existence of tribal conservation

plans and partnerships and consider the government-to-government relationship of the United States with tribal entities. We also consider any social impacts that might occur because of the designation.

In preparing this proposal, we have determined that there are currently no permitted conservation plans or other management plans for Wright's marsh thistle. Only 0.88 ha (2.18 ac) of proposed critical habitat lands for Wright's marsh thistle belong to the Mescalero Apache Tribe; we have initiated coordination with the Tribe regarding the proposed critical habitat designation and will continue to offer government-to-government consultation with them throughout development of the final rulemaking. We anticipate no impact on tribal lands, partnerships, or permitted management plans from this proposed critical habitat designation. There are no adequate partnerships, Tribal partnerships, management, or protection afforded by cooperative management efforts sufficient to provide for the conservation of the species. There are no areas whose exclusion would result in conservation, or in the continuation, strengthening, or encouragement of partnerships.

Summary of Exclusions

After analyzing these potential impacts, we are not considering any exclusions at this time from the proposed designation under section 4(b)(2) of the Act based on economic impacts, national security impacts, or other relevant impacts such as partnerships, management, or protection afforded by cooperative management efforts. All areas proposed for critical habitat will benefit from additional regulation for the protection from destruction or adverse modification as a result of actions with a Federal nexus. All areas would see educational benefits of mapping essential habitat for recovery of the listed species. During the development of a final designation, we will consider any additional information received through the public comment period regarding other relevant impacts to determine whether any specific areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 424.19.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

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

(3) Use clear language rather than jargon;

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

(5) Use lists and tables wherever possible.

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

Regulatory Planning and Review—Executive Orders 12866 and 13563

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has waived their review regarding their significance determination of this proposed rule.

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

Regulatory Flexibility Act—5 U.S.C. 601 et seq.

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service-sector businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

The Service's current understanding of the requirements under the RFA, as amended, and following recent court decisions, is that Federal agencies are only required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself and are, therefore, not required to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies will be

directly regulated by this designation. There is no requirement under RFA to evaluate the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities are directly regulated by this rulemaking, the Service certifies that, if made final, the proposed critical habitat designation will not have a significant economic impact on a substantial number of small entities.

In summary, we have considered whether the proposed designation would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if made final, the proposed critical habitat designation would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Reducing Regulation and Controlling Regulatory Costs—Executive Order 13771

We do not believe this proposed rule is an E.O. 13771 (''Reducing Regulation and Controlling Regulatory Costs'') (82 FR 9339, February 3, 2017) regulatory action because we believe this rule is not significant under E.O. 12866; however, the Office of Information and Regulatory Affairs has waived their review regarding their E.O. 12866 significance determination of this proposed rule.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. A significant energy action is one that promulgates, or is expected to lead to the promulgation of, a final rule that is both (1) a significant regulatory action under E.O. 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy, or a final rule that is designated by the Administrator of OIRA as a significant energy action. OIRA has determined that this rule is not significant. Further, in our economic analysis, we did not find that the designation of this proposed critical habitat will have an annual effect on the economy of $100 million or more or significantly affect energy supplies, distribution, or use due to the lack of any energy supply or distribution lines within the proposed critical habitat designation. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act—2 U.S.C. 1501 et seq.

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) This rule may have a small perceptional effect on the City of Santa Rosa, New Mexico, due to the designation of critical habitat. In practice, small governments like Santa Rosa are affected by critical habitat only to the extent that any programs having Federal funds, permits, or other authorized activities must ensure that their actions will not adversely affect the critical habitat. Therefore, a Small Government Agency Plan is not required. However, we did notify the City of Santa Rosa of the proposed critical habitat with the publication of this proposed rule, and we invite their comments on the proposal with regard to any potential effects.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for Wright's marsh thistle in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed and concludes that, if adopted, this designation of critical habitat for Wright's marsh thistle would not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of this proposed critical habitat designation with, appropriate State resource agencies in New Mexico. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the rule would not have substantial direct effects either on the States, or on the relationship between the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, the rule identifies the elements of physical or biological features essential to the conservation of the species. The designated areas of critical habitat are presented on maps, and the rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995—44 U.S.C. 3501 et seq.

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act—42 U.S.C. 4321 et seq.

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)). However, when the range of the species includes States within the Tenth Circuit, such as that of the Wright's marsh thistle, under the Tenth Circuit ruling in *Catron County Board of Commissioners* v. *U.S. Fish and Wildlife Service,* 75 F.3d 1429 (10th Cir. 1996), we undertake a NEPA analysis for critical habitat designation. We invite the public to comment on the extent to which this proposed regulation may have a significant impact on the human environment, or fall within one of the categorical exclusions for actions that have no individual or cumulative effect on the quality of the human environment. We will complete our analysis, in compliance with NEPA, before finalizing this proposed rule.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes.

There are tribal lands included in the proposed designation of critical habitat for Wright's marsh thistle. Using the criteria described above under *Criteria Used To Identify Critical Habitat,* we have determined that some tribal lands that are occupied by the species contain the features essential for the conservation the species. Only 0.88 ha (2.18 ac) of proposed critical habitat lands belong to the Mescalero Apache Tribe. We have begun government-to-government consultation with the Tribe, and we will continue to consult with the Tribe throughout the public comment period on this proposed rule and during development of the final designation of critical habitat for the species. We will consider Tribal lands for exclusion from the final critical habitat designation to the extent consistent with the requirements of 4(b)(2) of the Act. The Mescalero Apache Tribe is the main tribe whose lands and trust resources may be affected by this proposed rule. There may be some other tribes with trust resources in the area but we have no specific documentation of this. We sent a notification letter to the Mescalero Apache Tribe on April 6, 2014, describing the exclusion process under section 4(b)(2) of the Act, and we have engaged in conversations with the Tribe about the proposal to the extent possible without disclosing predecisional information via requests for additional information in September 2016 and January 2018. We will attempt to schedule a meeting with the Tribe, as well as other interested parties, shortly after publication of this proposed rule so that we can give them as much time as possible to comment.

References Cited

A complete list of references cited in this proposed rule is available on the internet at *http://www.regulations.gov* and upon request from the New Mexico Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the New Mexico Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.12(h) by adding an entry for ''*Cirsium wrightii*'' to the List of Endangered and Threatened Plants in alphabetical order under FLOWERING PLANTS to read as set forth below:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Scientific name	Common name	Where listed	Status	Listing citations and applicable rules
FLOWERING PLANTS				
*	*	*	*	* * *
Cirsium wrightii	Wright's marsh thistle	Wherever found	T	[**Federal Register** citation when published as a final rule]; 50 CFR 17.73(a);[4d] 50 CFR 17.96(a).[CH]
*	*	*	*	* * *

■ 3. Add § 17.73 to read as follows:

§ 17.73 Special rules—flowering plants.

(a) *Cirsium wrightii* (Wright's marsh thistle).

(1) *Prohibitions.* The following prohibitions apply to the Wright's marsh thistle except as provided under paragraph (a)(2) of this section:

(i) Remove and reduce to possession from areas under Federal jurisdiction, as set forth at § 17.61(c)(1) for endangered plants.

(ii) Maliciously damage or destroy the species on any areas under Federal jurisdiction, or remove, cut, dig up, or damage or destroy the species on any other area in knowing violation of any State law or regulation or in the course of any violation of a State criminal trespass law, as set forth at section 9(a)(2)(B) of the Act.

(2) *Exceptions from prohibitions.* The following exceptions from prohibitions apply to the Wright's marsh thistle:

(i) The prohibitions described in paragraph (a)(1) of this section do not apply to activities conducted as authorized by a permit issued in accordance with the provisions set forth at § 17.72.

(ii) Any employee or agent of the Service or of a State conservation agency that is operating a conservation program pursuant to the terms of a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by that agency for such purposes, may, when acting in the course of official duties, remove and reduce to possession from areas under Federal jurisdiction members of the Wright's marsh thistle that are covered by an approved cooperative agreement to carry out conservation programs.

(b) [Reserved]

■ 4. In § 17.96, amend paragraph (a) by adding an entry for ''*Cirsium wrightii* (Wright's marsh thistle)'' in alphabetical order under Family Asteraceae to read as follows:

§ 17.96 Critical habitat—plants.

(a) *Flowering plants.*

* * * * *

Family Asteraceae: *Cirsium wrightii* (Wright's marsh thistle)

(1) Critical habitat units are depicted for Chavez, Eddy, Guadalupe, Otero, and Socorro Counties, New Mexico, on the maps in this entry.

(2) Within these areas, the physical or biological features essential to the conservation of Wright's marsh thistle consist of the following components:

(i) Water-saturated soils with surface or subsurface water flow that allows permanent root saturation and seed germination;

(ii) Alkaline soils;

(iii) Full sunlight; and

(iv) Diverse floral communities to attract pollinators.

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of this rule.

(4) *Critical habitat map units.* Data layers defining map units were created using the latest imagery available through Esri (*https://www.esri.com/en-us/home*). The actual source is DigitalGlobe and the year of the imagery was 2016. Critical habitat units were then mapped using ArcGIS ArcMap 10.4. All data are in North America Albers Equal Area Conic projection, Datum North American 1983. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's internet site at *https://www.fws.gov/southwest/es/NewMexico/index.cfm,* at *http://www.regulations.gov* under Docket No. FWS–R2–ES–2018–0071, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) *Note:* Index map follows:

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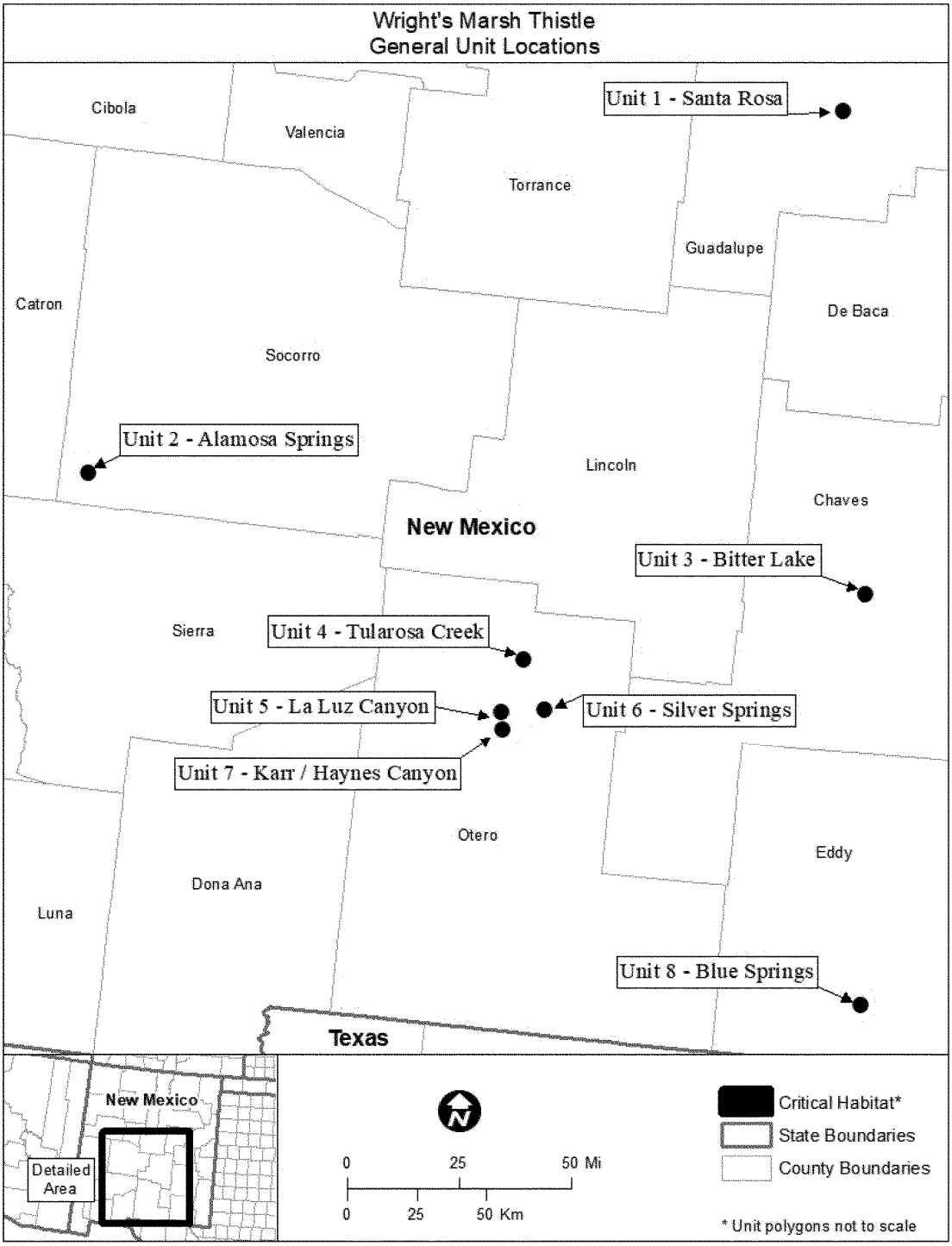
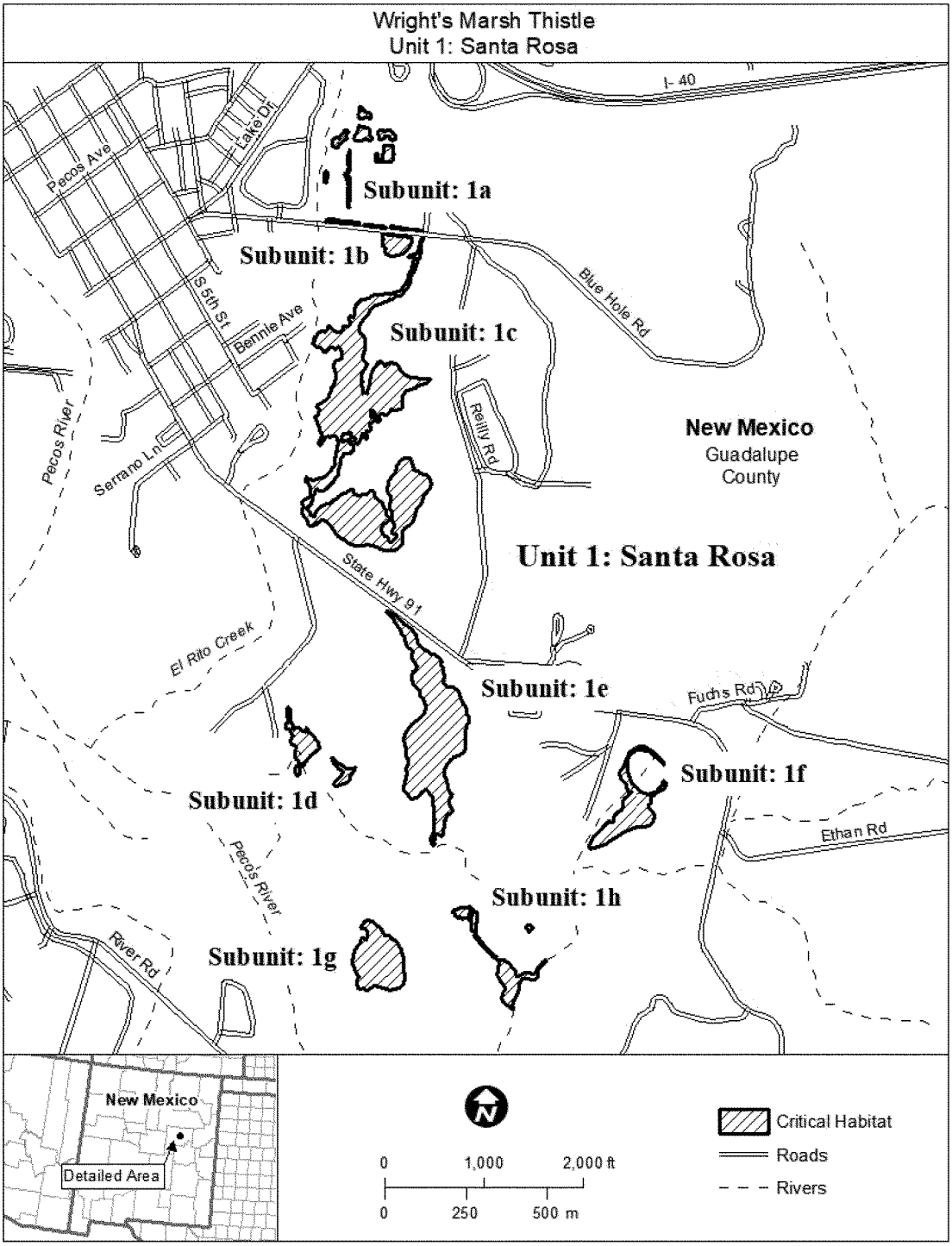
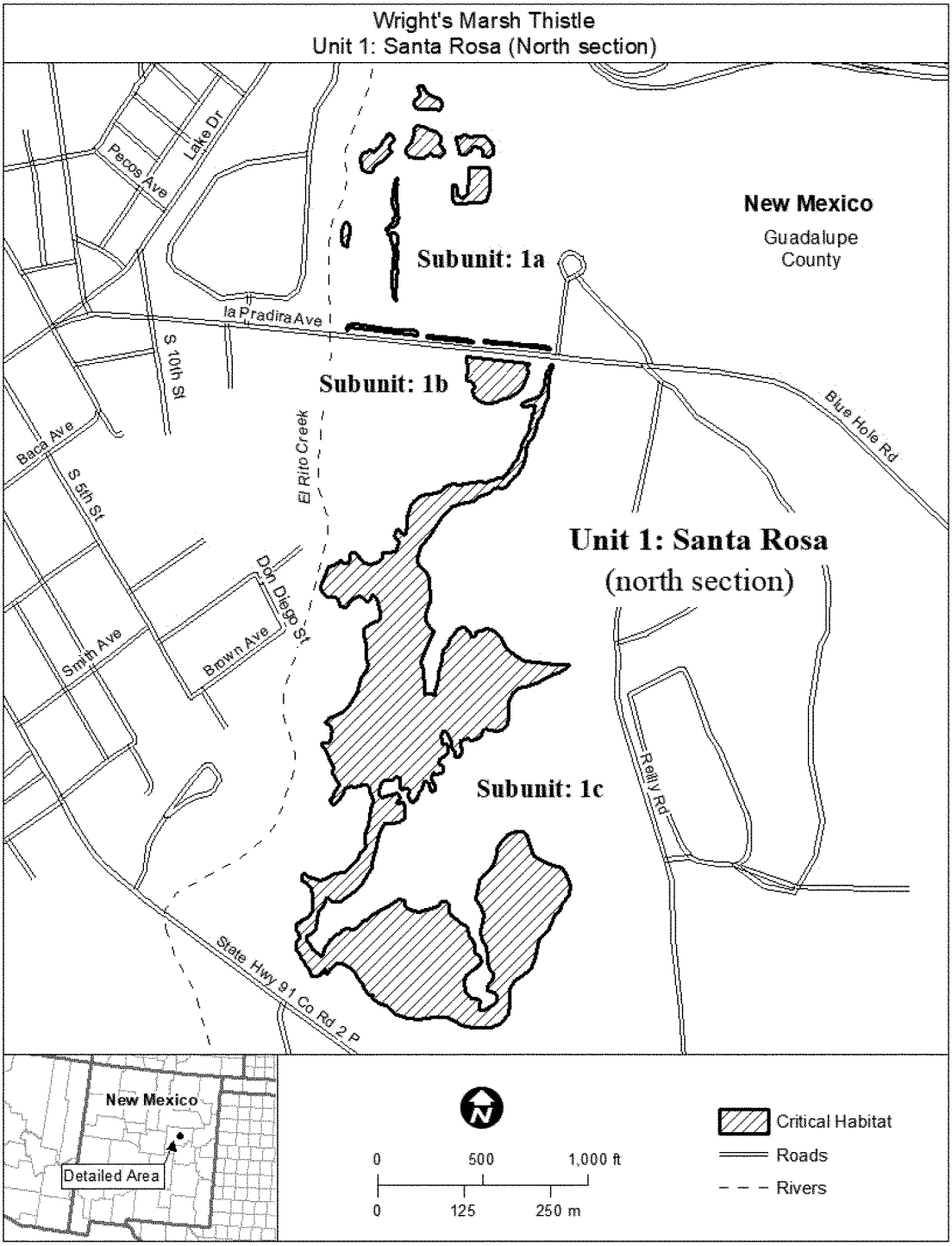


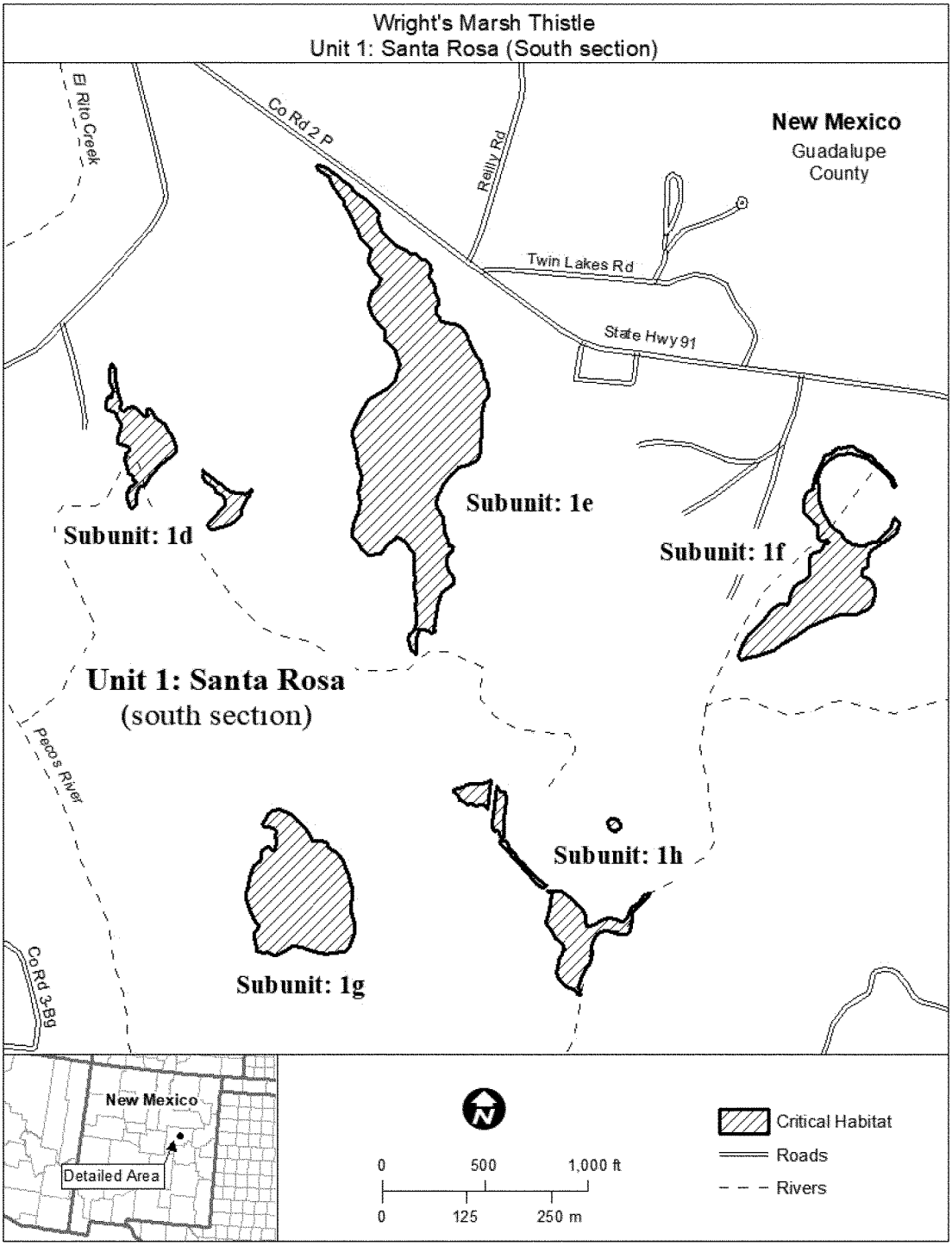
(6) Unit 1: Santa Rosa, Guadalupe County, New Mexico.

(i) *General description:* Unit 1 consists of 26.6 hectares (ha) (65.7 acres (ac)) in Guadalupe County, New Mexico, and is composed of lands in State (12.65 ha (31.2 ac)), City of Santa Rosa (9.88 ha (24.4 ac)), and private (4.09 ha (10.16 ac)) ownership.

(ii) Maps of Unit 1 follow:


Wright's Marsh Thistle
Unit 1: Santa Rosa
I- 40
Pecos Ave
Lake Dr
Subunit: 1a
Subunit: 1b
S 5th St
Bennie Ave
Subunit: 1c
Blue Hole Rd
Reilly Rd
Pecos River
Serrano Ln
New Mexico
Guadalupe
County
Unit 1: Santa Rosa
State Hwy 91
El Rito Creek
Subunit: 1e
Fuchs Rd
Subunit: 1f
Subunit: 1d
Ethan Rd
Pecos River
Subunit: 1h
River Rd
Subunit: 1g
New Mexico
Detailed Area
0 1,000 2,000 ft
0 250 500 m
Critical Habitat
Roads
Rivers

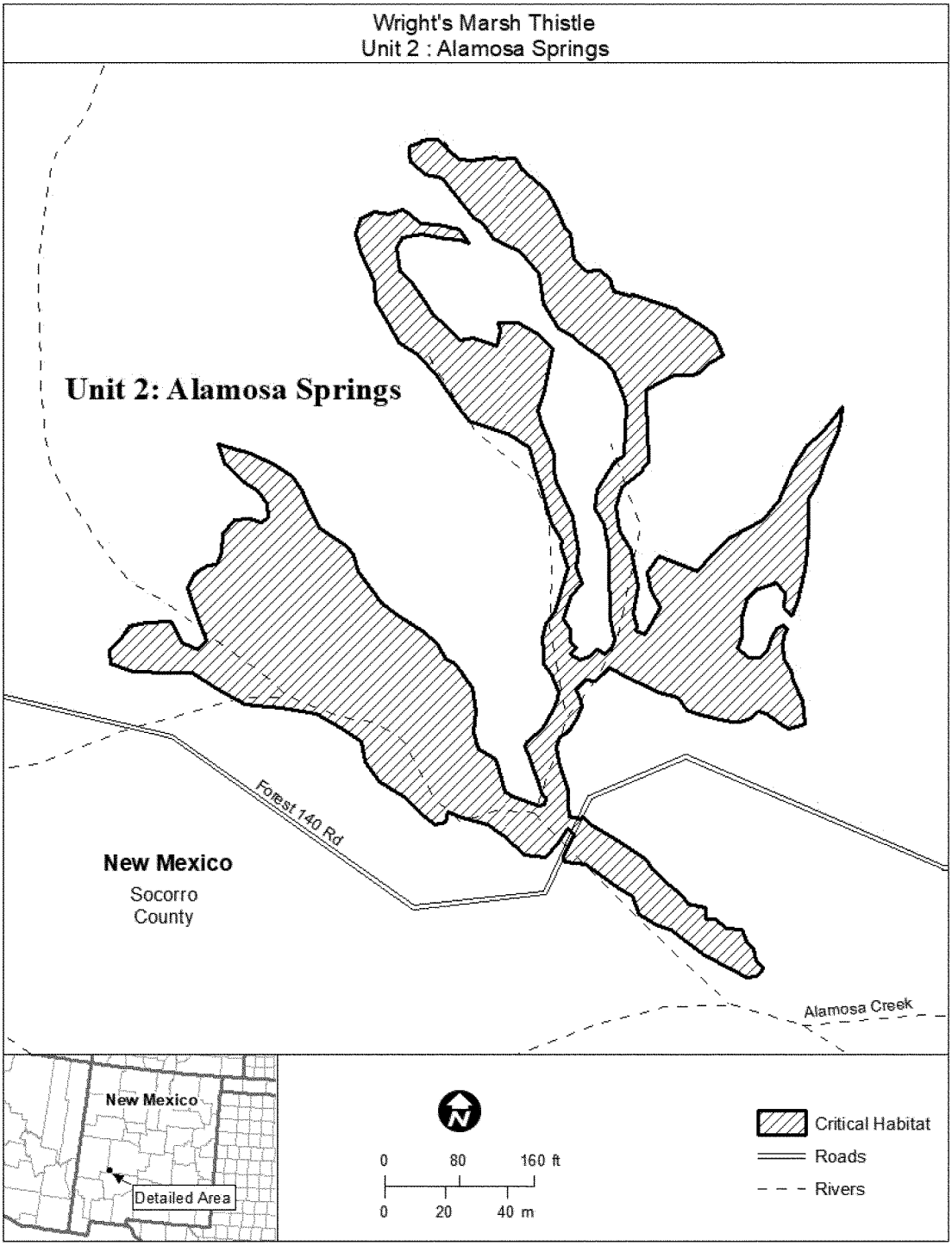

Wright's Marsh Thistle
Unit 1: Santa Rosa (North section)
New Mexico
Guadalupe County
Subunit: 1a
Subunit: 1b
Subunit: 1c
Unit 1: Santa Rosa
(north section)
la Pradira Ave
Pecos Ave
Lake Dr
S 10th St
Baca Ave
S 5th St
Smith Ave
Brown Ave
Don Diego St
El Rito Creek
Blue Hole Rd
Reilly Rd
State Hwy 91 Co Rd 2 P
New Mexico
Detailed Area
0 500 1,000 ft
0 125 250 m
Critical Habitat
Roads
Rivers



(7) Unit 2: Alamosa Springs, Socorro County, New Mexico.

(i) *General description:* Unit 2 consists of 1.58 ha (3.9 ac) in Socorro County, New Mexico, and is composed of lands in private ownership.

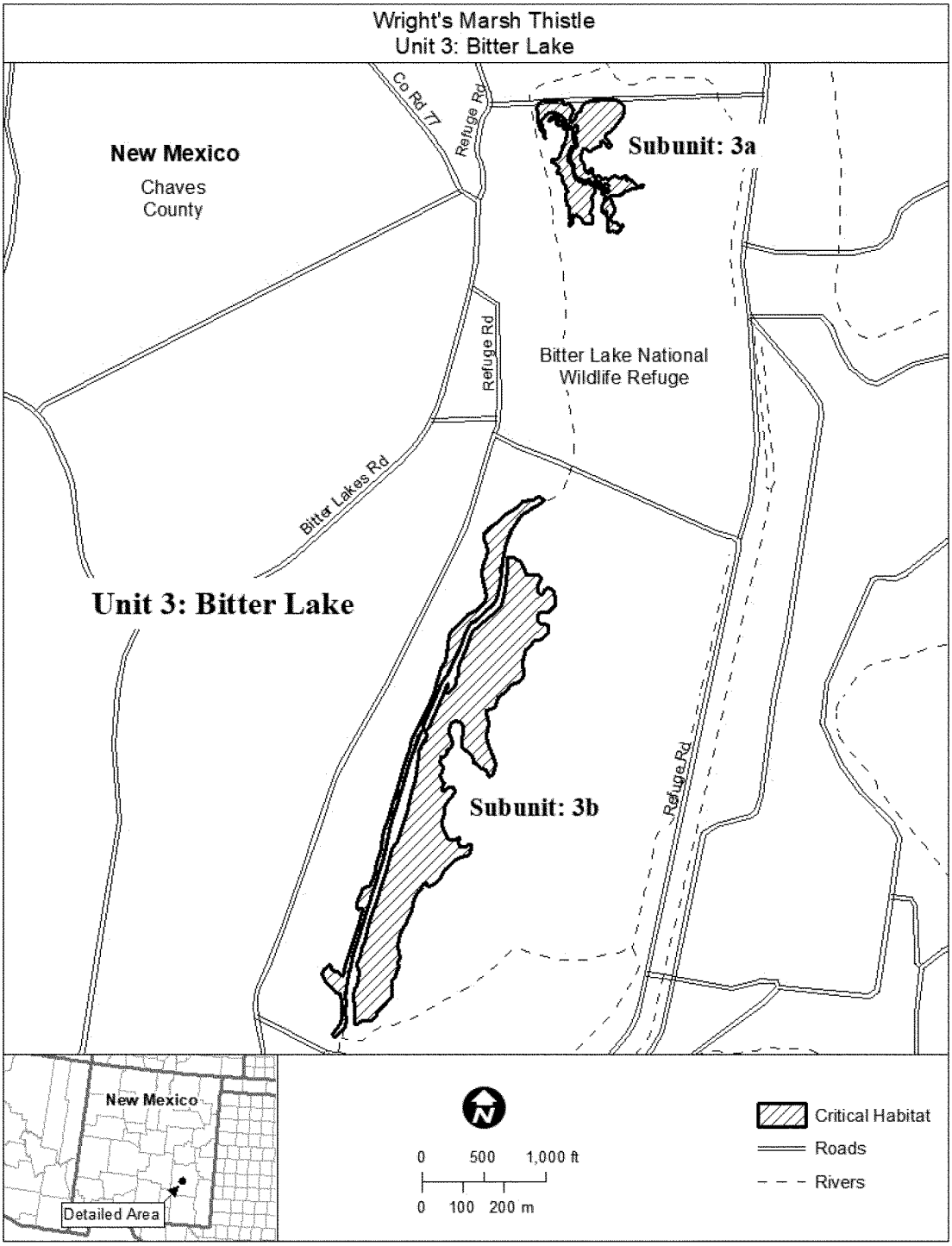
(ii) Map of Unit 2 follows:



(8) Unit 3: Bitter Lake, Chaves County, New Mexico.

(i) *General description:* Unit 3 consists of 19.0 ha (47.0 ac) in Chaves County, New Mexico, and is composed of lands under Federal management, specifically the U.S. Fish and Wildlife Service's Bitter Lake National Wildlife Refuge.

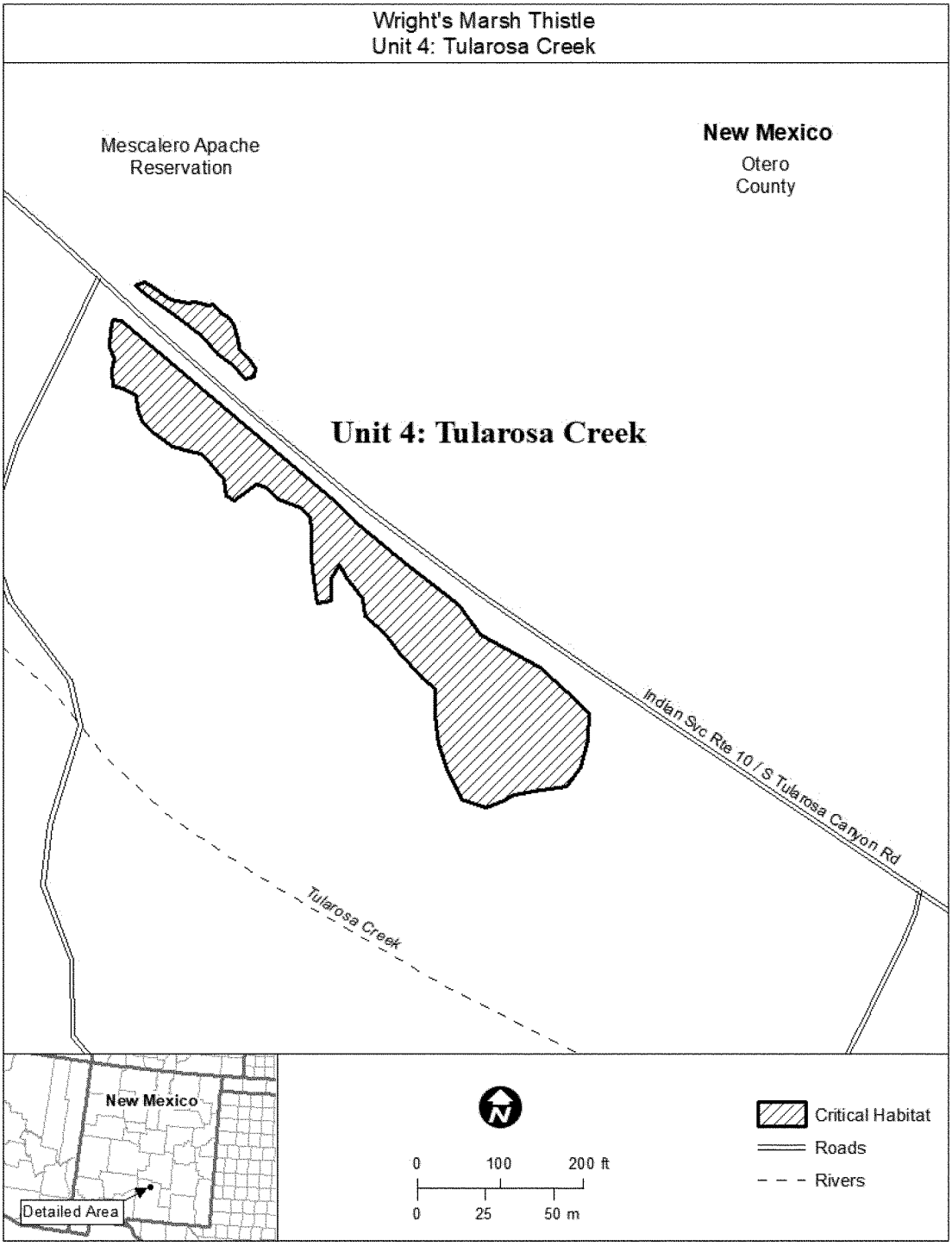
(ii) Map of Unit 3 follows:



(9) Unit 4: Tularosa Creek, Otero County, New Mexico.

(i) *General description:* Unit 4 consists of 0.65 ha (1.6 ac) in Otero County, New Mexico, and is composed of lands in tribal ownership.

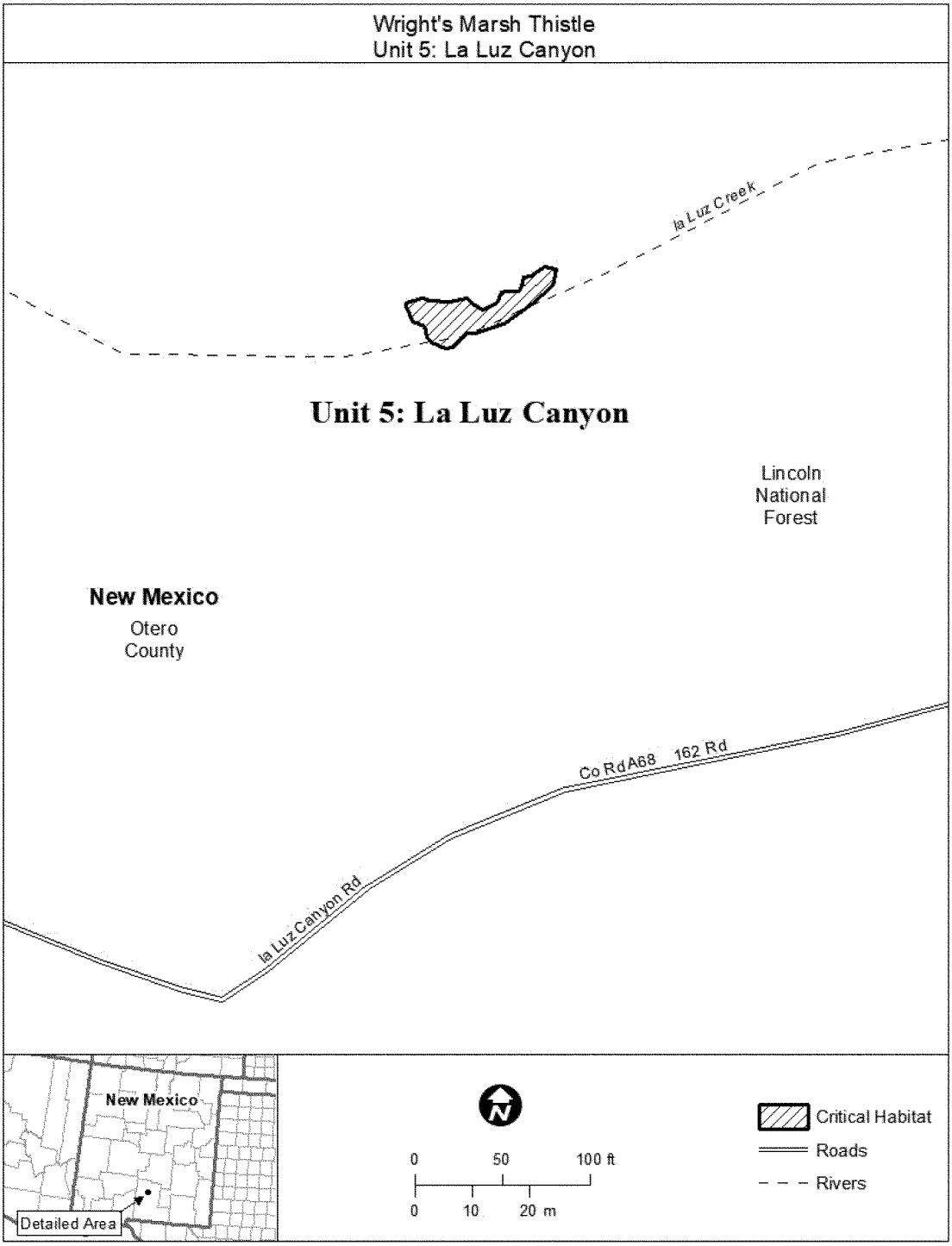
(ii) Map of Unit 4 follows:



(10) Unit 5: La Luz Canyon, Otero County, New Mexico.

(i) *General description:* Unit 5 consists of 0.01 ha (0.03 ac) in Otero County, New Mexico, and is composed of lands under Federal management, specifically the U.S. Forest Service's Lincoln National Forest.

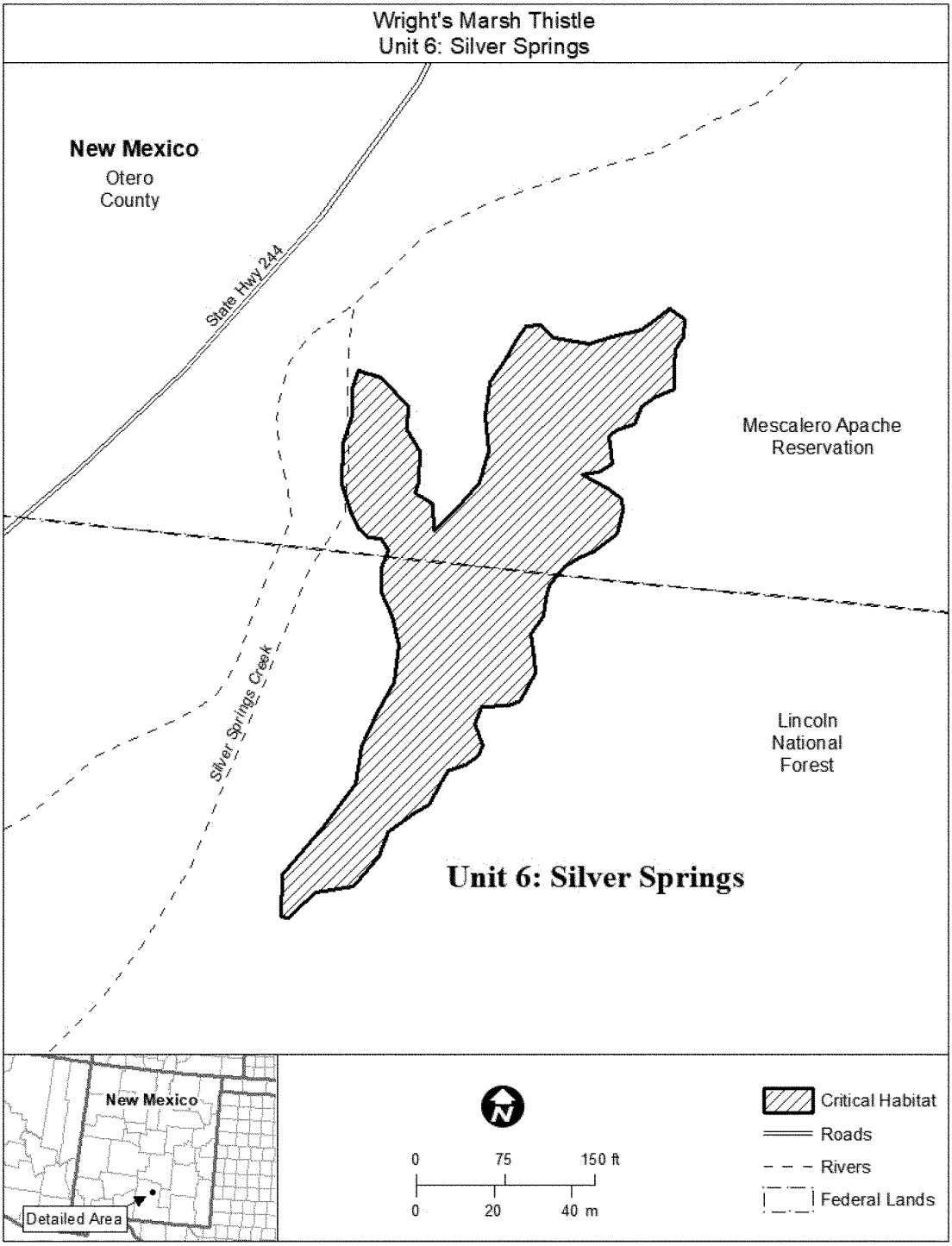
(ii) Map of Unit 5 follows:



(11) Unit 6: Silver Springs, Otero County, New Mexico.

(i) *General description:* Unit 6 consists of 0.62 ha (1.53 ac) in Otero County, New Mexico, and is composed of lands under Federal management (0.38 ha (0.95 ac)), specifically the U.S. Forest Service's Lincoln National Forest, and tribal ownership (0.23 ha (0.58 ac)).

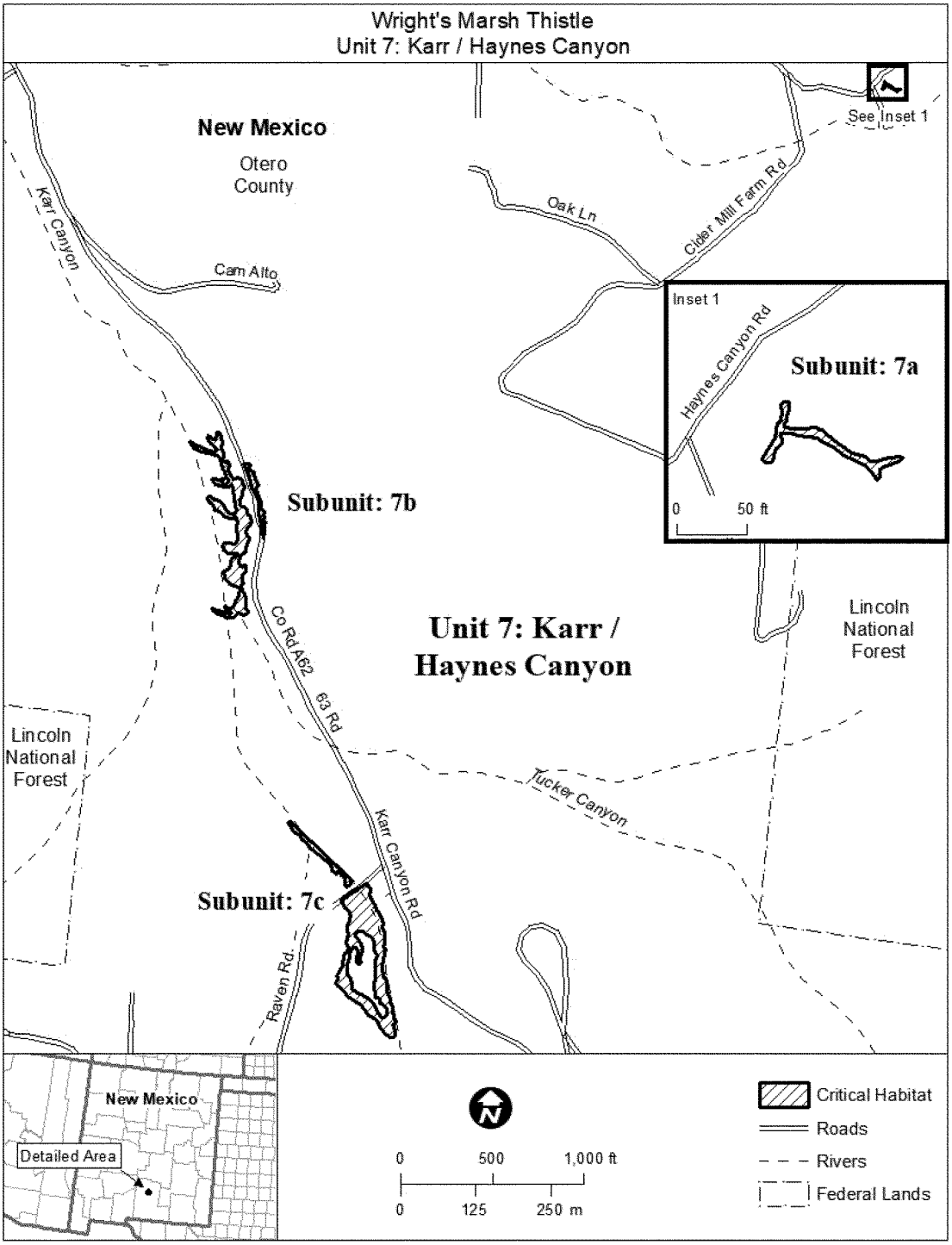
(ii) Map of Unit 6 follows:



(12) Unit 7: Karr/Haynes Canyon, Otero County, New Mexico.

(i) *General description:* Unit 7 consists of 1.79 ha (4.42 ac) in Otero County, New Mexico, and is composed of lands in private ownership.

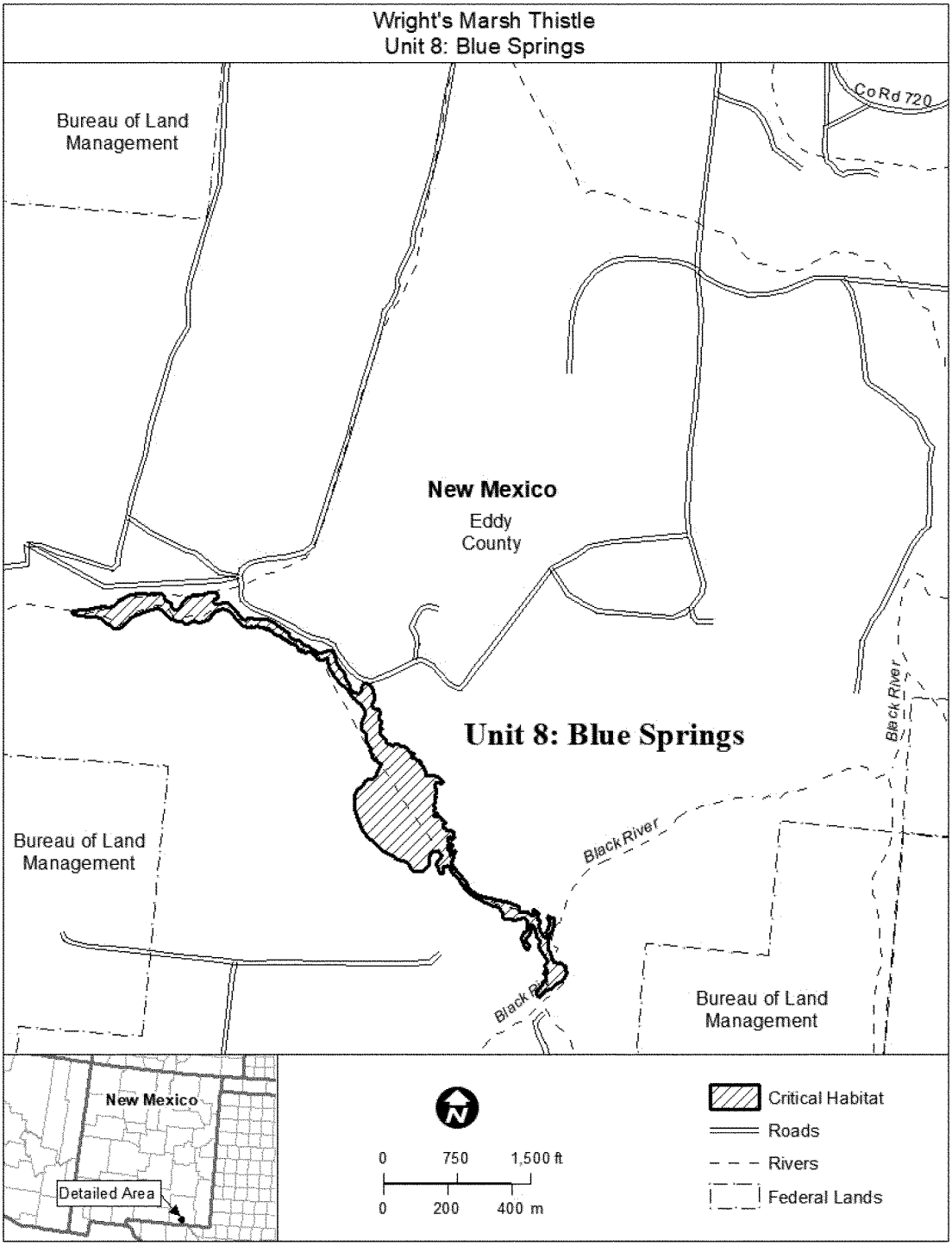
(ii) Map of Unit 7 follows:



(13) Unit 8: Blue Springs, Eddy County, New Mexico.

(i) *General description:* Unit 8 consists of 14.04 ha (34.7 ac) in Eddy County, New Mexico, and is composed of lands in private ownership.

(ii) Map of Unit 8 follows:



* * * * *

Aurelia Skipwith,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2020–19337 Filed 9–28–20; 8:45 am]

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FEDERAL REGISTER

Vol. 85 Tuesday,
No. 189 September 29, 2020

Part V

Department of Defense

Defense Acquisition Regulations System
48 CFR Parts 203, 204, 205, et al.
Defense Federal Acquisition Regulations; Interim Rules and Final Rule

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 225, and 252

[Docket DARS–2020–0035]

RIN 0750–AK94

Defense Federal Acquisition Regulation Supplement: Restriction on the Acquisition of Tantalum (DFARS Case 2020–D007)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Interim rule.

SUMMARY: DoD is issuing an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2020 that prohibits the acquisition of tantalum metal and alloys from North Korea, China, Russia, and Iran.

DATES: Effective October 1, 2020.

Comments on the interim rule should be submitted in writing to the address shown below on or before November 30, 2020, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2020–D007, using any of the following methods:

○ *Federal eRulemaking Portal: http://www.regulations.gov.* Search for ''DFARS Case 2020–D007'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select ''Comment Now'' and follow the instructions to submit a comment. Please include your name, company name (if any), and ''DFARS Case 2020–D007'' on any attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2020–D007 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Amy Williams, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is revising the DFARS to implement section 849 of the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116–92). Section 849 adds tantalum to the definition of ''covered materials'' in 10 U.S.C. 2533c. With some exceptions, 10 U.S.C. 2533c prohibits the acquisition of any covered material melted or produced in any covered country (North Korea, China, Russia, or Iran), or any end item, manufactured in any covered country, that contains a covered material. ''Covered material'' also includes samarium-cobalt magnets, neodymium-iron-boron magnets, tungsten metal powder, and tungsten heavy alloy or any finished or semi-finished components containing tungsten heavy alloy.

II. Discussion and Analysis

This rule adds tantalum to the restriction at DFARS 225.7018, by amending the title of the section, adding ''tantalum metal and alloys'' to the definition of ''covered material'' at DFARS 225.7018–1, and including tantalum in the explanation of exceptions at DFARS 225.7018–3 paragraphs (c)(1)(ii) (exception for commercially available off-the-shelf (COTS) items inapplicable to a mill product that has not been incorporated into an end item, subsystem, assembly, or component) and (d)(1) (meaning of nonavailabilty of a covered material in the required form). Although the 10 U.S.C. 2533c provides that the exception to the restriction on tungsten for COTS items does not apply to a COTS item that is 50 percent or more tungsten by weight, DoD notes that section 849 does not add a similar condition with regard to tantalum metal and alloys.

In addition, a new paragraph (c) is added at DFARS 225.7018–2, Restriction, to explain that the restriction on production of tantalum metal and alloys, including the reduction of tantalum chemicals such as oxides, chlorides, or potassium salts, to metal powder and all subsequent phases of production of tantalum metal and alloys, such as consolidation of metal powders.

These same changes are also incorporated in the clause at 252.225–7052, now titled ''Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten,'' and there are conforming changes to the clause title at DFARS 212.301(f)(ix)(FF) and 225.7018–5. There are no changes to the procedures for nonavailability determinations.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule amends the clause at DFARS 252.225–7052, Restriction on Acquisition of Certain High Performance Magnets and Tungsten, to apply to tantalum. DFARS 252.225–7052 does not apply to acquisitions below the simplified acquisition threshold, in accordance with 41 U.S.C. 1905, but applies to contracts for the acquisition of commercial items, except as provided in the statute at 10 U.S.C. 2533c(c)(3).

A. Applicability to Contracts at or Below the Simplified Acquisition Threshold

41 U.S.C. 1905 governs the applicability of laws to contracts or subcontracts in amounts not greater than the simplified acquisition threshold. It is intended to limit the applicability of laws to such contracts or subcontracts. 41 U.S.C. 1905 provides that if a provision of law contains criminal or civil penalties, or if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt contracts or subcontracts at or below the SAT, the law will apply to them. The Principal Director, Defense Pricing and Contracting (DPC), is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the FAR system of regulations. DoD does not intend to make that determination. Therefore, this rule will not apply below the simplified acquisition threshold.

B. Applicability to Contracts for the Acquisition of Commercial Items, Including COTS Items

10 U.S.C. 2375 governs the applicability of laws to contracts and subcontracts for the acquisition of commercial items, including COTS items, and is intended to limit the applicability of laws to contracts and subcontracts for the acquisition of commercial items, including COTS items. 10 U.S.C. 2375 provides that if a provision of law contains criminal or civil penalties, or if the Under Secretary of Defense (Acquisition and Sustainment) (USD (A&S)) makes a written determination that it is not in the best interest of the Federal

Government to exempt commercial item contracts, the provision of law will apply to contracts for the acquisition of commercial items. Due to delegations of authority from USD (A&S), the Principal Director, DPC, is the appropriate authority to make this determination. DoD has made that determination to apply this rule to the acquisition of commercial items, including COTS items, if otherwise applicable.

10 U.S.C. 2533c specifically exempts the acquisition of an end item that is a COTS item, other than a COTS item that is 50 percent or more tungsten by weight, or a mill product that has not been incorporated into an end item, subsystem, assembly, or component. Although 10 U.S.C. 2533c does not refer to 10 U.S.C. 2375 and does not provide that, notwithstanding that statute, it shall be applicable to contracts for the procurement of commercial items, it is the clear intent of 10 U.S.C. 2533c to cover commercial items other than those specifically exempted. Therefore, DoD has signed a determination of applicability to acquisitions of commercial items, except as exempted in the statute.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This rule is not subject to the requirements of E.O. 13771, because this rule is issued with respect to a national security function of the United States.

VI. Regulatory Flexibility Act

DoD does not expect this interim rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an initial regulatory flexibility analysis (IRFA) has been performed and is summarized as follows:

This rule is required to implement section 849 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020.

The objective of the rule is to prohibit acquisition of tantalum metal and alloys from North Korea, China, Russia, or Iran.

Based on Federal Procurement Data System data for FY 2017, DoD awarded in the United States 13,400 contracts that exceeded $250,000 and were for the acquisition of manufactured end products, excluding those categories that could not include tantalum (such as clothing and fabrics, books, or lumber products). These contracts were awarded to 5,073 unique entities, of which 3,074 were small entities. It is not known what percentage of these awards involved tantalum, or what lesser percentage might involve tantalum from China, North Korea, Russia, or Iran.

There are no projected reporting or recordkeeping requirements. However, there may be compliance costs to track the origin of covered materials.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

DoD is exempting acquisitions equal to or less than the simplified acquisition threshold in accordance with 41 U.S.C. 1905. DoD was unable to identify any other alternatives that would reduce burden on small businesses and still meet the objectives of the statute.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2020–D007), in correspondence.

VII. Paperwork Reduction Act

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

VIII. Determination To Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense that urgent and compelling reasons exist to promulgate this interim rule without prior opportunity for public comment. Section 849 adds tantalum to the other covered materials prohibited by 10 U.S.C. 2533c if melted or produced in any covered country or any end item that contains a covered material manufactured in any covered country. Covered countries are North Korea, China, Russia, and Iran.

Implementation of this prohibition is urgent, because the law was effective upon enactment (December 2019) and decreasing our dependence on covered materials that originate in covered countries is a matter of national security. It is a matter of national security to reduce U.S. dependence on the covered countries specified in section 849, because tantalum is an important element in the supply chain for production of both U.S. military systems, and nonmilitary systems that DoD uses. A shortage of supply of these covered materials would therefore hinder maintenance and replacement of many DoD military systems, and would also have a negative impact on the broader industrial base upon which DoD depends. Restricting acquisition from China and the other covered countries will promote growth in domestic capability and reduce dependence on foreign sources that are not our allies.

However, pursuant to 41 U.S.C. 1707 and FAR 1.501–3(b), DoD will consider public comments received in response to this interim rule in the formation of the final rule.

List of Subjects in 48 CFR Parts 212, 225, and 252

Government procurement.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

■ Therefore, 48 CFR parts 212, 225, and 252 are amended as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 2. Amend section 212.301 by revising paragraph (f)(ix)(FF) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

* * * * *

(f) * * *

(ix) * * *

(FF) Use the clause at 252.225–7052, Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten, as prescribed in 225.7018–5.

* * * * *

PART 225—FOREIGN ACQUISITION

■ 3. Amend section 225.7002–2 by revising paragraph (b)(2) to read as follows:

225.7002–2 Exceptions.

* * * * *

(b) * * *

(2) The supporting documentation for the determination shall include an analysis and written certification by the requiring activity, with specificity, why alternatives that would not require a domestic nonavailability determination are unacceptable.

* * * * *

■ 4. Amend section 225.7003–3 by revising paragraph (b)(5)(i) to read as follows:

225.7003–3 Exceptions.

* * * * *

(b) * * *

(5) * * *

(i) The Secretary of the military department concerned is authorized, without power of redelegation, to make a domestic nonavailability determination that applies to only one contract. The supporting documentation for the determination shall include an analysis and written documentation by the requiring activity, with specificity, why alternatives that would not require a domestic nonavailability determination are unacceptable.

* * * * *

■ 5. Revise the section 225.7018 heading to read as follows:

225.7018 Restriction on acquisition of certain magnets, tantalum, and tungsten.

* * * * *

■ 6. In section 225.7018–1 revise the definition of ''Covered material'' to read as follows:

225.7018–1 Definitions.

* * * * *

Covered material means—

(1) Samarium-cobalt magnets;

(2) Neodymium-iron-boron magnets;

(3) Tantalum metal and alloys;

(4) Tungsten metal powder; and

(5) Tungsten heavy alloy or any finished or semi-finished component containing tungsten heavy alloy.

* * * * *

■ 7. Amend 225.7018–2 by—

■ a. Redesignating paragraph (c) as paragraph (d); and

■ b. Adding a new paragraph (c).

The addition reads as follows:

225.7018–2 Restriction.

* * * * *

(c) For production of tantalum metal and alloys, this restriction includes the reduction of tantalum chemicals such as oxides, chlorides, or potassium salts, to metal powder and all subsequent phases of production of tantalum metal and alloys, such as consolidation of metal powders.

* * * * *

225.7018–3 [Amended]

■ 8. Amend section 225.7018–3 by—

■ a. In (c)(1)(ii) removing ''tungsten heavy alloy mill product'' and adding ''tantalum metal, tantalum alloy, or tungsten heavy alloy mill product'' in its place;

■ b. In (c)(2) removing ''PGI 225.7018–3(c)(1)(ii)'' and adding ''PGI 225.7018–3(c)(2)'' in its place;

■ c. In paragraph (d) introductory text removing ''concerned,'' and adding ''concerned, as specified in 225.7018–4,'' in its place; and

■ d. In paragraph (d)(1) removing ''tungsten heavy alloy'' and adding ''tantalum metal, tantalum alloy, or tungsten heavy alloy'' in its place.

■ 9. Amend section 225.7018–4 by—

■ a. Revising paragraph (a)(2); and

■ b. In paragraph (a)(3)(ii) removing ''individual waivers'' and adding ''individual nonavailability determinations'' in its place.

The revision reads as follows:

225.7018–4 Nonavailability determination.

(a) * * *

(2) The supporting documentation for the determination shall include an analysis and written certification by the requiring activity that describes, with specificity, why alternatives that would not require a nonavailability determination are unacceptable. The template for an individual nonavailability determination is available at PGI 225.7018–4(a)(2).

* * * * *

225.7018–5 [Amended]

■ 10. Amend section 225.7018–5 by removing ''Magnets and Tungsten'' and adding ''Magnets, Tantalum, and Tungsten'' in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 11. Amend section 252.225–7052 by—

■ a. Revising the section heading, clause title, and clause date;

■ b. In paragraph (a) revising the definition of ''Covered material'';

■ c. Redesignating paragraph (b)(3) as paragraph (b)(4);

■ d. Adding new paragraph (b)(3);

■ e. In paragraphs (c)(1)(i)(B) and (c)(2)(i) removing ''tungsten heavy alloy'' and adding ''tantalum metal, tantalum alloy, or tungsten heavy alloy'' in both places; and

■ f. Adding a paragraph heading to paragraph (d).

The revisions and additions read as follows:

252.225–7052 Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten.

* * * * *

Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten (Oct 2020)

(a) * * *

Covered material means—

(1) Samarium-cobalt magnets;

(2) Neodymium-iron-boron magnets;

(3) Tantalum metal and alloys;

(4) Tungsten metal powder; and

(5) Tungsten heavy alloy or any finished or semi-finished component containing tungsten heavy alloy.

* * * * *

(b) * * *

(3) For production of tantalum metal and alloys, this restriction includes the reduction of tantalum chemicals such as oxides, chlorides, or potassium salts, to metal powder and all subsequent phases of production of tantalum metal and alloys, such as consolidation of metal powders.

* * * * *

(d) *Subcontracts.* * * *

[FR Doc. 2020–21121 Filed 9–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

48 CFR Parts 203, 205, 211, 212, 215, 217, 219, 225, 228, 236, 237, 246, 250, and 252

[Docket DARS–2020–0002]

RIN 0750–AK76

Defense Federal Acquisition Regulation Supplement: Inflation Adjustment of Acquisition-Related Thresholds (DFARS Case 2019–D036)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement the inflation adjustment of acquisition-related dollar thresholds. A statute requires an adjustment every five years of acquisition-related thresholds for inflation using the Consumer Price Index for all urban consumers, except for the Construction Wage Rate Requirements statute (Davis-Bacon Act), Service Contract Labor Standards statute, and trade agreements

thresholds. DoD also used the same methodology to adjust some nonstatutory DFARS acquisition-related thresholds.

DATES: Effective October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly R. Ziegler, Telephone 571–372–6095.

SUPPLEMENTARY INFORMATION:

I. Background

This rule amends multiple DFARS parts to further implement 41 U.S.C. 1908. Section 1908 requires an adjustment every five years (on October 1 of each year evenly divisible by five) of statutory acquisition-related thresholds for inflation, using the Consumer Price Index (CPI) for all urban consumers, except for the Construction Wage Rate Requirements statute (Davis-Bacon Act), Service Contract Labor Standards statute, and trade agreements thresholds (see FAR 1.109). As a matter of policy, DoD also uses the same methodology to adjust some nonstatutory DFARS acquisition-related thresholds.

DoD published a proposed rule in the **Federal Register** at 85 FR 19716 on April 8, 2020. The preamble to the proposed rule contained detailed explanation of—

- What an acquisition-related threshold is;
- What acquisition-related thresholds are not subject to escalation adjustment under this case; and
- How DoD analyzes statutory and non-statutory acquisition-related thresholds.

No respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis

Although there were no public comments, two corrections were made to the final rule to: (1) Add the threshold at DFARS 215.403–1(c)(4)(B) and 225.7201; and (2) update the threshold pointer, an address, and web page citation at DFARS 252.225–7004.

Although the actual CPI of 258.115 for March 2020 was lower than the projected CPI of 258.606 for March 2020 used for the proposed rule, the difference was insignificant and did not result in revisions to any proposed threshold increases. The final rule is based on the actual CPI of 258.115 for March 2020. The CPI as of the end of March 2020, 6 months before the effective date of the rule, is used as the cutoff in order to allow time for approval and publication of the final rule.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not create any new provisions or clauses, nor does it change the applicability of any existing provisions or clauses included in solicitations and contracts valued at or below the simplified acquisition threshold, or for commercial items, including COTS items.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

The rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act.

DoD has prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This rule amends the Defense Federal Acquisition Regulation Supplement to implement 41 U.S.C. 1908 and other acquisition-related dollar thresholds that are based on policy rather than statute in order to adjust for the changing value of the dollar. 41 U.S.C. 1908 requires adjustment every five years of statutory acquisition-related dollar thresholds, except for Construction Wage Rate Requirements statute (Davis-Bacon Act), Service Contract Labor Standards statute, and trade agreements thresholds. While reviewing all statutory acquisition-related thresholds, this case presented an opportunity to also review all nonstatutory acquisition-related thresholds in the DFARS that are based on policy. The objective of the rule is to maintain the status quo, by adjusting acquisition-related thresholds for inflation.

This rule will likely affect to some extent all small business concerns that submit offers or are awarded contracts by the Department of Defense (DoD). However, the threshold changes in this rule are not expected to have any significant economic impact on small business concerns because they are intended to maintain the status quo by adjusting for changes in the value of the dollar. Data generated from the Federal Procurement Data System (FPDS) for fiscal years 2017 through 2019, indicates that the DoD has awarded an average of 1,494,202 contracts to 56,851 unique small entities during the three year period. It is assumed that all 56,851 unique small entities may be affected by this rule, however, the impact will most likely be beneficial, by preventing burdensome requirements from applying to more and more acquisitions, as the dollar loses value.

The rule does not impose any new reporting, recordkeeping, or compliance requirements. Changes in thresholds for approved information collection requirements are intended to maintain the status quo and prevent those requirements from increasing over time.

There are no practical alternatives that will accomplish the objectives of the statute.

VII. Paperwork Reduction Act

The Paperwork Reduction Act does apply. The changes to the DFARS do not impose new information collection requirements that require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.* By adjusting the thresholds for inflation, the status quo for the current information collection requirements are maintained under OMB clearance numbers 0704–0229, DFARS Part 225, Foreign Acquisition and related clauses and 0704–0286, DFARS Part 205, Publicizing Contract Actions and Provision of Information to Cooperative Agreement Holders.

List of Subjects in 48 CFR Parts 203, 205, 207, 211, 212, 215, 217, 219, 225, 228, 232, 234, 236, 237, 250, and 252

Government Procurement.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 203, 205, 211, 212, 215, 217, 219, 225, 228, 236, 237, 246, 250, and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 203, 205, 211, 212, 215, 217, 219,

225, 228, 236, 237, 246, 250, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 203—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

203.1004 [Amended]

■ 2. Amend section 203.1004 in paragraph (b)(2)(ii) by removing ''$5.5 million'' and adding ''$6 million'' in its place.

PART 205—PUBLICIZING CONTRACT ACTIONS

205.303 [Amended]

■ 3. Amend section 205.303 by removing ''$7 million'' wherever it appears and adding ''$7.5 million'' in its place.

205.470 [Amended]

■ 4. Amend section 205.470 by removing ''$1,000,000'' and adding ''$1.5 million'' in its place.

PART 211—DESCRIBING AGENCY NEEDS

211.503 [Amended]

■ 5. Amend section 211.503 in paragraph (b) by removing ''$700,000'' and adding ''$750,000'' in its place in two places.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

212.271 [Amended]

■ 6. Amend section 212.271 by removing ''$40,000'' and adding ''$45,000'' in its place.

PART 215—CONTRACTING BY NEGOTIATION

215.403–1 [Amended]

■ 7. Amend section 215.403–1 in paragraph (c)(4)(B) by removing ''$19.5 million'' and adding ''$20 million'' in its place.

PART 217—SPECIAL CONTRACTING METHODS

217.170 [Amended]

■ 8. Amend section 217.170 in paragraphs (d)(1)(iv) and (d)(5) introductory text by removing ''$135.5 million'' and adding ''$150 million'' in its place in both places.

217.171 [Amended]

■ 9. Amend section 217.171 in paragraph (d) by removing ''$678.5 million'' and adding ''$750 million'' in its place.

217.172 [Amended]

■ 10. Amend section 217.172 in paragraphs (c), (d), and (f)(1) and (2) by removing ''$678.5 million'' and adding ''$750 million'' in its place wherever it appears.

PART 219—SMALL BUSINESS PROGRAMS

219.502–2 [Amended]

■ 11. Amend section 219.502–2 in paragraph (1) by removing ''$2.5 million'' and adding ''$3 million'' in its place.

PART 225—FOREIGN ACQUISITION

■ 12. Revise section 225.7201 to read as follows:

225.7201 Policy.

10 U.S.C. 2410g requires offerors and contractors to notify DoD of any intention to perform any part of a DoD contract outside the United States and Canada that—

(a) Exceeds $750,000 in value; and

(b) Could be performed inside the United States or Canada.

225.7204 [Amended]

■ 12. Amend section 225.7204 in paragraphs (a) and (b) by removing ''$13.5 million'' and adding ''$15 million'' in its place in both places.

225.7703–2 [Amended]

■ 13. Amend section 225.7703–2—

■ a. In paragraph (b)(2)(i) by removing ''$93 million'' and adding ''$100 million'' in its place; and

■ b. In paragraph (b)(2)(ii) introductory text by removing ''Director, Defense Procurement and Acquisition Policy'' and adding ''Principal Director, Defense Pricing and Contracting'' in its place and by removing ''$93 million'' and adding ''$100 million'' in its place.

PART 228—BONDS AND INSURANCE

228.102–1 [Amended]

■ 14. Amend section 228.102–1 in the introductory text and paragraph (1) by removing ''$35,000'' and adding ''$40,000'' in its place in both places.

PART 236—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

236.303–1 [Amended]

■ 15. Amend section 236.303–1 in paragraph (a)(4)(i) introductory text and (a)(4)(ii) by removing ''$4 million'' and adding ''$4.5 million'' in its place in both places.

PART 237—SERVICE CONTRACTING

237.170–2 [Amended]

■ 16. Amend section 237.170–2 in paragraphs (a)(1) and (2) by removing ''$93 million'' and adding ''$100 million'' in its place in both places.

PART 246—QUALITY ASSURANCE

■ 17. Amend section 246.402 introductory text by removing ''$300,000'' and adding ''$350,000'' in its place.

PART 250—EXTRAORDINARY CONTRACTUAL ACTIONS AND THE SAFETY ACT

250.102–1 [Amended]

■ 18. Amend section 250.102–1 in paragraph (b) by removing ''$70,000'' and adding ''$75,000'' in its place.

250.102–1–70 [Amended]

■ 19. Amend section 250.102–1–70 in paragraph (b)(1) by removing ''$70,000'' and adding ''$75,000'' in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.225–7003 [Amended]

■ 20. Amend section 252.225–7003 by—

■ a. Removing the clause date ''(OCT 2015)'' and adding ''(OCT 2020)'' in its place; and

■ b. In paragraph (b)(1), removing ''$13.5 million'' and adding ''$15 million'' in its place; and

■ c. In paragraph (b)(2)(i) removing ''$700,000'' and adding ''$750,000'' in its place.

252.225–7004 [Amended]

■ 21. Amend section 252.225–7004 by—

■ a. Removing the clause date ''(MAY 2019)'' and adding ''(OCT 2020)'' in its place;

■ b. In paragraph (b)(1), removing ''225.870–4(c)(2)(i)(A)(*1*)'' and adding 225.7201(a)'' in its place;

■ c. In paragraph (c)(5) removing ''Deputy Director of Defense Procurement and Acquisition Policy (Contract Policy and International Contracting), OUSD(AT&L) DPAP/CPIC'' and adding ''Principal Director, Defense Pricing and Contracting (Contract Policy), OUSD(A&S) DPC/CP'' in its place; and

■ d. In paragraph (d)(2), removing ''*http://www.dtic.mil/whs/directives/infomgt/forms/formsprogram.htm*'' and adding ''*https://www.esd.whs.mil/Directives/forms/*'' in its place.

[FR Doc. 2020–21122 Filed 9–28–20; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 204, 212, 217, and 252

[Docket DARS–2020–0034]

RIN 0750–AJ81

Defense Federal Acquisition Regulation Supplement: Assessing Contractor Implementation of Cybersecurity Requirements (DFARS Case 2019–D041)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Interim rule.

SUMMARY: DoD is issuing an interim rule to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a DoD Assessment Methodology and Cybersecurity Maturity Model Certification framework in order to assess contractor implementation of cybersecurity requirements and enhance the protection of unclassified information within the DoD supply chain.

DATES: Effective November 30, 2020.

Comments on the interim rule should be submitted in writing to the address shown below on or before November 30, 2020, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2019–D041, using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Search for ''DFARS Case 2019–D041''. Select ''Comment Now'' and follow the instructions provided to submit a comment. Please include ''DFARS Case 2019–D041'' on any attached documents.
- *Email: osd.dfars@mail.mil.* Include DFARS Case 2019–D041 in the subject line of the message.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Ms. Heather Kitchens, telephone 571–372–6104.

SUPPLEMENTARY INFORMATION:

I. Background

The theft of intellectual property and sensitive information from all U.S. industrial sectors due to malicious cyber activity threatens economic security and national security. The Council of Economic Advisors estimates that malicious cyber activity cost the U.S. economy between $57 billion and $109 billion in 2016. Over a ten-year period, that burden would equate to an estimated $570 billion to $1.09 trillion dollars in costs. As part of multiple lines of effort focused on the security and resiliency of the Defense Industrial Base (DIB) sector, the Department is working with industry to enhance the protection of unclassified information within the supply chain. Toward this end, DoD has developed the following assessment methodology and framework to assess contractor implementation of cybersecurity requirements, both of which are being implemented by this rule: the National Institute of Standards and Technology (NIST) Special Publication (SP) 800–171 DoD Assessment Methodology and the Cybersecurity Maturity Model Certification (CMMC) Framework. The NIST SP 800–171 DoD Assessment and CMMC assessments will not duplicate efforts from each assessment, or any other DoD assessment, except for rare circumstances when a re-assessment may be necessary, such as, but not limited to, when cybersecurity risks, threats, or awareness have changed, requiring a re-assessment to ensure current compliance.

A. NIST SP 800–171 DoD Assessment Methodology

DFARS clause 252.204–7012, Safeguarding Covered Defense Information and Cyber Incident Reporting, is included in all solicitations and contracts, including those using Federal Acquisition Regulation (FAR) part 12 commercial item procedures, except for acquisitions solely for commercially available off-the-shelf (COTS) items. The clause requires contractors to apply the security requirements of NIST SP 800–171 to ''covered contractor information systems,'' as defined in the clause, that are not part of an IT service or system operated on behalf of the Government. The NIST SP 800–171 DoD Assessment Methodology provides for the assessment of a contractor's implementation of NIST SP 800-171 security requirements, as required by DFARS clause 252.204–7012. More information on the NIST SP 800–171 DoD Assessment Methodology is available at *https://www.acq.osd.mil/dpap/pdi/cyber/strategically_assessing_contractor_implementation_of_NIST_SP_800-171.html.*

The Assessment uses a standard scoring methodology, which reflects the net effect of NIST SP 800–171 security requirements not yet implemented by a contractor, and three assessment levels (Basic, Medium, and High), which reflect the depth of the assessment performed and the associated level of confidence in the score resulting from the assessment. A Basic Assessment is a self-assessment completed by the contractor, while Medium or High Assessments are completed by the Government. The Assessments are completed for each covered contractor information system that is relevant to the offer, contract, task order, or delivery order.

The results of Assessments are documented in the Supplier Performance Risk System (SPRS) at *https://www.sprs.csd.disa.mil/* to provide DoD Components with visibility into the scores of Assessments already completed; and verify that an offeror has a current (*i.e.,* not more than three years old, unless a lesser time is specified in the solicitation) Assessment, at any level, on record prior to contract award.

B. Cybersecurity Maturity Model Certification Framework

Building upon the NIST SP 800–171 DoD Assessment Methodology, the CMMC framework adds a comprehensive and scalable certification element to verify the implementation of processes and practices associated with the achievement of a cybersecurity maturity level. CMMC is designed to provide increased assurance to the Department that a DIB contractor can adequately protect sensitive unclassified information such as Federal Contract Information (FCI) and Controlled Unclassified Information (CUI) at a level commensurate with the risk, accounting for information flow down to its subcontractors in a multi-tier supply chain. A DIB contractor can achieve a specific CMMC level for its entire enterprise network or particular segment(s) or enclave(s), depending upon where the information to be protected is processed, stored, or transmitted.

The CMMC model consists of maturity processes and cybersecurity best practices from multiple cybersecurity standards, frameworks, and other references, as well as inputs from the broader community. The CMMC levels and the associated sets of processes and practices are cumulative. The CMMC model encompasses the basic safeguarding requirements for FCI specified in FAR clause 52.204–21, Basic Safeguarding of Covered

Contractor Information Systems, and the security requirements for CUI specified in NIST SP 800–171 per DFARS clause 252.204–7012. Furthermore, the CMMC model includes an additional five processes and 61 practices across Levels 2–5 that demonstrate a progression of cybersecurity maturity.

Level	Description
1	Consists of the 15 basic safeguarding requirements from FAR clause 52.204–21.
2	Consists of 65 security requirements from NIST SP 800–171 implemented via DFARS clause 252.204–7012, 7 CMMC practices, and 2 CMMC processes. Intended as an optional intermediary step for contractors as part of their progression to Level 3.
3	Consists of all 110 security requirements from NIST SP 800–171, 20 CMMC practices, and 3 CMMC processes.
4	Consists of all 110 security requirements from NIST SP 800–171, 46 CMMC practices, and 4 CMMC processes.
5	Consists of all 110 security requirements from NIST SP 800–171, 61 CMMC practices, and 5 CMMC processes.

In order to achieve a specific CMMC level, a DIB company must demonstrate both process institutionalization or maturity and the implementation of practices commensurate with that level. CMMC assessments will be conducted by accredited CMMC Third Party Assessment Organizations (C3PAOs). Upon completion of a CMMC assessment, a company is awarded a certification by an independent CMMC Accreditation Body (AB) at the appropriate CMMC level (as described in the CMMC model). The certification level is documented in SPRS to enable the verification of an offeror's certification level and currency (*i.e.* not more than three years old) prior to contract award. Additional information on CMMC and a copy of the CMMC model can be found at *https://www.acq.osd.mil/cmmc/index.html.*

DoD is implementing a phased rollout of CMMC. Until September 30, 2025, the clause at 252.204–7021, Cybersecurity Maturity Model Certification Requirements, is prescribed for use in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items, excluding acquisitions exclusively for COTS items, if the requirement document or statement of work requires a contractor to have a specific CMMC level. In order to implement the phased rollout of CMMC, inclusion of a CMMC requirement in a solicitation during this time period must be approved by the Office of the Under Secretary of Defense for Acquisition and Sustainment.

CMMC will apply to all DoD solicitations and contracts, including those for the acquisition of commercial items (except those exclusively COTS items) valued at greater than the micro-purchase threshold, starting on or after October 1, 2025. Contracting officers will not make award, or exercise an option on a contract, if the offeror or contractor does not have current (*i.e.* not older than three years) certification for the required CMMC level. Furthermore, CMMC certification requirements are required to be flowed down to subcontractors at all tiers, based on the sensitivity of the unclassified information flowed down to each subcontractor.

II. Discussion and Analysis

A. NIST SP 800–171 DoD Assessment Methodology

This rule amends DFARS subpart 204.73, Safeguarding Covered Defense Information and Cyber Incident Reporting, to implement the NIST SP 800–171 DoD Assessment Methodology. The new coverage in the subpart directs contracting officers to verify in SPRS that an offeror has a current NIST SP 800–171 DoD Assessment on record, prior to contract award, if the offeror is required to implement NIST SP 800–171 pursuant to DFARS clause 252.204–7012. The contracting officer is also directed to include a new DFARS provision 252.204–7019, Notice of NIST SP 800–171 DoD Assessment Requirements, and a new DFARS clause 252.204–7020, NIST SP 800–171 DoD Assessment Requirements, in solicitations and contracts including solicitations using FAR part 12 procedures for the acquisition of commercial items, except for solicitations solely for the acquisition of COTS items.

The new DFARS provision 252.204–7019 advises offerors required to implement the NIST SP 800–171 standards of the requirement to have a current (not older than three years) NIST SP 800–171 DoD Assessment on record in order to be considered for award. The provision requires offerors to ensure the results of any applicable current Assessments are posted in SPRS and provides offerors with additional information on conducting and submitting an Assessment when a current one is not posted in SPRS.

The new DFARS clause 252.204–7020 requires a contractor to provide the Government with access to its facilities, systems, and personnel when it is necessary for DoD to conduct or renew a higher-level Assessment. The clause also requires the contractor to ensure that applicable subcontractors also have the results of a current Assessment posted in SPRS prior to awarding a subcontract or other contractual instruments. The clause also provides additional information on how a subcontractor can conduct and submit an Assessment when one is not posted in SPRS, and requires the contractor to include the requirements of the clause in all applicable subcontracts or other contractual instruments.

B. Cybersecurity Maturity Model Certification

This rule adds a new DFARS subpart, Subpart 204.75, Cybersecurity Maturity Model Certification (CMMC), to specify the policy and procedures for awarding a contract, or exercising an option on a contract, that includes the requirement for a CMMC certification. Specifically, this subpart directs contracting officers to verify in SPRS that the apparently successful offeror's or contractor's CMMC certification is current and meets the required level prior to making the award.

A new DFARS clause 252.204–7021, Cybersecurity Maturity Model Certification Requirements, is prescribed for use in all solicitations and contracts or task orders or delivery orders, excluding those exclusively for the acquisition of COTS items. This DFARS clause requires a contractor to: Maintain the requisite CMMC level for the duration of the contract; ensure that its subcontractors also have the appropriate CMMC level prior to awarding a subcontract or other contractual instruments; and include the requirements of the clause in all subcontracts or other contractual instruments.

The Department took into consideration the timing of the requirement to achieve a CMMC level certification in the development of this rule, weighing the benefits and risks associated with requiring CMMC level certification: (1) At time of proposal or offer submission; (2) at time of award;

or (3) after contract award. The Department ultimately adopted alternative 2 to require certification at the time of award. The drawback of alternative 1 (at time of proposal or offer submission) is the increased risk for contractors since they may not have sufficient time to achieve the required CMMC certification after the release of the Request for Information (RFI). The drawback of alternative 3 (after contract award) is the increased risk to the Department with respect to the schedule and uncertainty with respect to the case where the contractor is unable to achieve the required CMMC level in a reasonable amount of time given their current cybersecurity posture. This potential delay would apply to the entire supply chain and prevent the appropriate flow of CUI and FCI. The Department seeks public comment on the timing of contract award, to include the effect of requiring certification at time of award on small businesses.

C. Conforming Changes

This rule also amends the following DFARS sections to make conforming changes:

- Amends the list in DFARS section 212.301 of solicitation provisions and contract clauses that are applicable for the acquisition of commercial items to include the provisions and clauses included in this rule.
- Amends DFARS 217.207, Exercise of Options, to advise contracting officers that an option may only be exercised after verifying the contractor's CMMC level, when CMMC is required in the contract.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule creates the following new solicitation provision and contract clauses:

- DFARS 252.204–7019, Notice of NIST SP 800–171 DoD Assessment Requirements;
- DFARS clause 252.204–7020, NIST SP 800–171 DoD Assessment Requirements; and
- DFARS clause 252.204–7021, Cybersecurity Maturity Model Certification Requirements.

The objective of this rule is provide the Department with: (1) The ability to assess contractor implementation of NIST SP 800–171 security requirements, as required by DFARS clause 252.204–7012, Safeguarding Covered Defense Information and Cyber Incident Reporting; and (2) assurances that DIB contractors can adequately protect sensitive unclassified information at a level commensurate with the risk, accounting for information flowed down to subcontractors in a multi-tier supply chain. Flowdown of the requirements is necessary to respond to threats that reach even the lowest tiers in the supply chain. Therefore, to achieve the desired policy outcome, DoD intends to apply the new provision and clauses to contracts and subcontracts for the acquisition of commercial items and to acquisitions valued at or below the simplified acquisition threshold, but greater than the micro-purchase threshold. The provision and clauses will not be applicable to contracts or subcontracts exclusively for the acquisition of commercially available off-the-shelf items.

IV. Expected Cost Impact and Benefits

A. Benefits

The theft of intellectual property and sensitive information from all U.S. industrial sectors due to malicious cyber activity threatens U.S. economic and national security. The aggregate loss of intellectual property and certain unclassified information from the DoD supply chain can undercut U.S. technical advantages and innovation, as well as significantly increase risk to national security. This rule is expected to enhance the protection of FCI and CUI within the DIB sector.

B. Costs

A Regulatory Impact Analysis (RIA) that includes a detailed discussion and explanation about the assumptions and methodology used to estimate the cost of this regulatory action is available at *www.regulations.gov* (search for ''DFARS Case 2019–D041'' click ''Open Docket,'' and view ''Supporting Documents''). The total estimated public and Government costs (in millions) associated with this rule, calculated in perpetuity in 2016 dollars at a 7 percent discount rate, is provided as follows:

Total cost (in millions)	Public	Govt	Total
Annualized Costs	$6,500.5	$0.3	$6,500.7
Present Value Costs	92,863.6	3.7	92,867.3

The following is a breakdown of the public and Government costs and savings associated with each component of the rule:

1. NIST SP 800–171 DoD Assessments

The following is a summary of the estimated public and Government costs (in millions) associated with the NIST SP DoD Assessments, calculated in perpetuity in 2016 dollars at a 7 percent discount rate:

DoD assessments	Public	Government	Total
Annualized Costs	$6.7	$9.5	$16.3
Present Value Costs	96.1	136.2	232.3

2. CMMC Requirements

The following is a summary of the estimated public and Government costs (in millions) associated with the CMMC requirements, calculated in perpetuity in 2016 dollars at a 7 percent discount rate:

CMMC requirements	Public	Government	Total
Annualized Costs	$6,525.0	$8.9	$6,533.9
Present Value Costs	93,213.6	127.3	93,340.9

3. Elimination of Duplicate Assessments

The following is a summary of the estimated public and Government savings (in millions) associated with the elimination of duplicate assessments, calculated in perpetuity in 2016 dollars at a 7 percent discount rate:

Eliminate duplication	Public	Government	Total
Annualized Savings	-$31.2	-$18.2	-$49.4
Present Value Savings	-446.1	-259.8	-705.9

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is an economically significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is a major rule under 5 U.S.C. 804.

VI. Executive Order 13771

The rule is not subject to the requirements if E.O. 13771, because this rule is being issued with respect to a national security function of the United States.

VII. Regulatory Flexibility Act

DoD expects this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Therefore, an initial regulatory flexibility analysis has been performed and is summarized as follows:

A. Reasons for the Action

This rule is necessary to address threats to the U.S. economy and national security from ongoing malicious cyber activities, which includes the theft of hundreds of billions of dollars of U.S. intellectual property. Currently, the FAR and DFARS prescribe contract clauses intended to protect FCI and CUI within the DoD supply chain. Specifically, the clause at FAR 52.204–21, Basic Safeguarding of Covered Contractor Information Systems, is prescribed at FAR 4.1903 for use in Government solicitations and contracts and requires contractors and subcontractors to apply basic safeguarding requirements when processing, storing, or transmitting FCI in or from covered contractor information systems. The clause focuses on ensuring a basic level of cybersecurity hygiene and is reflective of actions that a prudent business person would employ.

In addition, DFARS clause 252.204–7012, Safeguarding Covered Defense Information and Cyber Incident Reporting, requires defense contractors and subcontractors to provide ''adequate security'' to store, process, or transmit CUI on information systems or networks, and to report cyber incidents that affect these systems or networks. The clause states that to provide adequate security, the Contractor shall implement, at a minimum, the security requirements in ''National Institute of Standards and Technology (NIST) Special Publication (SP) 800–171, Protecting Controlled Unclassified Information (CUI) in Nonfederal Systems and Organizations.'' Contractors are also required to flow down DFARS Clause 252.204–7012 to all subcontracts, which involve CUI.

However, neither the FAR clause, nor the DFARS clause, provide for DoD verification of a contractor's implementation of basic safeguarding requirements or the security requirements specified in NIST SP 800–171 prior to contract award.

Under DFARS clause 252.204–7012, DIB companies self-attest that they will implement the requirements in NIST SP 800–171 upon submission of their offer. A contractor can document implementation of the security requirements in NIST SP 800–171 by having a system security plan in place to describe how the security requirements are implemented, in addition to associated plans of action to describe how and when any unimplemented security requirements will be met. As a result, the current regulation enables contractors and subcontractors to process, store, or transmit CUI without having implemented all of the 110 security requirements and without establishing enforceable timelines for addressing shortfalls and gaps.

Findings from DoD Inspector General report (DODIG–2019–105 ''Audit of Protection of DoD Controlled Unclassified Information on Contractor-Owned Networks and Systems'') indicate that DoD contractors did not consistently implement mandated system security requirements for safeguarding CUI and recommended that DoD take steps to assess a contractor's ability to protect this information. The report emphasizes that malicious actors can exploit the vulnerabilities of contractors' networks and systems and exfiltrate information related to some of the Nation's most valuable advanced defense technologies.

Although DoD contractors must include DFARS clause 252.204–7012 in subcontracts for which subcontract performance will involve covered defense information (DoD CUI), this does not provide the Department with sufficient insights with respect to the cybersecurity posture of DIB companies throughout the multi-tier supply chain for any given program or technology development effort.

Furthermore, given the size and scale of the DIB sector, the Department cannot scale its organic cybersecurity assessment capability to conduct on-site assessments of approximately 220,000 DoD contractors every three years. As a result, the Department's organic assessment capability is best suited for conducting targeted assessments for a subset of DoD contractors.

Finally, the current security requirements specified in NIST SP 800–171 per DFARS clause 252.204–7012, do not sufficiently address additional threats to include Advanced Persistent Threats (APTs).

Because of these issues and shortcomings and the associated risks to national security, the Department determined that the status quo was not acceptable and developed a two-pronged approach to assess and verify the DIB's ability to protect the FCI and CUI on its information systems or networks, which is being implemented by this rule:

- *The National Institute of Standards and Technology (NIST) Special Publication (SP) 800–171 DoD Assessment Methodology.* A standard methodology to assess contractor implementation of the cybersecurity requirements in NIST SP 800–171,

''Protecting Controlled Unclassified Information (CUI) In Nonfederal Systems and Organizations.''

• *The Cybersecurity Maturity Model Certification (CMMC) Framework.* A DoD certification process that measures a company's institutionalization of processes and implementation of cybersecurity practices.

B. Objectives of, and Legal Basis for, the Rule

This rule establishes a requirement for contractors to have a current NIST SP 800–171 DoD Assessment and the appropriate CMMC level certification prior to contract award and during contract performance. The objective of the rule is to provide the Department with: (1) The ability to assess at a corporate-level a contractor's implementation of NIST SP 800–171 security requirements, as required by DFARS clause 252.204–7012, Safeguarding Covered Defense Information and Cyber Incident Reporting; and (2) assurances that a DIB contractor can adequately protect sensitive unclassified information at a level commensurate with the risk, accounting for information flow down to its subcontractors in a multi-tier supply chain.

1. NIST SP 800–171 DoD Assessment Methodology

In February 2019, the Under Secretary of Defense for Acquisition and Sustainment directed the Defense Contract Management Agency (DCMA) to develop a standard methodology to assess contractor implementation of the cybersecurity requirements in NIST SP 800–171 at the corporate or entity level. The DCMA Defense Industrial Base Cybersecurity Assessment Center's NIST SP 800–171 DoD Assessment Methodology is the Department's initial strategic DoD/corporate-wide assessment of contractor implementation of the mandatory cybersecurity requirements established in the contracting regulations. Results of a NIST SP 800–171 DoD Assessment reflect the net effect of NIST SP 800–171 security requirements not yet implemented by a contractor, and may be conducted at one of three assessment levels. The DoD Assessment Methodology provides the following benefits:

• *Enables Strategic Assessments at the Entity-level.* The NIST SP 800–171 DoD Assessment Methodology enables DoD to strategically assess a contractor's implementation of NIST SP 800–171 on existing contracts that include DFARS clause 252.204–7012, and to provide an objective assessment of a contractor's NIST SP 800–171 implementation status.

• *Reduces Duplicative or Repetitive Assessments of our Industry Partners.* Assessment results will be posted in the Supplier Performance Risk System (SPRS), DoD's authoritative source for supplier and product performance information. This will provide DoD Components with visibility to summary level scores, rather than addressing implementation of NIST SP 800–171 on a contract-by-contract approach. Conducting such assessments at a corporate- or entity-level, significantly reduces the need to conduct assessments at the program or contract level, thereby reducing the cost to both DoD and industry.

• *Provides a Standard Methodology for Contractors to Self-assess Their Implementation of NIST SP 800–171.* The Basic Assessment provides a consistent means for contractors to review their system security plans prior to and in preparation for either a DoD or CMMC assessment.

The NIST SP 800–171 DoD Assessment Methodology provides a means for the Department to assess contractor implementation of these requirements as the Department transitions to full implementation of the CMMC, and a means for companies to self-assess their implementation of the NIST SP 800–171 requirements prior to either a DoD or CMMC assessment.

2. The CMMC Framework

Section 1648 of the National Defense Authorization Act for Fiscal Year (FY) 2020 (Pub. L. 116–92) directs the Secretary of Defense to develop a risk-based cybersecurity framework for the DIB sector, such as CMMC, as the basis for a mandatory DoD standard. Building upon the NIST SP 800–171 DoD Assessment Methodology, the CMMC framework adds a comprehensive and scalable certification element to verify the implementation of processes and practices associated with the achievement of a cybersecurity maturity level. CMMC is designed to provide increased assurance to the Department that a DIB contractor can adequately protect sensitive unclassified information (*i.e.* FCI and CUI) at a level commensurate with the risk, accounting for information flow down to its subcontractors in a multi-tier supply chain. Implementation of the CMMC Framework is intended to solve the following policy problems:

• *Verification of a contractor's cybersecurity posture.* DFARS clause 252.204–7012 does not provide for the DoD verification of a DIB contractor's implementation of the security requirements specified in NIST SP 800–171 prior to contract award. DIB companies self-attest that they will implement the requirements in NIST SP 800–171 upon submission of their offer. Findings from DoD Inspector General report (DODIG–2019–105 ''Audit of Protection of DoD Controlled Unclassified Information on Contractor-Owned Networks and Systems'') indicate that DoD contractors did not consistently implement mandated system security requirements for safeguarding CUI and recommended that DoD take steps to assess a contractor's ability to protect this information. CMMC adds the element of verification of a DIB contractor's cybersecurity posture through the use of accredited C3PAOs. The company must achieve the CMMC level certification required as a condition of contract award.

• *Comprehensive implementation of cybersecurity requirements.* Under DFARS clause 252.204–7012, a contractor can document implementation of the security requirements in NIST SP 800–171 by having a system security plan in place to describe how the security requirements are implemented, in addition to associated plans of action to describe how and when any unimplemented security requirements will be met. The CMMC framework does not allow a DoD contractor or subcontractor to achieve compliance status through the use of plans of action. In general, CMMC takes a risk-based approach to addressing cyber threats. Based on the type and sensitivity of the information to be protected, a DIB company must achieve the appropriate CMMC level and demonstrate implementation of the requisite set of processes and practices. Although the security requirements in NIST SP 800–171 addresses a range of threats, additional requirements are needed to further reduce the risk of Advanced Persistent Threats (APTs). An APT is an adversary that possesses sophisticated levels of expertise and significant resources, which allow it to create opportunities to achieve its objectives by using multiple attack vectors (*e.g.* cyber, physical, and deception). The CMMC model includes additional processes and practices in Levels 4 and 5 that are focused on further reducing the risk of APT threats. The CMMC implementation will provide the Department with an ability to illuminate the supply chain, for the first time, at scale across the entire DIB sector. The CMMC framework requires contractors to flow down the appropriate CMMC

certification requirement to subcontractors throughout the entire supply chain. DIB companies that do not process, store, or transmit CUI, must obtain a CMMC level 1 certification. DIB companies that process, store, or transmit CUI must achieve a CMMC level 3 or higher, depending on the sensitivity of the information associated with a program or technology being developed.

• *Scale and Depth.* DoD contractors must include DFARS clause 252.204–7012 in subcontracts for which subcontract performance will involve covered defense information (DoD CUI), but this does not provide the Department with sufficient insights with respect to the cybersecurity posture of DIB companies throughout the multi-tier supply chain for any given program or technology development effort. Given the size and scale of the DIB sector, the Department cannot scale its organic cybersecurity assessment capability to conduct on-site assessments of approximately 220,000 DoD contractors every three years. As a result, the Department's organic assessment capability is best suited for conducting targeted assessments for a subset of DoD contractors that support prioritized programs and/or technology development efforts. CMMC addresses the challenges of the Department scaling its organic assessment capability by partnering with an independent, non-profit CMMC–AB that will accredit and oversee multiple third party assessment organizations (C3PAOs) which in turn, will conduct on-site assessments of DoD contractors throughout the multi-tier supply chain. DIB companies will be able to directly schedule assessments with an accredited C3PAO for a specific CMMC level. The cost of these CMMC assessments will be driven by multiple factors including market forces, the size and complexity of the network or enclaves under assessment, and the CMMC level.

• *Reduces Duplicate or Repetitive Assessments of our Industry Partners.* Assessment results will be posted in the Supplier Performance Risk System (SPRS), DoD's authoritative source for supplier and product performance information. This will provide DoD Components with visibility to CMMC certifications for DIB contractor networks and an alternative to addressing implementation of NIST SP 800–171 on a contract-by-contract approach—significantly reducing the need to conduct assessments at the program level, thereby reducing the cost to both DoD and industry.

C. Description of and Estimate of the Number of Small Entities to Which the Rule Will Apply

This rule will impact all small businesses that do business with Department of Defense, except those competing on contracts or orders that are exclusively for COTS items or receiving contracts or orders valued at or below the micro-purchase threshold.

1. The NIST SP 800–171 DoD Assessment Methodology

According to data available in the Electronic Data Access system for fiscal years (FYs) 2016, 2017, and 2018, on an annual basis DoD awards on average 485,859 contracts and orders that contain DFARS clause 252.204–7012 to 39,204 unique awardees, of which 262,509 awards (54 percent) are made to 26,468 small entities (68 percent). While there may be some entities that have contracts that contain the clause at 252.204–7012, but never process CUI and, therefore, do not have to implement NIST SP 800–171, it is not possible for DoD to estimate what fraction of unique entities fall into this category. Assuming all of these small entities have covered contractor information systems that are required to be in compliance with NIST SP 800–171, then all of these entities would be required to have, at minimum, a Basic Assessment in order to be considered for award.

The requirement for the Basic Assessment would be imposed through incorporation of the new solicitation provision and contract clause in new contracts and orders. As such, the requirement to have completed a Basic Assessment is expected to phase-in over a three-year period, thus impacting an estimated 8,823 small entities each year. It is expected that the Medium and High Assessments, on the other hand, will be conducted on a finite number of awardees each year based on the capacity of the Government to conduct these assessments. DoD estimates that 200 unique entities will undergo a Medium Assessment each year, of which 148 are expected to be small entities. High Assessments are expected to be conducted on approximately 110 unique entities each year, of which 81 are expected to be small entities. DoD Assessments are valid for three years, so small entities will be required to renew, at minimum, their basic assessment every three years in order to continue to receive DoD awards or to continue performance on contracts and orders with options. The following is a summary of the number of small entities that will be required to undergo NIST SP 800–171 DoD Assessments over a three-year period:

Assessment	Year 1	Year 2	Year 3
Basic	8,823	8,823	8,823
Medium	148	148	148
High	81	81	81

The top five NAICS code industries expected to be impacted by this rule are as follows: 541712, Research and Development in the Physical, Engineering, and Life Sciences (Except Biotechnology); 541330, Engineering Services; 236220, Commercial and Institutional Building Construction; 541519, Other Computer Related Services; and 561210, Facilities Support Services. These NAICS codes were selected based on a review of NAICS codes associated with awards that include the clause at DFARS 252.204–7012.

2. The CMMC Framework

Given the enterprise-wide implementation of CMMC, the Department developed a five-year phased rollout strategy. The rollout is intended to minimize the financial impacts to the industrial base, especially small entities, and disruption to the existing DoD supply chain. The Office of the Secretary of Defense staff is coordinating with the Military Services and Department Agencies to identify candidate contracts during the first five years of implementation that will include the CMMC requirement in the statement of work.

Prior to October 1, 2025, this rule impacts certain large and small businesses that are competing on acquisitions that specify a requirement for CMMC in the statement of work. These businesses will be required to have the stated CMMC certification level at the time of contract award. Inclusion of a CMMC requirement in a

solicitation during this time period must be approved by the USD(A&S). It is estimated that 129,810 unique entities will pursue their initial CMMC certification during the initial five-year period. By October 1, 2025, all entities receiving DoD contracts and orders, other than contracts or orders exclusively for commercially available off-the-shelf items or those valued at or below the micro-purchase threshold, will be required to have the CMMC Level identified in the solicitation, but which at minimum will be a CMMC Level 1 certification. CMMC certifications are valid for three years; therefore, large and small businesses will be required to renew their certification every three years.

Based on information from the Federal Procurement Data System (FPDS), the number of unique prime contractors is 212,657 and the number of known unique subcontractors is 8,309. Therefore, the total number of known unique prime contractors and subcontractors is 220,966, of which approximately 163,391 (74 percent) are estimated to be unique small businesses. According to FPDS, the average number of new contracts for unique contractors is 47,905 for any given year. The timeline required to implement CMMC across the DoD contractor population will be approximately 7 years. The phased rollout plan for years 1–7 for small entities is detailed below with the total number of unique DoD contractors and subcontractors specified. The rollout assumes that for every unique prime contractor there are approximately 100 unique subcontractors. Each small business represented in the table would be required to pursue recertification every three years in order to continue to do business with DoD.

Year	Level 1	Level 2	Level 3	Level 4	Level 5	Total
1	665	110	335	0	0	1,110
2	3,323	555	1,661	2	2	5,543
3	11,086	1,848	5,543	4	4	18,485
4	21,248	3,542	10,624	6	6	35,426
5	21,245	3,541	10,623	7	7	35,423
6	21,245	3,541	10,623	7	7	35,423
7	19,180	3,197	9,590	7	7	31,981
1–7	97,992	16,334	48,999	33	33	163,391

The top five NAICS code industries expected to be impacted by this rule are as follows: 541712, Research and Development in the Physical, Engineering, and Life Sciences (Except Biotechnology); 541330, Engineering Services; 236220, Commercial and Institutional Building Construction; 541519, Other Computer Related Services; and 561210, Facilities Support Services. These NAICS codes are the same as the DoD Assessment NAICS codes and were selected based on a review of NAICS codes associated with awards that include the clause at FAR 52.204–21 or DFARS 252.204–7012.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

Details on the compliance requirements and associated costs, savings, and benefits of this rule are provided in the Regulatory Impact Analysis referenced in section IV of this preamble. The following is a summary of the compliance requirements and the estimated costs for small entities to undergo a DoD NIST SP 800–171 Assessment or obtain a CMMC certification. For both the DoD Assessment Methodology and the CMMC Framework, the estimated public costs are based on the cost for an entity to pursue each type of assessment: The Basic, Medium, or High Assessment under the DoD Assessment Methodology; or the CMMC Level 1, 2, 3, 4, or 5 certifications. The estimated costs attributed to this rule do not include the costs associated with compliance with the existing cybersecurity requirements under the clause at FAR 52.204–21 or associated with implementing NIST SP 800–171 in accordance with the clause at DFARS 252.204–7012, Safeguarding Covered Defense Information and Cyber Incident Reporting. Contractors who have been awarded a DoD contract that include these existing contract clauses should have already implemented these cybersecurity requirements and incurred the associated costs; therefore, those costs are not attributed to this rule.

1. DoD Assessment Methodology

To comply with NIST SP 800–171 a company must (1) implement 110 security requirements on their covered contractor information systems; or (2) document in a ''system security plan'' and ''plans of action'' those requirements that are not yet implemented and when the requirements will be implemented. All offerors that are required to implement NIST SP 800–171 on covered contractor information systems pursuant to DFARS clause 252.204–7012, will be required to complete a Basic Assessment and upload the resulting score to the Supplier Risk Management System (SPRS), DoD's authoritative source for supplier and product performance information. The Basic Assessment is a self-assessment done by the contractor using a specific scoring methodology that tells the Department how many security requirements have not yet been implemented and is valid for three years. A company that has fully implemented all 110 NIST SP 800–171 security requirements, would have a score of 110 to report in SPRS for their Basic Assessment. A company that has unimplemented requirements will use the scoring methodology to assign a value to each unimplemented requirement, add up those values, and subcontract the total value from 110 to determine their score.

In accordance with NIST SP 800–171, a contractor should already be aware of the security requirements they have not yet implemented and have documented plans of action for those requirements; therefore, the burden associated with conducting a self-assessment is the time burden associated with calculating the score. DoD estimates that the burden to calculate the Basic Assessment score is thirty minutes per entity at a journeyman-level-2 rate of pay (0.50 hour * $99.08/hour = $49.54/assessment)).

To submit the Basic Assessment, the contractor is required to complete 6 fields: System security plan name (if more than one system is involved); CAGE code associated with the plan; a brief description of the plan architecture; date of the assessment; total score; and the date a score of 110 will be achieved. All of this data is available from the Basic Assessment itself, the existing system security plan, and the plans of action. The contractor selects the date when the last plan of

action will be complete as the date when a score of 110 will be achieved. The burden to submit a Basic Assessment for posting in SPRS is estimated to be 15 minutes per entity at a journeyman-level-2 rate of pay (0.25 hour * $99.08/hour = $24.77/assessment)). Therefore, the total cost per assessment per entity is approximately $74.31 ($49.54 + $24.77).

The estimate for the rate of pay for both preparation and submission of the Basic Assessment is journeyman-level-2, which is an employee who has the equivalent skills, responsibilities, and experience as a General Schedule (GS) 13 Federal Government employee. While these are rather simple tasks that can reasonably be completed by a GS–11 equivalent employee, or even a GS–9 clerk, the GS–13 (or perhaps GS–11) is the most likely grade for several reasons. First, in a small company, the number of IT personnel are very limited. The employee that is available to complete this task would also have significant responsibilities for operation and maintenance of the IT system and, therefore, be at a higher grade than would otherwise be required if the only job was to prepare and submit the assessment. Second, while the calculation of the assessment is simple, the personnel who would typically have access to and understand the system security plan and plans of action in order to complete the Basic Assessment would be at the higher grade. Third, while the actual submission is a simple task, the person who would complete the assessment and submit the data in SPRS would be the person with SPRS access/responsibilities, and therefore at the higher grade. Fourth, given that proper calculation of the score and its submission may well determine whether or not the company is awarded the contract, the persons preparing and submitting the report are likely to be at a higher grade than is actually required to ensure this is done properly.

After a contract is awarded, DoD may choose to conduct a Medium or High Assessment of an offer based on the criticality of the program or the sensitivity of information being handled by the contractor. Under both the Medium and High Assessment DoD assessors will be reviewing the contractor's system security plan description of how each NIST SP 800–171 requirement is met and will identify any descriptions that may not properly address the security requirements. The contractor provides DoD access to its facilities and personnel, if necessary, and prepares for/participates in the assessment conducted by the DoD. Under a High Assessment a contractor will be asked to demonstrate their system security plan. DoD will post the results in SPRS.

For the Medium Assessment, DoD estimates that the burden for a small entity to make the system security plan and supporting documentation available for review by the DoD assessor is one hour per entity at a journeyman-level-2 rate of pay, a cost of $99.08/assessment (1 hour * $99.08/hour). It is estimated that the burden for a small entity to participate in the review and discussion of the system security plan and supporting documents with the DoD assessor is three hours, with one journeyman-level-2 and one senior-level-2 contractor employee participating in the assessment, a cost of $710.40/assessment ((3 hours * $99.08/hour = $297.24) + (3 hours * $137.72/hour = $413.16)). Assuming issues are identified by the DoD Assessor, DoD estimates that the burden for a small entity to determine and provide to DoD the date by which the issues will be resolved is one hour per entity at a journeyman-level rate of pay, a cost of $99.08/assessment (1 hour * $99.08/hour). Therefore, total estimated cost for a small entity that undergoes a Medium Assessment is $908.56/assessment ($99.08 + $710.40 + $99.08).

For the High Assessment, DoD estimates that the burden for a small entity to participate in the review and discussion of the system security plan and supporting documents to the DoD assessors is 116 hours per entity at a cost of $14,542.24/assessment. The cost estimate is based on 2 senior-level-2 employees dedicating 32 hours each, 8 senior-level-1 employees dedicating 4 hours each, and 10 journeyman-level employees dedicating 2 hours each ((2 * 32 hours * $137.72/hour = $8,814.08) + (8 * 4 hours * 117.08/hour = $3,746.56) + (10 * 2 hours * $99.08/hour = 1,981.60)). It is estimated that the burden to make the system security plan and supporting documentation available for review by the DoD assessors, prepare for demonstration of requirements implementation, and to conduct post review activities is 304 hours per entity, at a cost of $36,133.76/assessment. The cost estimate is based on 2 senior-level-2 employees dedicating 48 hours each, 8 senior-level-1 employees dedicating 16 hours each, and 10 journeyman-level employees dedicating 8 hours each ((2 * 48 hours * $137.72/hour = $13,221.12) + (8 * 16 hours * 117.08/hour = $14,986.24) + (10 * 8 hours * $99.08/hour = $7,926.40)). Therefore, total estimated cost for a small entity that undergoes a High Assessment is $50,676/assessment ($14,542.24 + $36,133.76). DoD considers this to be the upper estimate of the cost, as it assumes a very robust information technology workforce. For many smaller companies, which may not have a complex information system to manage, the information system staff will be a much more limited, and labor that can be devoted (or is necessary) to prepare for and participate in the assessment is likely to be significantly less than estimated.

The following table provides the estimated annual costs for small entities to comply with the DoD Assessment requirements of this rule. Since assessments are valid for three years, the cost per assessment has been divided by three to estimate the annual cost per entity:

Assessment	Cost/ assessment	Annual cost/entity	Total unique entities	Annual cost all entities
Basic	$75	$25	26,469	$655,637
Medium	909	303	444	134,467
High	50,676	16,892	243	4,104,756
Total	.....	.....	27,156	4,894,860

The following table presents the average annual cost per small entity for each DoD Assessment as a percentage of the annual revenue for a small entity for four of the top five NAICS codes. The low-end of the range of annual revenues presented in the table includes the average annual revenue for smaller sized firms. The high-end of the range includes the maximum annual revenue allowed by the Small Business Administration (SBA) for a small

business, per the SBA's small business size standards published at 13 CFR 121.201. NAICS code 541712 is excluded, because it is no longer an active NAICS code and the prior size standard was based on number of employees.

NAICS code	Range of annual revenues for small businesses (in millions)	Basic assessment annual cost as % of annual revenue	Medium assessment annual cost as % of annual revenue	High assessment annual cost as % of annual revenue
541330	$5–16.5	0.0005–0.0002	0.0061–0.0018	0.3378–0.1024
236220	$10–$39.5	0.0002–0.0001	0.0030–0.0008	0.1689–0.0428
541519	$10–$30.0	0.0002–0.0001	0.0030–0.0010	0.1689–0.0563
561210	$10–$41.5	0.0002–0.0001	0.0030–0.0007	0.1689–0.0407

2. CMMC Framework

This rule adds DFARS clause 252.204–7021, Cybersecurity Maturity Model Certification Requirement, which requires the contractor to have the CMMC certification at the level required in the solicitation by contract award and maintain the required CMMC level for the duration of the contract. In order to achieve a specific CMMC level, a DIB company must demonstrate both process institutionalization or maturity and the implementation of practices commensurate with that level. A DIB contractor can achieve a specific CMMC level for its entire enterprise network or particular segment(s) or enclave(s), depending upon where the information to be protected is processed, stored, or transmitted.

The following table provides a high-level description of the processes and practices evaluated during a CMMC assessment at each level; however, more specific information on the processes and practices associated with each CMMC Level is available at *https://www.acq.osd.mil/cmmc/index.html.*

Level	Description
1	Consists of the 15 basic safeguarding requirements from FAR clause 52.204–21.
2	Consists of 65 security requirements from NIST SP 800–171 implemented via DFARS clause 252.204–7012, 7 CMMC practices, and 2 CMMC processes. Intended as an optional intermediary step for contractors as part of their progression to Level 3.
3	Consists of all 110 security requirements from NIST SP 800–171, 20 CMMC practices, and 3 CMMC processes.
4	Consists of all 110 security requirements from NIST SP 800–171, 46 CMMC practices, and 4 CMMC processes.
5	Consists of all 110 security requirements from NIST SP 800–171, 61 CMMC practices, and 5 CMMC processes.

CMMC Assessments will be conducted by C3PAOs, which are accredited by the CMMC–AB. C3PAOs will provide CMMC Assessment reports to the CMMC–AB who will then maintain and store these reports in appropriate database(s). The CMMC–AB will issue CMMC certificates upon the resolution of any disputes or anomalies during the conduct of the assessment. These CMMC certificates will be distributed to the DIB contractor and the requisite information will be posted in SPRS.

If a contractor disputes the outcome of a C3PAO assessment, the contractor may submit a dispute adjudication request to the CMMC–AB along with supporting information related to claimed errors, malfeasance, or ethical lapses by the C3PAO. The CMMC–AB will follow a formal process to review the adjudication request and provide a preliminary evaluation to the contractor and C3PAO. If the contractor does not accept the CMMC–AB preliminary finding, the contractor may request an additional assessment by the CMMC–AB staff.

The costs associated with the preparation and the conduct of CMMC Assessments assumes that a small DIB company, in general, possesses a less complex and less expansive IT and cybersecurity infrastructure and operations relative to a larger DIB company. In estimating the cost for a small DIB company to obtain a CMMC certification, DoD took into account non-recurring engineering costs, recurring engineering costs, the cost to participate in the assessment, and re-certification costs:

- Nonrecurring engineering costs consist of hardware, software, and the associated labor. The costs are incurred only in the year of the initial assessment.
- Recurring engineering costs consist of any recurring fees and associated labor for technology refresh. The recurring engineering costs associated with technology refresh have been spread uniformly over a 5-year period (*i.e.,* 20% each year as recurring engineering costs).
- Assessment costs consist of contractor support for pre-assessment preparations, the actual assessment, and any post-assessment work. These costs also include an estimate of the potential C3PAO costs for conducting CMMC Assessment, which are comprised of labor for supporting pre-assessment preparations, actual assessment, and post-assessment work, plus travel cost.
- Re-certification costs are the same as the initial certification cost.

The following is a summary of the estimated costs for a small entity to achieve certification at each CMMC Level.

i. Level 1 Certification

Contractors pursuing a Level 1 Certification should have already implemented the 15 existing basic safeguarding requirements under FAR clause 52.204–21. Therefore, there are no estimated nonrecurring or recurring engineering costs associated with CMMC Level 1.

DoD estimates that the cost for a small entity to support a CMMC Level 1 Assessment or recertification is $2,999.56:

- *Contractor Support.* It is estimated that one journeyman-level-1 employee will dedicate 14 hours to support the assessment (8 hours for pre- and post-assessment support + 6 hours for the assessment). The estimated cost is $1,166.48 (1 journeyman * $83.32/hour * 14 hours).
- *C3PAO Assessment.* It is estimated that one journeyman-level-1 employee will dedicate 19 hours to conduct the assessment (8 hours for pre- and post-assessment support + 6 hours for the assessment + 5 hours for travel). Each employee is estimated to have 1 day of per diem for travel. The estimated cost

is $1,833.08 ((1 journeyman * $83.32/hour * 19 hours = $1,583.08) + (1 employees * 1 day * $250/day = $250 travel costs)).

ii. Level 2 Certification

Contractors pursuing a Level 2 Certification should have already implemented the 65 existing NIST SP 800–171 security requirements. Therefore, the estimated engineering costs per small entity is associated with implementation of 9 new requirements (7 CMMC practices and 2 CMMC processes). The estimated nonrecurring engineering cost per entity per assessment/recertification is $8,135. The estimated recurring engineering cost per entity per year is $20,154.

DoD estimates that the cost for a small entity to support a CMMC Level 2 Assessment or recertification is $22,466.88.

- *Contractor Support.* It is estimated that two senior-level-1 employees will dedicate 48 hours each to support the assessment (24 hours for pre- and post-assessment support + 24 hours for the assessment). The estimated cost is $11,239.68 (2 senior * $117.08/hour * 48 hours).
- *C3PAO Assessment.* It is estimated that one journeyman-level-2 employee and one senior-level-1 employee will dedicate 45 hours each to conduct the assessment (16 hours for pre- and post-assessment support + 24 hours for the assessment + 5 hours for travel). Each employee is estimated to have 3 days of per diem for travel. The estimated cost is $11,227.20 ((1 senior * $117.08/hour * 45 hours = $5,268.60) + (1 journeyman * $99.08/hour * 45 hours = $4,458.60) + (2 employees * 3 days * $250/day = $1,500 travel costs)).

iii. Level 3 Certification

Contractors pursuing a Level 3 Certification should have already implemented the 110 existing NIST SP 800–171 security requirements. Therefore, the estimated engineering costs per small entity is associated with implementation 23 new requirements (20 CMMC practices and 3 CMMC processes). The estimated nonrecurring engineering cost per entity per assessment/recertification is $26,214. The estimated recurring engineering cost per entity per year is $41,666.

DoD estimates that the cost for a small entity to support a CMMC Level 3 assessment or recertification is $51,095.60.

- *Contractor Support.* It is estimated that three senior-level-1 employees will dedicate 64 hours each to support the assessment (32 hours for pre- and post-assessment support + 32 hours for the assessment). The estimated cost is $22,479.36 (3 seniors * $117.08/hour * 64 hours).
- *C3PAO Assessment.* It is estimated that one senior-level-1 employee and three journeyman-level-2 employees will dedicate 57 hours each to conduct the assessment (24 hours for pre- and post-assessment support + 32 hours for the assessment + 5 hours for travel). Each employee is estimated to have 5 days of per diem for travel. The estimated cost is $28,616.24 ((1 senior * $117.08/hour * 57 hours = $6,673.56) + (3 journeyman * $99.08/hour * 57 hours = $16,942.68) + (4 employees * 5 days * $250/day = $5,000 travel costs)).

iv. Level 4 Certification

Contractors pursuing a Level 4 Certification should have already implemented the 110 existing NIST SP 800–171 security requirements. Therefore, the estimated engineering costs per small entity is associated with implementation 50 new requirements (46 CMMC practices and 4 CMMC processes). The estimated nonrecurring engineering cost per entity per assessment/recertification is $938,336. The estimated recurring engineering cost per entity per year is $301,514.

DoD estimates that the cost for a small entity to support a CMMC Level 4 Assessment or recertification is $70,065.04.

- *Contractor Support.* It is estimated that three senior-level-2 employees will dedicate 80 hours each to support the assessment (40 hours for pre- and post-assessment support + 40 hours for the assessment). The estimated cost is $33,052.80 (3 seniors * $137.72/hour * 80 hours)
- *C3PAO Assessment.* It is estimated that one senior-level-2 employee and three journeyman-level-2 employees will dedicate 69 hours each to conduct the assessment (32 hours for pre- and post-assessment support + 48 hours for the assessment + 5 hours for travel). Each employee is estimated to have 5 days of per diem for travel, plus airfare. The estimated cost is $37,012.24 ((1 senior * $137.72/hour * 69 hours = $9502.68) + (3 journeyman * $99.08/hour * 69 hours = $20,509.56) + (4 employees * 5 days * $250/day = $5,000 travel costs) + (4 employees * $500 = $2,000 airfare)).

v. Level 5 Certification

Contractors pursuing a Level 5 Certification should have already implemented the 110 existing NIST SP 800–171 security requirements. Therefore, the estimated engineering costs per small entity is associated with implementation 66 new requirements (61 CMMC practices and 5 CMMC processes). The estimated nonrecurring engineering cost per entity per assessment/recertification is $1,230,214. The estimated recurring engineering cost per entity per year is $384,666.

DoD estimates that the cost for a small entity to support a CMMC Level 5 Assessment or recertification is $110,090.80.

- *Contractor Support.* It is estimated that four senior-level-2 employees will dedicate 104 hours each to support the assessment (48 hours for pre- and post-assessment support + 56 hours for the assessment). The estimated cost is $57,291.52 (4 senior * $137.72/hour * 104 hours).
- *C3PAO Assessment.* It is estimated that one senior-level-2 employee, two senior-level-1 employees, and one journeyman-level-2 employee will dedicate 93 hours each to conduct the assessment (32 hours for pre- and post-assessment support + 56 hours for the assessment + 5 hours for travel). Each employee is estimated to have 7 days of per diem for travel. The estimated cost is $52,799.28 ((1 senior * $137.72/hour * 93 hours = $12,807.96) + (2 senior * $117.08/hour * 93 hours = $21,776.88) + (1 journeyman * $99.08/hour * 93 hours = $9,214.44) + (4 employees * 7 days * $250/day = $7,000 travel costs) + (4 employees * $500 = $2,000 airfare)).

vi. Total Estimated Annual Costs

The following table provides a summary of the total estimated annual costs for an individual small entity to obtain each CMMC certification level. Nonrecurring engineering costs are spread over a 20-year period to determine the average annual cost per entity. Assessment costs have been spread over a 3-year period, since entities will participate in a reassessment every 3 years.

CMMC cert	Average nonrecurring engineering costs	Recurring engineering costs	Average assessment costs	Total annual assessment cost
Level 1	$0	$0	$1,000	$1,000

CMMC cert	Average nonrecurring engineering costs	Recurring engineering costs	Average assessment costs	Total annual assessment cost
Level 2	407	20,154	7,489	28,050
Level 3	1,311	41,666	17,032	60,009
Level 4	46,917	301,514	23,355	371,786
Level 5	61,511	384,666	36,697	482,874

The following table presents the average annual cost per small entity for CMMC certifications at levels 1 through 3 as a percentage of the annual revenue for a small entity for four of the top five NAICS codes. The low-end of the range of annual revenues presented in the table includes the average annual revenue for smaller sized firms. The high-end of the range includes the maximum annual revenue allowed by the SBA for a small business, per the SBA's small business size standards published at 13 CFR 121.201. NAICS code 541712 is excluded, because it is no longer an active NAICS code and the prior size standard was based on number of employees.

NAICS code	Range of annual revenues for small businesses (in millions)	CMMC level 1 annual cost as % of annual revenue	CMMC level 2 annual cost as % of annual revenue	CMMC level 3 annual cost as % of annual revenue
541330	$5–$16.5	0.0200–0.0061	0.5610–0.1700	1.2002–0.3637
236220	$10–$39.5	0.0100–0.0025	0.2805–0.0710	0.6001–0.1519
541519	$10–$30.0	0.0100–0.0033	0.2805–0.0935	0.6001–0.2000
561210	$10–$41.5	0.0100–0.0024	0.2805–0.0676	0.6001–0.1446

For CMMC certification at levels 4 and 5, the following table presents the annual cost per small entity for CMMC certification at levels 4 and 5 as a percentage of the low, average, and high annual revenues for entities that have represented themselves as small in the System for Award Management (SAM) for their primary NAICS code and are performing on contracts that could be subject to a CMMC level 4 or 5 certification requirements. The values of the low, average, and high annual revenues are based on an average of the annual receipt reported in SAM by such entities for FY16 through FY20.

FY16 thru FY20	Annual revenue of entities represented as small for primary NAICS	Level 4 certification cost as % of annual revenue	Level 5 certification cost as % of annual revenue
Low	$6.5 million	5.67	7.36
Average	$22.9 million	1.62	2.11
High	$85 million	0.43	0.56

The following is a summary of the estimated annual costs in millions for all 163,391 small entities to achieve their initial CMMC certifications (and recertifications every three years) over a 10-year period:

Year	Level 1	Level 2	Level 3	Level 4	Level 5
1	$1.99	$5.58	$39.86	$0.00	$0.00
2	9.97	30.39	211.58	2.62	3.45
3	33.25	107.20	742.65	5.84	7.67
4	65.73	232.90	1,595.23	9.67	12.66
5	73.69	314.23	2,105.53	12.93	16.91
6	96.98	414.64	2,746.50	15.18	19.82
7	123.26	509.08	3,342.95	17.43	22.74
8	73.69	421.22	2,669.25	10.58	13.68
9	96.98	450.27	2,867.60	10.72	13.90
10	123.26	483.07	3,091.56	10.86	14.13

E. Relevant Federal Rules, Which May Duplicate, Overlap, or Conflict With the Rule

The rule does not duplicate, overlap, or conflict with any other Federal rules. Rather this rule validates and verifies contractor compliance with the existing cybersecurity requirements in FAR clause 52.204–21 and DFARS clause 252.204–7012, and ensures that the entire DIB sector has the appropriate cybersecurity processes and practices in place to properly protect FCI and CUI during performance of DoD contracts.

F. Description of Any Significant Alternatives to the Rule Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact of the Rule on Small Entities

DoD considered and adopted several alternatives during the development of

this rule that reduce the burden on small entities and still meet the objectives of the rule. These alternatives include: (1) Exempting contracts and orders exclusively for the acquisition of commercially available off-the-shelf items; and (2) implementing a phased rollout for the CMMC portion of the rule and stipulating that the inclusion a CMMC requirement in new contracts until that time be approved by the Office of the Under Secretary of Defense for Acquisition and Sustainment. Additional alternatives were considered, however, it was determined that these other alternatives did not achieve the intended policy outcome.

1. CMMC Model and Implementation

The Regulatory Impact Analysis (RIA) referenced in section IV of this preamble estimates that the total number of unique DoD contractors and subcontractors is 220,966, with approximately 163,391 or 74% being small entities. The RIA also specifies the estimates for the percentage of all contractors and subcontractors associated with each CMMC level. These estimates indicate that the vast majority of small entities (*i.e.,* 163,325 of 163,391 or 99.96%) will be required to achieve CMMC Level 1–3 certificates during the initial rollout. The Department looked at Levels 1 through 5 to determine if there were alternatives and whether these alternatives met the intended policy outcome.

For CMMC Level 1, the practices map directly to the basic safeguarding requirements specified in the clause at FAR 52.204–21. The phased rollout estimates that the majority of small entities (*i.e.,* 97,992 of the 163,325 or 60%) will be required to achieve CMMC Level 1. The planned implementation of CMMC Level 1 adds a verification component to the existing FAR clause by including an on-site assessment by a credentialed assessor from an accredited C3PAO. The on-site assessment verifies the implementation of the required cybersecurity practices and further supports the physical identification of contractors and subcontractors in the DoD supply chain. In the aggregate, the estimated cost associated with supporting this on-site assessment and approximated C3PAO fees does not represent a cost-driver with respect to CMMC costs to small entities across levels. An alternative to an on-site assessment is for contractors to provide documentation and supporting evidence of the proper implementation of the required cybersecurity practices through a secure online portal. These artifacts would then be reviewed and checked virtually by an accredited assessor prior to the CMMC–AB issuing a CMMC Level 1 certificate. The drawback of this alternative is the inability of the contractor to interact with the C3PAO assessor in person and provide evidence directly without transmitting proprietary information. Small entities will not receive as much meaningful and interactive feedback that would be part of a Level 1 on-site assessment.

For CMMC Level 2, the practices encompass only 48 of the 110 security requirements of NIST SP 800–171, as specified in DFARS clause 252.204–7012, and 7 additional cybersecurity requirements. In addition, CMMC Level 2 includes two process maturity requirements. The phased rollout estimates that approximately 10% of small entities may choose to use Level 2 as a transition step from Level 1 to Level 3. Small entities that achieve Level 1 can seek to achieve Level 3 (without first achieving a Level 2 certification) if the necessary cybersecurity practices and processes have been implemented. The Department does not anticipate releasing new contracts that require contractors to achieve CMMC Level 2. As a result, the Department did not consider alternatives with respect to CMMC Level 2.

For CMMC Level 3, the practices encompass all the 110 security requirements of NIST SP 800–171, as specified in DFARS clause 252.204–7012, as well as 13 additional cybersecurity requirements above Level 2. In addition, CMMC Level 3 includes three process maturity requirements. These additional cybersecurity practices were incorporated based upon several considerations that included public comments from September to December 2019 on draft versions of the model, inputs from the DIB Sector Coordinating Council (SCC), cybersecurity threats, the progression of cybersecurity capabilities from Level 3 to Levels 4, and other factors. The CMMC phased rollout estimates that 48,999 of the 163,325 small entities or 30% will be required to achieve CMMC Level 3. The alternatives considered include removing a subset or all of the 20 additional practices at Level 3 or moving a subset or all of the 20 additional practices from Level 3 to Level 4. The primary drawback of these alternatives is that the cybersecurity capability gaps associated with protecting CUI will not be addressed until Level 4, which will apply to a relatively small percentage of non-small and small entities. Furthermore, the progression of cybersecurity capabilities from Level 3 to Level 4 becomes more abrupt.

For CMMC Level 4, the practices encompass the 110 security requirements of NIST SP 800–171 as specified in DFARS clause 252.204–7012 and 46 additional cybersecurity requirements. More specifically, CMMC Level 4 adds 26 enhanced security requirements above CMMC Level 3, of which 13 are derived from Draft NIST SP 800–171B. In addition, CMMC Level 4 includes four process maturity requirements. The DIB SCC and the public contributed to the specification of the other 13 enhanced security requirements. For CMMC Level 4, an alternative considered is to define a threshold for contractors to meet 15 out of the 26 enhanced security requirements. In addition, contractors will be required to meet 6 out of the 11 remaining non-threshold enhanced security requirements. This alternative implies that a contractor will have to implement 21 of the 26 enhanced security requirements as well as the associated maturity processes. A drawback of this alternative is that contractors implement a different subset of the 11 non-threshold requirements which in turn, leads to a non-uniform set of cybersecurity capabilities across those certified at Level 4.

For CMMC Level 5, the practices encompass the 110 security requirements of NIST SP 800–171 as specified in DFARS clause 252.204–7012 and 61 additional cybersecurity requirements. More specifically, CMMC Level 5 adds 15 enhanced security requirements above CMMC Level 4, of which 4 are derived from Draft NIST SP 800–171B. In addition, CMMC Level 5 includes five process maturity requirements. The DIB SCC and the public contributed to the specification of the other 11 enhanced security requirements. For CMMC Level 5, the alternative considered is to define a threshold for contractors to meet 6 out of the 15 enhanced security requirements. In addition, contractors will be required to meet 5 out of the 9 remaining non-threshold enhanced security requirements. This alternative implies that a contractor will have implemented 11 of the 15 enhanced security requirements as well as the associated maturity processes. A drawback of this alternative is that contractors implement a different subset of the 9 non-threshold requirements which in turn, leads to a non-uniform set of cybersecurity capabilities across those certified at Level 5.

2. Timing of CMMC Level Certification Requirement

In addition to evaluating the make-up of the CMMC levels, the Department

took into consideration the timing of the requirement to achieve a CMMC level certification: (1) At time of proposal or offer submission, (2) in order to receive award, or (3) post contract award. The Department ultimately adopted alternative 2 to require certification at the time of award. The drawback of alternative 1 (at time of proposal or offer submission) is the increased risk for contractors since they may not have sufficient time to achieve the required CMMC certification after the release of the Request for Information (RFI). The drawback of alternative 3 (after contract award) is the increased risk to the Department with respect to the schedule and uncertainty with respect to the case where the contractor is unable to achieve the required CMMC level in a reasonable amount of time given their current cybersecurity posture. This potential delay would apply to the entire supply chain and prevent the appropriate flow of CUI and FCI. The Department seeks public comment on the timing of contract award, to include the effect of requiring certification at time of award on small businesses.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities. DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2019–D041), in correspondence.

VIII. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) provides that an agency generally cannot conduct or sponsor a collection of information, and no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, unless that collection has obtained OMB approval and displays a currently valid OMB Control Number.

DoD requested, and OMB authorized, emergency processing of the collection of information tied to this rule, as OMB Control Number 0750–0004, *Assessing Contractor Implementation of Cybersecurity Requirements,* consistent with 5 CFR 1320.13.

DoD has determined the following conditions have been met:

a. The collection of information is needed prior to the expiration of time periods normally associated with a routine submission for review under the provisions of the PRA, to enable the Department to immediately begin assessing the current status of contractor implementation of NIST SP 800–171 on their information systems that process CUI.

b. The collection of information is essential to DoD's mission. The collection of information is essential to DoD's mission. The National Defense Strategy (NDS) and DoD Cyber Strategy highlight the importance of protecting the Defense Industrial Base (DIB) to maintain national and economic security. To this end, DoD requires defense contractors and subcontractors to implement the NIST SP 800–171 security requirements on information systems that handle CUI, pursuant to DFARS clause 252.204–7012. This DoD Assessment Methodology enables the Department to assess strategically, at a corporate-level, contractor implementation of the NIST SP 800–171 security requirements. Results of a NIST SP 800–171 DoD Assessment reflect the net effect of NIST SP 800–171 security requirements not yet implemented by a contractor.

c. Moreover, DoD cannot comply with the normal clearance procedures, because public harm is reasonably likely to result if current clearance procedures are followed. Authorizing collection of this information on the effective date will motivate defense contractors and subcontractors who have not yet implemented existing NIST SP 800–171 security requirements, to take action to implement the security requirements on covered information systems that process CUI, in order to protect our national and economic security interests. The aggregate loss of sensitive controlled unclassified information and intellectual property from the DIB sector could undermine U.S. technological advantages and increase risk to DoD missions.

Upon publication of this rule, DoD intends to provide a separate 60-day notice in the **Federal Register** requesting public comment for OMB Control Number 0750–0004, *Assessing Contractor Implementation of Cybersecurity Requirements.*

DOD estimates the annual public reporting burden for the information collection as follows:

a. Basic Assessment

Respondents: 13,068.
Responses per respondent: 1.
Total annual responses: 13,068.
Hours per response: .75.
Total burden hours: 9,801.

b. Medium Assessment

Respondents: 200.
Responses per respondent: 1.
Total annual responses: 200.
Hours per response: 8.
Total burden hours: 1,600.

c. High Assessment

Respondents: 110.
Responses per respondent: 1.
Total annual responses: 110.
Hours per response: 420.
Total burden hours: 46,200.

d. Total Public Burden (All Entities)

Respondents: 13,068.
Total annual responses: 13,378.
Total burden hours: 57,601.

e. Total Public Burden (Small Entities)

Respondents: 8,823.
Total annual responses: 9,023.
Total burden hours: 41,821.

The requirement to collect information from offerors and contractors regarding the status of their implementation of NIST SP 800–171 on their information systems that process CUI, is being imposed via a new solicitation provision and contract clause. Per the new provision, if an offeror is required to have implemented the NIST SP 800–171 security requirements on their information systems pursuant to DFARS clause 252.204–7012, then the offeror must have, at minimum, a current self-assessment (or Basic Assessment) uploaded to DoD's Supplier Performance Risk System, in order to be considered for award. Depending on the criticality of the acquisition program, after contract award, certain contractors may be required to participate in a Medium or High assessment to be conducted by DoD assessor. During these post-award assessments, contractors will be required to demonstrate their implementation of NIST SP 800–171 security requirements. Results of a NIST SP 800–171 DoD Assessment reflect the net effect of NIST SP 800–171 security requirements not yet implemented by a contractor.

IX. Determination To Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense that urgent and compelling reasons exist to promulgate this interim rule without prior opportunity for public comment pursuant to 41 U.S.C. 1707(d) and FAR 1.501–3(b).

Malicious cyber actors have targeted, and continue to target, the DIB sector, which consists of over 200,000 small-to-large sized entities that support the warfighter. In particular, actors ranging from cyber criminals to nation-states continue to attack companies and organizations that comprise the Department's multi-tier supply chain including smaller entities at the lower

tiers. These actors seek to steal DoD's intellectual property to undercut the United States' strategic and technological advantage and to benefit their own military and economic development.

The Department has been focused on improving the cyber resiliency and security of the DIB sector for over a decade as evidenced by the development of minimum cybersecurity standards and the implementation of those standards in the National Institute of Standards and Technology (NIST) Special Publications (SP) and implementation of those standards in the FAR and DFARS. In 2013, DoD issued a final DFARS rule (78 FR 69273) that required contractors to implement a select number of security measures from NIST SP 800–53, Recommended Security Controls for Federal Information Systems and Organizations, to facilitate safeguarding unclassified DoD information within contractor information systems from unauthorized access and disclosure. In 2015, DoD issued an interim DFARS rule (80 FR 81472) requiring contractors that handle Controlled Unclassified Information (CUI) on their information systems to transition by December 31, 2017, from NIST SP 800–53 to NIST SP 800–171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations. NIST SP 800–171 was not only easier to use, but also provided security requirements that greatly increases the protections of Government information in contractor information systems once implemented. And, in 2016, the FAR Council mandated the use of FAR clause 52.204–21, Basic Safeguarding of Covered Contractor Information Systems, to require all Government contractors to implement, at minimum, some basic policies and practices to safeguard Federal Contract Information (FCI) within their information systems. Since then, the Department has been engaging with industry on improving their compliance with these exiting cybersecurity requirements and developing a framework to institutionalize cybersecurity process and practices throughout the DIB sector.

Notwithstanding the fact that these minimum cybersecurity standards have been in effect on DoD contracts since as early as 2013, several surveys and questionnaires by defense industrial associations have highlighted the DIB sector's continued challenges in achieving broad implementation of these security requirements. In a 2017 questionnaire, contractors and subcontractors that responded acknowledged implementation rates of 38% to 54% for at least 10 of the 110 security requirements of NIST SP 800–171.[1] In a separate 2018 survey, 36% of contractors who responded indicated a lack of awareness of DFARS clause 252.204–7012 and 45% of contractors acknowledged not having read NIST SP 800–171.[2] In a 2019 survey, contractors that responded rated their level of preparedness for a Defense Contract Management Agency standard assessment of contractor implementation of NIST SP 800–171 at 56%.[3] Furthermore, for the High Assessments conducted on-site by DoD to date, only 36% of contractors demonstrated implementation of all 110 of the NIST SP 800–171 security requirements.

Although these industry surveys represent a small sample of the DIB sector, the results were reinforced by the findings from DoD Inspector General report in 2019 (DODIG–2019–105 ''Audit of Protection of DoD Controlled Unclassified Information on Contractor-Owned Networks and Systems'') indicate that DoD contractors did not consistently implement mandated system security requirements for safeguarding CUI and recommended that DoD take immediate steps to assess a contractor's ability to protect this information. The report emphasizes that malicious actors can exploit the vulnerabilities of contractors' networks and systems and exfiltrate information related to some of the Nation's most valuable advanced defense technologies.

Defense contractors must begin viewing cybersecurity as a part of doing business, in order to protect themselves and to protect national security. The various industry surveys and Government assessments conducted to date illustrate the following: Absent a requirement for defense contractors to demonstrate implementation of standard cybersecurity processes and practices, cybersecurity requirements will not be fully implemented, leaving DoD and the DIB unprotected and vulnerable to malicious cyber activity. To this end, section 1648 of the NDAA for FY 2020 (Pub. L. 116–92) directed the Secretary of Defense to develop a consistent, comprehensive framework to enhance cybersecurity for the U.S. defense industrial base no later than February 1, 2020. In the Senate Armed Services Committee Report to accompany the NDAA for FY 2020, the Committee expressed concern that DIB contractors are an inviting target for our adversaries, who have been conducting cyberattacks to steal critical military technologies.

Developing a framework to enhance the cybersecurity of the defense industrial base will serve as an important first step toward securing the supply chain. Pursuant to section 1648, DoD has developed the CMMC Framework, which gives the Department a mechanism to certify the cyber posture of its largest defense contractors to the smallest firms in our supply chain, who have become primary targets of malicious cyber activity.

This rule is an important part of the cybersecurity framework,[4] and builds on the existing FAR and DFARS clause cybersecurity requirements by (1) adding a mechanism to immediately begin assessing the current status of contractor implementation of NIST SP 800–171 on their information systems that process CUI; and (2) to require contractors and subcontractors to take steps to fully implement existing cybersecurity requirements, plus additional processes and practices, to protect FCI and CUI on their information systems in preparation for verification under the CMMC Framework. There is an urgent need for DoD to immediately begin assessing where vulnerabilities in its supply chain exist and take steps to correct such deficiencies, which can be accomplished by requiring contractors and subcontractors that handle DoD CUI on their information systems to complete a NIST SP 800–171 Basic Assessment. In fact, while this rule includes a delayed effective date, contractors and subcontractors that are required to implement NIST SP 800–171 pursuant to DFARS clause 252.204–7012, are encouraged to immediately conduct and submit a self-assessment as described in this rule to facilitate the Department's assessment.

It is equally urgent for the Department to ensure DIB contractors that have not fully implemented the basic safeguarding requirements under FAR clause 52.204–21 or the NIST SP 800–171 security requirements pursuant to DFARS 252.204–7012 begin correcting these deficiencies immediately. These are cybersecurity requirements contractors and subcontractors should have already implemented (or in the

[1] Aerospace Industries Association. ''Complying with NIST 800–171.'' Fall 2017.

[2] National Defense Industrial Association (NDIA). ''Implementing Cybersecurity in DoD Supply Chains.'' White Paper. July 2018.

[3] NDIA. ''Beyond Obfuscation: The Defense Industry's Position within Federal Cybersecurity Policy.'' A Report of the NDIA Policy Department. October 2018. Page 20 and page 24.

[4] Section 1648 of the NDAA for FY 2020 mandates the formulation of ''unified cybersecurity . . . regulations . . . to be imposed on the defense industrial base for the purpose of assessing the cybersecurity of individual contractors,''

case of implementation of NIST SP 800–171, have plans of action to correct deficiencies) on information systems that handle CUI. Under the CMMC Framework, a contractor is able to achieve CMMC Level 1 Certification if they can demonstrate implementation of the basic safeguarding requirements in the FAR clause. Similarly, a contractor is able to achieve CMMC Level 3 if they can demonstrate implementation of the NIST SP 800–171 security requirements, plus some additional processes and practices. This rule ensures contractors and subcontractors focus on full implementation of existing cybersecurity requirements on their information systems and expedites the Department's ability to secure its supply chain.

For the foregoing reasons, pursuant to 41 U.S.C. 1707(d), DoD finds that urgent and compelling circumstances make compliance with the notice and comment requirements of 41 U.S.C. 1707(a) impracticable, and invokes the exception to those requirements under 41 U.S.C. 1707(d) and FAR 1.501–3(b).[5] While a public comment process will not be completed prior to the rule's effective date, DoD has incorporated feedback solicited through extensive outreach already undertaken pursuant to section 1648(d) of the NDAA for FY 2020, including through public meetings and extensive industry outreach conducted over the past year. However, pursuant to 41 U.S.C. 1707 and FAR 1.501–3(b), DoD will consider public comments received in response to this interim rule in the formation of the final rule.

List of Subjects in 204, 212, 217, and 252

Government procurement.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 204, 212, 217, and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 204, 212, 217, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

[5] FAR 1.501–3(b) states that ''[a]dvance comments need not be solicited when urgent and compelling circumstances make solicitation of comments impracticable prior to the effective date of the coverage, such as when a new statute must be implemented in a relatively short period of time. In such case, the coverage shall be issued on a temporary basis and shall provide for at least a 30 day public comment period.''

PART 204—ADMINISTRATIVE MATTERS

■ 2. Amend section 204.7302 by revising paragraph (a) to read as follows:

204.7302 Policy.

(a)(1) Contractors and subcontractors are required to provide adequate security on all covered contractor information systems.

(2) Contractors required to implement NIST SP 800–171, in accordance with the clause at 252.204–7012, Safeguarding Covered Defense Information and Cyber incident Reporting, are required at time of award to have at least a Basic NIST SP 800–171 DoD Assessment that is current (*i.e.,* not more than 3 years old unless a lesser time is specified in the solicitation) (see 252.204–7019).

(3) The NIST SP 800–171 DoD Assessment Methodology is located at *https://www.acq.osd.mil/dpap/pdi/cyber/strategically_assessing_contractor_implementation_of_NIST_SP_800-171.html.*

(4) High NIST SP 800–171 DoD Assessments will be conducted by Government personnel using NIST SP 800–171A, ''Assessing Security Requirements for Controlled Unclassified Information.''

(5) The NIST SP 800–171 DoD Assessment will not duplicate efforts from any other DoD assessment or the Cybersecurity Maturity Model Certification (CMMC) (see subpart 204.75), except for rare circumstances when a re-assessment may be necessary, such as, but not limited to, when cybersecurity risks, threats, or awareness have changed, requiring a re-assessment to ensure current compliance.

* * * * *

■ 3. Revise section 204.7303 to read as follows:

204.7303 Procedures.

(a) Follow the procedures relating to safeguarding covered defense information at PGI 204.7303.

(b) The contracting officer shall verify that the summary level score of a current NIST SP 800–171 DoD Assessment (*i.e.,* not more than 3 years old, unless a lesser time is specified in the solicitation) (see 252.204–7019) for each covered contractor information system that is relevant to an offer, contract, task order, or delivery order are posted in Supplier Performance Risk System (SPRS) (*https://www.sprs.csd.disa.mil/*), prior to—

(1) Awarding a contract, task order, or delivery order to an offeror or contractor that is required to implement NIST SP 800–171 in accordance with the clause at 252.204–7012; or

(2) Exercising an option period or extending the period of performance on a contract, task order, or delivery order with a contractor that is that is required to implement the NIST SP 800–171 in accordance with the clause at 252.204–7012.

■ 4. Amend section 204.7304 by revising the section heading and adding paragraphs (d) and (e) to read as follows:

204.7304 Solicitation provisions and contract clauses.

* * * * *

(d) Use the provision at 252.204–7019, Notice of NIST SP 800–171 DoD Assessment Requirements, in all solicitations, including solicitations using FAR part 12 procedures for the acquisition of commercial items, except for solicitations solely for the acquisition of commercially available off-the-shelf (COTS) items.

(e) Use the clause at 252.204–7020, NIST SP 800–171 DoD Assessment Requirements, in all solicitations and contracts, task orders, or delivery orders, including those using FAR part 12 procedures for the acquisition of commercial items, except for those that are solely for the acquisition of COTS items.

■ 5. Add subpart 204.75, consisting of 204.7500 through 204.7503, to read as follows:

Subpart 204.75—Cybersecurity Maturity Model Certification

Sec.

204.7500 Scope of subpart.
204.7501 Policy.
204.7502 Procedures.
204.7503 Contract clause.

Subpart 204.75—Cybersecurity Maturity Model Certification

204.7500 Scope of subpart.

(a) This subpart prescribes policies and procedures for including the Cybersecurity Maturity Model Certification (CMMC) level requirements in DoD contracts. CMMC is a framework that measures a contractor's cybersecurity maturity to include the implementation of cybersecurity practices and institutionalization of processes (see *https://www.acq.osd.mil/cmmc/index.html*).

(b) This subpart does not abrogate any other requirements regarding contractor physical, personnel, information, technical, or general administrative security operations governing the protection of unclassified information,

nor does it affect requirements of the National Industrial Security Program.

204.7501 Policy.

(a) The contracting officer shall include in the solicitation the required CMMC level, if provided by the requiring activity. Contracting officers shall not award a contract, task order, or delivery order to an offeror that does not have a current (*i.e.,* not more than 3 years old) CMMC certificate at the level required by the solicitation.

(b) Contractors are required to achieve, at time of award, a CMMC certificate at the level specified in the solicitation. Contractors are required to maintain a current (*i.e.,* not more than 3 years old) CMMC certificate at the specified level, if required by the statement of work or requirement document, throughout the life of the contract, task order, or delivery order. Contracting officers shall not exercise an option period or extend the period of performance on a contract, task order, or delivery order, unless the contract has a current (*i.e.,* not more than 3 years old) CMMC certificate at the level required by the contract, task order, or delivery order.

(c) The CMMC Assessments shall not duplicate efforts from any other comparable DoD assessment, except for rare circumstances when a re-assessment may be necessary such as, but not limited to when there are indications of issues with cybersecurity and/or compliance with CMMC requirements.

204.7502 Procedures.

(a) When a requiring activity identifies a requirement for a contract, task order, or delivery order to include a specific CMMC level, the contracting officer shall not—

(1) Award to an offeror that does not have a CMMC certificate at the level required by the solicitation; or

(2) Exercise an option or extend any period of performance on a contract, task order, or delivery order unless the contractor has a CMMC certificate at the level required by the contract.

(b) Contracting officers shall use Supplier Performance Risk System (SPRS) (*https://www.sprs.csd.disa.mil/*) to verify an offeror or contractor's CMMC level.

204.7503 Contract clause.

Use the clause at 252.204–7021, Cybersecurity Maturity Model Certification Requirements, as follows:

(a) Until September 30, 2025, in solicitations and contracts or task orders or delivery orders, including those using FAR part 12 procedures for the acquisition of commercial items, except for solicitations and contracts or orders solely for the acquisition of commercially available off-the-shelf (COTS) items, if the requirement document or statement of work requires a contractor to have a specific CMMC level. In order to implement a phased rollout of CMMC, inclusion of a CMMC requirement in a solicitation during this time period must be approved by OUSD(A&S).

(b) On or after October 1, 2025, in all solicitations and contracts or task orders or delivery orders, including those using FAR part 12 procedures for the acquisition of commercial items, except for solicitations and contracts or orders solely for the acquisition of COTS items.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 6. Amend section 212.301, by adding paragraphs (f)(ii)(K), (L), and (M) to read as follows:

212.301 Solicitation provisions and contract clauses for acquisition of commercial items.

* * * * *

(f) * * *

(ii) * * *

(K) Use the provision at 252.204–7019, Notice of NIST SP 800–171 DoD Assessment Requirements, as prescribed in 204.7304(d).

(L) Use the clause at 252.204–7020, NIST SP 800–171 DoD Assessment Requirements, as prescribed in 204.7304(e).

(M) Use the clause at 252.204–7021, Cybersecurity Maturity Model Certification Requirements, as prescribed in 204.7503(a) and (b).

* * * * *

PART 217—SPECIAL CONTRACTING METHODS

■ 7. Amend section 217.207 by revising paragraph (c) to read as follows:

217.207 Exercise of options.

(c) In addition to the requirements at FAR 17.207(c), exercise an option only after:

(1) Determining that the contractor's record in the System for Award Management database is active and the contractor's Data Universal Numbering System (DUNS) number, Commercial and Government Entity (CAGE) code, name, and physical address are accurately reflected in the contract document. See PGI 217.207 for the requirement to perform cost or price analysis of spare parts prior to exercising any option for firm-fixed-price contracts containing spare parts.

(2) Verifying in the Supplier Performance Risk System (SPRS) (*https://www.sprs.csd.disa.mil/*) that—

(i) The summary level score of a current NIST SP 800–171 DoD Assessment (*i.e.,* not more than 3 years old, unless a lesser time is specified in the solicitation) for each covered contractor information system that is relevant to an offer, contract, task order, or delivery order are posted (see 204.7303).

(ii) The contractor has a CMMC certificate at the level required by the contract, and that it is current (*i.e.,* not more than 3 years old) (see 204.7502).

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 8. Add sections 252.204–7019, 252.204–7020, and 252.204–7021 to read as follows:

Sec.

* * * * *

252.204–7019 Notice of NIST SP 800–171 DoD Assessment Requirements.

252.204–7020 NIST SP 800–171 DoD Assessment Requirements.

252.204–7021 Contractor Compliance with the Cybersecurity Maturity Model Certification Level Requirement.

* * * * *

252.204–7019 Notice of NIST SP 800–171 DoD Assessment Requirements.

As prescribed in 204.7304(d), use the following provision:

NOTICE OF NIST SP 800–171 DOD ASSESSMENT REQUIREMENTS (NOV 2020)

(a) *Definitions.*

Basic Assessment, Medium Assessment, and *High Assessment* have the meaning given in the clause 252.204–7020, NIST SP 800–171 DoD Assessments.

Covered contractor information system has the meaning given in the clause 252.204–7012, Safeguarding Covered Defense Information and Cyber Incident Reporting, of this solicitation.

(b) *Requirement.* In order to be considered for award, if the Offeror is required to implement NIST SP 800–171, the Offeror shall have a current assessment (*i.e.,* not more than 3 years old unless a lesser time is specified in the solicitation) (see 252.204–7020) for each covered contractor information system that is relevant to the offer, contract, task order, or delivery order. The Basic, Medium, and High NIST SP 800–171 DoD Assessments are described in the NIST SP 800–171 DoD Assessment Methodology located at *https://www.acq.osd.mil/dpap/pdi/cyber/strategically_assessing_contractor_implementation_of_NIST_SP_800-171.html.*

(c) *Procedures.* (1) The Offeror shall verify that summary level scores of a current NIST SP 800–171 DoD Assessment (*i.e.,* not more than 3 years old unless a lesser time is

specified in the solicitation) are posted in the Supplier Performance Risk System (SPRS) (*https://www.sprs.csd.disa.mil/*) for all covered contractor information systems relevant to the offer.

(2) If the Offeror does not have summary level scores of a current NIST SP 800–171 DoD Assessment (*i.e.,* not more than 3 years old unless a lesser time is specified in the solicitation) posted in SPRS, the Offeror may conduct and submit a Basic Assessment to *webptsmh@navy.mil* for posting to SPRS in the format identified in paragraph (d) of this provision.

(d) *Summary level scores.* Summary level scores for all assessments will be posted 30 days post-assessment in SPRS to provide DoD Components visibility into the summary level scores of strategic assessments.

(1) *Basic Assessments.* An Offeror may follow the procedures in paragraph (c)(2) of this provision for posting Basic Assessments to SPRS.

(i) The email shall include the following information:

(A) Cybersecurity standard assessed (*e.g.,* NIST SP 800–171 Rev 1).

(B) Organization conducting the assessment (*e.g.,* Contractor self-assessment).

(C) For each system security plan (security requirement 3.12.4) supporting the performance of a DoD contract—

(*1*) All industry Commercial and Government Entity (CAGE) code(s) associated with the information system(s) addressed by the system security plan; and

(*2*) A brief description of the system security plan architecture, if more than one plan exists.

(D) Date the assessment was completed.

(E) Summary level score (*e.g.,* 95 out of 110, NOT the individual value for each requirement).

(F) Date that all requirements are expected to be implemented (*i.e.,* a score of 110 is expected to be achieved) based on information gathered from associated plan(s) of action developed in accordance with NIST SP 800–171.

(ii) If multiple system security plans are addressed in the email described at paragraph (d)(1)(i) of this section, the Offeror shall use the following format for the report:

System security plan	CAGE codes supported by this plan	Brief description of the plan architecture	Date of assessment	Total score	Date score of 110 will achieved

(2) *Medium and High Assessments.* DoD will post the following Medium and/or High Assessment summary level scores to SPRS for each system assessed:

(i) The standard assessed (*e.g.,* NIST SP 800–171 Rev 1).

(ii) Organization conducting the assessment, *e.g.,* DCMA, or a specific organization (identified by Department of Defense Activity Address Code (DoDAAC)).

(iii) All industry CAGE code(s) associated with the information system(s) addressed by the system security plan.

(iv) A brief description of the system security plan architecture, if more than one system security plan exists.

(v) Date and level of the assessment, *i.e.,* medium or high.

(vi) Summary level score (*e.g.,* 105 out of 110, not the individual value assigned for each requirement).

(vii) Date that all requirements are expected to be implemented (*i.e.,* a score of 110 is expected to be achieved) based on information gathered from associated plan(s) of action developed in accordance with NIST SP 800–171.

(3) *Accessibility.* (i) Assessment summary level scores posted in SPRS are available to DoD personnel, and are protected, in accordance with the standards set forth in DoD Instruction 5000.79, Defense-wide Sharing and Use of Supplier and Product Performance Information (PI).

(ii) Authorized representatives of the Offeror for which the assessment was conducted may access SPRS to view their own summary level scores, in accordance with the SPRS Software User's Guide for Awardees/Contractors available at *https://www.sprs.csd.disa.mil/pdf/SPRS_Awardee.pdf.*

(iii) A High NIST SP 800–171 DoD Assessment may result in documentation in addition to that listed in this section. DoD will retain and protect any such documentation as ''Controlled Unclassified Information (CUI)'' and intended for internal DoD use only. The information will be protected against unauthorized use and release, including through the exercise of applicable exemptions under the Freedom of Information Act (*e.g.,* Exemption 4 covers trade secrets and commercial or financial information obtained from a contractor that is privileged or confidential).

(End of provision)

252.204–7020 NIST SP 800–171 DoD Assessment Requirements.

As prescribed in 204.7304(e), use the following clause:

NIST SP 800–171 DOD ASSESSMENT REQUIREMENTS (NOV 2020)

(a) *Definitions.*

Basic Assessment means a contractor's self-assessment of the contractor's implementation of NIST SP 800–171 that—

(1) Is based on the Contractor's review of their system security plan(s) associated with covered contractor information system(s);

(2) Is conducted in accordance with the NIST SP 800–171 DoD Assessment Methodology; and

(3) Results in a confidence level of ''Low'' in the resulting score, because it is a self-generated score.

Covered contractor information system has the meaning given in the clause 252.204–7012, Safeguarding Covered Defense Information and Cyber Incident Reporting, of this contract.

High Assessment means an assessment that is conducted by Government personnel using NIST SP 800–171A, Assessing Security Requirements for Controlled Unclassified Information that—

(1) Consists of—

(i) A review of a contractor's Basic Assessment;

(ii) A thorough document review;

(iii) Verification, examination, and demonstration of a Contractor's system security plan to validate that NIST SP 800–171 security requirements have been implemented as described in the contractor's system security plan; and

(iv) Discussions with the contractor to obtain additional information or clarification, as needed; and

(2) Results in a confidence level of ''High'' in the resulting score.

Medium Assessment means an assessment conducted by the Government that—

(1) Consists of—

(i) A review of a contractor's Basic Assessment;

(ii) A thorough document review; and

(iii) Discussions with the contractor to obtain additional information or clarification, as needed; and

(2) Results in a confidence level of ''Medium'' in the resulting score.

(b) *Applicability.* This clause applies to covered contractor information systems that are required to comply with the National Institute of Standards and Technology (NIST) Special Publication (SP) 800–171, in accordance with Defense Federal Acquisition Regulation System (DFARS) clause at 252.204–7012, Safeguarding Covered Defense Information and Cyber Incident Reporting, of this contract.

(c) *Requirements.* The Contractor shall provide access to its facilities, systems, and personnel necessary for the Government to conduct a Medium or High NIST SP 800–171 DoD Assessment, as described in NIST SP 800–171 DoD Assessment Methodology at *https://www.acq.osd.mil/dpap/pdi/cyber/strategically_assessing_contractor_implementation_of_NIST_SP_800-171.html,* if necessary.

(d) *Procedures.* Summary level scores for all assessments will be posted in the Supplier Performance Risk System (SPRS) (*https://www.sprs.csd.disa.mil/*) to provide DoD

Components visibility into the summary level scores of strategic assessments.

(1) *Basic Assessments.* A contractor may submit, via encrypted email, summary level scores of Basic Assessments conducted in accordance with the NIST SP 800–171 DoD Assessment Methodology to *webptsmh@navy.mil* for posting to SPRS.

(i) The email shall include the following information:

(A) Version of NIST SP 800–171 against which the assessment was conducted.

(B) Organization conducting the assessment (*e.g.,* Contractor self-assessment).

(C) For each system security plan (security requirement 3.12.4) supporting the performance of a DoD contract—

(*1*) All industry Commercial and Government Entity (CAGE) code(s) associated with the information system(s) addressed by the system security plan; and

(*2*) A brief description of the system security plan architecture, if more than one plan exists.

(D) Date the assessment was completed.

(E) Summary level score (*e.g.,* 95 out of 110, NOT the individual value for each requirement).

(F) Date that all requirements are expected to be implemented (*i.e.,* a score of 110 is expected to be achieved) based on information gathered from associated plan(s) of action developed in accordance with NIST SP 800–171.

(ii) If multiple system security plans are addressed in the email described at paragraph (b)(1)(i) of this section, the Contractor shall use the following format for the report:

System security plan	CAGE codes supported by this plan	Brief description of the plan architecture	Date of assessment	Total score	Date score of 110 will achieved

(2) *Medium and High Assessments.* DoD will post the following Medium and/or High Assessment summary level scores to SPRS for each system security plan assessed:

(i) The standard assessed (*e.g.,* NIST SP 800–171 Rev 1).

(ii) Organization conducting the assessment, *e.g.,* DCMA, or a specific organization (identified by Department of Defense Activity Address Code (DoDAAC)).

(iii) All industry CAGE code(s) associated with the information system(s) addressed by the system security plan.

(iv) A brief description of the system security plan architecture, if more than one system security plan exists.

(v) Date and level of the assessment, *i.e.,* medium or high.

(vi) Summary level score (*e.g.,* 105 out of 110, not the individual value assigned for each requirement).

(vii) Date that all requirements are expected to be implemented (*i.e.,* a score of 110 is expected to be achieved) based on information gathered from associated plan(s) of action developed in accordance with NIST SP 800–171.

(e) *Rebuttals.* (1) DoD will provide Medium and High Assessment summary level scores to the Contractor and offer the opportunity for rebuttal and adjudication of assessment summary level scores prior to posting the summary level scores to SPRS (see SPRS User's Guide *https://www.sprs.csd.disa.mil/pdf/SPRS_Awardee.pdf*).

(2) Upon completion of each assessment, the contractor has 14 business days to provide additional information to demonstrate that they meet any security requirements not observed by the assessment team or to rebut the findings that may be of question.

(f) *Accessibility.* (1) Assessment summary level scores posted in SPRS are available to DoD personnel, and are protected, in accordance with the standards set forth in DoD Instruction 5000.79, Defense-wide Sharing and Use of Supplier and Product Performance Information (PI).

(2) Authorized representatives of the Contractor for which the assessment was conducted may access SPRS to view their own summary level scores, in accordance with the SPRS Software User's Guide for Awardees/Contractors available at *https://www.sprs.csd.disa.mil/pdf/SPRS_Awardee.pdf.*

(3) A High NIST SP 800–171 DoD Assessment may result in documentation in addition to that listed in this clause. DoD will retain and protect any such documentation as ''Controlled Unclassified Information (CUI)'' and intended for internal DoD use only. The information will be protected against unauthorized use and release, including through the exercise of applicable exemptions under the Freedom of Information Act (*e.g.,* Exemption 4 covers trade secrets and commercial or financial information obtained from a contractor that is privileged or confidential).

(g) *Subcontracts.* (1) The Contractor shall insert the substance of this clause, including this paragraph (g), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items (excluding COTS items).

(2) The Contractor shall not award a subcontract or other contractual instrument, that is subject to the implementation of NIST SP 800–171 security requirements, in accordance with DFARS clause 252.204–7012 of this contract, unless the subcontractor has completed, within the last 3 years, at least a Basic NIST SP 800–171 DoD Assessment, as described in *https://www.acq.osd.mil/dpap/pdi/cyber/strategically_assessing_contractor_implementation_of_NIST_SP_800-171.html,* for all covered contractor information systems relevant to its offer that are not part of an information technology service or system operated on behalf of the Government.

(3) If a subcontractor does not have summary level scores of a current NIST SP 800–171 DoD Assessment (*i.e.,* not more than 3 years old unless a lesser time is specified in the solicitation) posted in SPRS, the subcontractor may conduct and submit a Basic Assessment, in accordance with the NIST SP 800–171 DoD Assessment Methodology, to *webptsmh@navy.mil* for posting to SPRS along with the information required by paragraph (d) of this clause.

(End of clause)

252.204–7021 Contractor Compliance with the Cybersecurity Maturity Model Certification Level Requirement.

As prescribed in 204.7503(a) and (b), insert the following clause:

CONTRACTOR COMPLIANCE WITH THE CYBERSECURITY MATURITY MODEL CERTIFICATION LEVEL REQUIREMENT (NOV 2020)

(a) *Scope.* The Cybersecurity Maturity Model Certification (CMMC) CMMC is a framework that measures a contractor's cybersecurity maturity to include the implementation of cybersecurity practices and institutionalization of processes (see *https://www.acq.osd.mil/cmmc/index.html*).

(b) *Requirements.* The Contractor shall have a current (*i.e.* not older than 3 years) CMMC certificate at the CMMC level required by this contract and maintain the CMMC certificate at the required level for the duration of the contract.

(c) *Subcontracts.* The Contractor shall—

(1) Insert the substance of this clause, including this paragraph (c), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items, excluding commercially available off-the-shelf items; and

(2) Prior to awarding to a subcontractor, ensure that the subcontractor has a current (*i.e.,* not older than 3 years) CMMC certificate at the CMMC level that is appropriate for the information that is being flowed down to the subcontractor.

(End of clause)

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Part VI

Department of Housing and Urban Development

24 CFR Parts 5, 14, 75, et al.

Enhancing and Streamlining the Implementation of Section 3 Requirements for Creating Economic Opportunities for Low- and Very Low-Income Persons and Eligible Businesses; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5, 14, 75, 91, 92, 93, 135, 266, 570, 574, 576, 578, 905, 964, 983, and 1000

[Docket No. FR–6085–F–03]

RIN 2501–AD87

Enhancing and Streamlining the Implementation of Section 3 Requirements for Creating Economic Opportunities for Low- and Very Low-Income Persons and Eligible Businesses

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: Section 3 of the Housing and Urban Development Act of 1968, as amended by the Housing and Community Development Act of 1992 (Section 3), contributes to the establishment of stronger, more sustainable communities by ensuring that employment and other economic opportunities generated by Federal financial assistance for housing and community development programs are, to the greatest extent feasible, directed toward low- and very low-income persons, particularly those who receive government assistance for housing. In accordance with statutory authority, HUD is charged with the responsibility to implement and enforce Section 3. HUD's regulations implementing the requirements of Section 3 have not been updated since 1994 and are not as effective as HUD believes they could be. This final rule updates HUD's Section 3 regulations to create more effective incentives for employers to retain and invest in their low- and very low-income workers, streamline reporting requirements by aligning them with typical business practices, provide for program-specific oversight, and clarify the obligations of entities that are covered by Section 3. These changes will increase Section 3's impact for low- and very low-income persons, increase compliance with Section 3 requirements, and reduce regulatory burden.

DATES: *Effective Date:* November 30, 2020.

Compliance Dates: Public housing financial assistance recipients must implement their Section 3 activities pursuant to these regulations and comply with the reporting requirements starting with the recipient's first full fiscal year after July 1, 2021. These regulations are applicable to Section 3 projects for which assistance or funds are committed on or after July 1, 2021.

FOR FURTHER INFORMATION CONTACT: For questions, please contact the following people (the phone numbers are not toll-free):

For Public Housing Financial Assistance: Merrie Nichols-Dixon, Director, Office of Policy Program and Legislation, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW, Room 3178, Washington, DC 20410; telephone 202–402–4673 (not a toll-free number).

For Community Development Block Grant (CDBG)/CDBG Disaster Recovery/ Section 108 Loan Guarantee Program: Jessie Handforth Kome, Director, Office of Block Grant Assistance, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW, Room 7282, Washington, DC 20410; telephone 202–708–3587 (voice/TDD) (not a toll-free numbers).

For HOME or Housing Trust Fund Section 3 projects: Virginia Sardone, Director, Office of Affordable Housing Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW, Room 10168, Washington, DC 20410; telephone 202–402–4606 (not a toll-free number).

For Office of Housing programs: Thomas R. Davis, Director, Office of Recapitalization, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW, Room 6230, Washington, DC 20410; telephone 202–402–7549 (voice/TDD) (these are not toll-free numbers).

Persons with hearing or speech impairments may access this number through TTY by calling the Federal Relay Service, at toll-free, 800–877–8339. General email inquiries regarding Section 3 may be sent to: *section3@hud.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 3 of the Housing and Urban Development Act of 1968 (Pub. L. 90–448, approved August 1, 1968) (Section 3) was enacted to bring economic opportunities generated by certain HUD financial assistance expenditures, to the greatest extent feasible, to low- and very low-income persons residing in communities where the financial assistance is expended. Section 3 recognizes that HUD funds are often one of the largest sources of Federal funds expended in low- and very low-income communities and, where such funds are spent on activities such as construction and rehabilitation of housing and other public facilities, the expenditure results in economic opportunities. By directing HUD-funded economic opportunities to residents and businesses in the community where the funds are expended, the expenditure can have the dual benefit of creating new or rehabilitated housing and other facilities while providing opportunities for employment and training for the residents of these communities.

The Section 3 statute establishes priorities for employment and contracting for public housing programs and for other programs that provide housing and community development assistance. For example, the prioritization as it relates to public housing assistance places an emphasis on public housing residents, in contrast to the prioritization as it relates to housing and community development assistance, which places more emphasis on residents of the neighborhood or service area in which the investment is being made.

In the 25 years since HUD promulgated the current Section 3 regulations, significant legislation has been enacted that affects Section 3.[1] In addition, HUD has also heard from the public that there is a need for regulatory changes to clarify and simplify the existing requirements. HUD's experience in administering Section 3 over time has also provided insight as to how HUD could improve its Section 3 regulations. HUD, thus, concluded that regulatory changes were necessary to streamline Section 3 and more effectively benefit low- and very low-income persons through HUD financial assistance to achieve the Section 3 statute's purposes.

II. The Proposed Rule

HUD issued a proposed rule on April 4, 2019 (84 FR 13177) to update the existing regulations and streamline the Section 3 program.

Promote Sustained Employment and Career Development

The proposed rule included multiple elements designed to increase Section 3's impact in directing employment opportunities and sustaining employment for the people served by

[1] This legislation includes, but is not limited to, the following: Reforms made to HUD's Indian housing programs by the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA) (Pub. L. 104–330, approved October 26, 1996); public housing reforms made by the Quality Housing and Work Responsibility Act of 1998 (QHWRA) (Pub. L. 105–276, approved October 21, 1998); reforms made to HUD's supportive housing programs by the Section 202 Supportive Housing for the Elderly Act of 2010 (Pub. L. 111–372, approved January 4, 2011); and the Frank Melville Supportive Housing Investment Act of 2010 (Pub. L. 111–347, approved January 4, 2011).

HUD financial assistance programs. The rule proposed tracking and reporting labor hours instead of new hires. While the previous new hire framework was valuable for measuring entry into employment, the new hire framework did not capture the extent to which new hiring opportunities are created relative to the total work performed, nor whether those opportunities are sustained over time. The proposed rule's focus on labor hours sought to measure total actual employment and the proportion of the total employment performed by low- and very low-income workers. In addition, the change to labor hours emphasized continued employment. For example, the prior exclusive focus on counting new hires regarded five new hires for one-month opportunities as a more valued outcome than one 12-month opportunity, and it did not distinguish between full- and part-time employment. A full-time job sustained over a long period allows a low- or very low-income worker to gain skills and is a strong indicator of progress towards self-sufficiency. The new focus on labor hours would ensure that longer-term, full-time opportunities are appropriately recognized.

HUD's proposed rule also sought comment on maintaining the new hire framework for only Public Housing Agencies (PHAs). HUD held a number of listening sessions and heard from some PHAs that they would prefer to keep reporting new hires rather than switch to reporting labor hours. Therefore, while HUD believes tracking labor hours is the best option and would simplify reporting, HUD did seek comment on the alternative option of maintaining the new hires framework for PHAs.

Align Section 3 Reporting With Standard Business Practices

HUD also proposed tracking labor hours rather than new hires because it would be more consistent with business practices. Most construction contractors working on HUD assisted projects already track labor hours in their payroll systems because they pay their employees based on an hourly wage. In some cases, they are also subject to prevailing wage requirements.[2] HUD believes a consistent labor-hour tracking mechanism makes compliance with Section 3 easier not only for recipients of HUD assistance, but also for contractors and subcontractors. The proposed rule provided that for employers who do not track labor hours in detail through a time-and-attendance system, such employers could provide a good faith assessment of the labor hours for a full- or part-time employee. However, if a time-and-attendance system is later implemented, the accurate labor hour accounting would be required.

Applicability and Thresholds

The Section 3 statute applies to both: (1) HUD's Public Housing Program, and (2) Other HUD programs that provide housing and community development assistance. For ease in administration for recipients using one or both of these HUD funding streams, the proposed rule provided definitions for these types of funding and specified Section 3 requirements for each type. The proposed rule included the following definitions for the scope of such financial assistance:

(1) Public housing financial assistance covers:

(a) Development assistance provided pursuant to Section 5 of the United States Housing Act of 1937 (the 1937 Act),

(b) operations and management assistance provided pursuant to Section 9(e) of the 1937 Act (Operating Fund), and

(c) development, modernization, and management assistance provided pursuant to Section 9(d) of the 1937 Act (Capital Fund); and

(2) Section 3 projects cover HUD program assistance used for housing rehabilitation, housing construction and other public construction projects that generally exceed a $200,000 project threshold or any Section 3 project funding from HUD's Lead Hazard Control and Healthy Homes programs.

The proposed definitions defined the scope of programs subject to Section 3 requirements but did not expand such coverage beyond the compliance requirements of HUD's prior regulations. HUD proposed the $200,000 threshold for housing rehabilitation, housing construction and other public construction projects because work below that amount would likely not trigger long-term employment opportunities for which the recipient could show measurable labor hours. The proposed rule also clarified that contracts, subcontracts, grants, or subgrants subject to Section 7(b) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5307(b)) or subject to tribal preference requirements as authorized under Section 101(k) of the Native American Housing Assistance and Self-Determination Act (25 U.S.C. 4111(k)) must provide preferences in employment, training, and business opportunities to Indians and Indian organizations.

Reporting and Targeted Section 3 Workers

The proposed rule aimed to align Section 3 reporting requirements more closely to the statutory priorities; HUD's previous regulation tracked only public housing residents or low- or very low-income persons who lived in the metropolitan area or nonmetropolitan county of the project, rather than whether the statutory priorities were met. The rule proposed a new definition of ''Section 3 worker'' as any worker or who meets at least one of the following criteria: Low- or very low-income, as established by HUD's income limits; living in a Qualified Census Tract (QCT); or employed by a Section 3 business concern.[3]

The proposed rule also included a new ''Targeted Section 3 worker'' definition so that HUD could track, and recipients could target, the hiring of Section 3 workers in selected categories. The Section 3 statute requires certain financial assistance recipients to prioritize their efforts to direct employment and economic opportunities to specific groups of low- and very low-income individuals. The ''Targeted Section 3 worker'' reflects both statutory and policy priorities that HUD wishes to specifically track. For public housing financial assistance, the proposed definition of a Targeted Section 3 worker was a Section 3 worker who is also:

(1) A worker employed by a Section 3 business concern; or

(2) A worker who is currently or who was when hired by the worker's current employer, a resident in a public housing project or Section 8-assisted housing; or

(3) A resident of other projects managed by the PHA that is expending assistance; or

(4) A current YouthBuild participant.

For other HUD assistance programs, the proposed priorities were:

(1) Residents within the service area or the neighborhood of the project, and

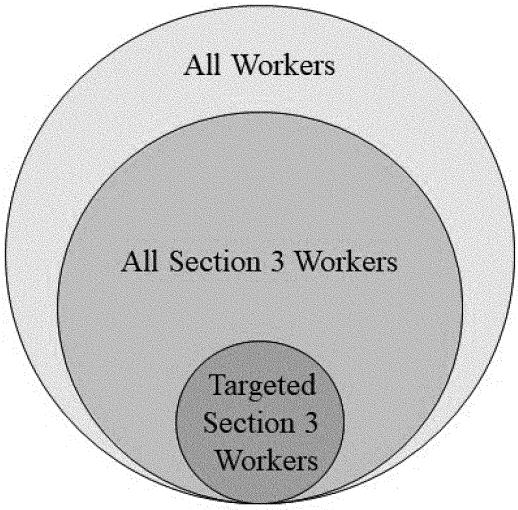
(2) YouthBuild participants.

[2] See 42 U.S.C. 1437j(a), 24 CFR 905.308(b)(3)(ii), 24 CFR 965.101, 25 U.S.C. 4225(b)(1)(A), and 24 CFR 1006.345(b).

[3] Section 3 business concern means: (1) A business concern that meets one of the following criteria: (i) It is at least 51 percent owned by low- or very low-income persons; (ii) Over 75 percent of the labor hours performed for the business are performed by low- or very low-income persons; or (iii) It is a business at least 25 percent owned by current public housing residents or residents who currently live in Section 8-assisted housing. (2) The status of a Section 3 business concern shall not be negatively affected by a prior arrest or conviction of its owner(s) or employees. (3) Nothing in this part shall be construed to require the contracting or subcontracting of a Section 3 business concern. Section 3 business concerns are not exempt from meeting the specifications of the contract.

There is also a statutory contracting priority for businesses that provide economic opportunities for low- and very low-income workers. Therefore, HUD proposed including labor hours worked by the Section 3 business concern employees for both Section 3 workers and Targeted Section 3 workers. HUD also proposed a new Section 3 business concern definition that reflected the change to labor hours and increased the threshold of work performed by a business by low- and very low-income workers given the proposed rule's inclusion of all Section 3 business concerns' labor hours in the definition of both Section 3 workers and Targeted Section 3 workers.

The proposed rule created the following construct for measuring workers:



Benchmarks

The proposed rule provided that a new Section 3 benchmark measurement would serve as a safe harbor for those recipients that meet the new benchmark. The primary objective of the proposed rule was to reflect and monitor grantees' abilities to direct job opportunities that are generated by HUD financial assistance to Section 3 workers and Targeted Section 3 workers. The proposal included using benchmarks based on ratios of Section 3 workers and Targeted Section 3 workers in comparison to all workers. HUD proposed that the benchmarks would be set by **Federal Register** Notice and amended periodically to provide for updating of the benchmarks to align with the reporting data HUD received. As HUD gathers more data under the new rule, HUD could increase or decrease benchmark figures over time, or tailor different benchmarks for different geographies and different funding types. If a recipient certifies compliance with the statutory priorities and meets the outcome benchmarks, HUD will presume the recipient is complying with Section 3 requirements, absent evidence to the contrary. Recipients are still required to report their outcomes, and HUD will monitor them accordingly through the data reporting methods used to oversee all other program requirements in each applicable program area. Otherwise, recipients would be required to submit qualitative reports on their efforts, as they are required to do under HUD's previous rule when they do not meet the safe harbor, and HUD may conduct monitoring to review the recipient's compliance, again consistent with practices used to monitor program participants' compliance with other program requirements.

The proposed rule also provided a burden relieving measure for PHAs with fewer than 250 units. For these PHAs, they would only be required to report on Section 3 qualitative efforts and would not need to track labor hours for Section 3 workers and Targeted Section 3 workers.

Multiple Funding Sources

The proposed rule created a new section for housing rehabilitation, housing construction, or other public construction projects assisted with funds from more than one HUD program. Specifically, the proposed rule provided that when a Section 3 project is funded by public housing financial assistance, the public housing financial assistance must be tracked and reported consistent with the public housing financial assistance requirements in subpart B, while the community development financial assistance may follow the requirements in subpart B or subpart C. The proposed rule directed that when a Section 3 project receives housing and community development assistance from two different HUD programs, HUD would designate guidance through a single reporting office.

Integrate Section 3 Into Program Enforcement

Since HUD program office staff are regularly in touch with HUD's funding recipients on other compliance requirements, HUD proposed that program offices incorporate Section 3 compliance and oversight into regular program oversight and make Section 3 an integral part of the program's oversight work. The proposed rule also streamlined the complaint and compliance process to make Section 3 compliance consistent with existing practices for other requirements. The proposed rule shifted the delegation of authority for Section 3 enforcement and compliance responsibilities from the Assistant Secretary for Fair Housing and Equal Opportunity to reside with each of the applicable HUD program offices.

III. Changes Made at the Final Rule Stage

After review and consideration of the public comments and upon HUD's further consideration of Section 3 and the issues raised in the proposed rule, HUD has adopted the proposed rule as final with a few changes in this final rule. HUD also made minor edits to clarify the rule's language. The following highlights the substantive changes made by HUD in this final rule from the proposed rule.

Removing Alternative 2 for New Hires

After considering the data, Section 3's statutory goals, and the public comments, HUD is not retaining the tracking of new hires for PHAs, but instead requiring tracking of labor hours for all Section 3 outcomes. HUD agrees with commenters that it is in the best interest of the communities served by HUD to implement a more impactful Section 3 standard across all HUD-funded programs. Using different metrics for different programs would unnecessarily further complicate Section 3 reporting. Tracking labor hours is meant to ensure that Section 3 workers have sustained employment and career opportunities. HUD believes that the use of new hires provides an incomplete measure of the employment and local contracting opportunities available to low- and very low-income persons envisioned by the Section 3 statute. HUD expects the labor hour data to present a more accurate assessment of Section 3's impact. The focus on labor hours will measure total actual employment and the proportion of the total employment performed by low- and very low-income workers, which will mitigate contractors' ability to manipulate their Section 3 outcomes.

Section 3 Project Threshold

HUD received many public comments on proposed changes to the Section 3 Project threshold. HUD still considers the $200,000 threshold for Section 3 projects appropriate given the percentage of projects that will continue to be covered and are likely to result in opportunities for employment of low- and very low-income workers when expended on construction-related activities. However, in response to public comments, HUD is providing that in this final rule, the Secretary may adjust the threshold, through a **Federal Register** Notice subject to public comment, in order to ensure Section 3 compliance. HUD's proposed rule already provided for the Secretary to update the threshold not less than once every five years based on a national construction cost inflation factor; the final rule now provides that the Secretary updates the benchmarks not less frequently than once every three years. HUD believes adding this flexibility is responsive to the comments received by the public. HUD will continue to work with program participants to adjust the thresholds accordingly, if necessary, based on the updated data provided under this final rule.

Setting a Project Threshold for Lead Hazard Control Grants

HUD also received comments regarding the exclusion of projects under HUD's Lead Hazard Control and Healthy Homes program from the $200,000 project threshold. Lead hazard control projects are generally smaller, so many commenters suggested a lower threshold for such projects. On the other hand, other commenters noted that not including a threshold for lead hazard control grants altogether may incidentally include small grants that should not be subject to Section 3. For example, some Lead and Healthy Homes Technical Studies grants study the health effects of installed housing components in projects typically smaller than $100,000. As expected, they did not result in opportunities for employment of Section 3 workers under the previous regulations. At the final rule stage, HUD is therefore adopting a $100,000 project threshold for all projects that receive funding from HUD's Lead Hazard Control and Healthy Homes programs. HUD adopted this number to match the contract threshold in the previous regulations (see previous 24 CFR 135.3(a)(3)).

Removing the Qualified Census Tract Definition

After considering Section 3's statutory goals and the public comments, HUD is removing the QCT definition from this final rule. The addition of this criteria was to encourage hiring in the QCT and to make targeted hiring easier, but HUD recognizes that the inclusion of workers in these areas could inadvertently include individuals who are not low- or very low-income. Rather than the broad QCT definition, HUD is limiting the Section 3 worker definition to be more consistent with the statute, which requires prioritization of low- and very low-income workers and YouthBuild participants. This should also alleviate any potential burden on participants associated with the QCT designation.

Changing the Section 3 Business Concern Definition

In adopting the proposed definition of Section 3 business concern in this final rule, HUD is maintaining the over 75 percent of the labor hours performed for the business on construction are performed by low- or very low-income persons standard, but adding in that such performance must be over the last three-month period to help businesses determine whether or not they meet the criteria. HUD is also maintaining a separate criterion for businesses owned and controlled by current public housing residents or residents who currently live in Section 8-assisted housing, but increasing the required percentage of owned and controlled to 51%. This change is in response to public comments and to maintain consistency with HUD's public housing regulations on contracting with resident-owned businesses at 24 CFR part 963. HUD also added a change to the documentation timing in paragraph (1) of the Section 3 business concern definition to allow a six-month grace period. HUD understands that businesses need time when bidding on contracts and prior to the contract's execution to assemble materials and to assess labor hours. This change is responsive to commenters who expressed concerns about Section 3 status retention, since labor hours can be dependent on the number of contracts on which a business bids and receives.

Changing the Professional Services Definition

In this final rule, HUD is amending the professional services definition to clarify that only non-construction services that require an advanced degree or professional licensing, rather than all non-construction services, are excluded from Section 3. HUD wants to ensure this final rule's emphasis encapsulates the statutory requirement to prioritize low- and very low-income workers, and provides this category of exempted workers from reporting given the challenge to hire low- and very low-income workers in jobs that require such degrees and licensing.

Counting Labor Hours for 5 Years

HUD's proposed rule provided that labor hours for Section 3 workers and Targeted Section 3 workers could be counted as long as the worker met the definition of a Section 3 worker or Targeted Section 3 worker at the time of hire. Based on public comments and further consideration, HUD agrees that a worker whose income has risen should only be counted for Section 3 purposes for a limited time period. HUD wants to ensure employers are invested in keeping Section 3 workers employed, and that there is enough opportunity to build skills and experience so that Section 3 workers may develop self-sufficiency and compete for other jobs in the future. Therefore, HUD provides that for purposes of reporting the labor hours for Section 3 workers and Targeted Section 3 workers, an employer may choose whether the workers are defined as Section 3 workers for a five-year period at the time of the workers' hire, or when the

workers are first certified as meeting the Section 3 worker definition.

Delayed Effective Date

The rule provides for a delayed transition to labor hours and the associated recordkeeping requirements. HUD recognizes that employers and grantees will need time to transition their systems and reporting practices as a result of this final rule. HUD is mindful of the need to update policies and procedures for planning purposes, and the importance of implementing the rule such that employers will be able to comply. Therefore, HUD has provided for a transition period through at least July 1, 2021. During this transition period, HUD expects that employers and grantees will begin following this final rule's requirements for new grants, commitments, and contracts. The exact date on which any particular recipient of HUD funding will be able to implement the conversion to the new requirements will vary during this transition period, but the transition must be complete by July 1, 2021. The reporting requirements and labor hours tracking will not begin until the dates for each entity specified in the ''Compliance Date'' section above.

IV. Discussion of Public Comments and HUD's Responses

The public comment period on the proposed rule closed on June 3, 2019, and HUD received 163 public comments. The comments came from state and city government agencies and housing administrations, housing authorities, non-profits, independent consultants, private citizens, housing authority directors, small businesses, the construction industry, and housing authority associations. The following presents the significant issues and questions related to the proposed rule raised by the commenters, and HUD's responses to these issues and questions. HUD would like to thank all the commenters for their thoughtful responses.

''Best Efforts'' and ''Greatest Extent Feasible''

In the proposed rule, HUD included a specific question for public comment regarding these statutory terms. Some commenters suggested the terms are interchangeable. One commenter suggested that HUD use the term ''reasonable best efforts'' for CDBG and HOME recipients and remove the term ''greatest extent feasible'' from the Section 3 regulations or use only ''best efforts.'' Other commenters argued that these words are key to the intent of the statute, which is to provide recipients leeway when constraints outside their control impede implementation, and recommended that HUD provide guidance materials on how to show best efforts when organizations do not meet their Section 3 goals, such as data collection forms which would indicate best efforts or non-exclusive lists of examples of ''best efforts'' and ''greatest extent feasible.''

In contrast, some commenters suggested that these terms are not interchangeable. One commenter said that ''best efforts'' should be measured by tracking outreach and outcomes of outreach and ''greatest extent feasible'' is the result of ''best efforts.'' Another commenter argued that ''best efforts'' can be more clearly defined than ''greatest extent feasible,'' as specific actions can demonstrate efforts, while feasibility is a more passive analysis of what is possible. One commenter argued that the ''greatest extent feasible'' is a much more rigid and prescriptive standard than the ''best efforts'' standard and noted that courts have found that the ''best efforts'' requirement ''specifically avoids creating a mandatory obligation on the part of the agencies the statute affects.'' This ''best efforts'' standard likewise ''does not call for perfect compliance.'' This commenter encouraged HUD to allow PHAs to retain greater discretion over the development of their own Section 3 programs.

A commenter suggested that Subpart B participants should continue to use ''best efforts'' while Subpart C participants should use ''greatest extent feasible,'' and agencies receiving funding that triggers compliance under Subparts B and C should use the ''best efforts'' standard. One commenter suggested using the term ''best efforts'' to comply with employment, contracting and training opportunities.

Commenters also urged HUD to enforce the terms ''best efforts'' and ''greatest extent possible,'' suggesting that whatever the standard, if an activity by a recipient, contractor or subcontractor does not adequately serve to hire, train, and retain a Section 3 worker, then it should not meet the standard. These commenters provided an example of a PHA's best effort. Commenters noted that while the recipient or contractor appears to meet the Section 3 goal, or at least made ''best efforts'' to reach the goal, in practicality such effort is not workable.

One commenter wrote that the terms without any definition are too broad and should be defined to assist in compliance with Section 3. Another commenter proposed that HUD should define the terms by how they will be measured; for instance, that ''best efforts'' could be determined by a specific set of metrics around recruitment efforts and the percentage of Section 3 workers in the area. One commenter suggested a way to draft the rule using dollars spent to track compliance such that these terms would not be necessary.

Other commenters requested that HUD not define these terms or should not restrictively define these terms because HUD should trust the judgment and common sense of its professional field staff to determine compliance, because documenting compliance according to specific definitions could create additional administrative burden, because there are constraints outside the grantee's control, and because guidelines may stifle innovation.

HUD Response: HUD appreciates commenters' responses to the specific question regarding ''best efforts'' and ''greatest extent feasible'' in the proposed rule. ''Best efforts'' and ''greatest extent feasible'' are statutory terms, used in the statute in different contexts. As such, HUD will continue to use both terms to track compliance. HUD agrees with commenters that there are many ways to interpret the language. Traditionally, HUD has used the terms interchangeably, as referenced in the statute, and will continue to be consistent with the statutory language. *See* 12 U.S.C. 1701u(b)–(d). HUD also agrees with commenters who noted these terms are integral to the statutory intent and provide flexibility, rather than administrative burden, to grantees or recipients.

HUD notes that some perceive ''best efforts'' to be the more rigorous standard, while others perceive ''greatest extent feasible'' to be the more rigorous standard. HUD has determined not to define the difference between these two terms, but rather to increase the emphasis on outcomes as a result of these efforts. A recipient's reported results will be compared to the outcome metrics defined in the benchmark Notice. HUD program staff will evaluate the level of effort expended by those recipients that fail to meet the benchmark safe harbor, and thus will ensure that the statutory terms are being properly enforced. HUD included a list of examples in the regulation at §§ 75.15 and 75.25, including engagement in outreach efforts to generate job applicants who are Targeted Section 3 workers, providing training or apprenticeship opportunities, and providing technical assistance to help Section 3 workers compete for jobs (*e.g.,* resume assistance, coaching).

Move to Labor Hours

Support for Using ''Labor Hours''

Many commenters supported the shift to labor hours and, notwithstanding the alternatives presented in the proposed rule for PHAs, encouraged HUD to do the same for public housing construction, modernization, and similar work. These commenters stated that the ''new hire'' loophole should be eliminated for both housing and community development and public housing projects. Commenters stated that, in practice, contractors have only brought on new hires for short periods of time; the shift to labor hours will promote longer term employment. Commenters also stated that the shift to labor hours would solve the problem of contractors using dishonest practices to meet benchmarks, such as hiring Section 3 residents to fill the 30% benchmark only to lay them off shortly thereafter, or employing Section 3 hires for less than 20 hours a week. Commenters stated that allowing PHAs and their contractors to use ''new hires'' could provide a loophole to PHAs, allowing them to hire Section 3 workers for a limited or short time frame in order to comply with the regulation. Short-term employment does not allow residents to obtain technical skills, knowledge, or adequate savings. PHAs should be required to use labor hours worked because they can evade Section 3 compliance through manipulative hiring practices.

Commenters stated that the ''labor hours'' standard is far more effective, less susceptible to manipulation and administratively easier to verify. Commenters stated that the new hire standard is vulnerable to manipulation, because any contractor or subcontractor that performs work on more than one project at a time can easily avoid Section 3 hiring responsibilities by placing their new hires on non-Section 3 covered projects. Commenters asserted the new hire standard may be the single greatest barrier to achieving the employment potential of Section 3.

HUD Response: HUD agrees that counting new hires can be problematic and that collecting labor hours can be a more effective measure. As stated in the proposed rule, HUD believes that counting labor hours is consistent with the statute and mitigates contractors' ability to manipulate their Section 3 outcomes. HUD has adopted the suggestion by the commenters and in the final rule applies the labor hour requirements to both housing and community development and public housing projects.

Support for Using New Hires

Many commenters supported retaining the new hires metrics. Commenters stated that tracking by labor hours is burdensome, will increase administrative costs, and will not streamline the Section 3 reporting requirements. One commenter refuted HUD's hypothesis articulated in the proposed rule and stated that a labor hours metric is unlikely to capture the data on sustained employment opportunities that HUD is seeking. Another commenter stated that the proposed labor hours metric would decrease the number of firms willing to bid on contracts, increase the cost of public contracting for both the PHA and contractors, and provide no appreciable increase in Section 3 workers. Commenters stated that HUD should continue to track compliance by new hires for both Subparts B and C.

One commenter stated that labor hours should only apply to projects that already require the collection of certified payrolls as part of Davis Bacon compliance. Another commenter recommended HUD look to existing programs such as the Department of Transportation's Disadvantaged Business Enterprises for guidance to make substantive changes to Section 3.

Commenters stated that the changes will generate additional administrative burdens. Commenters especially emphasized the potential impact on the Housing Trust Fund (HTF) program and state CDBG and HOME program implementation because states, particularly small and rural community sub-grantees, have limited capacity. Commenters recommended HUD give State CDBG programs a similar alternative to the one offered to PHAs in § 75.15(d). Another commenter proposed HUD allow State CDBG programs to use a good faith assessment of hours, stating that § 75.25(a)(4) will help but will not eliminate the difficulty for State CDBG programs. Another commenter specifically referenced HOME funding and the HTF regulations, noting that stated HTF regulations do not trigger Davis-Bacon and it is rare for a HOME-funded project to trigger Davis-Bacon and prevailing wage requirements.

Commenters stated that HUD's assumption that labor hours are already tracked by most contractors and subcontractors to comply with the prevailing wage requirement is false. Commenters specifically noted that not all CDBG programs are subject to such requirements. One commenter wrote that even a small maintenance contract could result in 6 extra work hours for staff charged with ensuring correct payroll entries and compliance, stating that a current contract that does not track labor hours would have an increase of approximately $606,000 of federal funding required to administer the contracts, an additional 5% of costs. Another commenter stated that the proposed shift to labor hours will create an estimated 110 hours of additional administrative effort for the commenter per construction project, and will not impact the duration of Section 3 worker employment or allow HUD to better determine if long-term employment opportunities are generated. One commenter stated that tracking labor hours would require city contractors and subcontractors to track project labor hours using LCPtracker as the city does, necessitating increased administrative staff and resulting in higher contract amounts. One commenter stated that payrolls required for Davis-Bacon compliance are often submitted in hard copy, so compliance with the shift to labor hours would require manual data entry, a significant added labor-intensive task. Commenters also stated that many contractors are small business owners who do not have payroll software and many housing authorities do not have sufficient staff to track hours worked on all projects. Commenters also noted that many medium and smaller sized PHAs do not use LCPtracker and instead rely on contractor payrolls to monitor Davis-Bacon and Section 3. Other commenters stated that tracking hours could be more burdensome than tracking new hires, because new hires are only reported once. Tracking the workers' hours necessitates verifying each Section 3 employee each week for the duration of their employment.

HUD Response: HUD carefully considered the diverse public comments on the use of labor hours versus retaining new hires as the measurement for assessing compliance with Section 3 requirements. HUD believes that the use of new hires provides an incomplete measure of the economic opportunities available to low and very low-income persons envisioned by the Section 3 statute. HUD believes that moving to the labor hours metric provides a more robust measure of how Section 3 is intended to work and mitigates contractors' ability to manipulate Section 3 outcomes. HUD concluded the benefits of the labor hours approach outweighs the marginal cost that would result from this shift. HUD has determined that, while public commenters have concerns about possible burdens that result from the

proposed transition to recording labor hours instead of new hires, it is in the best interest of the communities served by HUD to implement a more impactful Section 3 standard across all HUD-funded programs. The use of labor hours is intended to ensure that recipients of these program funds are fully in compliance with the intent of Section 3—maximizing the economic opportunities arising from Federally funded activities that are available to low- and very low-income persons, including those who reside in public housing.

HUD also notes that the comments revealed a diversity of understanding with respect to HUD's record-keeping expectations in measuring the labor hours metric. HUD does not anticipate the level of detail in record-keeping that is required under the Davis-Bacon prevailing wage framework for purposes of Section 3. The proposed rule does not require prevailing-wage-style payroll reports. HUD does anticipate that either employers have some form of time and attendance system, particularly where employment uses an hourly wage structure, or that employers have salaried staff. The final rule does not require any change in these systems, nor necessitate any software approach to tracking payroll. Those employers that use a time and attendance system to track hourly wages may rely on that data, while the final rule provides a good faith reporting exception which applies to all entities that do not have an existing time and attendance system. The final rule has been modified in an effort to clarify that the good faith exemption applies to all Section 3 reporting entities (not only contractors and subcontractors) and that data from any existing salary-based or time-and-attendance-based payroll records can be used in good faith reporting under Section 3. HUD is mindful of the need to update policies and procedures for planning purposes, and the importance of implementing the rule such that employers will be able to comply. Therefore, HUD has provided for a transition period and a bifurcated compliance date. Public housing financial assistance recipients must comply with the reporting requirements starting with the recipient's first full fiscal year after this final rule's effective date. Section 3 project recipients must comply with the reporting requirements starting with the recipient's first full program year for projects committed or awarded after this final rule's effective date.

Many Section 3 Positions Are Short-Term in Nature

One commenter stated that many of the jobs made available under Section 3 requirements are short term positions specific to the needs of the individual project and/or worksite. These positions provide opportunities for the target population of low-skilled workers to build work experience (leading to possible economic advancement) while helping ensure project costs remain reasonable. Another commenter stated that the Section 3 goal leading to long-term employment and career advancement is unrealistic, as most opportunities generated by Section 3 projects are construction-related and therefore seasonal or project-based; it would be burdensome and complicated to track via labor hours long-term employment that results from a Section 3 worker being hired on a subsequent Section 3 project by a different contractor. Contractors do not keep pools of long-term general laborers on hand for consecutive projects as a means of employing Section 3 workers. Other commenters stated that nothing in the statute states that long-term employment through public housing or other housing and community development funding is the goal of Section 3; the statutory intent is to provide employment and training opportunities to residents of low-income communities where Federal housing and community development dollars are being spent, and tracking new hires better meets this intent.

Similarly, commenters stated Section 3 workers are more likely to assist in temporary work for PHAs. Using new hires better fits with this economic reality. One commenter stated that contractors do not reduce the number of part-time employees so they can provide full-time, long-term employment to fewer Section 3 workers. Other commenters stated that the nature of the construction industry is episodic; workers are not employed by one company for long periods of time, but from project to project, and workers often move from one company to another. The number of hours that a specific person works is generally based on what is required for the project and the type of work they are doing. Commenters asserted it is unreasonable to think that hours for lower-skilled employees will dramatically be increased for a specific construction project by moving to a ''labor hours'' standard.

Commenters also stated that the move to labor hours will confuse contractors and create more complexity. Another commenter anticipated pushback from contractors declining to bid, which can lead to an increase in the cost of developing affordable housing. Commenters stated that tracking labor hours could provide contractors with an incentive to hire fewer low-income residents by employing those hired for a greater number of hours. This would have a negative effect on the number of low-income residents hired overall.

HUD Response: HUD recognizes that many Section 3 opportunities are short-term employment opportunities. The shift from measuring new hires to measuring labor hours continues to value these short-term opportunities as creating significant economic opportunities for low- and very-low-income workers, and these short-term opportunities will likely remain a primary source of Section 3 opportunities. At the same time, the shift in metrics more accurately reflects the nature and extent of these employment opportunities and places greater relative weight on those opportunities which do provide long-term career ladders and sustained employment opportunities.

There is no obligation on a reporting employer to track an employee's work beyond the immediate short-term seasonal or project-based employment. The opportunity to track an employee over time is solely an opportunity which can be seized by those reporting employers who have invested the extra time and effort to nurture an employee over time. That extra effort to develop a career track is not recognized by the previous new hire metrics but is recognized in the labor hour metrics. It should be noted, however, that the use of the labor hour metric to reward retention applies only to the relationship with the current employer. (*See* § 75.11(a)(2) ''A worker who currently fits or when hired fit at least one of the following categories, as documented within the past five years . . .'') This provides an option for employers to look back to the worker's status at the time of original employment but does not require that an employer do so if the employer only wants to reference the employee's current status. Contrary to the concept referenced in the comments, there is no ability to claim long-term employment when hired on a subsequent Section 3 project by a different contractor.

This rule updates HUD's Section 3 regulations to create more effective incentives for employers to retain and invest in low- and very low-income workers. It is HUD's opinion that the change from new hires to labor hours, in combination with the opportunity to

provide good faith assessments, is consistent with businesses' existing payroll systems. Finally, HUD is of the opinion that this change will better advance the goal of sustained employment and career opportunities for low- and very low-income workers.

Alternatives

Several commenters suggested alternative frameworks for measuring Section 3 results, in some cases using the labor hours metric and/or the new hire metric already articulated in the current and proposed rules and in some cases proposing new alternative metrics entirely.

Some commenters recommended including definitions for both Alternative 1 and Alternative 2 so that agencies may exercise whichever option best suits their local circumstances. One commenter recommended using the $200,000 project threshold or $400,000 recipient threshold to determine whether labor hours or new hires should be the appropriate reporting metric, as larger projects have greater potential to create long term employment opportunities. One commenter focused on the safe harbor benchmark, stating PHAs should have the choice of labor hours at 10% or new hires at 30%. A commenter stated that if labor hours is adopted, all recipients and subrecipients should have the same flexibility allowed to PHAs.

Another commenter stated that ''labor hours worked'' should be used in conjunction with ''30% new hires.'' The commenter wrote that many PHAs do not track the generated new hires metric making the current 30% of new hires mandate irrelevant—some PHAs allow contractors and subcontractors to select how many hires they will take onto a project despite it coming short of the 30% benchmark. The commenter wrote that tracking both ''labor hours worked'' along with the ''30% new hires'' provides further assurance that a recipient's contractors and subcontractors do not avoid their responsibilities to pay the prevailing wage in accordance with the Davis Bacon Act.

Other commenters argued neither labor hours worked, nor number of new hires are accurate metrics for Section 3 compliance and impact, where the goal of Section 3 is sustained economic independence and economic enhancement for Section 3 workers in and around HUD's investment areas. Commenters suggested compliance should instead be measured by: (1) Payroll dollars paid to Section 3 employees; (2) training dollars spent training Section 3 workers; and (3) contract dollars paid to Section 3 contractors. Commenters further asserted tracking employment status would be unnecessary if all Section 3 employment payroll dollars were captured as a percentage of gross payroll dollars instead. Another commenter stated that an alternate suggestion would be to delineate Section 3 workers as full-time or part-time, and that tracking hours by using these two categories would be effective while still giving HUD information about the hours being completed by each worker. One commenter recommended Alternative 2, which continues to track new hires with the addition of Targeted Section 3 workers.

One commenter stated that transparency is needed, and the new revisions of Section 3 should include that contractors and subcontractors must make public the total amount of workers expected to complete a construction project.

Commenters proposed a third alternative to the two proposed, which is to stay with the current existing Section 3 goals, for both new hires (30% of new hires) and for contracting with Section 3 business concerns (10% of construction dollars and 3% of other dollars). Changes to what is already understood by contractors will be administratively burdensome and will require additional education and training for contractors and subcontractors.

HUD Response: HUD appreciates the alternatives suggested and has considered the various comments regarding the alternatives presented in the proposed rule and the modifications to those alternatives presented in the comments. HUD has concluded that both the use of Alternative 2 (New Hires) and the use of a hybrid drawing from both Alternative 1 and Alternative 2 provide an incomplete measure of employment opportunities generated through Section 3. Therefore, HUD decided not to retain the new hire standard. Rather than apply new hires recordkeeping to some programs and labor hours to others, HUD believes it is more efficient and effective for purposes of HUD's objectives with respect to Section 3 to apply the same standard across the board. HUD has determined to align Section 3 reporting requirements with typical payroll business practices by tracking labor hours (whether based on prevailing wage data, non-prevailing wage time-and-attendance system data, good faith assessments of hourly workers not tracked through a data system, or good faith assessments of salaried employees). While commenters varied on whether tracking Section 3 outcomes through labor hours will be easier for recipients of HUD funding, HUD has concluded that the consistent labor hours metric more accurately reflects the impact of Section 3 and the economic development opportunities created. With respect to the alternatives regarding aggregate payroll tracking or tracking full-time and part-time positions, HUD believes that tracking of labor hours will adequately show hours worked. HUD has determined that tracking of training will be done qualitatively when appropriate.

Process for Tracking Labor Hours

Commenters stated that while they appreciated the idea of streamlining the metric, tracking new hires vs. hours may be a disincentive to developers if the tracking is more onerous or complicated than the current method. If tracking labor hours is a goal similar to Davis Bacon, then the process should be fully integrated with the Davis Bacon procedure including the duration of tracking (only until project completion), reporting requirements, and procedures. Commenters stated that ascertaining whether an employer has any new hires is not a simple task; it involves (1) reviewing pre-award payroll records to determine who was on the employee's payroll at the time of contract award and (2) reviewing ongoing payroll records for the duration of the contract to determine whether any new employees have been hired. Commenters also stated that it makes no sense to apply the ''labor hours'' standard to only one type of construction and rehabilitation project but not to another, based solely on the type of HUD funds involved. If a contractor employs no Section 3 workers, there should be no requirement to provide the data.

Commenters stated inexpensive software is available that enables contractors to submit electronic payroll reports and allows PHAs and other Section 3 funding recipients to easily determine the hours worked on the project, in each trade, by all workers and by Section 3 residents. Commenters noted such software is available to recipients of housing and community development assistance and also to PHAs and other public housing financial assistance recipients. Commenters stated that commonly used Contract Management and Payroll systems such as LCPtracker and B2GNow have features that align with compliance practices and make monitoring more effective. One commenter stated that HUD could provide appropriate software to all

agencies to assist them in tracking and reporting labor hours. A commenter noted that its city has a Federal labor standard software tracker which only 21% of contracts use, and this rule would require 100% of contractors to use the software, resulting in increased administrative work, contract costs, and system management.

One commenter noted that it would be easier to track labor hours with LCPtracker software if the reporting were more aligned with Davis-Bacon reporting. Commenters also saw potential in the hourly tracking if there were a way to eliminate double paperwork by adding Section 3 reporting to the existing Davis-Bacon worksheets. On the other hand, when Davis-Bacon does not apply to a Section 3 project, some commenters felt the administrative burden of tracking hours could be higher. More information would be needed about how the reporting requirements would be implemented before it could be definitively agreed that tracking hours is less burdensome than tracking new hires.

HUD Response: HUD recognizes the diversity of views on whether tracking labor hours would be less burdensome for organizations obligated to report Section 3 results. Based on the comments, HUD has concluded that it is likely to be less burdensome to track labor hours in many circumstances, and HUD has clarified the applicability of the good faith exemption to mitigate any potential burden for those who do not have payroll systems which would align to a labor-hours reporting metric. For those efforts subject to Davis Bacon requirements, which includes many HUD-funded construction endeavors, tracking labor hours consistent with existing tracking for prevailing wage requirements would almost certainly reduce burden on recipients. HUD is aware that there are existing software options that have the potential for capturing total labor hours and labor hours contributed by Section 3 workers. HUD also is exploring whether and how to operationalize and integrate HUD's Section 3 Performance Evaluation and Registry System (SPEARS) with outside software vendors. The SPEARS system already has optional data fields to capture the Aggregate Number of Staff Hours Worked and Total Staff Hours Worked by Section 3 Employees, and the system will be modified to align with the final rule. Underlying these considerations, however, is HUD's belief, as described above, that tracking labor hours will better allow HUD to determine if long-term employment opportunities are being generated, and that the metric should be consistent without regard to the identity of the recipient of HUD funds. Unlike a labor hours measure, the new hire measure does not consider the share of actual work done by low- and very low-income workers, and new Section 3 hires may not be given the opportunity to work a substantial number of hours.

Labor Hours Based on Good Faith Assessment

One commenter stated that the proposed new rule allows for recipients to rely on a contractor's ''good faith assessment'' of labor hours (rather than payroll reports) if the contractor is not subject to other requirements specifying time and attendance reporting. Since a large proportion of housing rehabilitation and construction projects do not meet the unit thresholds that trigger Federal labor standards (*i.e.* eight units for CDBG, 12 units for HOME), grant administrators will regularly have to report labor hours based on a contractor's ''good faith assessment.'' Use of this approach will introduce an unknown error margin into the calculation of labor hour benchmarks. This lack of data integrity calls into question the meaning of the proposed benchmarks and the soundness of using ''labor hours'' as a unit of measurement. Commenters stated that Section 3 businesses who report labor hours in ''good faith'' need to have specific recording requirements (*i.e.,* software) to avoid manipulation; it is more efficient to rely on tracking systems instead of contractors' good faith submissions. Commenters stated that not all HUD construction projects are subject to Davis-Bacon compliance and even a good faith assessment of labor hours will require significant PHA resources to monitor, review, and compile. One commenter stated that while the proposed rule states that HUD will permit ''a good faith assessment of the labor hours'' for certain employers, recipients could still be required to establish new compliance procedures, including determining how to protect the privacy of Section 3 workers and businesses when supplied with labor hours supporting documentation.

HUD Response: The final rule is explicit that employers are not required to acquire a time-and-attendance system in order to comply with the Section 3 rule. The ''good faith assessment'' is a limited exception to be used by employers who do not have systems in place to track labor hours. This rule was put in place to avoid increased administrative burdens. HUD is aware of the margin of error represented in the good faith assessments, but has concluded that even with this margin of error, the labor hours metric provides a more accurate reflection of the economic opportunities created in connection with HUD-funded activities than the new hires metric. The exception does not apply if the employer is subject to other time-specific requirements.

Section 3 Applicability Threshold, HUD's Lead Hazard Control and Healthy Homes Programs and All Section 8 Programs

Total Funds Threshold or per Project Threshold Versus an Increased Threshold

The proposed rule set the Section 3 applicability threshold for Section 3 projects to projects where the amount of assistance exceeds $200,000. HUD received comments both in favor of maintaining the current $200,000 threshold and in favor of the new proposed threshold. Commenters also addressed the use of a project versus a total funding threshold. In addition, other commenters provided a range of alternative frameworks for setting the threshold amount—different numbers and the inclusion or exclusion of different kinds of funding in the threshold calculations.

Some commenters recommended that the $200,000 threshold be based on the total amount of funding received within the fiscal year because it is a more simplified and streamlined process. Commenters stated the change to a per project threshold would result in many housing production projects that are mainly small and resource constrained having to comply with Section 3 requirements for the first time, noting that a per project threshold can become complicated and burdensome when a recipient handles a large volume of contracts that are funded by multiple sources. Commenters went on to state that a per project threshold would reduce the number of economic opportunities directed to low-income persons and recommended continuing to subject Project Based Voucher programs to Section 3 requirements to ensure those opportunities are directed toward low-income persons and businesses that employ them. Commenters in this line of thought noted that the $200,000 per project threshold would potentially exempt projects where the HUD funding is less than $200,000, even though the combined total project funding is much higher. Commenters stated this could lead to a decrease in the number of projects subject to Section 3 and an

overall reduction in Section 3 program impact.

Other commenters supported the per project threshold generally without commenting on the amount or supported the $200,000 per project threshold and saw it as an improvement. Some of these commenters noted that while $200,000 is an improvement over the current threshold, it does not relieve underlying concerns that contractors may break up activities into small contracts of less than $200,000 each to avoid accountability. Several commenters agreed that a $200,000 per project threshold would still allow contractors awarded significant funding to avoid Section 3 requirements by carrying out small discreet activities even though they cumulatively spend more than the threshold amount. A commenter suggested that the final rule include a prohibition on such activity, so that HUD has authority to pursue enforcement measures if HUD determines a recipient is ''gaming the system'' to avoid Section 3 obligations.

Other commenters provided alternative threshold amounts at a range of figures up to $1 million. Some commenters stated the $200,000 per project threshold will not necessarily result in employment opportunities for low-income people, arguing a higher project amount does not inevitably translate to the need for new employees or a benefit to Section 3 business concerns. Commenters suggested an alternative $250,000 threshold which would coincide with the Office of Management and Budget simplified acquisition threshold and could automatically change when that amount is updated. Other commenters supported using the $250,000 threshold for all projects to include PHAs. Some large PHAs with Section 3 experience recommended raising the threshold to $350,000 on a per project basis and making this threshold consistent across all programs and funding sources. Commenters in agreement with this notion also noted that HUD has determined that employment opportunities in CDBG funded projects under $350,000 are very minimal, and these commenters argued that the same is also true of public housing projects. Commenters also recommended $400,000 or higher to increase the number of program recipients exempted from Section 3 requirements from less than 4 percent to 20 percent, greatly reducing the compliance burden for smaller grantees. Still other commenters recommended a higher threshold of $750,000, tied to the single audit threshold, noting that smaller grants generally will not involve sufficient hiring opportunities to warrant the increased administrative burden. Other commenters recommended that a $1 million threshold would be a better measure of a project of a scale that would have the potential to drive the hiring of Section 3 workers and justify the additional administrative burden on recipients, subrecipients, and contractors to implement the program, particularly state CDBG programs that primarily fund public infrastructure. Another commenter recommended exempting grantees that receive $1 million or less annually in CDBG or HOME funds because such grantees focus on a finite set of activities that involve small projects.

Commenters stated that a low threshold will create an undue compliance burden for small projects. Commenters suggested that adopting a higher per project threshold would still ensure the majority of CPD grants are covered but would likely offer significant regulatory relief for smaller grantees, builders, developers, contractors, and subcontractors who are disproportionately burdened by regulatory obligations. Some commenters who advocated for a higher threshold linked their reasoning to the effect of the threshold amount on contractors and subcontractors, noting that Section 3 obligations apply to recipients, their sub-recipients and so on. Commenters described cases in which builders forgo using covered funds to avoid the liability and compliance burdens of Section 3, and situations where developers experience costly delays on projects while searching for qualified subcontractors who are not deterred by the Section 3 paperwork and certifications.

Commenters also suggested that both a recipient threshold at $400,000 and a project threshold of $200,000, applicable across all programs, would be most appropriate to reduce reporting burdens with a limited impact on the dollar amounts of funding covered. Another recommendation was to apply Section 3 obligations to any entity that receives at least $200,000 during a program year for a specific program activity. Other commenters suggested either the threshold for contracts should remain $100,000 in HUD assistance; or a ''total contract value'' threshold should be defined that will trigger Section 3 on HUD-funded contracts, regardless of the dollar amount of the HUD funding. Other commenters offered an alternative threshold of 10 percent of construction costs per project. Commenters also reiterated that some CDBG grant awards are very small, ranging from $50,000 to $200,000, so units of general local government have difficulty finding contractors to bid on the projects, let alone finding a contractor that is a Section 3 business concern and is willing to work on a small project. Finally, commenters suggested limiting activities that trigger the threshold to only construction and rehabilitation, as defined within the Section 3 statute for CDBG, HOME and other CPD programs.

HUD Response: HUD acknowledges the considerations raised by all the commenters in their responses. HUD found that the portion of Section 3 expenditures excluded by the $200,000 per project threshold generate relatively few Section 3 jobs. After weighing the various considerations, this final rule maintains the $200,000 per project threshold in general but makes changes to the Lead Hazard Control & Healthy Homes Programs threshold. HUD believes that project funding levels help accurately define thresholds because the amount of funding spent on a project is directly related to the economic opportunities generated by the project. HUD acknowledges the potential disadvantages mentioned by commenters to using a per project threshold but reiterates the per project threshold will help provide opportunities for those who are recipients of Federal financial assistance for housing or residents of the community in which the Federal financial assistance is spent. In addition, HUD remains open to adjusting thresholds in the future based on updated data analysis. The final rule clarifies that HUD may change the thresholds and benchmarks at a later date via **Federal Register** notice, subject to public comment, based on updated data input and accounting for inflation. HUD also notes that not every contractor, subcontractor or sub-recipient must use Section 3 workers. A funds recipient could meet its Section 3 benchmarks with one contract to a Section 3 business concern where the number of labor hours worked is 25% or more of all the labor hours worked by all workers on a Section 3 project while not using Section 3 workers for other work. The recipient has flexibility in determining how to meet its benchmarks.

Lead Hazard Control & Healthy Homes Programs Inclusion

Commenters who advocated for a single consistent per project threshold across all programs stated that the Lead Hazard Control and Healthy Homes programs should also be subject to the same threshold. Other commenters

agreed that Lead Hazard Control and Healthy Homes projects should be exempted from administrative and compliance burdens based on a threshold of $200,000 or greater, stating these projects are unlikely to generate many employment opportunities because they are small and Lead Hazard Control abatement and interim controls is to be done by trained and certified workers.

Some commenters agreed that including Lead Hazard Control projects with no threshold would increase the administrative burden without a benefit, and while the exclusion is understandable, HUD should pursue a standardized threshold to avoid complicating Section 3 by creating a different scope for Lead Hazard Control and Healthy Homes programs. Commenters generally supported higher thresholds for Lead Hazard Control and Healthy Homes programs. A commenter suggested it may be appropriate to use the community development assistance threshold for simplicity. Alternatively, commenters suggested a more modest reporting threshold of not less than $50,000 for Lead Hazard Control and Healthy Homes projects, stating that for grantees working on multifamily projects in high cost cities, projects where the contract is less than $50,000 tend to be awarded to smaller contractors. A $50,000 threshold would meet HUD's admirable intention of ensuring greater Section 3 participation from Lead Hazard Control and Healthy Homes grantees without imposing hardship on such small contractors.

HUD Response: HUD agrees that the $200,000 threshold should not apply to Lead Hazard Control and Healthy Homes programs since those projects are generally smaller dollar amounts. However, in keeping with Section 3's statutory priorities and applicability, HUD is choosing to adopt a $100,000 project threshold regarding application of Section 3 to Lead Hazard Control and Healthy Homes programs.

Section 8 Programs Exclusion

Many commenters supported the exclusion of Section 8 programs in the proposed rule, as Section 8 programs are not included in the statute. Commenters went on to note that because Section 3 programs are development subsidy sources and Section 8 programs provide operating subsidies, Section 8 assistance recipients should not be subject to Section 3 regulatory responsibilities. Commenters noted that the primary purpose of Section 8 programs is to provide a rental subsidy that covers the difference between the contract rent and 30 percent of the tenant's income, stating these programs are ''affordability tools, not construction tools,'' and agreed HUD should not increase regulatory burdens on housing providers by expanding the scope of Section 3 to programs not covered in the statute.

Some commenters urged that for Subpart B, HUD should retain an option for PHAs to report on Section 3 requirements for Section 8 funded programs, noting that these programs generate significant employment and training opportunities for Section 3 workers. Commenters suggested HUD format Section 3 reporting so that Section 8 funded placements can be captured as part of a PHA's overall efforts. Commenters also suggested the current reporting system be updated to allow for the reporting of other placements that might be excluded with the new proposed rule, such as placements under professional service contracts.

HUD Response: Section 8 programs are not covered under the Section 3 statute. Therefore, HUD in this final rule maintains the clarification in the proposed rule that Section 8 programs are excluded from Section 3 requirements.

Section 3 Project Definition

Commenters recommended that HUD more clearly define ''project'' for the purpose of Section 3, and asked how HUD would view a job order contract of more than $200,000 that may work on various locality-owned sites (*e.g.,* all of a locality's schools or homeless shelters). These commenters also asked, if several unrelated HUD-funded activities are taking place at the same location and have a combined value of more than $200,000 constitutes a project. Lastly, the commenters asked whether the per-project threshold is based solely on construction-related activities, and whether the level of Federal assistance to a project must exceed the $200,000 threshold to trigger Section 3.

Another commenter recommended that HUD define ''project'' as follows: Project means a site or sites together with any building or multiple buildings located on the site(s) that are under common ownership, management, and financing and are to be assisted with Section 3 covered funds as a single undertaking. A program that funds multiple buildings under separate ownership, management and financing is not a project.

HUD Response: HUD supports the Section 3 Project definition within the proposed rule and believes it is consistent with the statutory requirements of HUD programs. HUD also intends to provide sub-regulatory guidance and technical assistance on a program-by-program basis to assist recipients with Section 3 implementation.

Section 3 Worker

Rule Rewards Creating Opportunities for Persons Who Are Not Low-Income

Commenters stated that the rule, particularly the definitions of Section 3 worker, rewards creating opportunities for persons who are not low-income, which would be counterproductive to the intent of the Section 3 program. A commenter stated that the proposed definition could inadvertently include individuals who are not low-income because categories (ii) and (iii) are not income-based.

Specifically, some commenters objected to category (ii) which allowed workers who live in a Qualified Census Tract (QCT) to be included in the definition of ''Section 3 worker'' because these individuals will not necessarily be low-income. One commenter noted this is especially true in large metropolitan cities with mixed income communities and gentrifying areas. Another commenter stated that researching employee residence as of the date of hire to determine census tract qualification will be difficult or impossible for long-term employees who may have moved multiple times. Commenters warned that the QCT designation would create a risk of potential abuse by recipients. Some commenters suggested removing the QCT criteria altogether since the definition already includes a low- or very low-income person.

Other commenters objected to category (iii) which included all Section 3 business concern employees as Section 3 workers. These commenters stated that someone working at a Section 3 business concern is not necessarily a resident of HUD-assisted housing, nor is it likely that a business owned by 51% low-income people would hire only public housing or HUD-assisted residents. For this reason, commenters recommended that HUD should exclude ''a worker employed by a Section 3 business'' from its definition and benchmarks and the definition of Section 3 worker and Targeted Section 3 worker. One commenter noted the phrase ''worker is employed by a Section 3 business'' is included in both the Section 3 worker and Targeted Section 3 worker definitions and recommended including this term in the Targeted Section 3 worker definition

only and not the Section 3 worker definition.

HUD Response: HUD agrees that paragraph (1)(ii) could inadvertently include individuals who are not low-income. This final rule removes paragraph (1)(ii) regarding the QCT from the definition of ''Section 3 worker'' from this final rule. However, HUD disagrees that the category of Section 3 business concerns should be removed from the Section 3 worker and Targeted Section 3 worker definitions. The Section 3 statute states that HUD must prioritize Section 3 business concerns. If HUD did not include Section 3 business concerns in the definitions that are used for the benchmarks, PHAs and other HUD funded entities would have no incentive to hire Section 3 businesses. Including all Section 3 business concern employees in the definition of Section 3 worker and Targeted Section 3 worker creates an incentive to contract with a Section 3 business while maintaining a single reporting metric. The final rule maintains that all hours worked on the project by the Section 3 business counts towards the benchmarks. HUD believes these changes are consistent with the statute.

Prior Conviction

One commenter wrote that convictions for certain categories of crimes may have a direct bearing on the worker's suitability for particular jobs. Previous theft convictions, for example, may be relevant for a worker who will be involved in procurement and distribution of materials. Other commenters supported this language, stating that ''there is no evidence that hiring an individual with a criminal history will have a negative impact on employee success.'' The commenters also noted that the language is consistent with other HUD guidance on the use of background reports in housing decisions. However, one commenter suggested a minor revision to clarify the regulation: ''A recipient, contractor, or subcontractor shall not refuse to hire a Section 3 worker on the basis of a prior arrest or conviction, unless otherwise required by Federal, state, or local law.''

HUD Response: HUD agrees with the commenters that convictions for certain crimes, such as fraud or theft, might affect a worker's qualifications for a particular position, and that ''there is no evidence that hiring an individual with a criminal history will have a negative impact on employee success.'' HUD notes that the Section 3 worker definition provides that an individual's prior arrest or conviction shall not negatively impact their Section 3 worker status, but the definition maintains the requirement that the individual is qualified for the job. Job qualifications may include the worker's arrest or conviction history. The rule does not require a Section 3 worker with a criminal history to be hired. HUD has considered the suggestions and has chosen to keep the regulatory language in § 75.5. *See Section 3 business concern,* § 75.5 (''The status of a Section 3 business concern shall not be negatively affected by a prior arrest or conviction of its owner(s) or employees.''); *Section 3 worker,* § 75.5 (''The status of a Section 3 worker shall not be negatively affected by a prior arrest or conviction.''); *Targeted Section 3 worker,* § 75.5 (''does not exclude an individual that has a prior arrest or conviction.'')

Additional Categories

One commenter stated that the proposed rule no longer explicitly lists a public housing resident as a ''Section 3 resident'' and does not provide for the employer to continue counting that worker in the future. Another commenter suggested that staff hired by a PHA should be counted toward Section 3 requirements. Commenters suggested additional categories and expansion of existing categories, and requested HUD explicitly list the following: people immediately prior to hiring are public housing, Section 8, Section 811, Section 202 residents or other low-income people, and women. Commenters recommended that a ''Section 3 worker'' should be a worker whose income is below the limit set by HUD, or a resident of public or HUD-assisted housing.

One commenter supported the change to using an individual's status as low-income versus household income, which will increase the pool of persons that can be counted as a Section 3 worker and make meeting the benchmarks more attainable. Commenters requested clarification on whether the HUD-defined low-income level will be based on individual or family income and one commenter recommended the use of only an individual's income.

HUD Response: HUD wants to clarify that, while the definition of Section 3 worker does not include public housing residents, it does include all workers whose income is below the income limit established by HUD, which is the same limit that would qualify someone for public housing. Therefore, public housing residents would be considered Section 3 workers. HUD does not believe that all staff hired by a PHA should be counted as Section 3 workers. Those staff that meet the qualification of a low or very low-income person, as defined by HUD's income limit, would already qualify, and HUD does not think it is appropriate to include all PHA staff. As for expanding the categories further, the Section 3 statute is specific as to the priorities that HUD should be providing with employment and other economic opportunities generated by Federal financial assistance. Therefore, HUD is not expanding the scope of Section 3 workers beyond those listed in the statute. HUD changed the Section 3 worker definition to include a worker whose income is below the income limit established by HUD in place of the family income and appreciates the comments in support of the change.

Setting Time Limits

Commenters recommended that HUD should keep the existing standard of a three-year period for counting workers in order to account for staff turnover and to generate more accurate metrics. Other commenters recommended HUD limit someone counting as a Section 3 person to 5 years. Another commenter stated that because many contractors and subcontractors report no new hires for specific projects, a Section 3 worker should be defined as one who ''at the time of hire'' was low- or very low-income. One commenter asked HUD to be more specific in defining a Section 3 worker rather than stating low-income is a ''limit established by HUD.''

HUD Response: HUD agrees with the commenters that a worker whose income has risen should only be counted for Section 3 purposes for five years. HUD wants to ensure employers are invested in keeping Section 3 workers employed, and that there is enough opportunity to build skills and experience so that Section 3 workers may develop self-sufficiency and compete for other jobs in the future. An employer may choose whether the workers are defined as Section 3 workers for that five-year period at the time of the workers' hire, or the date from which the workers are certified as meeting the Section 3 worker definition.

Guidance

Commenters requested that HUD provide more specific guidance regarding how to calculate labor hours for the purpose of determining Section 3 status. For example, is there a set timeline for consideration, such as during the past year or several years? Or is it based on the business' last 1–2 payrolls to capture the most recent picture of employment? Commenters stated that it is unclear over what time period labor hours are to be measured.

One commenter stated that it is unclear whether the ''labor hours'' standard relies on the labor hours on the Section 3 project, or in general.

HUD Response: HUD will provide additional guidance to assist PHAs and grantees in how to calculate labor hours. Generally, labor hours will be calculated based on the labor performed on a Section 3 project for housing and community development financial assistance or on all labor hours performed within the fiscal year for public housing assistance.

Subrecipient

One commenter stated that using the applicable definition of subrecipient in the HOME program would mean that multifamily owners contracting directly with the State may not have to comply with Section 3 requirements because they are not included in that definition for the HOME program in 24 CFR 92.2. This commenter also noted that multifamily owners are also not often contractors (under the proposed definition), because they do not enter into a contract with a recipient to perform the work. This commenter suggested inclusion of owners in the HOME program and changing the definition of subrecipient to say ''has the meaning provided in the applicable program regulations, and in 2 CFR 200.93'' or suggested HUD amend the definition of contractor to further define the phrase by adding ''work in conjunction with a Section 3 project,'' to more clearly identify that it includes an owner in the HOME program that contracts with general contractors.

HUD Response: HUD appreciates the comment. However, subrecipient has different meanings in different programs, which is why HUD defined it as either the meaning as is applied in the specific program or 2 CFR 200.93.

Targeted Section 3 Worker Definition

Some commenters supported the new ''Targeted Section 3 worker'' definition and eliminating tracking Section 3 business concern types separately. Some commenters stated that the Targeted Section 3 worker concept is consistent with the goal of expanding employment opportunities for individuals that receive Federal assistance for housing. Another commenter agreed with HUD's efforts to track and target certain high priority Section 3 workers separately and efforts to fold Section 3 business concern engagement into other benchmarks.

Other commenters opposed the ''Targeted Section 3 worker'' definition, stating that it is duplicative with worker categories already given preference under § 75.9. Commenters stated a separate reporting category for ''Targeted Section 3 worker'' merely complicates reporting requirements for recipients, contractors, and subcontractors, and recommended HUD keep the existing definition and the existing priority preference order. Other commenters noted that tracking additional information to determine Section 3 compliance would be burdensome.

A commenter recommended that hours worked by Section 3 business employees be categorized as regular Section 3 worker hours and Targeted Section 3 worker hours depending on the employee's status to avoid inflated reporting of hours worked by targeted Section 3 workers. Other commenters suggested that a worker employed by a Section 3 business only be included in the ''Targeted Section 3 worker'' definition because it was created to better align the regulation with the law.

Commenters stated that counting all Section 3 business concern employees as Targeted Section 3 workers is problematic and risks questionable data. HUD should exclude ''a worker employed by a Section 3 business'' from the definition of Targeted Section 3 worker and Section 3 worker. Including ''a worker employed by a Section 3 business'' in the definition of ''Targeted Section 3 worker'' dilutes the purpose of creating a Targeted worker designation. It also frustrates the purpose of the statute, which is to give priority to public housing and other HUD-assisted residents in employment and training opportunities, along with low-income families near the Section 3 project location.

Commenters also suggested that HUD include public and HUD-assisted housing residents in the Targeted Section 3 worker definition for Section 3 projects, not just PHA projects. The proposed definition of Targeted Section 3 worker for PHA projects more accurately interprets the statutory priority of Section 3 to employ public housing and other Federally assisted residents than the definition for CPD recipients. One commenter recommended that HUD include the word priority in the definition of ''Targeted Section 3 worker'' to clarify the requirements and add objective criteria or guidance by which to monitor or measure success or satisfactory performance.

HUD Response: HUD appreciates the commenters' recommendation to target public and HUD-assisted housing residents in both funding types. However, the statute specifies priority categories differently for recipients of public housing financial assistance and housing and community development financial assistance. The Targeted Section 3 worker is a concept designed to serve as a proxy for the highest priority categories, allowing HUD to collect data through standardized reporting regarding the funding recipients' efforts with respect to the priority categories. HUD believes that the definitions of Targeted Section 3 worker for both public housing financial assistance and other housing and community development financial assistance funds provide good reporting proxies for the statutory priorities and should remain as proposed. As Targeted Section 3 workers are a proxy for the priority categories solely for reporting purposes, and do not replace the prioritization that funding recipients must apply in their efforts under Section 3, the use of the word ''priority'' in the definition would be inappropriate.

§ 75.11 Targeted Section 3 Worker for Public Housing Financial Assistance

Commenters stated that HUD should combine 75.11(a)(2)(i) and (ii) into a single category, ''residents of public and HUD-assisted housing'' to more clearly include residents of all HUD-assisted housing programs and conversion projects. Commenters supported the addition of Section 8 assisted households. This change mirrors the Section 3 statute, which broadly emphasizes employment and training opportunities for ''recipients of government assistance for housing.'' Some commenters recommended deleting paragraph § 75.11(a)(1), because it is redundant with § 75.5. Commenters also asked HUD to clarify what ''residents of other projects managed by the PHA'' covers. One commenter suggested HUD add ''administered by the PHA'' when describing Section 8 assisted housing.

HUD Response: HUD appreciates the support for the categories in § 75.11 and recommendations to make changes to include additional HUD programs. HUD believes that consistent with the statute, the Targeted Section 3 worker definition for public housing financial assistance should focus on the categories as listed. To be inclusive of residents in other housing assisted by the PHA and residents of housing in the property management portfolio of the PHA, both categories have been included in the regulation in place of the vaguer term ''managed by the PHA.'' Those residents would also count as Section 3 workers for purposes of Targeted Section 3 workers for public housing financial assistance. The rule's current ''resident

of other projects managed by the PHA'' has been replaced, which should address the commenter's concerns.

§ 75.21 Targeted Section 3 Worker for Housing and Community Development Financial Assistance

One commenter wrote that limiting the definition to a geographic area eliminates large sectors of nearby Section 3 workers and business. Another commenter noted some State CDBG programs do not operate in areas where public housing residents or YouthBuild participants typically live. Commenters also stated that the proposed definition gives broader opportunity to identify low-income construction employees for Section 3 projects but requires wage calculations and census tract verification from contractors already burdened by paperwork and will remove the focus from employing eligible persons living within a neighborhood.

HUD Response: HUD retained the proposed Targeted Section 3 worker definition in the final rule. The rule creates the ''Targeted Section 3 worker'' concept so that HUD can track, and recipients can target, the hiring of Section 3 workers in selected categories based on the statute's hiring priorities. The Targeted Section 3 worker category also incorporates the statutory requirements of contracting with business concerns employing low- and very low-income persons. For other HUD housing and community development financial assistance programs, such as the State CDBG program or HOME Investment Partnerships programs, Targeted Section 3 workers would be low- or very low-income workers residing within a one-mile radius of the Section 3 project. If fewer than 5,000 people live within that one-mile radius, the circle may be expanded outward until that population is reached.

The requirement that contractors verify whether workers are low or very low-income for tracking purposes is not new. Contractors were already required to verify new hires as qualifying for Section 3 status, and the statute requires that employment and other economic opportunities generated by work in connection with housing rehabilitation, housing construction or other public construction projects receiving housing and community development assistance be directed to low- and very low-income persons in the local community. HUD's proposal to use Targeted Section 3 workers for housing and community development programs that fall within a defined service area should reduce burden because HUD's mapping tool will identify the jurisdiction the contractor should target.

§ 75.5: Section 3 Business Concern Definition

Previous Rule's ''Dollar Value'' Method

Commenters stated that the previous ''dollar value'' method of reporting contracts awarded to Section 3 business concerns should be kept, as it gives recipients and general contractors a clear benchmark to achieve when selecting subcontractors and aligns with methods many are already using to report on minority-, women-, and veteran-owned businesses. Commenters noted Section 3 is designed to promote wealth-building in addition to employment opportunities and the ''dollar value'' method is a better measure of economic opportunities provided to low-income owners of Section 3 business concerns than the labor hours worked by their employees. Without having a metric tied to the number of contracts awarded to Section 3 business concerns, commenters anticipated a reduction in the number of contract awards, and a reduction in employment opportunities. One commenter stated that both definitions will likely continue to be a challenging means of qualifying for eligibility and may prove difficult to document.

HUD Response: HUD found the Section 3 business concern definition to be consistent with both the previous regulation and with the statute, although HUD notes that the final rule's definition does impose more rigorous criteria for qualifying as a Section 3 business concern with respect to the percentage of workers who must be Section 3 workers. This additional rigor in the criteria ensures that, if qualifying on the basis that the firm employs Section 3 workers, a high percentage of workers are in fact Section 3 workers, and ensures that, if qualifying on the basis that the owner is a low-income individual, the owner is in operational control and will benefit from the wealth creation opportunities. The changes to the Section 3 business concern definition do not depend on the change in reporting to a labor hours metric.

HUD recognizes that some in the industry have found the ''dollar value'' method to be workable, and that the dollar value metric does provide a measure of the extent of contracting to Section 3 business concerns. However, HUD believes there is value in having a unitary reporting metric—labor hours—and has designed the metric to measure both direct employment and to reflect prioritization of contracting with Section 3 business concerns. HUD believes that this new method will be effective, will encourage wealth creation opportunities for the owners of Section 3 business concerns, and will provide the opportunity for recipients of HUD financial assistance to determine which projects use Section 3 businesses in a way that is not administratively burdensome.

Rule Rewards Creating Opportunities for Persons Who Are Not Low-Income

One commenter stated that the focus on hours worked is appropriate in light of the statute's focus on providing economic opportunities to low-income residents, but aggregating hours poses a risk that non-low-income people at Section 3 business concerns may report hours, though this risk is mitigated by the Section 3 business concern definition. Another commenter stated that the 51% owned and 75% labor hours requirements allow Section 3 business concerns to employ persons who are not low-income or very low-income.

Another commenter supported replacing the aggregate dollars spent metric, but stated that including all Section 3 business concerns' employee hours will lead to the misleading inclusion of non-low-income worker hours in the data; only the hours worked by the low- and very low-income employees of a Section 3 business concern should be reported as Section 3 hours worked.

HUD Response: According to the Section 3 statute, HUD must prioritize businesses that provide economic opportunities for low- and very-low-income persons. The statute does not require that HUD prioritize business that only provide economic opportunities for such persons. If HUD were to include only the Section 3 workers in the reporting metrics, the regulation would not effectuate the statutory requirement to also place an emphasis on Section 3 business concerns. The Section 3 statute states that HUD must prioritize Section 3 business concerns in the awarding of contracts. By collecting labor hour data on all employees of Section 3 business concerns, HUD is creating an incentive to contract with a Section 3 business concern while maintaining a unitary reporting metric for Section 3 performance. The final rule maintains the provision of the proposed rule that all hours worked on the project by the Section 3 business concern counts towards the benchmarks, with the awareness that this reporting framework will collect labor hour data for workers who are not low-income. This serves as the incentive to contract with Section 3

business concerns. HUD believes these changes are consistent with the statute.

Verification

A commenter stated that nothing addresses processes for verification of Section 3 business concern eligibility, and that HUD should enhance the Section 3 business concern registry to include confirmation of eligibility or work with Equal Employment Opportunity Commission to assist jurisdictions with certification programs. One commenter noted that using the Section 3 business concern registry to project availability of Section 3 workers is unreliable because the registry is a self-reporting structure with no mechanism to verify the business on the list, it assumes such businesses are able to work in any geographic area, and many PHAs in rural and suburban areas have reported that there are no Section 3 business concerns in their areas.

Another commenter raised the issue that verifying Census tract designations would create an additional burden, especially Census tract data that changes over time, which will result in fewer contractors participating in Section 3 projects.

One commenter stated apprehension about this part of the definition because accurately tracking and reporting labor hours will be much more challenging than tracking and reporting full-time employees. The proposed definition also makes it difficult for Section 3 business concerns and the entities that contract with them to predict with confidence that they will retain their Section 3 status, as labor hours can be dependent on the number of contracts a business bids for and receives.

Another commenter requested clarification regarding how long a business retains the Section 3 business concern status once it is certified as a Section 3 business concern. Commenters suggested HUD or the local government should bear the responsibility for verifying the eligibility of a Section 3 business concern, rather than shunting that responsibility to the builder, general contractor, or subcontractors. HUD's online Section 3 Business Registry [4] was a positive first step, but HUD does not verify the self-certifications submitted by the business concerns, and it cautions database users to perform due diligence before awarding contracts.

HUD Response: HUD plans to continue the use of the Section 3 Business Registry as an available public tool. While HUD appreciates the suggestion that HUD or the local government make determinations of eligibility for Section 3 business concerns, HUD believes that, consistent with other paperwork requirements, it is appropriate that the entity receiving HUD financial assistance ensure compliance with Section 3 requirements, which includes confirming that both Section 3 workers and Section 3 Business concerns qualify as such under this regulation. HUD addressed commenters' concerns about Census tract designations by removing that language from the rule, and concerns about labor hours are addressed in previous comment responses. Once a business is certified as a Section 3 business concern, it will retain that status as long as it continues to meet the definition. Status is determined at the time of hiring for each contract and is no different from any other definition. Currently, business concerns self-certify, and verification is done by HUD. The timing is on a project by project basis.

(1)(i) ''At least 51 percent owned by low- or very low-income persons''

One commenter stated that this part of the definition follows the statute's intent. Another commenter stated that 51 percent ownership by low- or very low-income persons is unrealistic without training programs on business management.

HUD Response: HUD appreciates the feedback from commenters and is keeping this part of the Section 3 business concern definition as it is. HUD has found this definition to be consistent with both the previous regulation and with the statute. HUD notes that the definition also includes other methods by which a business concern may be defined as a Section 3 business concern. *See* 24 CFR 135.5; 12 U.S.C. 1701u (e)(2).

(1)(ii) ''Over 75 percent of the labor hours. . . performed by low- or very low-income persons''

Commenters supported changes to definitions of Section 3 business concerns, Section 3 workers, and Targeted Section 3 workers under the new hire approach. One commenter stated that the decision to focus on percentage of hours worked by Section 3 individuals will result in a decrease of self-identified Section 3 business concerns. The commenter asserted that although it is a better metric for proving actual commitment to long-term employment of Section 3 individuals, gathering the data will be overly burdensome. One commenter stated that this option will present undue hardship to small businesses and should be omitted. Another commenter stated that this requirement will negatively affect HOME and CDBG funded projects.

Some commenters supported tracking Section 3 hiring separately from Section 3 business concern tracking. Section 3 business concerns are already encouraged to retain existing employees to meet the previous Section 3 business concern definition. Counting existing employees to meet both the contract and hiring goals may result in decreased new hiring in connection with Section 3 covered assistance. Commenters recommended only tracking new Section 3 hires employed by Section 3 business concerns relative to a contractor's hiring goals.

One commenter also stated that even though the proposed rule provides a mechanism for PHAs to continue documenting compliance through a ''new hire'' metric, this proposed definition would still require PHAs to analyze a business's labor hours in order to determine whether a business could qualify as a Section 3 business concern.

One commenter noted the new burden would affect businesses who may not meet the new markers and might reevaluate the benefits of working with PHAs given the increased work to track labor hours. The commenter noted in an environment where getting bids is already difficult this would further dissuade them from doing business with PHAs. Other commenters suggested focusing on long-term employment goals for employees, developing benchmarks for growth of Section 3 business concerns, providing micro-business support, and targeting capital construction projects for mentorship and sub-contracting with Section 3 business concerns.

Some commenters stated that the definition of a Section 3 business concern should remain defined in part as a business where at least 30% of the permanent, full-time workforce are currently Section 3 residents, or were Section 3 residents within three years of the date of first employment at the business concern.

Commenters stated that this proposed amendment would render most Section 3 business concern owners in the commenter's city ineligible, as over 50% qualified by meeting the existing standard for the makeup of their workforce (30% full time permanent employees who are Section 3 residents). The result will be fewer Section 3 business concerns maintaining and/or seeking certification and will further compound the challenges of helping low-income workers access jobs. Most Section 3 business concerns do not

[4] HUD, *What is the Section 3 Business Registry?,* Hud.gov, *https://portalapps.hud.gov/Sec3BusReg/BRegistry/What.*

possess the infrastructure to support tracking this information. A commenter stated that 75 percent of labor hours is too high as a standard for determining Section 3 business concern eligibility. A smaller percentage would be more appropriate, or perhaps HUD could allow businesses to qualify either by labor hours or percentage of staff. Commenters stated that the 75 percent criterion would defeat important purposes of the Section 3 program which include encouraging business creation and increasing contract opportunities for businesses that employ a substantial number of low-income residents.

One commenter stated that it would significantly increase compliance costs, and that HUD appears to assume that every project will be tracking employee hours worked due to the applicability of federal prevailing wage requirements, but this is not the case. This commenter's program includes projects that are not subject to prevailing wage requirements, but that are subject to Section 3. Another commenter stated that the new definitions could pose significant challenges to businesses as they will have to first determine which employees are considered low- and very low-income persons, and then have to calculate if their labor hours are over 75 percent.

One commenter agreed that reporting on business concerns should not be an aggregate of dollars spent. The commenter recommended that HUD keep the self-certification tool and website resource and incentivize Section 3 contractors to register to make this resource as useful as possible. The commenter observed a review of the website shows that some states do not have any Section 3 contractors listed.

Commenters stated that the change from 30 percent of full-time employees to 75 percent of labor hours performed will limit Section 3 business concerns only to those lower-skilled businesses (cleaning companies, moving companies, perhaps landscaping or painting companies) that hire an overwhelming majority of their workers as low-income.

One commenter stated that the proposal will not have the intended impact of increasing access to opportunity. This change would look backwards rather than measuring opportunities provided as a direct result of the contract award. In practice, this change would significantly impact administrative efforts, would adversely affect other qualified Section 3 business concerns, and potentially limit employment opportunities available to the targeted population.

One commenter stated that the rule should keep the threshold at 30% but change it to hours worked rather than new hires and retain other elements of the current definition. The commenter recommended that HUD only count the hours worked by Section 3 residents toward the percentage goals of hours worked by Section 3 residents (not all employees of the Section 3 business concern). The commenter believes the 30% benchmark creates an incentive for established businesses to create a professional development component to their project approach, while 75% is much too high for most businesses to pursue.

One commenter recommended the definition be modified to include more than 75 percent of the labor hours worked at the business are performed by public housing, Section 8, Section 811, or Section 202 residents or persons who, immediately prior to the date of hire, were low-or very low-income, particularly women. Commenters suggested removing the 75 percent labor hour portion all together. If HUD proceeds with this definition, it should consider a transition period so existing Section 3 business concerns can adjust to the new definition.

HUD Response: HUD believes that the refined definition continues to reflect the language and intent of the Section 3 statute, defining Section 3 business concerns in a way that furthers economic opportunities for low- and very low-income persons. HUD recognizes that 75% is a higher number than the prior new hire standard but believes that Section 3 business concerns should be either majority owned by low or very low-income persons or should primarily employ such individuals. HUD believes that the prior 30% standard does not ensure that a sufficiently substantial number of low- or very-low-income persons benefit from the priority contracting status that the Section 3 statute and regulation provide. Section 3 business concern employees are counted as Targeted Section 3 workers, giving HUD funding recipients and Section 3 projects an incentive to hire them to meet their Targeted Section 3 Benchmark numbers. HUD acknowledges that the revised definition of Section 3 business concerns may result in a decrease in firms qualifying for the designation, but the benefits of qualification will be more directly targeted to low- and very-low-income persons. HUD notes that the safe harbor benchmarks can be adjusted by notice periodically, which is intended to allow HUD to modify the benchmarks to accommodate geographies where the initially proposed benchmarks cannot be met due to the unavailability of Section 3 workers and Section 3 business concerns. HUD amended this provision to clarify that the 75% of labor hours should be determined based on looking back over the last 3 months of work performed for the business. The determination as a Section 3 business concern is made at the time the contract or subcontract is executed, so that the program participants have certainty in their Section 3 strategies. However, the final rule also provides flexibility to establish Section 3 business concern status during the Section 3 covered activity, to provide further incentive to employ Section 3 workers. If the business performed multiple projects, all of the hours on the projects over the prior three-month period should be considered for making the determination.

HUD notes the comment that observed a Section 3 business concern might need to track labor hours to be qualified, even if the federal funding recipient is reporting new hires. By eliminating the new hire alternative reporting metric, HUD anticipates that this dimension of documenting qualification as a Section 3 business concern will be mitigated. HUD further notes that businesses do not need to track labor hours precisely. HUD is not presuming the applicability of prevailing wage requirements, but rather is presuming that all employers paying an hourly wage will have some method to tabulate the number of hours worked, and for those that do not have a tracking mechanism in place, the final rule permits them to rely on a good faith assessment. An objective of Section 3 is to provide employment opportunities for public housing and low-income residents, which can lead to a focus on long-term employment goals. Other activities identified by the commenters are better suited for business development and therefore are outside the scope of this rule.

As for the concern that the definition will limit wage growth or promotion or result in Section 3 business concerns where all employees have low-income wages, HUD provides that the qualification of a Section 3 worker takes place at either the date of the Section 3 covered activity or the date of initial hire by the employer, not more than five years previously. Labor hours of an employee who is low- or very low-income at hire will continue to count for 5 years even if that person grows into a new, more advanced position. HUD anticipates that the employee with 5 years of experience with that same employer would be moving up in the business and would eventually need to

be replaced by a new, presumably low- or very-low-income entry-level employee. The definition has been modified to clarify this framework and to reduce the potential incentive to maintain workers at lower salaries simply to qualify as a Section 3 business concern. HUD also acknowledges that many entry-level opportunities for low-wage workers are in businesses and industries with a high percentage of low-wage employment possibilities. HUD determined not to implement a transition period, although contracts with Section 3 business concerns entered into under the regulations in place prior to the final rule's compliance date will continue to be considered Section 3 business concerns.

(1)(iii) at least 25 percent owned by current public housing residents or Section 8 residents

One commenter stated that the revised definition of at least 25 percent owned by current public housing residents, or residents who currently live in Section 8 assisted housing, will be easier to justify than evidence of a commitment to subcontract 25 percent or more of the dollar amount to all subcontracts. Other commenters stated that the third option for defining ''Section 3 business concern'' should be modified to require that the business have 51% ownership by public housing or Section 8 residents. These commenters warned that unless residents have majority control there is a danger of the business being a front for owners who might not represent residents' interests.

Further, the statute defines a Section 3 business concern as one with Section 3 residents having a controlling interest, or the business employs a substantial number of Section 3 residents. The commenter does not believe that this new proposed criterion is appropriate. Commenters also thought it would be inconsistent with the Congressional statutory intent that economic opportunities be provided to business concerns that are *majority owned and controlled* by low- and very low-income people and/or residents of government assisted housing. (12 U.S.C. 1701u(b)). Commenters further argued reducing the required ownership percentage would also be inconsistent with HUD's public housing regulations at 24 CFR part 963, which defines resident-owned business as one ''(1) which is at least 51% owned by one or more public housing residents and, (2) whose management and daily business operations are controlled by one or more such individuals.'' Commenters felt reducing the required ownership percentage would invite manipulation and abuse, the prevention of which would require a significant administrative burden. Commenters recommended the Section 3 regulations should be designed to encourage entrepreneurial development, not a passive ownership interest.

HUD Response: HUD agrees with commenters that the 25% ownership language may create the risk of unscrupulous business practices. Therefore, HUD revised the final rule to require a Section 3 business concern seeking to meet this third test be 51% owned and controlled by PHA residents and Section 8 residents, in place of the 25% test contained in the proposed rule. This number is also more consistent with HUD's current contracting provision for PHA resident owned businesses in 24 CFR part 963.

Wages

Commenters stated that businesses should not be rewarded for paying low wages; businesses should not receive a contracting preference by virtue of the fact that they pay their employees low wages. The commenters asserted Section 3 regulations should be designed to reward businesses that provide economic opportunities to low-income persons so that they have a chance to work their way out of poverty, and the income determination must be made immediately prior to the date of hire. According to the commenters, HUD's regulations should also reward employers who provide decent-paying jobs so that their employees no longer need to depend on HUD assistance to make ends meet. Commenters observed that by determining the low-income status of employees at the time of contract award (the labor hours ''are performed by low- or very low-income persons'') the definition inadvertently restricts eligibility to businesses whose employees are currently low-income. For these reasons, the commenters proposed that the definition of ''Section 3 business concern'' be changed to ''Over 75 percent of the labor hours performed for the business are performed by persons who were low- or very low-income immediately prior to the date of hire and whose current wage is equal to or greater than 80 percent of the area median income.''

HUD Response: The Section 3 regulations are designed to provide jobs for low-income persons. As these individuals gain experience, HUD anticipates wages will increase, and the individuals should be able to work their way out of poverty. The definition has been modified to clarify this framework by including a three-month documentation period and to reduce the potential incentive to maintain workers at lower salaries simply to qualify as a Section 3 business concern.

Contract Requirement

One commenter expressed concern over the elimination of Section 3 business concern contracting requirements because the commenter's agency spends a lot of resources on outreach, but recognized many housing authorities lack the resources or diverse vendor marketplaces to do the same.

HUD Response: HUD recognizes that not all PHAs will have the same resources to outreach to Section 3 business concerns. HUD believes, however, that counting the Section 3 business concern employees as Targeted Section 3 workers will incentivize PHAs to target Section 3 business concerns to help meet their Targeted Section 3 worker benchmark. HUD will continue to have a Section 3 business concern directory as well to make it easy for PHAs and other entities to identify Section 3 business concerns in their jurisdiction. HUD also believes that making the definition consistent with the PHA resident-owned businesses definition in 24 CFR part 963 will also provide another avenue for finding Section 3 business concerns.

Alternative Suggestions for the Definition of Section 3 Business Concern

One commenter recommended that HUD extend Section 3 business concern status to businesses funded through the Opportunity Zone program.[5] Commenters suggested defining a Section 3 business concern as meeting one of the following categories, in the following priority order: (1) Businesses owned 100% by Section 3 persons; (2) businesses owned and operated at a minimum 51% by Section 3 Persons; (3) Businesses whose total employees consist of a minimum of 75% Section 3 persons who reside within the project area; (4) Businesses whose total contract specific staffing (not back office administration unless the opportunity created is a back office position) has more than 50% Section 3 persons residing in the project area; (5) businesses owned by persons providing a negotiated employment level greater than 30% of total project staffing to Section 3 persons; (6) businesses who commit to directly conduct or to sub-contract professional employment readiness and employment trade skills training related to the project work or other in-demand employment

[5] *See* HUD, *Opportunity Now, Hud.gov*, *https://opportunityzones.hud.gov/.*

disciplines, at a minimum of 10% of their total contract award, plus or minus change orders, to Section 3 persons. Under (1), (2), (5), and (6), there is a priority order for the Section 3 persons as well: (A) Public housing assisted persons at the property where the work is being executed. When a contract is issued for service work covering multiple properties of the PHA, any public housing person from that PHA's portfolio shall compete equally for any opportunities created as a direct result of the expenditure. (B) When the service contract only covers one public housing property, the persons from that property will receive first priority for opportunities and then persons from other properties of the PHA's public housing portfolio will be secondly considered. (C) Housing Choice Voucher holders of that specific housing authority that administers that voucher will be third priority. (D) Persons residing in any project-based Section 8 property owned in whole or in part by that PHA. (E) Current YouthBuild participants. (F) All other low- and very low-income persons within the legal boundaries of the service area of the project.

HUD Response: HUD appreciates all the different options provided by commenters. However, HUD believes the final Section 3 business concern definition provided in this final rule provides a balance that is consistent with the statute and ensures that most Section 3 business concerns are in fact aimed at employing low- and very low-income persons. See responses above for additional discussion of the Section 3 business concern definition.

Small PHA Reporting

Support

Some commenters supported reporting flexibility for small PHAs, and especially the removal of the non-construction contract goal of 3 percent of all covered contracts to Section 3 business concerns, which they said is challenging to meet due to the amount of professional service contracts. One commenter suggested that for consistency and clarity, the final rule should exclude all PHAs with 250 or fewer units from reporting on benchmarks, regardless of procurement cost. The commenter also suggested that since the proposed rule exempts Section 8 funding from having to meet Section 3 requirements, the final rule should clarify the definition of a small agency for the purposes of Section 3 reporting to mean an agency with 250 or fewer public housing units. Another commenter recommended defining ''small PHA'' in a way that alleviates regulatory burdens for as many agencies as possible and suggested defining small PHA as those having 550 or fewer combined public housing and Section 8 units; or, as Section 8 funding is not covered by Section 3, utilize a 250 unit threshold.

Another commenter supported the small PHA reporting exemption suggesting that HUD should define a small PHA in a way that would maximize the number of agencies exempted from detailed reporting, recommending 550 combined units (consistent with the Economic Growth, Regulatory Relief, and Consumer Protection Act of 2018 and the Housing and Economic Recovery Act of 2008) or 250 public housing units (as Section 8 assistance is not covered by Section 3).

HUD Response: HUD continues to support the Small PHA reporting provision in the proposed rule. Small PHAs with less than 250 public housing units will not be required to report the number of labor hours and instead will be required to report their qualitative efforts. The final rule does not require a commitment to award at least 3 percent of the total dollar amount of all other Section 3 covered contracts to Section 3 business concerns. HUD currently is also not changing the number of public housing units for determining the Small PHA exception.

All PHAs Should Report for Data Collection and Compliance

Some commenters recommended that all PHAs, regardless of size, should be required to report for data collection and compliance. Other commenters specifically objected to the labor hours reporting exemption for PHAs with fewer than 250 housing units, because inexpensive software is available for PHAs to track and report labor hours. Other commenters suggested removing all exceptions for PHAs. Additional commenters elaborated that reporting requirements should be the same for all entities with no exceptions, noting that every recipient and every dollar should be included in order to guarantee that opportunities reach the poorest and smallest communities.

Commenters noted that small PHAs should not be exempt because they could have significant contractor and subcontractor activity in any given year. Specifically, one commenter noted that the $200,000 threshold should apply to small PHAs because they have the same opportunity to create jobs as other entities. Another commenter noted that not requiring small PHAs to report creates a loophole that hinders opportunity.

HUD Response: HUD has heard from small PHAs that they do not receive enough funding or have sufficient pools of Section 3 workers to support annual new hire or labor hour reporting. Close to one-half of small PHAs with less than 250 public housing units receive less than the $200,000 project threshold applicable to Section 3 projects that receive other HUD assistance such as CDBG and HOME funding. Due to Operating Fund shortfalls, small PHAs can take advantage of the authority under section 9(g)(2) of the United States Housing Act of 1937 to use its Operating and Capital Funds flexibly to fund any eligible activities under either funding stream. Some small PHAs compensate by promoting economic opportunities through referrals of residents to employers and job fairs, providing training facilities and offerings, and other local efforts. To recognize these other activities and the generally low amount of funds available or used for capital projects, small PHAs will report qualitatively on their efforts.

No Good Faith Assessment for Small PHAs

Some commenters objected to allowing small PHAs to supply a ''good faith'' assessment of hours worked because doing so would invite those entities to bypass important tracking requirements, suggesting that HUD should require quarterly, instead of annual reporting.

HUD Response: The small carve out for good faith assessment is not limited to small PHAs. As stated in the proposed rule, it is a limited exception where PHAs and other recipients of public housing financial assistance could use the reporting of a good faith assessment of the labor hours of a full-time or part-time employee from contractors and subcontractors that have not been subject to requirements specifying time and attendance reporting, and do not have systems already in place to track labor hours. This is to address employers that do not already track labor hours without making changes in time and attendance or payroll. It is not a permanent exception and if in the future the contractor or subcontractor is required to track labor hours under some other authority, or begins to voluntarily track labor hours, the exception would no longer apply.

Qualitative Reporting

Another commenter noted that the rule lacks information on what qualitative reporting will be required of small PHAs to substantiate the claim that such reporting will be less

burdensome and recommended that small PHAs have the option to track labor hours or do qualitative reporting.

HUD Response: The rule seeks not to be too prescriptive on qualitative reporting to provide small PHAs with the flexibility to report on a range of activities. HUD is considering some of the following to signify qualitative efforts: Outreach efforts to generate job applicants who are Targeted Section 3 workers; direct on-the-job training (including apprenticeships); indirect training such as arranging for, contracting for, or paying tuition for, off-site training technical assistance to help Section 3 workers; and outreach efforts to identify and secure bids from Section 3 business concerns. HUD plans to create a form for tracking and reporting qualitative efforts, to ease burden on recipients. HUD agrees that small PHAs should have the option of conforming to the more quantitative reporting standards and has modified the text to permit such option.

Dollar Threshold for Small PHAs

A few commenters also recommended use of a dollar threshold for public housing assistance similar to that used for other HUD assistance as a means to reduce reporting burdens on small agencies. One commenter suggested that using a dollar threshold, rather than a threshold based on number of public housing units, is a more practical and effective means of identifying those smaller projects that are less likely to generate significant Section 3 employment opportunities. Another commenter further suggested that thresholds established in the proposed rule for Community Planning and Development (CPD) should be applied across the board to all programs and noted that using a per-project or per-recipient threshold would more accurately exclude or include small PHAs based on funding. This commenter also suggested establishing a threshold for work-able non-working residents below which small PHAs would not have to report.

HUD Response: HUD continues to maintain that a dollar threshold for public housing financial assistance is not consistent with the statute. Section 3 applies to public housing operating, development, modernization, and management assistance, which covers virtually all housing authority projects and activities. HUD believes that the statute's expansive coverage of public housing projects and activities indicates that any attempt to diminish the coverage would be inconsistent with the statute.

Subcontractors

Several commenters noted that Section 3 requirements should not apply to subcontractors. Commenters stated that extending reporting requirements to subcontractors would discourage participation in PHA contracting opportunities, adversely impacting competition in the market, driving up construction costs and limiting economic opportunities. Other commenters added that HUD should consider ways to reduce administrative requirements on subcontractors wherever possible, echoing concerns that regulatory burdens which do not acknowledge subcontractor's practical limitations will discourage private sector partners from working with PHAs.

The commenters also suggested that regulatory relief for subcontractors could be achieved in a number of different ways, which range from exempting small subcontractors, excluding subcontractors from Section 3 obligations if their contracts are below a certain dollar threshold or below a percentage of the total covered funding on the Section 3 project. Commenters also suggested HUD consider limiting Section 3 obligations to the recipient, general contractor and immediate subcontractor(s), noting that relieving some or all Section 3 obligations on subcontractors may attract more high-quality tradespeople to affordable housing construction projects and possibly also lower the construction costs on Low Income Housing Tax Credit (LIHTC) and other affordable housing projects with covered HOME or CDBG funds.

Other commenters who expressed concerns about the reporting requirements for grantees and subcontractors also suggested thresholds for subcontractor reporting. Some commenters suggested retaining the existing $100,000 threshold, though one commenter recommended a reduced compliance level, allowing subcontractors to track Section 3 employees instead of labor hours, to reduce the administrative burden on small entities who lack the capacity to track hours. Some commenters suggested a reporting requirement threshold of $250,000 to align with the OMB procurement threshold, one of whom recommended this threshold also apply to contractors and offered the $10,000 micro purchase threshold as an alternative. Other commenters suggested a compliance threshold of $200,000.

A number of commenters supported reporting requirements for both contractors and subcontractors. One commenter recommended excluding second tier and below subcontractors from requirements, noting that large PHAs are more likely to award or fund multimillion-dollar projects that have more than 25 first-tier subcontractors. Two commenters mentioned the role of contractors simplifying the reporting mechanism for subcontractors and encouraging subcontractors to comply with requirements. One commenter also suggested that the funding recipient should be allowed to decide the extent of the Section 3 reporting requirements for subcontractors.

One commenter requested clarification as to how Section 3 requirements ''flow down'' to contractors and subcontractors for housing and community development financial assistance, noting the current regulation includes references to recipients as well as contractors and subcontractors when describing numerical goals and hiring/contracting preferences. The commenter went on to state that Subpart C of the Proposed Rule references only the recipient when describing the employment, training and contracting requirements and safe harbors, and removes the $100,000 contractor and subcontractor threshold in the current regulation for triggering Section 3 requirements. The commenter noted that while the Proposed Rule does mandate that each recipient ''require subrecipients, contractors, and subcontractors'' to meet the hiring/contracting requirements, they would propose a clarification on the extent to which contractors, subcontractors and subrecipients on Section 3 projects are bound by the requirements.

HUD Response: HUD is sensitive to the potential burden that Section 3 compliance may impose and has focused on outcomes, allowing the recipient to direct where the recipient's efforts, and its contractors' and subcontractors' efforts, will have maximum effect.

In the statute, the sections addressing public housing programs specifically include ''contractors and subcontractors'' in Section 3 requirements. In contrast, the statute does not reference ''subcontractors'' in the sections addressing other covered housing and community development assistance. Section 3's applicability to subcontractors as set forth in this final rule closely tracks the statute's requirements. The reporting requirements, however, focus on outcomes, deferring to the recipient to focus their efforts for maximum impact with respect to Section 3, and aligning the contractual obligations the recipient imposes on contractors and

subcontractors accordingly. Unlike the current rule, which applies Section 3 compliance to all subcontractors in excess of a $100,000 contract threshold, the final rule does not apply specific Section 3 reporting obligations to any subcontractor and instead such requirements would stem from the recipient. *See* § 135.3(a)(3)(ii)(B). The proposal to reinstate the $100,000 contract size threshold or any alternative threshold would limit the recipient's flexibility to determine how to achieve the ''greatest extent feasible'' standard most effectively. Similarly, subcontractors are excluded from the contract language provisions in Section 75.27(a), but subcontractors are still required to meet Section 3 requirements in Section 75.19, which provides the recipient flexibility to achieve the goal. The rule implements the suggestion provided in the comments that the recipient be allowed to decide on the extent of the Section 3 reporting requirements for subcontractors where the statute does not constrain HUD from providing this flexibility.

Definition for ''neighborhood'' or ''service area''

Some commenters supported the proposed definition, stating that the definitions are reasonable and will simplify compliance. Other commenters accepted only the one-mile radius definition of ''service area'' or ''neighborhood,'' but suggested that HUD eliminate the population requirement given the impact on rural areas.

Some commenters disagreed with the proposed definition, stating that metrics will be skewed based on close proximity to more affluent areas. Another commenter thought the definition is inconsistent with the statutory intent to encourage employment opportunities among low- and very low-income persons, noting a single definition cannot capture the expansive geographic areas. Another commenter noted the definition will actually limit mobility and the long-term success of resident programs because contracts will not provide opportunities to residents in successive projects in different neighborhoods. Some commenters wrote that the definition limits businesses in diverse economies and in high-cost cities that need more flexibility to recruit. One commenter wrote that this new definition would significantly reduce the labor pool of eligible Section 3 new hires, making it difficult to achieve benchmarks. Other commenters wrote that it may exclude local public housing or Section 8 residents. Another commenter thought that it would add challenges for contractors in identifying and prioritizing eligible workers.

Other commenters noted that the restriction does not account for Section 3 covered projects in areas that are not low-income, such as some CDBG expenditures. In addition, commenters noted that such a limitation could have the unintended consequence of excluding large groups of people from the pool of potential employees, especially in cities that are combatting racial segregation. Another commenter stated that the requirements are too geographically limited as to whom and where recipients/contractors must provide opportunities. Additionally, it does not account for opportunities that are accessible beyond the prescribed radii by using mass transit and other commuting opportunities.

Some commenters noted that a new definition would add unnecessary administrative burdens which increases the cost of program management and compliance. One commenter wrote that determining how to meet a 5,000-person radius would be burdensome. Other commenters wrote that completing data analysis of employee home locations and certification would be administratively burdensome and could be covered under state and local data privacy laws. In addition, a commenter stated that the definition may limit PHAs' abilities to hire individuals in their communities who would otherwise qualify as a Section 3 worker and stated that entities receiving community development funds are better at determining which individuals would benefit most from Section 3 employment.

Several commenters suggested that HUD retain the definition of ''service area'' as it exists in the current rule at 24 CFR 135.5. Another commenter supported Section 3 and encouraged the retention of flexible approaches to compliance, such as those outlined in 24 CFR 135.30. Any proposed rule changes should consider geographical and service population differences. The commenter supported maintaining the rule as is, noting it provides flexibility for compliance through training, hiring, or contracting. Similarly, another commenter noted that there should be flexibility and factors other than hours worked and earned to provide Section 3 credit.

HUD Response: HUD notes that the neighborhood or service area requirement applies to the prioritization of effort with respect to housing and community development financial assistance, not public housing funds. The hiring prioritization is different for this category of funding, and pursuant to the statute is focused on residents of the geographic area in which the work is being done, not on the rent-assisted status of the workers. Consequently, in this context, HUD is not adjusting the regulatory text to acknowledge the availability of transit or to prioritize employment of low- and very-low-income people from a broader geography.

The rule seeks not to limit the labor pool available within specific geographic areas, but to allow flexibility for smaller and more rural areas through the definition. HUD believes counting individuals who live within one mile of the worksite and within an expandable circle centered around the worksite that encompasses 5,000 people provides a definitive means of determining who counts as a Targeted Section 3 worker within the service area or the project neighborhood. Where the one-mile radius circle centered around the worksite has less than 5,000 people, the radius would be expanded outwardly to achieve the desired population of 5,000 people. This expansion would address many of the commenters' concerns regarding smaller communities or rural areas. For the benefit of densely settled urban areas, HUD recognizes there may be more than 5,000 people, but will hold at the one-mile geographic diameter.

HUD believes this final rule does take into consideration geographical and service population differences and retains flexibility for compliance through training, hiring, or contracting. Additionally, the rule is meant to streamline the Section 3 process to make it consistent with the statute and easier to implement. Compliance can be evaluated qualitatively if the labor hours benchmark cannot be met. Under this rule, both measurements are permissible, and the requirements for qualitative evaluation are laid out in the rule. In addition, HUD intends to create a web-based tool to support recipients, subrecipients, contractors, and subcontractors in determining the geographic area encompassing Targeted Section 3 workers.

Allow Grantees To Define ''Neighborhood'' or ''Service Area''

Commenters recommended that grantees be given the ability to define ''service area'' for themselves. Another commenter urged HUD to adopt something other than a ''one-size-fits-all'' approach so that small rural counties would not have difficulty utilizing federal funding. One commenter noted for example that in New Orleans, there are clearly defined

neighborhoods that most residents and officials understand and recognize, some having a larger area than a one-mile radius. The commenter stated that allowing for a more localized definition of 'project area,' rather than using HUD's definition of a one-mile radius or 5,000 person population guideline, increases local participation in projects that impact those individuals and their immediate surroundings and makes the most sense for their community. This commenter stated that recipients should be able to define their geographic size for purposes of how they focus their priorities regarding low-income persons residing within the service area or neighborhood in which the project is located, and communicate their determination to sub-recipients, contractors and subcontractors. Another suggestion was to have localities work with their local HUD office to define service area based on the locality's characteristics.

Commenters suggested that HUD allow residents and businesses from anywhere in the state to receive priority consideration or to give state recipients deference in establishing areas for purposes of meeting Section 3 requirements. Additionally, one commenter stated that service area may change based on project type, some serving entire communities while others serve smaller sections of a community, rendering the one-mile radius inapplicable depending on the project's scope of impact.

The commenters noted that limiting preference to a certain ''service area'' may have the unintended consequence of excluding large groups of people from the pool of potential employees. The commenters proposed allowing localities to either target job opportunities to low-income hires from anywhere within the locality, or work with their local HUD offices to define appropriate service areas based on the characteristics of the locality. One commenter wrote that the one-mile radius is too limiting and that residents within the community should be considered.

Some commenters suggested that HUD define service area to be ''the area within or contiguous to a PHA's jurisdictional boundaries.'' Other commenters suggested that HUD define ''service area'' or ''neighborhood'' in the following tiered manner: (1) PHA residents in project area; (2) Section 3 residents in project area; (3) extremely low-income or homeless individuals in project area; (3) YouthBuild in project area; and (5) next closest PHA in project area.

One commenter suggested that HUD should give preference to eligible residents of the neighborhood surrounding the PHA before other residents of the metropolitan area and should utilize the language in Subpart C § 75.19 reading ''Section 3 workers residing within the service area or the neighborhood of the project.'' One commenter stated that Section 3 Employment Priorities, as written, is very clear as to the order of Section 3 applicant priorities, starting with residents in closest proximity to the construction project, but disagreed that the one mile and 5,000 population radius is an appropriate geographic, using two PHA examples of Cayce Place and Edgehill to show that these metrics would be skewed based upon the close proximity to those earning twice the AMI and with property values in the hundreds of thousands of dollars.

HUD Response: As noted above, the neighborhood or service area requirement applies to the prioritization of effort with respect to housing and community development financial assistance, not public housing funds, and the focus in this context is on residents of the geographic area in which the work is being done. HUD believes that its proposed framework of counting individuals who live within one mile of the worksite and within an expandable circle centered around the worksite that encompasses 5,000 people provides a definitive means of determining who counts as a Targeted Section 3 worker within the service area or the neighborhood of the project. HUD believes the proposed Section 3 regulation takes the varied geographical areas into account and provides a streamlined framework that more specifically determines who might benefit from employment and training opportunities available within the area surrounding a Section 3 project. Where the radius or circle centered around the worksite has less than 5,000 people, the radius would be expanded outwardly to achieve the desired population of 5,000 people. All Targeted Section 3 workers identified by the geographic radius must also qualify as Section 3 workers, so this would not include higher-income workers within the neighborhood or service area.

Rural Areas and Contractors

Several commenters noted concerns about the effect of the proposed ''service area'' definition on Section 3 implementation in rural areas. One commenter stated it would be unrealistic and burdensome for employers in rural areas to administer and monitor the one-mile radius, and that it does not reflect the realities of construction employment in small rural states where the service area is the entire state. One commenter also stated that in areas of low population density, there often will not be sufficient residents or businesses that are capable of performing the work required for housing and community development projects. Other commenters wrote that, given chronic and widespread labor shortages, it is inadvisable to have such a small geographic restriction on the labor pool of Section 3 workers.

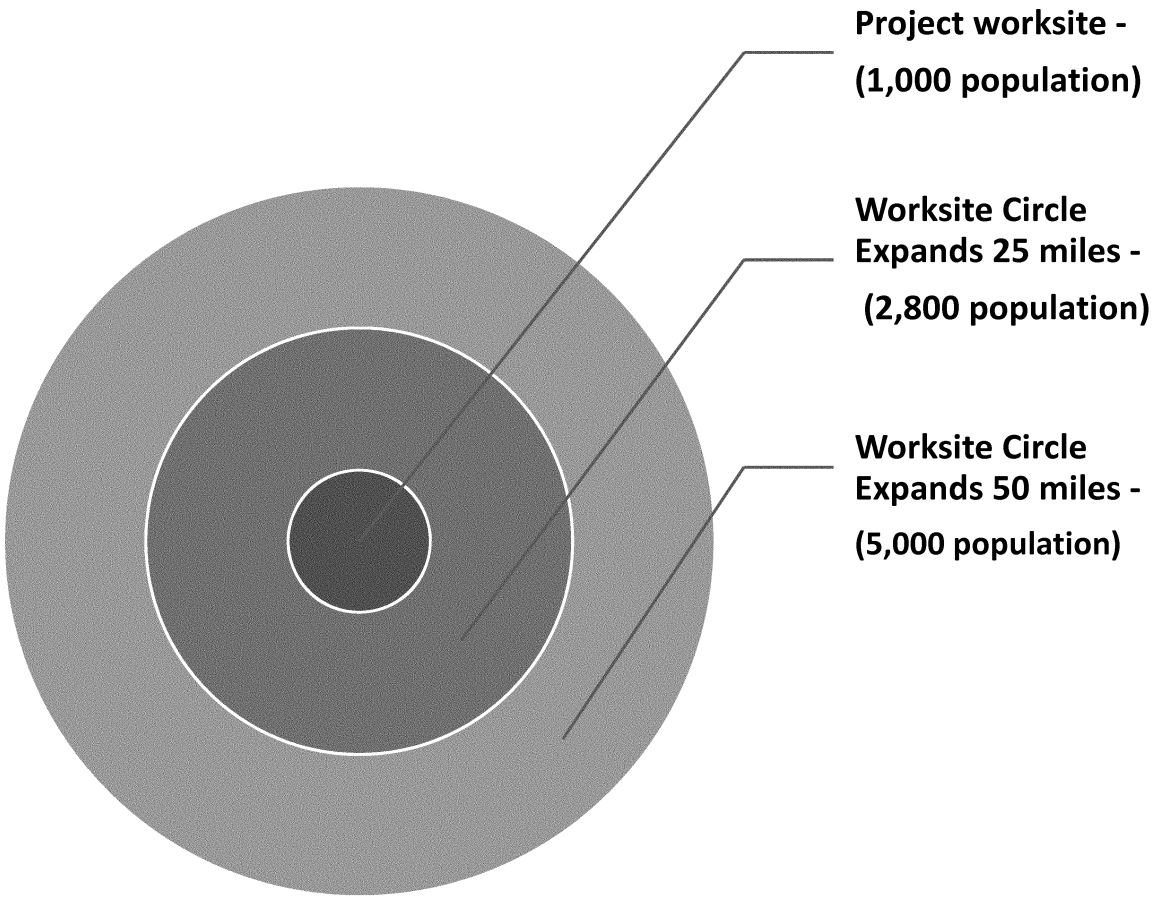
Other commenters accepted the one-mile radius definition of ''service area'' or ''neighborhood,'' but stated the 5,000-person population radius is too large for rural areas. Another commenter noted that the population threshold could increase the service area size exponentially in cities and counties where the population is less than 5,000.

One commenter in Utah opposed the proposed definition, arguing that changing the definition of ''neighborhood'' to 5,000 people would not work because of the state's very large rural geographic area. The commenter stated HUD's determination that most (77%) current CPD projects had a population of 5,000 people within one mile of the project site is not applicable in Utah, which has only 29 counties. The commenter detailed that 70% of Utah's population resides its 4 urban counties, and Utah's CDBG projects are part of the 23% that do not have 5,000 people within a one-mile radius of a project site.

One commenter mentioned the impact of the proposed definition on small contractors or those outside the immediate service area, noting that CBDG and HOME funds are often financing projects completed by small contractors who need to travel outside of a service area to complete work on a project. Another commenter rejected the proposed definition, suggesting that for small town jurisdictions, the ''service area'' or ''neighborhood'' should apply within the recipient's jurisdiction, which may be an entire county. One commenter mentioned that finding Section 3 contractors or businesses is already challenging and should not be limited by a ''service area'' or ''neighborhood'' definition.

HUD Response: HUD acknowledges and has carefully considered the concerns of commenters representing small and rural areas regarding the proposed definition of neighborhood/service area. As previously stated, HUD supports the proposed framework of counting individuals who live within one mile of the worksite and within an expandable circle centered around the

worksite that encompasses 5,000 people. This concept was designed specifically to address the unique needs and challenges facing rural and small communities. The graphic provides an example on how a circle centered around a worksite with fewer than 5,000 people may be expanded until the desired population goal of 5,000 people is met or eligible Targeted Section 3 workers are counted.



Above: Graphic depiction showing how the one-mile radius can be expanded where there are fewer than 5,000 people until the 5,000-person population is found.

The text as written will provide a definitive means of determining who counts as a Targeted Section 3 worker within the service area or the neighborhood of the project. HUD believes the proposed Section 3 regulation takes the varied geographical areas into account and provides a streamlined framework that more specifically determines who might benefit from employment and training opportunities available within the area surrounding a Section 3 project. HUD also notes that over time, as outcome results are reported to HUD, the benchmarks may be tailored to certain types of projects and geographies by notice, with the explicit intention that it may be appropriate to set different benchmarks for rural areas given the availability of labor and the patterns of contracting work in rural areas.

Web Tool

Some commenters noted that HUD's proposal to provide a web tool to aid in the process of determining a geographic service area would be helpful. One commenter urged HUD to provide the proposed web tool that will help determine the geographic area that encompasses Targeted Section 3 workers before it proceeds with the current definition and finalizes the rule. Commenters requested that HUD provide it to state and local recipients, sub-recipients, contractors, and subcontractors for testing before implementation. Though encouraged by the prospect of a web tool to help determine the geographic area that encompasses Targeted Section 3 workers, some commenters still argued for a broader definition and geographic areas that define Targeted Section 3 workers. Some commenters thought the web tool would not alleviate burden from the contractor that would still need to determine if a worker meets the requirements to be in the geographically defined area.

HUD Response: HUD agrees with the suggestion to provide a web tool to aid in the process of determining a geographic neighborhood/service area. As stated in the proposed rule, HUD will create and provide this tool at the issuance of the final rule to aid recipients, subrecipients, contractors, and subcontractors to determine the geographic area that encompasses Targeted Section 3 workers under this

definition. HUD will also explore the option of creating a mobile tool to help recipients with monitoring and compliance determinations.

Exceptions

Commenters suggested the proposed definition should not apply to Puerto Rico considering its geographic composition.

HUD Response: HUD has decided to retain the proposed definition for all recipients, including Puerto Rico. HUD believes the proposed regulation takes the varied geographical areas into account and provides a streamlined framework that will enable eligible workers to benefit from employment and training opportunities available within the area surrounding a Section 3 project.

YouthBuild Participants

Some commenters were in favor of or not opposed to expanding the definition to include previous YouthBuild workers that are under 24 years of age and those who are still eligible to participate in YouthBuild but may have graduated out of the program. One commenter was opposed to expanding the definition on the grounds that it would require onerous and complex background checks and research to determine whether a participant meets the alternate definition. One commenter recommended that the definition be changed to include previous YouthBuild workers who successfully graduated from the program and are either under age 24 or are otherwise still eligible for YouthBuild programs. Other commenters proposed that the definition of YouthBuild participant should be as broad as possible, regardless of age, while other commenters proposed the definition to include other programs which teach relevant skills, such as Service and Conservation Corps participants and graduates, participants/graduates of ''pre-apprenticeship'' training programs, participants/graduates of ''youth corps,'' VFW Local Program participants, and AmeriCorps participants.

HUD Response: HUD appreciates the commenters' support of the YouthBuild program, and after careful deliberation, has decided to keep the definition consistent with the current regulations and current YouthBuild participants. *See* 29 U.S.C. 3226; 24 CFR 135.5. HUD determined that given the work required to certify current YouthBuild workers, that adding a longer-term duration would create an additional paperwork requirement on both the person claiming the status and the entity reporting the status. It may also cause confusion using a certain period of time. Additionally, a YouthBuild worker can still qualify for 5 years if they are employed at the end of their YouthBuild experience.

Applicability and Scope

One commenter supported the rule's change to applicability. Another commenter supported Section 3 as an important mechanism to strengthen communities, reduce poverty, and increase residents' economic self-sufficiency. One commenter proposed that these rules should apply to all developers, contractors, and sub-contractors; all professional, skilled, unskilled, technical, and consulting service contracts compensated partially or fully by HUD funds—no exceptions. Another commenter suggested these rules shall be applicable to all professional, skilled, unskilled, technical, and consulting service contracts line items.

Other commenters suggested that HUD should clarify that owners and managers of HOPE VI, Choice Neighborhoods and Mixed-Financed Developments are subject to Section 3 Hiring and Contracting requirements in their own operations and should extend this requirement to Rental Assistance Demonstration (RAD) converted projects. One commenter supported HUD's separation of PHA requirements from non-PHA requirements because it did not make sense for non-PHAs to follow regulations intended for PHAs.

A commenter supported HUD's clarification regarding Section 3 applicability to projects receiving HUD assistance of $200,000 or greater. Another commenter warned that this rule states that Section 3 will apply when the amount of HUD assistance is greater than $200,000 on a per-project basis, which would potentially exempt projects where the HUD funding is less than $200,000, even though the combined total funding is much higher, leading to a decrease in number of projects subject to Section 3.

One commenter suggested that PBV and PBRA contracts should be exempt from Section 3 compliance. Another commenter suggested that, rather than a per-project basis, it would be simpler to apply Section 3 to individual contracts for housing and public construction funded with HUD assistance.

HUD Response: HUD shares the view that Section 3 is an important mechanism to strengthen communities, reduce poverty, and increase economic self-sufficiency. HUD seeks to focus Section 3's applicability where it can have a real impact, and to exempt from Section 3 those cases where applicability imposes burdens not commensurate with outcomes. HUD has concluded that in certain circumstances, particularly professional services, there are very few opportunities for Section 3 outcomes. The proposed definitions defined the scope of programs subject to Section 3 requirements but did not expand such coverage beyond what HUD's existing regulations already required for compliance. HUD proposed the $200,000 threshold for housing rehabilitation, housing construction and other public construction projects because work below that amount would likely not trigger long-term employment opportunities for which the recipient could show measurable labor hours. HUD disagrees that Section 3 should be applied to all types of work, without exception, and reaffirms in the final rule the exception for professional services. The proposed rule does, however, give credit in the reporting for opportunities that are created in the professional services context by including professional services labor hours in the numerator, and not in the denominator, of the reported outcome ratios. The final rule applies Section 3 in a manner consistent with the statute. HUD has determined that monthly rental assistance payments, such as those provided under Section 8 project-based voucher or project-based rental assistance housing assistance payment contracts, are not covered by the statute. Properties converted to Section 8 rental assistance through the RAD are covered by the rules applicable to Section 8. However, the RAD governing notice does apply Section 3 requirements to those activities occurring after the date of the RAD conversion which are contractually obligated as part of the RAD conversion.

Employment Priorities § 75.9 / § 75.19

Some commenters supported separating the agencies which fund Section 3 projects from PHAs and mirroring the statute. Other commenters felt that the priorities should be the same for both Section 3 projects and PHA financial assistance. Other commenters suggested that HUD give preferences to certain groups, while other commenters thought HUD should consider adding geographic considerations into the definition. One commenter suggested that the last priority level should be expanded to any person if the PHA can reasonably demonstrate there are not sufficient Section 3 residents with the requisite job skills within a project's geographic area. Commenters also asked HUD to clarify that otherwise eligible workers of PHAs, even if under private

management, are included in this category, as well as recipients of Section 8 assistance or voucher assistance residing in properties managed by other entities. One commenter suggested HUD change the regulatory language to insert the word ''priority'' in § 75.19 to clarify the requirement and make the sections consistent with § 75.9.

HUD Response: HUD appreciates the comments that supported the employment prioritizations. These prioritizations follow the statutory prioritizations, and HUD is including that language for clarity for recipients implementing the regulations. HUD has rephrased § 75.19 to include the word ''priority,'' consistent with the language of the statute. While HUD appreciates the alternative suggestions, these regulations are meant to streamline the Section 3 process to make it consistent with the statute and easier to implement. HUD believes that the existing regulatory text does that and is making no changes to this section. HUD, however, encourages the HUD financial assistance recipients to consider all the diverse suggestions provided when working on outreach to persons who are low- and very low-income persons to meet the Section 3 benchmarks including residents of PHAs under private management such as those residing in a mixed-finance development project.

Reporting § 75.15 / § 75.25

Consolidated Plan Regulations

A commenter recommended that the Consolidated Plan regulations at 24 CFR 91.520(a) be amended to specifically include Section 3 reporting; PIH will need to develop a Section 3 reporting format.

HUD Response: HUD will review Department-level strategies on how to effectively incorporate Section 3 reporting into current systems and data collection tools, including the Consolidated Plan. As a result, HUD will issue sub-regulatory guidance on reporting per program area and provide technical assistance to recipients for Section 3 compliance.

Systems

A commenter warned that HUD will need to modify IDIS to allow CDBG and HOME recipients to report on their Section 3 actions annually because CDBG and HOME recipients will report on their Section 3 actions in IDIS using a similar form as HUD Form 60002 that has been modified to capture labor hours worked. This commenter stated that this move will eliminate redundancy and ease the administrative burden for grantees.

HUD Response: HUD agrees that the Integrated Disbursement and Information System (IDIS) and DRGR should be modified to ensure accurate Section 3 compliance reporting for CDBG and HOME recipients. HUD will also adjust our data collection systems as necessary to ease administrative burden for grantees and to eliminate redundancy.

Report Through Action Plan and/or CAPER and Effective Date

A commenter supported HUD's effort and recommended reporting through the Action Plan and/or the Consolidated Annual Performance Evaluation Report (CAPER), only on completed projects. One commenter recommended that the final rule be effective for funds granted in the next Federal fiscal year after publication of the final rule so there is time for contracts/written agreements with sub-awardees to be amended, and in order to avoid having CAPER reporting requirements from annual federal years with two separate program requirements.

HUD Response: HUD supports efficient and effective Section 3 compliance reporting through current mechanisms, such as the Annual Action Plan and/or CAPER, for applicable HUD programs. As stated in the proposed rule, HUD believes that requiring reporting annually, but consistent with timeframes that PHAs and other recipients of other housing financial assistance are already using to submit documents to HUD, will relieve existing burden. HUD may also look into reporting into other existing systems rather than requiring PHAs and other recipients to log into and report under a separate system, such as the existing SPEARS.

Double Counting

A commenter stated that reporting responsibilities when multiple government agencies provide HUD CPD funds are unclear and requested HUD determine whether agencies will be responsible for reporting outcomes for each federal investment or whether HUD will prevent double counting by limiting reporting to one funding agency per Section 3 project.

HUD Response: Section 75.29(b) specifies that when there is funding from multiple programs that exceed the threshold in § 75.3(a)(2), the recipient will report to the applicable HUD program office. Some HUD systems allow for indicating when there are multiple HUD funds so that reporting can be limited to one system. However, not all HUD systems provide for that type of designation. HUD will provide additional guidance to recipients that have multiple funding sources on the proper process for reporting Section 3 project completion.

Separate Reporting by Funding Source

One commenter requested HUD clarify whether PHAs will still be required to report separately by funding source (*e.g.,* Operating Funds and Capital Funds) or whether the hires report will be aggregated to report only on PHA total funds. This decision will impact how PHAs currently collect and track Section 3 hires. A commenter supported elimination of separate reporting on contracting with Section 3 business concerns. Other commenters stated that the reporting and monitoring required to remove professional services labor hours from overall labor hours would add additional administrative burden to PHAs and could prove challenging in the overall reporting process.

HUD Response: Under the final rule, for non-MTW agencies, reporting initially will remain at the grant or individual program level, but HUD may explore agency-level reporting where possible to streamline and simplify. PHAs will still be required to report by separate funding source or in the aggregate for MTW agencies. For ease in administration, the rule will provide separate definitions for these types of funding and separate subparts relating to: (1) Public housing financial assistance, which covers (a) development assistance provided pursuant to Section 5 of the United States Housing Act of 1937 (the 1937 Act), (b) operations and management assistance provided pursuant to Section 9(e) of the 1937 Act (Operating Fund), and (c) development, modernization, and management assistance provided pursuant to Section 9(d) of the 1937 Act (Capital Fund); and (2) Section 3 projects, which means housing rehabilitation, housing construction and other public construction projects assisted with HUD housing and community development assistance when the amount of the assistance to the project exceeds $200,000, or $100,000 where the assistance is from HUD's Lead Hazard Control and Healthy Homes programs. There are no current plans to aggregate the information or eliminate reporting on contracting with Section 3 business concerns. Small PHAs with less than 250 public housing units will be permitted to report qualitatively. HUD is exploring how best to implement qualitative reporting for small PHAs, and as indicated above

may study whether other reporting methods should be contemplated in the future. As stated in the final rule, HUD believes that tracking labor hours consistent with existing tracking for prevailing wage requirements would reduce burden on recipients. HUD also believes that tracking labor hours will better allow HUD to determine if long-term employment opportunities are being generated.

Exempt Commodity Purchases, Non-Construction, and Professional Services

Commenters strongly agreed with the change to exempt both commodities purchases (material supply contracts) as well as professional services (contracts for legal, accounting, financial consulting, environmental assessment, A&E services and other professional services) from the calculation of contract dollars and new hires for reporting. One commenter supported exclusion of Section 3 requirements on non-construction professional services (*e.g.,* legal, accounting, and engineering) but has concerns that not all Section 3 workers want careers in the construction field and some employment is generated in non-construction contracts.

HUD Response: The final rule maintains the exemption of material supply contracts and maintains the structure presented in the proposed rule which does not require separate reporting of contracting with Section 3 business concerns. HUD is providing clarification on the exemption for professional services in the definition of ''professional services'' in this final rule, by defining professional as services that require an advanced degree or professional licensing.

HUD acknowledges that many low-income workers seek employment in jobs other than construction. However, data indicate that there are relatively few opportunities for Section 3 hiring in professional services fields such as legal services and civil engineering. Many of the positions within these professional services fields require specialized degrees and in many cases the hiring is not directly tracked to a specific federally funded project or activity. The reporting structure in the rule allows a recipient to count as Section 3 labor hours and as Targeted Section 3 labor hours any work performed by a Section 3 worker or a Targeted Section 3 worker (*i.e.,* in the numerator of the calculation), even when the professional services as a whole are not counted in the baseline reporting (*i.e.,* in the denominator of the calculation). The effect of this reporting structure is to give a recipient a bonus if they are able to report Section 3 hires in the professional services context.

Frequency of Reporting

Commenters stated that annual reporting does not facilitate capture and correcting of non-compliance. Some commenters recommended all PHAs should provide Section 3 reports quarterly instead of at the end of the fiscal year. Another commenter recommended that reporting should be done on a monthly basis.

One commenter strongly supported a return to annual reporting and integration of reporting with other funding program reporting requirements. Another commenter supported annual reporting for reducing administrative burden of more frequent reporting. Another commenter supported the proposed change to annual reporting on projects completed within the reporting year.

HUD Response: The reporting requirements represents a balance between frequent reporting, effective reporting, and administrative burden. Frequent reporting allows HUD to keep a closer eye on compliance, and early oversight can result in identification of non-compliant actors when there is still opportunity to influence change. Frequent reporting also risks identifying as non-compliant those endeavors where the Section 3 opportunities are sequenced later in the effort's timeline, resulting in ineffective reporting. This is often the case in construction efforts that begin with heavy machinery work and end with trades where Section 3 opportunities are more commonly created. Additionally, there is an administrative burden for the reporting entity, and an oversight responsibility for HUD, each time Section 3 reports must be submitted. HUD notes the variety of opinion represented in the comments, with suggestions of monthly, quarterly, and annual reporting, as well as the project-based reporting permitted in the proposed rule. HUD has determined not to revise the rule. As a result, reporting is on an annual basis for ongoing endeavors such as PHA operations or multi-year infrastructure or disaster recovery efforts. For discrete projects such as development of a singular multifamily apartment building, the reporting is on a project basis, and reported to HUD in the recipient's annual report corresponding to the year of the project's completion. Acknowledging the value of early intervention, the final rule also shifts oversight of Section 3 from a centralized HUD office, which typically does not have visibility into whether the funding recipient is embracing and effectively implementing its Section 3 obligations, to the program office which is in regular communication with the funding recipient. Part of HUD's intention with respect to this shift in oversight is to integrate discussions of Section 3 compliance into regular oversight discussions so that there are opportunities to influence improvement in Section 3 performance on an ongoing basis.

Submission Timing

Commenters recommended that HUD should provide further guidance on how and when annual reports will be submitted and stated that meeting the current January 10th deadline is a challenge for PHAs because end-of-year hires may be undercounted because paperwork may still be in process in January. Commenters stated that if the new regulations require reporting consistent with the timeframes that PHAs are already using, it will assist PHAs in providing the most accurate and up-to-date information. The commenters recommended that HUD refine the proposed reporting frequency regulations to read: ''recipients must report annually after the end of their reporting year to HUD . . .'' and HUD should provide PHAs 90 days from the end of their reporting year to have sufficient time to collect and aggregate data.

Another commenter noted that MTW PHAs provide annual reports based on the past fiscal year and updating the system to include such Section 3 reporting would be easier to use. This commenter also noted that it needs to be clarified how the reporting would deal with differing timelines for annual reporting versus the duration of projects with funds triggering Section 3 reporting.

HUD Response: As noted above, HUD will issue sub-regulatory guidance on reporting by program area. HUD anticipates that it may be able to integrate Section 3 reporting into the funding recipients' other, programmatic, reporting structures, which already have existing time frames for submission of reports. The rule does specify that reporting is based on the recipient's fiscal year, which language has not been changed. Section 3 requirements may not be waived by MTW agencies. MTW only provides flexibility for requirements promulgated under the 1937 Act, while Section 3 is a provision of the Housing and Urban Development (HUD) Act of 1968. Since HUD has a specific online system to collect Section 3 data—SPEARS—all PHAs, including MTW agencies, should report into that system. HUD will consider providing

training specific to MTW agencies, in addition to training for a more general audience, on how to use the SPEARS system.

Major Construction Project Administrative Burdens

Commenters warned that large workforces and the use of multiple subcontractors on major construction projects would lead to heavy administrative burdens which may discourage subrecipients or contractors from bidding. These commenters recommended contractors be allowed to self-certify to relieve administrative burdens.

HUD Response: HUD appreciates the commenters' concerns but determined that self-certification would not provide HUD with an adequate compliance oversight mechanism. There is no provision in the rule for self-certification of meeting the benchmark requirements.

Increasing Costs

One commenter stated that the requirements are already burdensome to their local governments, administrators, contractors and sub-contractors and the proposed rule would increase the burden, leading to fewer contractors willing to participate in CDBG projects, driving up costs, and leading to smaller projects and fewer beneficiaries. One commenter supported keeping reporting requirements to a minimum because both PHAs and HUD staff have limited capacity for reporting and providing constructive feedback.

One commenter stated the ability to identify workers individually rather than relying on the business concern to meet Section 3 definitions provides additional opportunity to demonstrate Section 3 compliance where there was none before, but this creates an additional burden to document safe harbor, particularly for Lead Hazard and Healthy Homes projects where a lower project dollar threshold is imposed. The commenter went on to suggest HUD consider providing additional funding for contractors to meet the financial impact of the paperwork burden of documenting compliance. Similarly, other commenters noted that under the previous rule the dollar threshold is zero, whereas under the proposed rule, despite the type of HUD funds received, every penny contracted, invested, or applied to any contract project, regardless of ownership, would have triggered full Section 3 compliance.

Commenters also expressed concern for the burden on contractors to meet hourly benchmarks while working through a pool of unskilled new hires and potential costs to the owner if a new hire fails to meet job requirements. One commenter stated that a significant increase in Federal funding would be required to fund the increased administrative burden of the proposed rule. Other commenters stated that due to the lack of resources many PHAs have, HUD should ask for increased funding for public housing so that PHAs can sufficiently meet Section 3's intended goals. Commenters suggested HUD consider creating Section 3 technical assistance funding that can be used to build PHAs' technical knowledge and capacity.

HUD Response: HUD will continue to look for ways to reduce the impact of Section 3 reporting requirements using existing reporting and compliance systems that decrease administrative burden on recipients. HUD believes the use of labor hours, rather than new hires, will reduce costs as many construction contractors already track labor hours to meet prevailing wage requirements. This practice is proposed to provide a consistent labor hour tracking mechanism that will make compliance with Section 3 easier not only for recipients of HUD assistance, but also for contractors and subcontractors. HUD anticipates a reduction in reporting and recordkeeping burdens equal to approximately 64,270 hours, or $2.4 million annually. This rule will not have any impact on the level of funding for covered HUD programs. Funding is determined independently by Congressional appropriations, authorizing statutes and regulatory formulas that set the amounts of Federal financial assistance provided by HUD grants. HUD is exploring ways to build upon ongoing Section 3 technical assistance and capacity building activities for recipients.

Disaster Recovery

A commenter warned that additional reporting requirements will be problematic for those managing disaster recovery and requested additional guidance for flexibility with the CDBG–DR program. Another commenter recommended HUD provide outreach and guidance on using CDBG–DR funds for job training and hiring initiatives during rebuilding efforts.

HUD Response: Reporting requirements already exist for reporting Section 3 compliance for CDBG–DR program activities. The proposed Section 3 rule will change the reporting scope, such as reporting hours instead of new hires. The rule, however, does not create additional reporting requirements. Like current practice, the size of a grant award and project scope will dictate the length of time it takes to complete reporting. Technical assistance on using CDBG–DR funds for job training and hiring initiatives during rebuilding efforts, as well as other Section 3 topics, will be provided to grantees upon request and as part of the ongoing grant management process.

Reporting Should Be on Projects Underway

One commenter recommended CPD project reporting should be based on projects underway, not only those projects completed during the program year. The rule is unclear on how Safe Harbor is met for Section 3 projects, though Reporting § 75.25 states HUD requires a compilation of data through the recipient's fiscal year. Commenter recommends Section 3 compliance be measured by combining all workers for all Section 3 projects. If percentages of Section 3 workers and Targeted Section 3 workers are met, this will show intent to comply.

HUD Response: HUD believes that CPD project reporting should be based on those projects completed during a program year. HUD anticipates that CPD programs will continue to report on Section 3 through CPD's current data collection mechanism. At minimum, CPD programs are required to report annually, but many programs update status more frequently during a recipient's fiscal year. HUD intends to issue guidance on the Section 3 requirements and provide technical assistance on a program-by-program basis.

Special Oversight Role of States in State Programs

One commenter recommended that the proposed Section 3 rule be amended to acknowledge the special oversight role of states in State programs. The current Section 3 regulation provides guidance on this point, while the proposed rule fails to include such guidance. Any final rule should include such guidance. *See* 24 CFR 135.32(f) and 24 CFR 570.

HUD Response: HUD supports retaining the current proposed rule's language. HUD believes the proposed language does fully address the roles and responsibilities of Section 3 recipients and provides adequate guidance to implement, monitor, and enforce Section 3 requirements.

Qualitative Form

One commenter recommended that HUD should provide the form for qualitative reporting required of small

PHAs to allow commenters to provide informed feedback.

HUD Response: HUD will provide a form for Small PHAs and others to use for qualitative reporting when an entity does not meet the benchmark. The form will be issued consistent with Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, and HUD will provide the opportunity for the public to provide comments on the form.

Recordkeeping (§ 75.31)

One commenter recommended moving § 75.31 to Subpart A where it would have general applicability to all recipients.

HUD Response: Subpart A and Subpart D provisions apply across the board. The rule is structured so that Section 3's general requirements are in Subpart A. Subpart B and C only apply depending on funding source. Other detailed requirements that apply across the board, such as recordkeeping and compliance, are in Subpart D. HUD believes this structure makes sense and is consistent with other rule structures.

Administrative and Compliance Costs

According to one commenter, this section implies the responsibility for ensuring workers meet the defined requirements in § 75.5, such as Census tract designation and annualized wage calculations, for CDBG Section 3 projects will lie with contractors, which will therefore be costly for contractors who lack the capacity or are already burdened by paperwork. The commenter suggested it may be easier to have recipients bear this burden.

In contrast, one commenter noted contractors would have to provide a personnel profile that includes, at a minimum, income, current address, address at time of hire, and YouthBuild status to establish whether an employee of a non-Section 3 business concern meets any of these criteria. Contractors and employees may balk at a request for this type of personal information, which may become public record. The additional administrative burden placed on otherwise qualified contractors may reduce contractor participation, thereby increasing costs and lessening the impact of Section 3 covered programs on their intended beneficiaries.

HUD Response: HUD believes the rule will not impose additional administrative and/or compliance costs for contractors. Administrative and compliance costs associated with Section 3 requirements should be properly resourced within a contractor's bid for a project and are already required for confirming compliance with existing Section 3 requirements. Contrary to the comments, contractors do not have to provide a personnel profile or any sort of personally identifiable information. HUD has never requested this detailed information and this rule does not change that; the data is only reported in aggregate, and records are maintained for verification only. Recipients may, but are not required to, assist contractors who lack capacity to adequately implement the Section 3 requirements.

Contracting Provision § 75.17 and § 75.27

Commenters urged HUD to retain standard Section 3 language to be included in contracts because the use of consistent language makes it easier for contractors to be certain of their obligations, limits the possibility of confusion for contractors working on multiple projects, and decreases administrative burden for agencies. Other commenters expressed concern about whether the Voluntary Compliance Agreement clause will continue to exist in contracts and who will enforce it.

HUD Response: HUD considered commenters' requests for standard contract language; however, the contract language must be customized depending upon the contract and the program. HUD anticipates providing sample language and/or discussion of contracting best practices but determined that the recipient is in the best position to determine what contract language is appropriate in each context.

Multiple Funding Sources/ Recordkeeping for Multiple Funding § 75.29 / § 75.31

Clear Standards and Secure Online Tool

Other commenters recommended that there should be clear standards for reporting on Section 3 regardless of the funding source to reduce the possibility of errors and to eliminate the need to report in different formats. These commenters suggested that if HUD defers to localities, the agency that is the primary recipient of HUD funding should determine which option of reporting should be used by subrecipients to allow for consistency in reporting approach. These commenters also recommended that public housing financial assistance guidelines should dictate reporting requirements for PHAs administering projects with multiple funding sources. For projects that are mix-funded with PHA and other HUD funding, § 75.29(a) says that the other HUD funding stream (*e.g.* CDBG) may report using the PHA criteria.

Commenters recommended that compliance documentation be accessible in a secure online tool or standard form which would measure new hires, hours percentages and training persons and hours. These commenters went on to suggest developing a form for contractors or subcontractors to complete to confirm workers' Section 3 eligibility, which would ease administration and will foster consistency. With respect to the self-certifications discussed in proposed § 75.31, it would be helpful if HUD were to provide a form for this purpose.

HUD Response: HUD thanks the commenters for their recommendation and notes that there will be a standard set of data reporting regardless of which system is used for reporting. The same data will be collected across programs for consistency; the only difference will be how it looks when reported.

Benchmarks for Section 3 Workers and Targeted Section 3 Workers

Many commenters supported including benchmarks for Section 3 workers and Targeted Section 3 workers. Some commenters supported HUD's initial benchmarks, as a starting point, and focus on labor hours. Additional commenters supported using both benchmarks stating that limiting the benchmark to only Targeted Section 3 workers would fail to encourage hiring of other Section 3 workers. Another commenter supported elimination of the 3% goal for non-construction contracts to be Section 3 business concerns. Other commenters supported the benchmarks with the caveat that HUD retain the new hire framework for PHAs or the tracking of the labor hours if they do not have an hour tracking system already in place. These commenters suggested evaluating the efficacy of this approach and revising as necessary if data indicates the change is not supporting sustained employment.

Other commenters stated that HUD's benchmark that Targeted Section 3 workers make up 5 percent of the total number of labor hours is too low. The commenters proposed that at least 15 percent of labor hours worked be the benchmark for Targeted Section 3 workers. The commenters stated that the Section 3 statute clearly prioritizes employment for residents of public housing and other HUD-assisted housing programs.

Some commenters noted that the benchmark for labor hours is too ambitious and unreasonable. Commenters cited to the fact that low-income workers are not necessarily qualified for construction jobs, even those jobs at the lower end of the

construction pay scale, and finding low-income workers who are both qualified for the positions and willing to work in construction is much harder than identifying the number of potentially eligible low-wage workers. Commenters also noted that many low-income persons have childcare and transportation challenges and many contractors do not have open positions to fill by low-income persons.

Another comment opposed the 5% Targeted Section 3 goal, stating it was unrealistic given most PHA residents are seniors, have some form of disability, or already work. Commenters also noted that the benchmarks will be especially difficult to achieve in rural locations.

One commenter opposed the two categories of Section 3 workers, noting the pool of workers is already small, and makes achievement of benchmarks challenging. While the additional categorization provides data collection value, it creates additional burden and goes beyond the statute's requirement. The commenter noted that the benchmark fails to recognize many other initiatives to assist residents to work towards long-term employment and self-sufficiency (such as Family Self-Sufficiency (FSS) programs).

Commenters also noted the current benchmarks have been difficult to meet, and that the new bar would likely require that all positions engaged, rather than only new hires, go to Section 3 workers. The commenter recommends that in an environment of under-funding and over-regulating that HUD establish a modest benchmark that recognizes training and adjust upward later, if necessary. The commenter noted the current recommendation is extremely aggressive and unreasonable; and would result in few agencies meeting the mark. Additionally, it would fail to reduce reporting burdens, align regulations with standard business practices, or increase Section 3 successes.

Other commenters focused on the Targeted Section 3 worker benchmark, noting that the category complicates tracking and decreases the likelihood of meeting benchmarks. The commenter suggested taking an alternate approach to tracking Targeted Section 3 workers without establishing a separate benchmark. One commenter stated that the benefits and goals of the Section 3 statute would be difficult to measure by tracking only Targeted Section 3 workers in that it would fail to represent the value of providing economic opportunities to individuals who are low-income but may live outside the immediate project area, who otherwise still qualify for Section 3 preference.

Other commenters stated that for Subpart C, HUD should only measure compliance of Section 3 with overall Section 3 worker tracking and should not apply Targeted Section 3 workers metrics or benchmarks. The commenters stated support for retaining the existing 30 percent benchmark for all Section 3 new hires but that it should not be required to be disaggregated between Section 3 and Targeted Section 3 workers. The commenters stated that this approach would keep the benchmarks in line with the goals of Section 3 while providing contractors and administering agencies with the ability to tailor implementation depending on the composition of the local workforce and specific project needs.

A commenter noted that they ran numbers with the new metric, along with other PHAs, and they all reported much lower percentages, in most cases half of the proposed numbers. The commenter raised a concern with employee displacement if contractors are required to meet this new ratio, which is inconsistent with the goal of Section 3 to create new jobs rather than displace existing employees or inflate project costs. The commenter noted that recipients hiring contractors instead of replacing or hiring more employees could game the system or add significant costs by hiring additional but unnecessary Section 3 workers for the project life.

HUD Response: The statute requires Section 3 prioritization and this rule's goal is to ensure statutory adherence and streamlined reporting. HUD created the Targeted Section 3 worker category to include both the statutory priorities and policy priorities, for example, tracking the hiring of public housing residents where public housing assistance is involved and tracking the residents of the neighborhood or service area when other housing and community development assistance is used. Prioritization is meaningless without the categorical distinction and HUD believes that technology enables better tracking compared to at the statute's inception. As for the benchmarks, HUD will establish the benchmarks via Federal Register Notices which will allow them to change over time, as data is reported and gathered. HUD believes 5% is a reasonable estimate from the Office of Policy Development and Research (PD&R) data. Additionally, compliance can be evaluated qualitatively if the hours benchmark cannot be met. Under this rule, both measurements are permissible, and the requirements for qualitative evaluation are laid out in the rule. HUD believes this flexibility will deter any incentive to hire unnecessary Section 3 workers.

Qualitative Measurement

One commenter supported changes to reporting requirements and appreciated the ability to report qualitative efforts if benchmarks are not met. One commenter stated that compliance should be evaluated qualitatively rather than using hours as a benchmark. Commenters stated that the proposed certification related to prioritization of Section 3 hiring efforts would be burdensome to agencies and contractors. The commenter wrote that HUD should require agencies to certify what efforts they have implemented to achieve the goals of the Section 3 program to be considered in compliance. This approach would maintain the benefits and incentives of the program and provide HUD with a tool for accountability.

HUD Response: The statute requires agencies and contractors to prioritize their hiring efforts according to the statute's terms. The rule requires funding recipients to certify that they have acted in compliance with the statute, and to report on the quantitative outcomes of their efforts relative to the benchmarks. HUD does not consider it burdensome for a recipient of HUD funding to certify that they have acted in compliance with the statute. Furthermore, compliance can be evaluated qualitatively if the hours benchmark cannot be met. Under this rule, both measurements are permissible, and the requirements for qualitative evaluation are laid out in the rule. If reporting is above the benchmark, then HUD will presume compliance with the regulatory requirements; HUD wants to see actual positive outcomes rather than just a recipient's inputs. HUD appreciates the request for additional compliance tools but believes that requiring such reporting for all agencies would be overly burdensome.

Safe Harbor

Commenters stated that the proposed rule is not clear on how Safe Harbor would be met for Section 3 projects. The commenters questioned what type of data collection would be used to assure accurate reporting and how to meet the percentages of Section 3 and Targeted Section 3 workers. The commenters asked whether there would be a tool to assist with this data collection.

HUD Response: HUD will issue sub-regulatory guidance and provide technical assistance on a program-by-program basis to assist recipients with

clearly understanding the Section 3 safe harbor parameters. Recipients will provide data regarding Section 3 and Targeted Section 3 workers through existing HUD information systems, as defined by each covered program. HUD will not impose additional data collection burdens on recipients because of the rule.

Small PHAs Should Have a Separate Benchmark

One commenter recommended that Safe Harbor benchmarks should be established for small PHAs and suggested HUD establish a minimum threshold of work-able and non-working residents. Another commenter stated that some smaller businesses do not usually track labor hours performed on specific projects, and it can be a struggle for them to learn how to do so. On Davis-Bacon projects, contractors are required to submit certified payroll; however, some projects may be subject to Section 3 that are not subject to Davis-Bacon and related acts. The commenter stated that requiring the tracking and reporting of labor hours could pose a significant additional burden to small contractors.

HUD Response: One of HUD's goals through this rule is to ensure that employment and other economic opportunities generated by Federal financial assistance for housing and community development programs are, to the greatest extent feasible, directed toward low- and very low-income persons, particularly (though not exclusively) those who receive government assistance for housing. HUD believes that it is essential to achieving this goal that small PHAs report on their efforts to comply with Section 3 but acknowledges that small PHAs may have more difficulty achieving the quantitative benchmarks and consequently has permitted a qualitative reporting alternative for small PHAs. HUD is considering further ways to streamline and ease qualitative reporting by creating a tracking form and timing submission deadlines consistently with timeframes that PHAs and other recipients of public housing financial assistance are already using to submit documents to HUD. HUD has established that small PHAs with less than 250 public housing units will not be required to report labor hours or meet benchmarks, but instead will be permitted to submit qualitative reports on their efforts to involve residents in job-seeking and training endeavors. HUD recognizes the challenge when small PHAs have very few work-able, non-working residents that would make meeting benchmarks very difficult.

Alternatives

One commenter suggested limiting the benchmark to only Targeted Section 3 workers in order to provide a more streamlined approach to reporting. The commenter stated that if the benchmark is narrowed to Targeted Section 3 workers, then tracking data for Section 3 workers should not be required. Other commenters recommended removing the Targeted Section 3 worker benchmark. One commenter stated that if labor hours are tracked, the requirement should be limited to Section 3 workers in general and that the benefits of adding the Targeted Section 3 worker subcategory are not apparent enough to outweigh the complications. One commenter supported giving PHAs and entities using housing and community development assistance a choice to use either targeted Section 3 workers or Section 3 workers as their benchmark.

Other commenters recommended other benchmarking alternatives. Some commenters recommended that the benchmark include a focus on Section 3 business concerns, such that 3% of all contracts are for Section 3 business concerns. One commenter stated benchmarks should ensure that local jobs are provided to local persons to reduce commute times and recommended using geographically determined numbers. The commenter noted that many factors can affect regions and a national number can skew the worker availability distribution. One commenter suggested that such regional benchmarks allow HUD to forecast how many PHAs and Section 3 projects could meet the benchmarks assuming agencies are using their ''best efforts'' to hire Section 3 workers and Section 3 projects are hiring and contracting with Section 3 workers and business concerns to the ''greatest extent feasible.'' According to comments, regional benchmarks can help account for uneven distribution of potential Section 3 workers throughout the country. Geographic standards may also help address differences between union and non-union states. If HUD were to set regional standards, there should be a national level appeals process. Commenters also suggested allowing use of local adjustment factors and economic data when establishing compliance benchmarks, especially unemployment rates which affect the ability to meet benchmarks.

One commenter stated the benchmark does not ensure Section 3 workers are engaged in a mix of job categories or trades, or opportunities for upward mobility; 30% of hours worked should be measured for each job category/trade and protected classes. Other commenters suggested HUD consider the type of public housing financial assistance or other variables. The commenter recommended that in addition to different types of benchmarks HUD should maintain a ceiling for these benchmarks. The commenter noted a goal of 80% of entities meeting the benchmarks would be appropriate.

Other commenters stated that in order to fulfill the statutory objectives of Section 3 to direct the financial opportunities to low- and very low-income persons and recipients of housing assistance, the final rule must: (1) Set benchmarks in a way that actually prioritizes HUD tenants; and (2) employ a definition of Section 3 worker and Targeted Section 3 worker that includes exclusively low-income individuals. Commenters also proposed separate benchmarks for public housing projects and non-public housing projects and provided a specific hierarchy of workers. Other commenters noted proposed benchmarks for PHAs should reflect the law's emphasis on providing opportunities for public and assisted housing recipients.

Commenters suggested an alternative approach for workforce utilization setting goals for all construction and other blue-collar employment, such as landscaping and janitorial. The commenters suggested that labor hours also consider demographics, length of project, geography, and size of contractors.

One commenter recommended that the determination of Section 3 compliance be measured by combining all workers for all Section 3 projects to get an overall picture of the number of low-income workers being paid with these federal dollars. If the percentages of Section 3 and Targeted Section 3 workers are met, this better shows intent to comply with the spirit of Section 3.

HUD Response: HUD appreciates the suggestions and has considered multiple benchmarking options. Creating separate benchmarks would make projects with co-funding difficult; the commenter's suggestions increase both complexity and the burden of reporting. HUD believes the current benchmark is a good starting place and notes that the regulation permits adjusting the benchmarks via **Federal Register** publication. HUD program staff will evaluate the level of effort expended by those recipients that fail to meet the benchmark safe harbor, and thus will ensure that the statutory terms are being properly enforced. HUD is most interested in strong outcomes for

Section 3 employees. In addition, HUD has no programs that align with specific regions and intends to see reporting data before making any additional distinctions, if appropriate.

Compliance (§ 75.33)

General

A comment stated HUD needs to strike a balance between the limits of state and local agency resources and Section 3's goals to provide more effective resources to foster compliance. Similarly, another comment suggested HUD utilize Community Compass technical assistance funds to create best practice resources and employ contractors to provide Section 3 compliance support to those jurisdictions and PHAs without designated staff for this purpose. Another comment recommended HUD simplify the compliance requirements by establishing a ''presumed eligibility'' criteria for businesses or residents located in HUD-approved Neighborhood Revitalization Strategy Areas, Choice Neighborhood target areas, Promise Zones, Empowerment Zones and Enterprise Communities, Opportunity Zones and other areas defined at 24 CFR part 570.208(a)(1)(vii).

A commenter suggested states and entitlement communities be required to develop Section 3 Plans that become part of the 5-year Consolidated Plan to allow time for compliance with the labor hours percentages while requiring demonstrated improvement over time. The plan should track Section 3 performance and demonstrate labor partnerships, construction, and training programs to target and find workers and an environment that promotes Section 3 goals. HUD should describe the plan's components, including how to notify the public of opportunities for involvement in designing the plan, how and when to notify the public when Section 3 employment and bidding opportunities arise, how to inform workers of their rights, and complaint processes. Commenters recommended HUD establish ethics standards for organizations who have a fiduciary responsibility over Section 3 funds. Other commenters suggested compliance failures to adhere to Section 3 business concern criteria should be cured within two payroll periods or be terminated; terminated contractors should be banned from receiving HUD funds for 3 years from the termination date; and that persons found to have falsified their residence to qualify as a Section 3 worker should be suspended from participation for 3 years.

Commenters stated HUD should: provide greater clarity on the obligations created by § 75.33(a), especially since the preceding section, § 75.31, imposes highly specific recordkeeping requirements; explain whether the recordkeeping obligation in § 75.33 is a restatement of the recordkeeping obligations set forth in § 75.31, or whether additional records are required to demonstrate compliance; and HUD should provide guidance on documentation and recordkeeping related to ''best efforts'' or ''greatest extent feasible'' efforts.

HUD Response: This rule is intended to strike a balance and foster compliance with Section 3's goals and will result in a reporting and recordkeeping burden reduction. HUD wants to ensure employers are invested in keeping Section 3 workers employed, and that there is enough opportunity to build skills and experience so that Section 3 workers may develop self-sufficiency and compete for other jobs in the future. HUD will review Department-level strategies on how to effectively incorporate Section 3 reporting into current systems and data collection tools, including the Consolidated Plan. HUD will issue sub-regulatory guidance on reporting by program area and provide technical assistance to recipients for Section 3 compliance. HUD appreciates the suggestions and notes that there will be standardized compliance procedures across programs, and this will include ethics standards. Section 75.33 is a reaffirmation of the recordkeeping requirement set forth in § 75.31, as recipients of HUD funding will need to have the records described in § 75.31 available if HUD needs to do a compliance review of a recipient's Section 3 performance. HUD determined not to define the difference between ''best efforts'' or ''greatest extent feasible,'' but rather to increase the emphasis on outcomes as a result of these efforts. Please see the ''Best efforts'' and ''greatest extent feasible'' section above. A recipient's reported results will be compared to the outcome metrics defined in the benchmark Notice. HUD program staff will evaluate the level of effort expended by those recipients that fail to meet the benchmark safe harbor, and thus will ensure that the statutory terms are being properly enforced.

Complaints and Monitoring

Commenters stated each HUD program should have a detailed complaint process. A commenter supported the integration of Section 3 into each program area but noted the lack of detailed complaint provisions, and suggested the final rule require each HUD program to have a detailed complaint process, with enforcement assigned to Davis-Bacon and Labor Relations (DBLR), Office of Field Policy and Management (FPM), or the Office of Fair Housing and Equal Opportunity (FHEO).

Commenters supported removing Section 3 enforcement from FHEO but strongly suggested HUD identify an office independent of the program offices to monitor and enforce Section 3 requirements, such as FPM, or a new Section 3 office fully funded and trained to work on Section 3. Giving responsibility for Section 3 compliance to the program that is responsible for funding that triggers Section 3 obligations is problematic because (1) HUD program staff have in the past referred to PHAs and jurisdictions, not the residents who are supposed to benefit from HUD programs, as their ''constituents,'' (2) there is currently no process for accepting and reviewing complaints in the proposed rule, (3) significant training and resources will be required to prepare program staff to oversee Section 3 compliance since they are not currently engaged in it. HUD should require that Section 3 policies, plans, procedures, and complaints are made publicly available by both the recipient and on HUD's website.

Other commenters agreed with the proposed shift of oversight from FHEO to program offices and believed this will improve oversight because program offices already monitor recipients on a day-to-day basis, thus Section 3 monitoring will become part of normal overall monitoring. Another commenter stated transferring oversight and compliance from FHEO to program offices is an appropriate change on the condition that oversight practices are standardized across program offices. Another commenter was concerned about the Section 3 complaint process for residents; HUD program areas do not have detailed provisions for residents to file complaints on the part of PHAs or jurisdictions that do not meet program requirements. At a minimum, if HUD defers to grantees to field complaints from individuals, the process should require a grantee to inform HUD of the resolution of each complaint much like CPD does with CDBG–DR complaints.

A further commenter stated it is not clear how the public will make complaints if the current complaint process is removed and asked how they will know which program office to contact. Other commenters suggested the final rule require a detailed complaint process identical or similar to

what is in the current rule. Further commenters expressed that HUD should keep the existing complaint process until it adopts a new one after public review and comment. Other commenters were concerned about the 958 Complaint Form's elimination and the impact on residents who will be left without protections or a process for monitoring and overseeing contractors who are violating Section 3 requirements. One commenter felt that to move the review process from FHEO to local HUD CPD would be disastrous.

A commenter noted that HOME and CDBG recipients do not seem to understand the importance of Section 3 and the compliance enforcement—appropriate remedies are not in place. According to one commenter, the promise of Section 3 has not yet been realized, largely due to the fact that none of the entities responsible for its administration—HUD, state and local governments, PHAs—have been sufficiently resourced to implement, monitor, and enforce Section 3 requirements. The HUD program offices responsible for funding all are currently under-resourced and could better fulfill their obligations in monitoring and enforcing Section 3 with dedicated staff.

One commenter had concerns about moving Section 3 regulations from 24 CFR part 135 under FHEO to the new part 75 under the Office of the Secretary; the commenter assumed Office of Field Policy and Management would have oversight of Section 3 under the proposed rule amendment and expressed concern over FPM's lack of capacity and technical knowledge to oversee monitoring and enforcement of Section 3. The commenter argued HUD has never seriously monitored and enforced the statute and that HUD program staff treat PHAs and jurisdictions as their constituents, not the residents who are the intended beneficiaries. Additionally, alternative procurement provisions should be created to help Section 3 business concerns compete with larger more established businesses.

One commenter was concerned about different program offices providing conflicting information and hoped HUD would provide standardization and clear guidance; others suggested HUD request adequate funding to hire the necessary headquarters and field office staff to provide Section 3 technical assistance and to robustly monitor and enforce Section 3, as well as seeking adequate funding so that all jurisdictions and PHAs can hire and retain staff to serve as Section 3 coordinators and to monitor and enforce Section 3 obligations. A commenter has received conflicting guidance from different program offices, resulting in findings and fines on several occasions.

HUD should provide further detail as to what standards each program office would be using to provide oversight and what procedures are in place to ensure that PHAs receive consistent oversight across offices. Further clarification is also needed as to how the responsible program office would be designated for oversight when a project uses multiple funding sources and triggers oversight from multiple program offices.

A commenter recommended HUD strengthen its compliance practices to incentivize performance while recognizing legitimate constraints. The commenter also recommends stating in the rule that HUD will deduct points in relevant HUD program Notices to applicants for competitive HUD funding who have not achieved Section 3 benchmarks and allowing applicants the ability to provide justifications for failure to meet benchmarks despite good faith efforts. The commenter also recommended allowing program offices to incentivize Section 3 compliance in funding Notices but have a Department-wide entity focus on all aspect of compliance (reporting, analysis, and information technology systems).

HUD Response: HUD took the concerns about the complaint process under advisement, and § 75.33(b) has been amended to include ''or local HUD field office.'' HUD believes Section 3's objectives will be better achieved by moving Section 3 oversight into the program offices so that HUD staff who are actively engaged with recipients in their program planning and activities will bring Section 3 concerns and considerations into their routine interactions with the recipients. HUD will provide external and internal technical guidance on complaint handling and routing. The Office of Field Policy and Management (FPM) will be taking a greater role at the field level by filtering complaints to the corresponding office, rather than every HUD program office having its own complaint process. The local HUD field office is part of the FPM organizational structure, and also provides individuals with a complaint venue when the complainant does not know which program office would be responsible. There will be variation in what guidance and/or compliance looks like for each program office, but HUD will provide support to the extent it is standardized across program offices.

Enforcement

Commenters stated any contractor or Section 3 resident found to falsify data in order to receive benefits from HUD funded training, contracting, and employment should be immediately removed and/or barred from participation in Section 3 programs for ten years. Violations should be posted and made available to the public for review. Every PHA should have a written Section 3 Plan-Policy in place and attached to any Request for Proposals for bids.

HUD Response: HUD believes that recipients should have the flexibility to determine how to implement Section 3. HUD also believes this new regulation will make such implementation easier. While the final rule does not require recipients to have Section 3 plans or policies, HUD views having them as a best practice that will aid recipients in achieving the Section 3 benchmarks. As for the concern about potential fraud, program offices will continue to monitor compliance with Section 3 requirements through evaluation of qualitative or quantitative reporting, complaint review, and program audits, if appropriate.

General Comments

One commenter said all policies should be expressed in ''simple'' terms for all stakeholders, especially residents, to understand. Commenters stated there is little point in creating policies and programs that produce only six-week or six-month jobs, or jobs that do not lead workers out of poverty. HUD recipients have difficulty in assisting residents in obtaining and maintaining any jobs, let alone high-wage jobs that will lead to careers and help residents leave poverty behind.

A commenter expressed the Section 3 rule is ''of great benefit to have in effect and keep up to date.'' Section 3 funding recipients should be mandated to actively seek employment at all times to the best of their ability and report an employment log to track job applications.

One commenter indicated many of the proposed changes do not reflect the construction trade's current realities and would impose costly new obligations on PHAs without a funding source to pay for those requirements. Another commenter argued Section 3 is ''just another burdensome regulation'' that ''doesn't produce a positive outcome.'' One commenter stated the proposed rule would have an adverse impact on the Section 3 participation that HUD desires, whereas others supported the proposed rule amendments.

One commenter stated public housing living conditions are poor; Section 3 programs are practically non-existent in the commenter's area; and the way that

public housing residents' income is calculated is problematic.

A commenter stated Section 3 is one of HUD's most important responsibilities since it creates the standards for employment, training, and contracting opportunities generated from HUD financial assistance. This commenter felt a stronger Section 3 rule can lead to increased hiring and contracting opportunities; overall the proposed rule has many merits and is an improvement. Similarly, another commenter stated the potential benefits of Section 3 have never been realized; the improvements to the rule have potential to improve outcomes.

According to one comment, the proposed rule amendments try to address Section 3 program implementation difficulties but still present incongruities; HUD should consider methods to enact preferences or incentives. A commenter stated it is difficult to find Section 3 employers in some jurisdictions, and some jurisdictions have no active YouthBuild program. Commenters noted most HUD households are headed by or include females, minorities, or female minorities. Section 3 regulations should be designed to give low- and very low-income people (particularly recipients of Federal housing assistance) a pathway out of poverty, and PHAs should be required to work with organizations that have a proven track record of successfully recruiting, training, and retaining women and minorities in the construction industry. A commenter recommended HUD work directly with the National Task Force on Tradeswomen's Issues.

HUD Response: HUD thanks the commenters for their responses. This rule is intended to strike a balance and foster compliance with Section 3's goals and will result in a reduction of reporting and recordkeeping burdens. HUD wants to ensure employers are invested in keeping Section 3 workers employed, and that there is enough opportunity to build skills and experience so that Section 3 workers may develop self-sufficiency and compete for other jobs in the future. HUD agrees that this regulation is designed to give low- and very low-income people (particularly recipients of Federal housing assistance) a pathway out of poverty. There is no mandate in the rule for Section 3 funding recipients to constantly apply for new jobs, nor are there requirements for PHAs to work with certain organizations.

Other Programs

Commenters noted opportunity discrimination is unconstitutional; all citizens have a right to wealth and prosperity. States can support and invest in their cities' workforce through equity and management but should first complete a local needs assessment. One commenter referred to Perkins V (the Strengthening Career and Technical Education for the 21st Century Act) requirements for eligible recipients to conduct a comprehensive local needs assessment every two years. One commenter suggested creating a Section 3 Score Card for public information to capture grantee compliance and ensure that contractor compliance with Section 3 requirements are considered for future employment and contracting opportunities, and improving the effectiveness of the program will enhance compliance to realistically measure targeted outcomes.

A commenter recommended HUD consider developing an annual recognition program for PHAs, subrecipients, contractors, and subcontractors for excellence in Section 3 performance, rather than redesigning the tracking and reporting requirements.

HUD Response: HUD thanks the commenters for their responses. HUD affirms that discrimination based on protected classes is unconstitutional. The Perkins programs noted in the comment are administered by the U.S. Department of Education and there are no requirements for eligible recipients to conduct a comprehensive local needs assessment every two years in the rule. There are no provisions to create a public Section 3 Score Card or an annual PHA recognition program at this time.

Technical Fix

One commenter noted in the amendment to 24 CFR 93.407(d), the proposed rule still references 24 CFR part 35 instead of 24 CFR part 75. The commenter recommended that HUD change the citation to reflect 24 CFR part 75.

HUD Response: Thank you for your comment, but HUD declines to change the citation. The amendment referred to is a technical amendment to the regulations unrelated to the Section 3 regulations. The cross-reference to 24 CFR part 35 is in reference to records demonstrating compliance with lead-based paint requirements, which continue to be covered by 24 CFR part 35.

HUD Program Collaboration

Commenters stated that funding for Section 3 coordinators, and technical assistance or written guidance on coordination with other self-sufficiency programs such as FSS would allow for Section 3 to more effectively meet its goals. One commenter opposed changes to the rule stating that HUD should not scale back its existing operations and rule. The commenter also recommended that HUD and other agencies ensure coordination with benefit planners so that people with disabilities are involved in planning neighborhoods and community opportunities for work.

HUD Response: HUD appreciates the suggestion for more funding for Section 3 coordinators. HUD believes that this rule will streamline the Section 3 regulations to create additional incentives and streamline reporting requirements, thereby offsetting the need for more funding. HUD notes that by conducting in-service trainings and proactively engaging with appropriate partners in the Social Security Administration (Work Incentives Planning Assistance), Department of Labor (ETA & ODEP) and Health and Human Services (CMS, ACF & ACL) to identify best practices and model approaches, FPM will make the appropriate decisions regarding potential coordination with FSS, other self-sufficiency programs, and/or programs for people with disabilities. HUD continues to encourage PHAs and recipients of HUD funds to coordinate with other agencies and local communities to assist in hiring Section 3 workers. This rule does not change that. Moving the oversight of the rule to FPM and the program offices will not scale back HUD's role in ensuring compliance with Section 3 requirements. HUD believes that the move will actually ensure better compliance given the new location of oversight and the new tracking mechanisms.

Title VI

One commenter suggested the Section 3 rule should include information that Title VI of the Civil Rights Act also applies to Section 3, prohibits against discrimination, and requires language assistance.

HUD Response: Title VI applies to any program or activity receiving Federal financial assistance from HUD. Section 3 is a requirement, not a program that receives HUD funding.

Extend Comment Period

One commenter recommended HUD extend the comment period for affordable housing developers to suggest more effective changes.

HUD Response: HUD believes that the 60-day comment period provided ample

opportunity for affordable housing developers and other members of the public to suggest changes to this rule.

Outside the Rulemaking Scope

One commenter, a stakeholder in a major metropolitan area PHA that is being monitored by a ''Federal Monitor'' as a result of a 958 Complaint, stated that the appointed Federal Monitor has no housing experience and that all parties involved have missed the most important purpose of Section 3, which is economic empowerment for low and very low-income persons residing in local communities for HUD invested projects.

One commenter proposed defining an execution fee as a ''percentage of bidder's final submitted price added by the recipient or general contractor because the contractor/subcontractor provided no Section 3 benefit.''

One commenter stated concern about the lack of focus on higher level training as a vehicle for individuals to develop skills and build a better future. The commenter stated that the proposed benchmarks and guidelines provide no framework for differentiating training or skilled work classifications from general labor, so there would be no incentive for creating higher level opportunities. The commenter requested that HUD provide guidance on how to encourage this sort of activity under the new benchmarks.

HUD Response: HUD thanks the commenters for their suggestions, however, these comments are outside the scope of this rulemaking.

Miscellaneous

Impact on Rural Areas and States

Commenters stated it is difficult to comply with Section 3 requirements in rural areas. The goals of Section 3 are more feasible in densely populated urban areas. The proposed rule does not improve this circumstance. Section 3 eligible individuals cannot take advantage of Section 3 opportunities in rural areas because they are nonexistent. There are not ample conditions to facilitate Section 3 in small communities and rural areas. Rural areas have less availability of contractors and employees and there needs to be flexibility to engage people outside their service area to complete projects. One commenter noted benchmarking methodology seems strongly skewed toward large urban centers and overlooks geographically large states with relatively small rural populations, and asked HUD to make exceptions for jurisdictions with smaller and more rural populations. Some commenters noted that contractors in rural states rarely need to hire new employees because the projects are small, the contractors have limited growth potential, or the employers have tenured staff. The commenter further stated that the new hire's length of employment coincides with the project and terminates at project completion.

Commenters noted Section 3 is particularly difficult for states to administer. Another commenter explained that as a state, it does not hire the contractors for the CDBG projects. The local jurisdictions do that. It has no opportunity to promote the hiring of Section 3 business concerns. The very small communities with which it works have implemented procurement policies that award contracts to the lowest responsible bidder. They will not award a contract to a higher bidder just because the bidder is a Section 3 business concern. The commenter stated that the Section 3 regulation should apply to the CDBG Entitlement program and not the Small Cities program. One commenter suggested that state CDBG recipients should have the same flexibility in reporting as small PHAs.

HUD Response: HUD acknowledges that implementing Section 3 in various geographic areas presents different challenges for rural areas versus densely populated urban areas. HUD believes this has been addressed within the proposed Section 3 regulation by using a circle centered around the worksite that expands until it reaches a population of at least 5,000. HUD further acknowledges that, in particularly remote areas, the expandable circle may reach a size that may be impracticable to match those benefiting from the project with the Section 3 benchmark. If the recipient is unable to meet the Section 3 benchmark described in § 75.11, it will be required to report in a form prescribed by HUD on the qualitative nature of its activities or those of its contractors and subcontractors. This will allow the recipient to explain in qualitative means why it was unable to meet the Section 3 benchmark. HUD is sympathetic to the issues raised for rural areas and will watch implementation carefully as it progresses, allowing for updates as deemed necessary. HUD will also provide sub-regulatory guidance on the submission of qualitative reports to enable smoother implementation of the requirement.

Coordination With Nonprofit Organizations and Other Agencies

Commenters suggested HUD require PHAs and other recipients to work with organizations with a proven record of accomplishment of success in the recruitment, training, and retention of women and minorities in the construction industry and other blue-collar occupations. The Department of Labor is already working with many of these organizations and has a list of apprenticeship training and technical assistance providers to help with the recruitment of Section 3 residents, pre-apprenticeship training and ongoing support. Commenters also suggested that HUD work directly with the many tradeswomen organizations, and other nonprofits already providing construction readiness training programs (also called pre-apprenticeship training) and the National Task Force on Tradeswomen's Issues. In 2018, women made up only 3.4% of construction workers. While this figure represents progress, it demonstrates the need for HUD and its recipients to partner with tradeswomen and other organizations who have expertise in successfully getting women and minorities into the construction trades, and, more importantly, creating a real opportunity for careers in the construction industry. One commenter recommended forging closer ties with the Tribal Employment Rights Offices and directing the HOME and CDBG programs to consider this approach to ensure tribal communities' benefit from HUD program projects nearby. Other commenters suggested planning grants to form or strengthen partnerships with Workforce Investment Boards or inter-agency collaborations with workforce programs within the Department of Labor.

HUD Response: HUD concurs that building strong collaborations between and among several Federal, state, and local partners will aid Section 3's goals. HUD will consult with the Departments of Labor, Health and Human Services, Commerce, Small Business Administration, and other agencies as determined by the HUD Secretary to meet the Section 3 statue's mandate at 12 U.S.C. 1701u(f). HUD will also take the comments provided under consideration as it looks for ways to conduct successful outreach and technical assistance strategies for Section 3 implementation.

Outreach and Training

Commenters recommended that HUD facilitate the competition for Section 3 excellence among developers and contractors by developing an online database of completed Section 3 covered projects that includes the names of the developer and general contractor, the nature and size of the project, and the Section 3 employment, contracting, training and retention outcomes

achieved. Commenters urged HUD to create a national database of Section 3 outcomes and to facilitate the inclusion of training and retention programs in bid materials by collecting and sharing best procurement practices.

One commenter suggested HUD should explicitly require PHAs and CDBG recipients to make reasonable efforts to connect Section 3 workers and Targeted Section 3 workers with local workforce development and career and technical education training. Another commenter recommended that the rule should give emphasis to training opportunities as is emphasized in the Section 3 statute because training is a potential response for recipients who are submitting qualitative reports for failure to meet Section 3 benchmarks.

One commenter stated there are no provisions in the rule regarding training. Similarly, another commenter noted the benchmark fails to recognize the statutory reference to training and employment opportunities. Likewise, commenters requested HUD clarify whether it is proposing new ways to track or report on Section 3 training. In the discussion of proposed §§ 75.15 and 75.25, HUD states that one of the qualitative measures a locality could use is paying for apprenticeship programs and/or offsite job training. One commenter welcomes any opportunity to expand these programs and recommends that HUD make job training an economic development activity instead of public service under the CDBG regulations. Alternatively, HUD could consider raising the public service cap for CDBG funds in order to accommodate additional job training programs.

A commenter recommended HUD provide outreach on training, employment and asset building programs to HUD assisted residents, including Family Self Sufficiency, Jobs Plus, and the Resident Opportunity and Self-Sufficiency programs. HUD should create resource guides on how CDBG has been used to support effective job training programs. A commenter suggested HUD should design a Section 3 worker's rights poster with input from HOME and CDBG grantees. Commenters noted changes to Section 3 reporting and tracking requirements may require additional resources for administering agencies, particularly PHAs in receipt of public housing assistance funds. HUD funding for the implementation of an IT system to enhance the current system and integrate with contractors would be particularly welcome to ease Section 3 monitoring and reporting for all parties. Having dedicated funding for the overall program, including support for resident training, IT system enhancements, and other related measures, would help to further Section 3 goals while limiting potential administrative burdens.

One commenter stated PHAs noted they are most successful in helping residents find employment when they can offer employment services and trainings to help them gain the skills necessary to access jobs. However, additional funding is needed for programs like Family Self Sufficiency, Resident Opportunities and Self-Sufficiency, Jobs-Plus Initiative, and the Public Housing Operating Fund. One commenter recommended that HUD provide recipients the addresses of all public housing, PBRA projects, and Housing Choice Voucher projects by counties to assist in matching workers' addresses and automatically designating them as Section 3 workers; that HUD assist Section 3 workers in housing assistance; that Section 3 workers receive a living wage; that HUD help provide life skills such as budget counseling; and that HUD be proactive in supporting and developing (in conjunction with the Department of Labor) apprenticeship and other training programs for assisted housing residents and other low-income people.

One commenter recommended that HUD incentivize widespread replication of successful mentorship programs; create regional programs patterned after successful mentorship programs that smaller PHAs can access cooperatively; ensure the program allows for a tiered approach that allows Section 3 contractors to gain vital experience on smaller projects then graduate up to increased responsibility; and ensure that the Section 3 program continues to allow PHAs to use Section 3 contractors to complete work at all levels, including very small projects. One commenter suggested HUD request that the President's Budget include adequate funding to enable HUD to hire the necessary headquarters and field office staff to provide Section 3 technical assistance and to robustly monitor and enforce Section 3. Also, the President's Budget should seek adequate funding so that all jurisdictions and PHAs can hire and retain staff to serve as Section 3 coordinators and to monitor and enforce Section 3 obligations.

HUD Response: HUD thanks the commenters for their suggestions; as HUD updates its systems, HUD will take the suggestions under advisement. HUD encourages CDBG recipients to collaborate with local workforce development boards and training providers to create effective connections between them and Section 3 and Targeted Section 3 workers. HUD will also provide sub-regulatory guidance and technical assistance promoting career and technical education training. HUD believes tracking labor hours provides a picture as to the success of providing job opportunities with HUD financial assistance, but as noted in the proposed rule the qualitative reporting will consider training. Reporting entities may consider training to help meet its employment goals and provide such information if goals are not met and entities are required to respond qualitatively. HUD will not provide a separate funding source; however, HUD will build on this final rule by providing technical assistance guidance for all HUD Section 3 programs. HUD will consider such guidance in creating materials for use by grantees. PHAs should already be tracking labor hours for Davis-Bacon or wage requirements and should not be doing anything more than what they did before to verify Section 3 workers as new hires. This rule just lays out the process for such verification. Once a PHA determines a Section 3 worker or Targeted Section 3 worker is hired or currently employed, the PHA would just report those hours as the numerator over the total labor hours funded with Operating and Capital Funds as the denominator.

HUD appreciates the input on ways HUD can help residents and is continuing to look at ways to make programs like Family Self Sufficiency, Resident Opportunities and Self-Sufficiency, Jobs-Plus Initiative more effective. HUD will be sure to consider those recommendations in future rulemaking. Section 3, however, is focused on how to provide job opportunities created by HUD federal financial assistance and does not have funding directly associated with it that can be used for those programs. Reporting entities may consider training to help meet their employment goals and provide such information if goals are not met and entities are required to respond qualitatively. HUD does not think it is appropriate to provide access to a list of all public housing, PBRA projects and Housing Choice Voucher residents to the public; such data sharing would implicate privacy concerns. Additionally, the PHA would have that information for seeking to hire such persons as Targeted Section 3 workers for public housing assistance.

HUD appreciates the suggestions and will consider them in providing guidance and technical assistance by both FPM and the program offices. HUD believes that there will be adequate funding for Section 3 technical assistance and monitoring in FPM. The FY2020 President's Budget Request

Congressional Justification specifically requested: ''$51.5 million to support 334 FTEs, consistent with the estimated 2019 Annualized CR level. Resources will support ongoing community engagement, monitoring and technical assistance pertaining to Section 3, compliance with the Davis-Bacon and Related Acts, enhancement of the overall customer experience and disaster recovery responsiveness at the state and local levels for clients and customers.'' [6] Federal financial assistance recipients should make their own determinations about staffing levels necessary to implement the assistance received.

Rental Assistance Demonstration (RAD)

Commenters recommended the RAD Notice should be amended to indicate that Section 3 obligations be extended post-conversion to PBV because currently Section 3 no longer applies unless additional Federal financial assistance is later used for rehabilitation. Commenters also asked for further clarification regarding RAD conversion applicability during and after construction. Eliminating RAD projects from Section 3 applicability will reduce contract awards that can provide opportunities to Section 3 residents. HUD should revise the rule to expand the definition of Targeted Section 3 worker to cover RAD and other HUD assisted tenants, and should require owners and managers of RAD-converted projects to hire, train, and contract with Section 3 residents to the greatest extent feasible in their own operations.

HUD Response: The Section 3 statute does not apply to properties that are recipients of Section 8 rental assistance unless they are recipients of other Federal funding covered by the Section 3 statute. A RAD transaction is a conversion at a moment in time and, subsequent to the conversion, the property is governed by the Section 8 requirements. HUD has administratively applied Section 3 during the RAD-related construction period even though not required by the RAD statute or the Section 3 statute. *See* RAD Notice Revision 4 and RAD program documents.[7] HUD has declined to extend Section 3 to the Section 8 portfolio, as that would be a significant expansion of the Section 3 statute's parameters. HUD has defined ''Targeted Section 3 workers'' to include residents of public housing and Section 8 housing, which means that HUD funding recipients must report on hiring of these types of HUD-assisted tenants, which includes tenants of RAD-converted Section 8 properties.

Notice of Funding Availability (NOFA)

One commenter wrote in support of the NOFA certification's removal. Several commenters supported the current requirement that NOFA applicants submit a certification of intent to comply with Section 3 requirements along with a statement of their proposed Section 3 activities. Commenters noted that performance among PHAs, developers, and contractors varies greatly when it comes to meeting Section 3 requirements. One commenter gave an example where a contractor might merely hold a job fair and interview any qualified Section 3 residents who apply, while another might make Section 3 hiring a condition of all major subcontract awards, contract with a community organization to conduct outreach and referral services, establish a pre-construction and/or on-the-job training program, provide job coaching and other supports, and retain Section 3 workers after completion of the Section 3 project. Commenters went on to state that using a bidder's past Section 3 performance and the quality of their proposed Section 3 plan can have a profound effect on the quality of economic opportunities provided to Section 3 residents.

HUD Response: HUD decided to continue with the change in the proposed rule and to omit specific requirements for Notices of Funding Availability (NOFA) in the final rule; however, the final rule will require that all NOFAs issued by HUD that announce the availability of funding covered by section 75.3 will include notice that part 75 is applicable to the funding and may include, as appropriate for specific NOFAs, points or bonus points for Section 3 plans. Where Section 3 is applicable, the inclusion of specific requirements in the regulation regarding the NOFA does not change the recipient's obligation to have a compliant Section 3 implementation strategy. Similarly, where Section 3 is not applicable, the regulatory language would not apply. The presence or absence of the NOFA clause in the regulation has no effect on applicability of Section 3. HUD anticipates that program offices will include scoring for Section 3 plans where relevant and exclude Section 3 scoring where the nature of the grant being awarded is incompatible with Section 3 endeavors (such as funding for sweat-equity homeownership initiatives). HUD is in the process of developing improved databases to inform program offices, funding recipients, and the public-at-large regarding Section 3-covered projects and the outcomes achieved. HUD hopes that these databases, plus anticipated technical assistance to disseminate information regarding Section 3 best practices, will provide a foundation for more impactful implementation of Section 3 over time.

Professional Services Exclusion

Commenters stated HUD should retain the 3% benchmark for professional services contracts, as it is not uncommon for professional services companies to meet the qualifications of a Section 3 business concern. It helps businesses who employ workers who were low-income when they were hires or businesses who were started by low-income or public housing residents that have grown professionally to provide employment opportunities to other low-income people.

Other commenters noted excluding professional services positions—typically higher paying, higher career growth—would effectively limit Section 3 workers to construction services, diminishing the potential positive impact of the statute. Ultimately, it will not provide HUD with adequate data on positive or negative impacts of Section 3's intended goals. The intended goal of the Section 3 statute is to positively impact the lives of HUD assisted residents through meaningful job placement and training that will ultimately lead to greater self-sufficiency. The current rule includes a goal of 30% of new hires in management and administrative jobs, technical, professional, building trades, and non-construction jobs and all levels. Professional service jobs include accounting, legal services, financial consulting, architectural and engineering services. The proposed rule indicates that professional services will be excluded from benchmarking requirements, but HUD will allow voluntary reporting of these workers. A commenter suggested maintaining the current rule's requirement of reporting on professional services but moving to total labor hours worked in both construction and non-construction services, and better tracking this data through streamlined reporting systems.

Other commenters supported excluding professional services from benchmarking requirements while allowing voluntary reporting of such workers; excluding certain types of contracts such as material and supply,

[6] HUD's FY2020 Congressional Justification for President's Budget, *https://www.hud.gov/sites/dfiles/CFO/documents/2020HUDCongressionalJustifications4-2-19.pdf.*

[7] Rental Assistance Demonstration—Final Implementation, Revision 4 Notice H–2019–09 PIH–2019–23 (HA), issued September 5, 2019.

and professional service; and excluding professional services from covered activities and suggested adding a benchmark for training activities. One commenter noted it experienced the same challenges as other HUD partners in meeting Section 3 goals when working with professional service vendors. However, the commenter noticed that in some cases vendors can carve out small segments of highly skilled work or training for low-income residents (*e.g.,* providing an internship or hiring a recent graduate to perform a small scope of work.) While the rule allows voluntary participation of professional service vendors, commenter suggests that HUD give discretion to recipients to mandate Section 3 participation by these partners, without necessarily holding them to specific benchmarks like contractors.

HUD Response: HUD acknowledges that there are occasions when employers can create opportunities for Section 3 employment in the professional services context, and HUD lauds these efforts. At the same time, data indicate that there are relatively few such opportunities for Section 3 hiring in professional services fields such as legal services and civil engineering. Many of the positions within these professional services fields require specialized degrees and in many cases the hiring is not directly tracked to a specific Federally funded project or activity. To ensure that the carve-out for professional services is relatively narrow, however, HUD has revised the definition of professional services. While keeping the modified exclusion for professional services in the final rule, HUD notes that the reporting structure in the proposed rule allows a recipient to count as Section 3 labor hours and as Targeted Section 3 labor hours any work performed by a Section 3 worker or a Targeted Section 3 worker (*i.e.,* in the numerator of the calculation), even when the professional services as a whole are not counted in the baseline reporting (*i.e.,* in the denominator of the calculation). The effect of this reporting structure is to give a recipient a bonus if they are able to report Section 3 hours in the professional services context. As referenced in the comments, vendors can sometimes create opportunities in the professional services context, and HUD seeks to reward this behavior. In addition, recipients are provided significant discretion in how they seek to implement their Section 3 obligations. A recipient could elect to require, at the local level, additional Section 3 obligations with respect to professional services through the terms of the funding contract.

V. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public.

This rule was determined to be a ''significant regulatory action'' as defined in Section 3(f) of the order (although not an economically significant regulatory action under the order). Consistent with Executive Order 13563, this rule creates new part 75 regulations that would replace the part 135 regulations, with the intention to make compliance with Section 3 more effective and less burdensome, and therefore, help to contribute to job creation for low- and very low-income persons. HUD has prepared a Regulatory Impact Analysis (RIA) that addresses the rule's costs and benefits. HUD's RIA is part of the docket file for this rule.

The docket file is available for public inspection in the Regulations Division, Office of the General Counsel, Room 10276, 451 7th Street SW, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the docket file by calling the Regulations Division at 202–402–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at toll-free 800–877–8339.

Environmental Impact

The final rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and on the private sector. This proposed rule does not impose a Federal mandate on any state, local, or tribal government, or on the private sector, within the meaning of UMRA.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As has been discussed in this preamble, this rule updates HUD's Section 3 regulations and replace them with a new 24 CFR part 75, for which the objective is to increase employment opportunities for low- and very low-income persons and businesses that are owned by or employ such persons. These entities generally are small and therefore strengthening the requirements of Section 3 should benefit small businesses that are Section 3 business concerns. This rule also considers the burden on small public housing agencies (PHAs), defined in this rule as a PHA that manages or operates fewer than 250 public housing units, and reduces the burden on them through a new streamlined reporting process that would not require them to report labor hours or new hires. There are approximately 2,950 PHAs, of which approximately 2,250 are small.

As more fully discussed in the accompanying RIA, the number of economic opportunities generated for Section 3 residents and businesses will not increase to the degree that this rule would have a significant economic impact on a substantial number of small entities. In addition, for those small entities that must comply with this rule, the changes made by this proposed rule are designed to reduce burden on them, as well as all recipients. The current recordkeeping and reporting requirements for Section 3 is 90,180

hours with a cost of $1,817,000. HUD estimated that this new rule will reduce the number of hours by 68 percent to 25,910 hours. The biggest reduction will be for small PHAs that will no longer need to do quantitative analysis with a total estimated time saving of 12,375 hours with a cost of $281,036, or approximately $125 for small PHAs. HUD also anticipates an across the board savings in recordkeeping given the time savings resulting from less time reporting new hires as a separate metric. For these reasons, HUD has determined that this rule would not have a significant economic impact on a substantial number of small entities.

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either: (1) Imposes substantial direct compliance costs on State and local governments and is not required by statute, or (2) preempts State law, unless the agency meets the consultation and funding requirements of Section 6 of the Executive Order. This final rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments nor preempt state law within the meaning of the Executive Order.

Paperwork Reduction Act

Currently, 24 CFR part 135 requires that all recipients track and report Section 3 information to HUD, includes prescriptive contractual language, requires compliance by contractors of the Section 3 requirements, contains reporting and recordkeeping requirements, and provides for the filing of Section 3 complaints. SPEARS is the main site in which HUD captures the number of Section 3 residents hired and the number of contracts awarded to Section 3 business concerns. The existing information collection requirement for these requirements has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and assigned OMB control number 2529–0043.

The rule would change the existing reporting requirement to decrease qualitatively those who need to report, excluding small PHAs and recipients of Section 3 projects under the $200,000 threshold, and require reporting only once a year by recipients of completed projects. HUD provides in §§ 75.15 and 75.25 that recipients would be required to submit reports to HUD annually either in a qualitative form or quantitative form. HUD includes all the large PHAs in the § 75.15(a) reporting number for reporting on the Section 3 benchmarks and estimates 2 hours to track and report annually given the amount of funds handled by these PHAs. HUD also estimates that a PHA will employ approximately seven contractors or subcontractors each fiscal year that would need to track and report up to the PHA, each at one-half an hour for reporting time. Lastly, HUD estimates that 5 percent of the 700 large PHAs may fail the Section 3 benchmarks and would need to report on their qualitative efforts along with the 2,250 small PHAs and estimates that such reporting would take one-half an hour.

As for § 75.25(a), HUD estimates that 66 percent of most program recipients would complete projects in a fiscal year that need to be reported except that for the HOME program, HUD estimates that 90 percent of HOME recipients would complete projects in a fiscal year, at an estimate of 3,600 recipients. Given these projects are more diverse in size, HUD estimates that the average time to report on the Section 3 benchmarks for recipients would be 1 hour. HUD also estimates that a Section 3 project will engage approximately five contractors or subcontractors each fiscal year that would also need to track and report up to the Section 3 project recipient, each at one-half an hour for reporting time. Lastly, HUD estimates that 5 percent of the 3,600 recipients may fail the Section 3 benchmarks and would need to report on their qualitative efforts and estimates that such reporting would take one-half an hour.

HUD also notes that the rule no longer requires the inclusion of prescriptive contractual language. See §§ 75.17 and 75.27. HUD believes that this change will result in a de minimis upfront burden related to updating contracts, if recipients, subrecipients, and contractors chose to do so, but that removing the requirement will actually reduce burden on recipients, subrecipients, and contractors on a sustained basis by giving them flexibility to use alternative or existing contractual language. HUD also provides for recordkeeping requirements at § 75.31 and believes that the maintaining of records by recipients will take a recipient approximately 2 hours. However, HUD notes that some programs, such as HOME, already have recordkeeping requirements that are part of existing approved Information Collection Requests and, thus, excludes those programs from the burden matrix. Lastly, HUD maintains the option for individuals to file complaints and retains the frequency number that was in the existing Section 3 reporting burden.

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. The current recordkeeping requirements for Section 3 is 90,180 hours with a cost of $1,817,000. HUD estimates that this new rule will reduce the number of hours by 68 percent to 25,910 hours for a total cost savings of approximately $1.2 million. The overall reporting and recordkeeping burden is estimated as follows:

Information collection	Number of respondents	Frequency of response per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
§ 75.15(a) Labor Hour or New Hire Reporting for PHA	700	1	2	1,400	$22.71	$31,794.00
§ 75.15(a) Labor Hour or New Hire Reporting for Contractors or Subcontractors of PHAs	4,900	1	0.5	2,450	22.71	55,639.50
§ 75.15(b)–(d) Qualitative Reporting for PHAs	2,300	1	0.5	1,150	22.71	26,116.50
§ 75.25(a) Labor Hour Reporting for Section 3 Projects	3,600	1	1	3,600	22.71	81,756.00
§ 75.25(a) Labor Hour Reporting for Contractors and Subcontractors on Section 3 Projects	10,800	1	0.5	5,400	22.71	122,634.00

Information collection	Number of respondents	Frequency of response per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
§ 75.25(b) Qualitative Reporting for Section 3 Projects	180	1	0.5	90	22.71	2,043.90
§ 75.31 Recordkeeping	5,900	1	2	11,800	22.71	267,978.00
§ 75.33 Complaints	20	1	1	20	10.00	200.00
Total				25,910		588,161.90

HUD will update the appropriate OMB control number 2529–0043 to reflect this reduction in burden.

Congressional Review of Final Rules

The Office of Information and Regulatory Affairs has determined that this final rule is not a major rule, as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking pursuant to the Congressional Review Act, Public Law 104–121, sec. 251, 110 Stat. 868, 873 (codified at 5 U.S.C. 804). This 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 the ability of U.S.-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects

24 CFR Part 5

Administrative practice and procedure, Aged, Claims, Crime, Government contracts, Grant programs-housing and community development, Individuals with disabilities, Intergovernmental relations, Loan programs-housing and community development, Low- and moderate-income housing, Mortgage insurance, Penalties, Pets, Public housing, Rent subsidies, Reporting and recordkeeping requirements, Social security, Unemployment compensation, Wages.

24 CFR Part 14

Claims, Equal access to justice, Lawyers, Reporting and recordkeeping requirements.

24 CFR Part 75

Administrative practice and procedure, Community development, Government contracts, Grant programs—housing and community development, Housing, Loan programs—housing and community development, Reporting and recordkeeping requirements, Small businesses.

24 CFR Part 91

Aged, Grant programs-housing and community development, Homeless, Individuals with disabilities, Low- and moderate-income housing, Reporting and recordkeeping requirements.

24 CFR Part 92

Administrative practice and procedure, Low- and moderate-income housing, Manufactured homes, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 93

Administrative practice and procedure, Grant programs-housing and community development, Low- and moderate-income housing, Manufactured homes, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 135

Administrative practice and procedure, Community development, Equal employment opportunity, Government contracts, Grant programs—housing and community development, Housing, Loan programs—housing and community development, Reporting and recordkeeping requirements, Small businesses.

24 CFR Part 266

Intergovernmental relations, Low- and moderate-income housing, Mortgage insurance, Reporting and recordkeeping requirements.

24 CFR Part 570

Administrative practice and procedure, American Samoa, Community development block grants, Grant programs-education, Grant programs-housing and community development, Guam, Indians, Loan programs-housing and community development, Low- and moderate-income housing, Northern Mariana Islands, Pacific Islands Trust Territory, Puerto Rico, Reporting and recordkeeping requirements, Student aid, Virgin Islands.

24 CFR Part 576

Community facilities, Grant programs-housing and community development, Grant programs-social programs, Homeless, Reporting and recordkeeping requirements.

24 CFR Part 578

Community development, Community facilities, Grant programs-housing and community development, Grant programs-social programs, Homeless, Reporting and recordkeeping requirements.

24 CFR Part 905

Grant programs-housing and community development, Public housing, Reporting and recordkeeping requirements.

24 CFR Part 964

Grant programs-housing and community development, Public housing, Reporting and recordkeeping requirements.

24 CFR Part 983

Grant programs-housing and community development, Low- and moderate-income housing, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 1000

Aged, Community development block grants, Grant programs-housing and community development, Grant programs-Indians, Indians, Individuals with disabilities, Public housing, Reporting and recordkeeping requirements.

Accordingly, for the reasons described in the preamble, under the authority 12 U.S.C. 1701u; 42 U.S.C. 3535(d), HUD amends 24 CFR parts 5, 14, 75, 91, 92, 93, 135, 266, 570, 576, 578, 905, 964, 983, and 1000 as follows:

PART 5—GENERAL HUD PROGRAM REQUIREMENTS; WAIVERS

■ 1. The authority for part 5 is revised to read as follows:

Authority: 12 U.S.C. 1701u and 1701x; 42 U.S.C. 1437a, 1437c, 1437d, 1437f, 1437n, 3535(d); Sec. 327, Pub. L. 109–115, 119 Stat. 2936; Sec. 607, Pub. L. 109–115, 119 Stat.

3051 (42 U.S.C. 14043e *et seq.*); E.O. 13279, 67 FR 77141, 3 CFR, 2002 Comp., p. 258; and E.O. 13559, 75 FR 71319, 3 CFR 2010 Comp., p. 273.

§ 5.105 [Amended]

■ 2. Amend § 5.105(a) by removing ''; section 3 of the Housing and Urban Development Act of 1968 (12 U.S.C. 1701u) and implementing regulations at 24 CFR part 135.''

PART 14—IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT IN ADMINISTRATIVE PROCEEDINGS

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

Authority: 5 U.S.C. 504(c)(1); 42 U.S.C. 3535(d).

§ 14.115 [Amended]

■ 4. Amend § 14.115 by removing and reserving paragraph (a)(5).

■ 5. Add part 75 to read as follows:

PART 75—ECONOMIC OPPORTUNITIES FOR LOW- AND VERY LOW-INCOME PERSONS

Subpart A—General Provisions

Sec.
75.1 Purpose.
75.3 Applicability.
75.5 Definitions.
75.7 Requirements applicable to HUD NOFAs for Section 3 covered programs.

Subpart B—Additional Provisions for Public Housing Financial Assistance

75.9 Requirements.
75.11 Targeted Section 3 worker for public housing financial assistance.
75.13 Section 3 safe harbor.
75.15 Reporting.
75.17 Contract provisions.

Subpart C—Additional Provisions for Housing and Community Development Financial Assistance

75.19 Requirements.
75.21 Targeted Section 3 worker for housing and community development financial assistance.
75.23 Section 3 safe harbor.
75.25 Reporting.
75.27 Contract provisions.

Subpart D—Provisions for Multiple Funding Sources, Recordkeeping and Compliance

75.29 Multiple funding sources.
75.31 Recordkeeping.
75.33 Compliance.

Authority: 12 U.S.C. 1701u; 42 U.S.C. 3535(d).

Subpart A—General Provisions

§ 75.1 Purpose.

This part establishes the requirements to be followed to ensure the objectives of Section 3 of the Housing and Urban Development Act of 1968 (12 U.S.C. 1701u) (Section 3) are met. The purpose of Section 3 is to ensure that economic opportunities, most importantly employment, generated by certain HUD financial assistance shall be directed to low- and very low-income persons, particularly those who are recipients of government assistance for housing or residents of the community in which the Federal assistance is spent.

§ 75.3 Applicability.

(a) *General applicability.* Section 3 applies to public housing financial assistance and Section 3 projects, as follows:

(1) *Public housing financial assistance.* Public housing financial assistance means:

(i) Development assistance provided pursuant to section 5 of the United States Housing Act of 1937 (the 1937 Act);

(ii) Operations and management assistance provided pursuant to section 9(e) of the 1937 Act;

(iii) Development, modernization, and management assistance provided pursuant to section 9(d) of the 1937 Act; and

(iv) The entirety of a mixed-finance development project as described in 24 CFR 905.604, regardless of whether the project is fully or partially assisted with public housing financial assistance as defined in paragraphs (a)(1)(i) through (iii) of this section.

(2) *Section 3 projects.* (i) Section 3 projects means housing rehabilitation, housing construction, and other public construction projects assisted under HUD programs that provide housing and community development financial assistance when the total amount of assistance to the project exceeds a threshold of $200,000. The threshold is $100,000 where the assistance is from the Lead Hazard Control and Healthy Homes programs, as authorized by Sections 501 or 502 of the Housing and Urban Development Act of 1970 (12 U.S.C. 1701z–1 or 1701z–2), the Lead-Based Paint Poisoning Prevention Act (42 U.S.C 4801 *et seq.*); and the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4851 *et seq.*). The project is the site or sites together with any building(s) and improvements located on the site(s) that are under common ownership, management, and financing.

(ii) The Secretary must update the thresholds provided in paragraph (a)(2)(i) of this section not less than once every 5 years based on a national construction cost inflation factor through **Federal Register** notice not subject to public comment. When the Secretary finds it is warranted to ensure compliance with Section 3, the Secretary may adjust, regardless of the national construction cost factor, such thresholds through **Federal Register** notice, subject to public comment.

(iii) The requirements in this part apply to an entire Section 3 project, regardless of whether the project is fully or partially assisted under HUD programs that provide housing and community development financial assistance.

(b) *Contracts for materials.* Section 3 requirements do not apply to material supply contracts.

(c) *Indian and Tribal preferences.* Contracts, subcontracts, grants, or subgrants subject to Section 7(b) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5307(b)) or subject to tribal preference requirements as authorized under 101(k) of the Native American Housing Assistance and Self-Determination Act (25 U.S.C. 4111(k)) must provide preferences in employment, training, and business opportunities to Indians and Indian organizations, and are therefore not subject to the requirements of this part.

(d) *Other HUD assistance and other Federal assistance.* Recipients that are not subject to Section 3 are encouraged to consider ways to support the purpose of Section 3.

§ 75.5 Definitions.

The terms *HUD, Public housing,* and *Public Housing Agency (PHA)* are defined in 24 CFR part 5. The following definitions also apply to this part:

1937 Act means the United States Housing Act of 1937, 42 U.S.C. 1437 *et seq.*

Contractor means any entity entering into a contract with:

(1) A recipient to perform work in connection with the expenditure of public housing financial assistance or for work in connection with a Section 3 project; or

(2) A subrecipient for work in connection with a Section 3 project.

Labor hours means the number of paid hours worked by persons on a Section 3 project or by persons employed with funds that include public housing financial assistance.

Low-income person means a person as defined in Section 3(b)(2) of the 1937 Act.

Material supply contracts means contracts for the purchase of products and materials, including, but not limited to, lumber, drywall, wiring, concrete, pipes, toilets, sinks, carpets, and office supplies.

Professional services means non-construction services that require an

advanced degree or professional licensing, including, but not limited to, contracts for legal services, financial consulting, accounting services, environmental assessment, architectural services, and civil engineering services.

Public housing financial assistance means assistance as defined in § 75.3(a)(1).

Public housing project is defined in 24 CFR 905.108.

Recipient means any entity that receives directly from HUD public housing financial assistance or housing and community development assistance that funds Section 3 projects, including, but not limited to, any State, local government, instrumentality, PHA, or other public agency, public or private nonprofit organization.

Section 3 means Section 3 of the Housing and Urban Development Act of 1968, as amended (12 U.S.C. 1701u).

Section 3 business concern means:

(1) A business concern meeting at least one of the following criteria, documented within the last six-month period:

(i) It is at least 51 percent owned and controlled by low- or very low-income persons;

(ii) Over 75 percent of the labor hours performed for the business over the prior three-month period are performed by Section 3 workers; or

(iii) It is a business at least 51 percent owned and controlled by current public housing residents or residents who currently live in Section 8-assisted housing.

(2) The status of a Section 3 business concern shall not be negatively affected by a prior arrest or conviction of its owner(s) or employees.

(3) Nothing in this part shall be construed to require the contracting or subcontracting of a Section 3 business concern. Section 3 business concerns are not exempt from meeting the specifications of the contract.

Section 3 project means a project defined in § 75.3(a)(2).

Section 3 worker means:

(1) Any worker who currently fits or when hired within the past five years fit at least one of the following categories, as documented:

(i) The worker's income for the previous or annualized calendar year is below the income limit established by HUD.

(ii) The worker is employed by a Section 3 business concern.

(iii) The worker is a YouthBuild participant.

(2) The status of a Section 3 worker shall not be negatively affected by a prior arrest or conviction.

(3) Nothing in this part shall be construed to require the employment of someone who meets this definition of a Section 3 worker. Section 3 workers are not exempt from meeting the qualifications of the position to be filled.

Section 8-assisted housing refers to housing receiving project-based rental assistance or tenant-based assistance under Section 8 of the 1937 Act.

Service area or the neighborhood of the project means an area within one mile of the Section 3 project or, if fewer than 5,000 people live within one mile of a Section 3 project, within a circle centered on the Section 3 project that is sufficient to encompass a population of 5,000 people according to the most recent U.S. Census.

Small PHA means a public housing authority that manages or operates fewer than 250 public housing units.

Subcontractor means any entity that has a contract with a contractor to undertake a portion of the contractor's obligation to perform work in connection with the expenditure of public housing financial assistance or for a Section 3 project.

Subrecipient has the meaning provided in the applicable program regulations or in 2 CFR 200.93.

Targeted Section 3 worker has the meanings provided in §§ 75.11, 75.21, or 75.29, and does not exclude an individual that has a prior arrest or conviction.

Very low-income person means the definition for this term set forth in section 3(b)(2) of the 1937 Act.

YouthBuild programs refers to YouthBuild programs receiving assistance under the Workforce Innovation and Opportunity Act (29 U.S.C. 3226).

§ 75.7 Requirements applicable to HUD NOFAs for Section 3 covered programs.

All notices of funding availability (NOFAs) issued by HUD that announce the availability of funding covered by § 75.3 will include notice that this part is applicable to the funding and may include, as appropriate for the specific NOFA, points or bonus points for the quality of Section 3 plans.

Subpart B—Additional Provisions for Public Housing Financial Assistance

§ 75.9 Requirements.

(a) *Employment and training.* (1) Consistent with existing Federal, state, and local laws and regulations, PHAs or other recipients receiving public housing financial assistance, and their contractors and subcontractors, must make their best efforts to provide employment and training opportunities generated by the public housing financial assistance to Section 3 workers.

(2) PHAs or other recipients, and their contractors and subcontractors, must make their best efforts described in paragraph (a)(1) of this section in the following order of priority:

(i) To residents of the public housing projects for which the public housing financial assistance is expended;

(ii) To residents of other public housing projects managed by the PHA that is providing the assistance or for residents of Section 8-assisted housing managed by the PHA;

(iii) To participants in YouthBuild programs; and

(iv) To low- and very low-income persons residing within the metropolitan area (or nonmetropolitan county) in which the assistance is expended.

(b) *Contracting.* (1) Consistent with existing Federal, state, and local laws and regulations, PHAs and other recipients of public housing financial assistance, and their contractors and subcontractors, must make their best efforts to award contracts and subcontracts to business concerns that provide economic opportunities to Section 3 workers.

(2) PHAs and other recipients, and their contractors and subcontractors, must make their best efforts described in paragraph (b)(1) of this section in the following order of priority:

(i) To Section 3 business concerns that provide economic opportunities for residents of the public housing projects for which the assistance is provided;

(ii) To Section 3 business concerns that provide economic opportunities for residents of other public housing projects or Section-8 assisted housing managed by the PHA that is providing the assistance;

(iii) To YouthBuild programs; and

(iv) To Section 3 business concerns that provide economic opportunities to Section 3 workers residing within the metropolitan area (or nonmetropolitan county) in which the assistance is provided.

§ 75.11 Targeted Section 3 worker for public housing financial assistance.

(a) *Targeted Section 3 worker.* A Targeted Section 3 worker for public housing financial assistance means a Section 3 worker who is:

(1) A worker employed by a Section 3 business concern; or

(2) A worker who currently fits or when hired fit at least one of the following categories, as documented within the past five years:

(i) A resident of public housing or Section 8-assisted housing;

(ii) A resident of other public housing projects or Section 8-assisted housing managed by the PHA that is providing the assistance; or

(iii) A YouthBuild participant.

(b) [Reserved]

§ 75.13 Section 3 safe harbor.

(a) *General.* PHAs and other recipients will be considered to have complied with requirements in this part, in the absence of evidence to the contrary, if they:

(1) Certify that they have followed the prioritization of effort in § 75.9; and

(2) Meet or exceed the applicable Section 3 benchmarks as described in paragraph (b) of this section.

(b) *Establishing benchmarks.* (1) HUD will establish Section 3 benchmarks for Section 3 workers or Targeted Section 3 workers or both through a document published in the **Federal Register**. HUD may establish a single nationwide benchmark for Section 3 workers and a single nationwide benchmark for Targeted Section 3 workers, or may establish multiple benchmarks based on geography, the type of public housing financial assistance, or other variables. HUD will update the benchmarks through a document published in the **Federal Register**, subject to public comment, not less frequently than once every 3 years. Such notice shall include aggregate data on labor hours and the proportion of PHAs and other recipients meeting benchmarks, as well as other metrics reported pursuant to § 75.15 as deemed appropriate by HUD, for the 3 most recent reporting years.

(2) In establishing the Section 3 benchmarks, HUD may consider the industry averages for labor hours worked by specific categories of workers or in different localities or regions; averages for labor hours worked by Section 3 workers and Targeted Section 3 workers as reported by recipients pursuant to this section; and any other factors HUD deems important. In establishing the Section 3 benchmarks, HUD will exclude professional services from the total number of labor hours as such hours are excluded from the total number of labor hours to be reported per § 75.15(a)(4).

(3) Section 3 benchmarks will consist of the following two ratios:

(i) The number of labor hours worked by Section 3 workers divided by the total number of labor hours worked by all workers funded by public housing financial assistance in the PHA's or other recipient's fiscal year.

(ii) The number of labor hours worked by Targeted Section 3 workers, as defined in § 75.11(a), divided by the total number of labor hours worked by all workers funded by public housing financial assistance in the PHA's or other recipient's fiscal year.

§ 75.15 Reporting.

(a) *Reporting of labor hours.* (1) For public housing financial assistance, PHAs and other recipients must report in a manner prescribed by HUD:

(i) The total number of labor hours worked;

(ii) The total number of labor hours worked by Section 3 workers; and

(iii) The total number of labor hours worked by Targeted Section 3 workers.

(2) Section 3 workers' and Targeted Section 3 workers' labor hours may be counted for five years from when their status as a Section 3 worker or Targeted Section 3 worker is established pursuant to § 75.31.

(3) The labor hours reported under paragraph (a)(1) of this section must include the total number of labor hours worked with public housing financial assistance in the fiscal year of the PHA or other recipient, including labor hours worked by any contractors and subcontractors that the PHA or other recipient is required, or elects pursuant to paragraph (a)(4) of this section, to report.

(4) PHAs and other recipients reporting under this section, as well as contractors and subcontractors who report to PHAs and recipients, may report labor hours by Section 3 workers, under paragraph (a)(1)(ii) of this section, and labor hours by Targeted Section 3 workers, under paragraph (a)(1)(iii) of this section, from professional services without including labor hours from professional services in the total number of labor hours worked under paragraph (a)(1)(i) of this section. If a contract covers both professional services and other work and the PHA, other recipient, contractor, or subcontractor chooses not to report labor hours from professional services, the labor hours under the contract that are not from professional services must still be reported.

(5) PHAs and other recipients may report on the labor hours of the PHA, the recipient, a contractor, or a subcontractor based on the employer's good faith assessment of the labor hours of a full-time or part-time employee informed by the employer's existing salary or time and attendance based payroll systems, unless the project or activity is otherwise subject to requirements specifying time and attendance reporting.

(b) *Additional reporting if Section 3 benchmarks are not met.* If the PHA's or other recipient's reporting under paragraph (a) of this section indicates that the PHA or other recipient has not met the Section 3 benchmarks described in § 75.13, the PHA or other recipient must report in a form prescribed by HUD on the qualitative nature of its Section 3 compliance activities and those of its contractors and subcontractors. Such qualitative efforts may, for example, include but are not limited to the following:

(1) Engaged in outreach efforts to generate job applicants who are Targeted Section 3 workers.

(2) Provided training or apprenticeship opportunities.

(3) Provided technical assistance to help Section 3 workers compete for jobs (*e.g.,* resume assistance, coaching).

(4) Provided or connected Section 3 workers with assistance in seeking employment including: drafting resumes, preparing for interviews, and finding job opportunities connecting residents to job placement services.

(5) Held one or more job fairs.

(6) Provided or referred Section 3 workers to services supporting work readiness and retention (*e.g.,* work readiness activities, interview clothing, test fees, transportation, child care).

(7) Provided assistance to apply for/or attend community college, a four-year educational institution, or vocational/technical training.

(8) Assisted Section 3 workers to obtain financial literacy training and/or coaching.

(9) Engaged in outreach efforts to identify and secure bids from Section 3 business concerns.

(10) Provided technical assistance to help Section 3 business concerns understand and bid on contracts.

(11) Divided contracts into smaller jobs to facilitate participation by Section 3 business concerns.

(12) Provided bonding assistance, guaranties, or other efforts to support viable bids from Section 3 business concerns.

(13) Promoted use of business registries designed to create opportunities for disadvantaged and small businesses.

(14) Outreach, engagement, or referrals with the state one-stop system as defined in Section 121(e)(2) of the Workforce Innovation and Opportunity Act.

(c) *Reporting frequency.* Unless otherwise provided, PHAs or other recipients must report annually to HUD under paragraph (a) of this section, and, where required, under paragraph (b) of this section, in a manner consistent with reporting requirements for the applicable HUD program.

(d) *Reporting by Small PHAs.* Small PHAs may elect not to report under

paragraph (a) of this section. Small PHAs that make such election are required to report on their qualitative efforts, as described in paragraph (b) of this section, in a manner consistent with reporting requirements for the applicable HUD program.

§ 75.17 Contract provisions.

(a) PHAs or other recipients must include language in any agreement or contract to apply Section 3 to contractors.

(b) PHAs or other recipients must require contractors to include language in any contract or agreement to apply Section 3 to subcontractors.

(c) PHAs or other recipients must require all contractors and subcontractors to meet the requirements of § 75.9, regardless of whether Section 3 language is included in contracts.

Subpart C—Additional Provisions for Housing and Community Development Financial Assistance

§ 75.19 Requirements.

(a) *Employment and training.* (1) To the greatest extent feasible, and consistent with existing Federal, state, and local laws and regulations, recipients covered by this subpart shall ensure that employment and training opportunities arising in connection with Section 3 projects are provided to Section 3 workers within the metropolitan area (or nonmetropolitan county) in which the project is located.

(2) Where feasible, priority for opportunities and training described in paragraph (a)(1) of this section should be given to:

(i) Section 3 workers residing within the service area or the neighborhood of the project, and

(ii) Participants in YouthBuild programs.

(b) *Contracting.* (1) To the greatest extent feasible, and consistent with existing Federal, state, and local laws and regulations, recipients covered by this subpart shall ensure contracts for work awarded in connection with Section 3 projects are provided to business concerns that provide economic opportunities to Section 3 workers residing within the metropolitan area (or nonmetropolitan county) in which the project is located.

(2) Where feasible, priority for contracting opportunities described in paragraph (b)(1) of this section should be given to:

(i) Section 3 business concerns that provide economic opportunities to Section 3 workers residing within the service area or the neighborhood of the project, and

(ii) YouthBuild programs.

§ 75.21 Targeted Section 3 worker for housing and community development financial assistance.

(a) *Targeted Section 3 worker.* A Targeted Section 3 worker for housing and community development financial assistance means a Section 3 worker who is:

(1) A worker employed by a Section 3 business concern; or

(2) A worker who currently fits or when hired fit at least one of the following categories, as documented within the past five years:

(i) Living within the service area or the neighborhood of the project, as defined in § 75.5; or

(ii) A YouthBuild participant.

(b) [Reserved]

§ 75.23 Section 3 safe harbor.

(a) *General.* Recipients will be considered to have complied with requirements in this part, in the absence of evidence to the contrary if they:

(1) Certify that they have followed the prioritization of effort in § 75.19; and

(2) Meet or exceed the applicable Section 3 benchmark as described in paragraph (b) of this section.

(b) *Establishing benchmarks.* (1) HUD will establish Section 3 benchmarks for Section 3 workers or Targeted Section 3 workers or both through a document published in the **Federal Register**. HUD may establish a single nationwide benchmark for Section 3 workers and a single nationwide benchmark for Targeted Section 3 workers, or may establish multiple benchmarks based on geography, the nature of the Section 3 project, or other variables. HUD will update the benchmarks through a document published in the **Federal Register**, subject to public comment, not less frequently than once every 3 years. Such notice shall include aggregate data on labor hours and the proportion of recipients meeting benchmarks, as well as other metrics reported pursuant to § 75.25 as deemed appropriate by HUD, for the 3 most recent reporting years.

(2) In establishing the Section 3 benchmarks, HUD may consider the industry averages for labor hours worked by specific categories of workers or in different localities or regions; averages for labor hours worked by Section 3 workers and Targeted Section 3 workers as reported by recipients pursuant to this section; and any other factors HUD deems important. In establishing the Section 3 benchmarks, HUD will exclude professional services from the total number of labor hours as such hours are excluded from the total number of labor hours to be reported per § 75.25(a)(4).

(3) Section 3 benchmarks will consist of the following two ratios:

(i) The number of labor hours worked by Section 3 workers divided by the total number of labor hours worked by all workers on a Section 3 project in the recipient's program year.

(ii) The number of labor hours worked by Targeted Section 3 workers as defined in § 75.21(a), divided by the total number of labor hours worked by all workers on a Section 3 project in the recipient's program year.

§ 75.25 Reporting.

(a) *Reporting of labor hours.* (1) For Section 3 projects, recipients must report in a manner prescribed by HUD:

(i) The total number of labor hours worked;

(ii) The total number of labor hours worked by Section 3 workers; and

(iii) The total number of labor hours worked by Targeted Section 3 workers.

(2) Section 3 workers' and Targeted Section 3 workers' labor hours may be counted for five years from when their status as a Section 3 worker or Targeted Section 3 worker is established pursuant to § 75.31.

(3) The labor hours reported under paragraph (a)(1) of this section must include the total number of labor hours worked on a Section 3 project, including labor hours worked by any subrecipients, contractors and subcontractors that the recipient is required, or elects pursuant to paragraph (a)(4) of this section, to report.

(4) Recipients reporting under this section, as well as subrecipients, contractors and subcontractors who report to recipients, may report labor hours by Section 3 workers, under paragraph (a)(1)(ii) of this section, and labor hours by Targeted Section 3 workers, under paragraph (a)(1)(iii) of this section, from professional services without including labor hours from professional services in the total number of labor hours worked under paragraph (a)(1)(i) of this section. If a contract covers both professional services and other work and the recipient or contractor or subcontractor chooses not to report labor hours from professional services, the labor hours under the contract that are not from professional services must still be reported.

(5) Recipients may report their own labor hours or that of a subrecipient, contractor, or subcontractor based on the employer's good faith assessment of the labor hours of a full-time or part-time employee informed by the employer's existing salary or time and attendance based payroll systems, unless the project or activity is

otherwise subject to requirements specifying time and attendance reporting.

(b) *Additional reporting if Section 3 benchmarks are not met.* If the recipient's reporting under paragraph (a) of this section indicates that the recipient has not met the Section 3 benchmarks described in § 75.23, the recipient must report in a form prescribed by HUD on the qualitative nature of its activities and those its contractors and subcontractors pursued. Such qualitative efforts may, for example, include but are not limited to the following:

(1) Engaged in outreach efforts to generate job applicants who are Targeted Section 3 workers.

(2) Provided training or apprenticeship opportunities.

(3) Provided technical assistance to help Section 3 workers compete for jobs (*e.g.,* resume assistance, coaching).

(4) Provided or connected Section 3 workers with assistance in seeking employment including: drafting resumes, preparing for interviews, and finding job opportunities connecting residents to job placement services.

(5) Held one or more job fairs.

(6) Provided or referred Section 3 workers to services supporting work readiness and retention (*e.g.,* work readiness activities, interview clothing, test fees, transportation, child care).

(7) Provided assistance to apply for/or attend community college, a four-year educational institution, or vocational/technical training.

(8) Assisted Section 3 workers to obtain financial literacy training and/or coaching.

(9) Engaged in outreach efforts to identify and secure bids from Section 3 business concerns.

(10) Provided technical assistance to help Section 3 business concerns understand and bid on contracts.

(11) Divided contracts into smaller jobs to facilitate participation by Section 3 business concerns.

(12) Provided bonding assistance, guaranties, or other efforts to support viable bids from Section 3 business concerns.

(13) Promoted use of business registries designed to create opportunities for disadvantaged and small businesses.

(14) Outreach, engagement, or referrals with the state one-stop system as defined in Section 121(e)(2) of the Workforce Innovation and Opportunity Act.

(c) *Reporting frequency.* Unless otherwise provided, recipients must report annually to HUD under paragraph (a) of this section, and, where required, under paragraph (b) of this section, on all projects completed within the reporting year in a manner consistent with reporting requirements for the applicable HUD program.

§ 75.27 Contract provisions.

(a) Recipients must include language applying Section 3 requirements in any subrecipient agreement or contract for a Section 3 project.

(b) Recipients of Section 3 funding must require subrecipients, contractors, and subcontractors to meet the requirements of § 75.19, regardless of whether Section 3 language is included in recipient or subrecipient agreements, program regulatory agreements, or contracts.

Subpart D—Provisions for Multiple Funding Sources, Recordkeeping, and Compliance

§ 75.29 Multiple funding sources.

(a) If a housing rehabilitation, housing construction or other public construction project is subject to Section 3 pursuant to § 75.3(a)(1) and (2), the recipient must follow subpart B of this part for the public housing financial assistance and may follow either subpart B or C of this part for the housing and community development financial assistance. For such a project, the following applies:

(1) For housing and community development financial assistance, a Targeted Section 3 worker is any worker who meets the definition of a Targeted Section 3 worker in either subpart B or C of this part; and

(2) The recipients of both sources of funding shall report on the housing rehabilitation, housing construction, or other public construction project as a whole and shall identify the multiple associated recipients. PHAs and other recipients must report the following information:

(i) The total number of labor hours worked on the project;

(ii) The total number of labor hours worked by Section 3 workers on the project; and

(iii) The total number of labor hours worked by Targeted Section 3 workers on the project.

(b) If a housing rehabilitation, housing construction, or other public construction project is subject to Section 3 because the project is assisted with funding from multiple sources of housing and community development assistance that exceed the thresholds in § 75.3(a)(2), the recipient or recipients must follow subpart C of this part, and must report to the applicable HUD program office, as prescribed by HUD.

§ 75.31 Recordkeeping.

(a) HUD shall have access to all records, reports, and other documents or items of the recipient that are maintained to demonstrate compliance with the requirements of this part, or that are maintained in accordance with the regulations governing the specific HUD program by which the Section 3 project is governed, or the public housing financial assistance is provided or otherwise made available to the recipient, subrecipient, contractor, or subcontractor.

(b) Recipients must maintain documentation, or ensure that a subrecipient, contractor, or subcontractor that employs the worker maintains documentation, to ensure that workers meet the definition of a Section 3 worker or Targeted Section 3 worker, at the time of hire or the first reporting period, as follows:

(1) For a worker to qualify as a Section 3 worker, one of the following must be maintained:

(i) A worker's self-certification that their income is below the income limit from the prior calendar year;

(ii) A worker's self-certification of participation in a means-tested program such as public housing or Section 8-assisted housing;

(iii) Certification from a PHA, or the owner or property manager of project-based Section 8-assisted housing, or the administrator of tenant-based Section 8-assisted housing that the worker is a participant in one of their programs;

(iv) An employer's certification that the worker's income from that employer is below the income limit when based on an employer's calculation of what the worker's wage rate would translate to if annualized on a full-time basis; or

(v) An employer's certification that the worker is employed by a Section 3 business concern.

(2) For a worker to qualify as a Targeted Section 3 worker, one of the following must be maintained:

(i) For a worker to qualify as a Targeted Section 3 worker under subpart B of this part:

(A) A worker's self-certification of participation in public housing or Section 8-assisted housing programs;

(B) Certification from a PHA, or the owner or property manager of project-based Section 8-assisted housing, or the administrator of tenant-based Section 8-assisted housing that the worker is a participant in one of their programs;

(C) An employer's certification that the worker is employed by a Section 3 business concern; or

(D) A worker's certification that the worker is a YouthBuild participant.

(ii) For a worker to qualify as a Targeted Section 3 worker under subpart C of this part:

(A) An employer's confirmation that a worker's residence is within one mile of the work site or, if fewer than 5,000 people live within one mile of a work site, within a circle centered on the work site that is sufficient to encompass a population of 5,000 people according to the most recent U.S. Census;

(B) An employer's certification that the worker is employed by a Section 3 business concern; or

(C) A worker's self-certification that the worker is a YouthBuild participant.

(c) The documentation described in paragraph (b) of this section must be maintained for the time period required for record retentions in accordance with applicable program regulations or, in the absence of applicable program regulations, in accordance with 2 CFR part 200.

(d) A PHA or recipient may report on Section 3 workers and Targeted Section 3 workers for five years from when their certification as a Section 3 worker or Targeted Section 3 worker is established.

§ 75.33 Compliance.

(a) *Records of compliance.* Each recipient shall maintain adequate records demonstrating compliance with this part, consistent with other recordkeeping requirements in 2 CFR part 200.

(b) *Complaints.* Complaints alleging failure of compliance with this part may be reported to the HUD program office responsible for the public housing financial assistance or the Section 3 project, or to the local HUD field office.

(c) *Monitoring.* HUD will monitor compliance with the requirements of this part. The applicable HUD program office will determine appropriate methods by which to oversee Section 3 compliance. HUD may impose appropriate remedies and sanctions in accordance with the laws and regulations for the program under which the violation was found.

PART 91—CONSOLIDATED SUBMISSIONS FOR COMMUNITY PLANNING AND DEVELOPMENT PROGRAMS

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

Authority: 42 U.S.C. 3535(d), 3601–3619, 5301–5315, 11331–11388, 12701–12711, 12741–12756, and 12901–12912.

§ 91.215 [Amended]

■ 7. Amend § 91.215(j) by removing ''24 CFR part 135'' and adding, in its place ''24 CFR part 75''.

§ 91.225 [Amended]

■ 8. Amend § 91.225(a)(7) by removing ''24 CFR part 135'' and adding, in its place ''24 CFR part 75''.

§ 91.325 [Amended]

■ 9. Amend § 91.325(a)(7) by removing ''24 CFR part 135'' and adding, in its place ''24 CFR part 75''.

§ 91.425 [Amended]

■ 10. Amend § 91.425(a)(1)(vii) by removing ''24 CFR part 135'' and adding, in its place ''24 CFR part 75''.

PART 92—HOME INVESTMENT PARTNERSHIPS PROGRAM

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

Authority: 42 U.S.C. 3535(d), 12 U.S.C. 1701x and 4568.

■ 12. Amend § 92.508 as follows:
■ a. Remove paragraph (a)(7)(i)(B);
■ b. Redesignate paragraph (a)(7)(i)(C) as (a)(7)(i)(B); and
■ c. Add paragraph (a)(7)(xi).
The addition reads as follows:

§ 92.508 Recordkeeping.

(a) * * *
(7) * * *
(xi) Documentation of actions undertaken to meet the requirements of 24 CFR part 75 which implements section 3 of the Housing Development Act of 1968, as amended (12 U.S.C. 1701u).
* * * * *

PART 93—HOUSING TRUST FUND

■ 13. The authority citation for part 93 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 12 U.S.C. 4568.

■ 14. Amend § 93.407 as follows:
■ a. Redesignate paragraphs (a)(5)(ii) through (ix) as paragraphs (a)(5)(iii) through (x);
■ b. Remove paragraph (a)(5)(i)(B);
■ c. Redesignate paragraph (a)(5)(i)(A) as paragraph (a)(5)(ii);
■ d. In newly redesignated paragraph (a)(5)(iv), remove ''24 part 35'' and add in its place ''24 CFR part 35''; and
■ e. Add paragraph (a)(5)(xi).
The addition reads as follows:

§ 93.407 Recordkeeping.

(a) * * *
(5) * * *
(xi) Documentation of actions undertaken to meet the requirements of 24 CFR part 75, which implements section 3 of the Housing and Urban Development Act of 1968, as amended (12 U.S.C. 1701u).
* * * * *

CHAPTER I—OFFICE OF ASSISTANT SECRETARY FOR EQUAL OPPORTUNITY, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT [AMENDED]

■ 15. Under the authority of 42 U.S.C. 3535(d), in chapter I, remove designated subchapter headings A and B.

PART 135 —[REMOVED]

■ 16. Remove part 135.

PART 266—HOUSING FINANCE AGENCY RISK-SHARING PROGRAM FOR INSURED AFFORDABLE MULTIFAMILY PROJECT LOANS

■ 17. The authority citation for part 266 continues to read as follows:

Authority: 12 U.S.C. 1707; 42 U.S.C. 3535(d).

§ 266.220 [Amended]

■ 18. Amend § 266.220(c) by removing ''; section 3 of the Housing and Urban Development Act of 1968 (12 U.S.C. 1701u), as implemented by 24 CFR part 135''.

PART 570—COMMUNITY DEVELOPMENT BLOCK GRANTS

■ 19. The authority citation for part 570 continues to read as follows:

Authority: 12 U.S.C. 1701x, 1701 x–1; 42 U.S.C. 3535(d) and 5301–5320.

§ 570.487 [Amended]

■ 20. Amend § 570.487(d) by removing ''24 CFR part 135'' and adding in its place ''24 CFR part 75''.

§ 570.607 [Amended]

■ 21. Amend § 570.607(b) by removing ''24 CFR part 135'' and adding in its place ''24 CFR part 75''.

PART 574—HOUSING OPPORTUNITIES FOR PERSONS WITH AIDS

■ 22. The authority citation for part 574 continues to read as follows:

Authority: 12 U.S.C. 1701x, 1701 x–1; 42 U.S.C. 3535(d) and 5301–5320.

§ 574.600 [Amended]

■ 23. Amend § 574.600 by adding ''and part 75'' after the phrase ''24 CFR part 5''.

PART 576—EMERGENCY SOLUTIONS GRANTS PROGRAM

■ 24. The authority citation for part 576 continues to read as follows:

Authority: 12 U.S.C. 1701x, 1701 x–1; 42 U.S.C. 11371 *et seq.,* 42 U.S.C. 3535(d).

§ 576.407 [Amended]

■ 25. Amend § 576.407(a) by removing ''24 CFR part 135'' and adding in its place ''24 CFR part 75''.

PART 578—CONTINUUM OF CARE PROGRAM

■ 26. The authority citation for part 578 continues to read as follows:

Authority: 12 U.S.C. 1701x, 1701 x–1; 42 U.S.C. 11381 *et seq.,* 42 U.S.C. 3535(d).

§ 578.99 [Amended]

■ 27. Amend § 578.99 by removing ''federal'' in the section heading and adding in its place ''Federal'' and removing ''24 CFR part 135'' in paragraph (i) and adding in its place ''24 CFR part 75''.

PART 905—THE PUBLIC HOUSING CAPITAL FUND PROGRAM

■ 28. The authority citation for part 905 continues to read as follows:

Authority: 42 U.S.C. 1437g, 42 U.S.C. 1437z–2, 42 U.S.C. 1437z–7, and 3535(d).

§ 905.308 [Amended]

■ 29. Amend § 905.308(b)(10) by removing ''24 CFR part 135'' and adding in its place ''24 CFR part 75''.

PART 964—TENANT PARTICIPATION AND TENANT OPPORTUNITIES IN PUBLIC HOUSING

■ 30. The authority citation for part 964 continues to read as follows:

Authority: 42 U.S.C. 1437d, 1437g, 1437r, 3535(d).

■ 31. Revise § 964.320 to read as follows:

§ 964.320 HUD Policy on training, employment, contracting and subcontracting of public housing residents.

In accordance with Section 3 of the Housing and Urban Development Act of 1968 and the implementing regulations at 24 CFR part 75, PHAs, their contractors and subcontractors shall make best efforts, consistent with existing Federal, State, and local laws and regulations, to give low and very low-income persons the training and employment opportunities generated by Section 3 covered assistance (as this term is defined in 24 CFR 75.3) and to give Section 3 business concerns the contracting opportunities generated by Section 3 covered assistance.

PART 983—PROJECT-BASED VOUCHER (PBV) PROGRAM

■ 32. The authority citation for part 983 continues to read as follows:

Authority: 42 U.S.C. 1437f and 3535(d).

§ 983.4 [Amended]

■ 33. Amend § 983.4 by removing the definition of ''Section 3—Training, employment and contracting opportunities in development''.

§ 983.154 [Amended]

■ 34. Amend § 983.154 by removing (c) introductory text and paragraph (c)(1) and redesignating paragraph (c)(2) as paragraph (c).

PART 1000—NATIVE AMERICAN HOUSING ACTIVITIES

■ 35. The authority citation for part 1000 continues to read as follows:

Authority: 25 U.S.C. 4101 *et seq.;* 42 U.S.C. 3535(d).

■ 36. Revise § 1000.42 to read as follows:

§ 1000.42 Are the requirements of Section 3 of the Housing and Urban Development Act of 1968 applicable?

No. Recipients shall comply with Indian preference requirements of Section 7(b) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5307(b)), or employment and contract preference laws adopted by the recipient's tribe in accordance with Section 101(k) of NAHASDA.

Benjamin S. Carson, Sr.,

Secretary.

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